

Medtronic

EVERA™ DR

Family of digital dual chamber implantable cardioverter defibrillators

Reference Manual

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

EVERA™ DR

Reference Manual

A reference manual for the Medtronic Evera DR family of digital dual chamber implantable cardioverter defibrillators.

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1 Introduction

1.1 Introduction

This manual describes the operation and intended use of features offered by Medtronic Evera DR ICD devices.

Throughout this manual, the word “device” refers to the implanted DR ICD device.

The programmer 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].

Tables in the feature programming sections summarize how to navigate to screens with programmable parameters for the feature. As shown in the example in Table 1, each table row lists a parameter or group of parameters with the path to a specific screen on the programmer. If the navigation path is the same for related parameters, the path is not repeated in the table. Additional rows are included for parameters that appear on different screens. Groups of parameters, such as “ATP parameters”, include the word “parameters”. Individual parameters, such as “Energy” and “Pathway”, do not.

Table 1. How to navigate to VF therapies parameters

Parameters	Path
VF therapies (Rx1 through Rx6)	Params > VF Therapies...
VF Therapy Status (On, Off)	
Energy	
Pathway	
ATP parameters (Rx1)	Params > VF Therapies... > ATP...
ChargeSaver parameters (ATP in Rx1)	Params > VF Therapies... > ATP... > During Charging > ChargeSaver...
Shared Settings (V. ATP and V. Therapies)	Params > VF Therapies... > Shared Settings...

The feature programming sections also include programming considerations. For detailed information about parameter settings, see the device manual for the specific device.

1.1.1 Product literature

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

- Read the product literature for information about prescribing, implanting, and using the device and conducting a patient follow-up session.

- Thoroughly read the technical manuals for the leads used with the device. Also read the technical manuals for other system components.
- Discuss the device and implant procedure with the patient and any other interested parties, and give them any patient information materials packaged with the device.

Additional manuals and documents with information about the device:

Device manual – Each device model has a separate device manual. The manual contains the specific features for the model, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

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

Radio regulatory compliance information – This document states that the device complies with Part 15 of the Federal Communications Commission (FCC) rules and outlines the conditions for operation that the device must meet. It also contains compliance information for Industry Canada.

Medical Procedure and EMI 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) in the home, at work, and in other environments.

1.1.2 Technical support

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

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

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

1.1.3 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 THAT RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

For more information, see Section 2.12, “Storing patient information”, page 47.

1.2 Evera DR ICD feature model matrix

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

Table 2. Product feature relationship

Features	Evera XT DR	Evera S DR
	DDBB1D1 DDBB1D4	DDBC3D1 DDBC3D4
Optivol 2.0 fluid status monitoring	X	
Heart Failure Management Report	X	

Note: All other features described in this manual apply to all Evera DR ICD devices.

2 Conducting a patient session with the programmer

2.1 Establishing telemetry between the device and the programmer

You can conduct a patient session using wireless or nonwireless telemetry.

You cannot switch between wireless and nonwireless telemetry during a patient session. If you are conducting a patient session and you wish to change the telemetry mode, you must end that session and start a new session using the alternative mode.

Refer to the programmer reference guide for information about setting up the programmer for a patient session.

2.1.1 Using Conexus wireless telemetry

To establish wireless telemetry, use the Medtronic CareLink Model 2090 Programmer with Conexus telemetry or the Medtronic Model 27901 Conexus Activator. The Conexus Activator is a hand-held, battery-powered communication device. It enables wireless telemetry in a Conexus-compatible heart device independently of a programmer. Once wireless telemetry is established, a practitioner can use the programmer to conduct a session without using the programming head.

Conexus wireless telemetry uses the Medical Implant Communications Service (MICS)¹ radio frequency band, which is designated worldwide for medical devices. Using this band protects devices against interference from home electronics, such as microwaves, cell phones, and baby monitors.

Conexus wireless telemetry is designed for use during implant and follow-up sessions.

At implant, Conexus wireless telemetry enables you to:

- interrogate the patient's wireless device without using a programming head (no programming head in the sterile field)
- maintain connectivity during induction and delivery of therapies
- program the device any time during the procedure while maintaining continuous patient monitoring

¹ Medical Implant Communications Service (MICS) is also referred to as the core 402-405 MHz band of the Medical Device Radiocommunication Service (MedRadio).

During follow-up sessions, Conexus wireless telemetry maintains continuous communication between the device and the programmer.

During remote follow-up sessions with the CareLink Network, Conexus wireless telemetry automatically transmits comprehensive arrhythmia and diagnostic device data. It transmits wirelessly without patient involvement.

2.1.1.1 How to activate wireless telemetry

1. Turn on the programmer.

Make sure the “Allow wireless communication” check box in the Find Patient window is selected.

2. Use the Conexus Activator, or briefly place the programming head over the device to activate wireless telemetry in the device.

When wireless telemetry is first established during a session, the telemetry status indicator in the upper left corner of the task bar changes from the programming head icon to the wireless telemetry icon, as shown in Figure 1 .

Figure 1. Wireless telemetry icon on the task bar



1 Wireless telemetry icon

The indicator bar on the icon displays the strength of the wireless signal. At least 3 of the green lights must be illuminated to ensure reliable telemetry has been established.

If you are using the Conexus Activator, press the blue button to activate wireless telemetry. A green light illuminates when you have successfully communicated with the device.

2.1.1.2 Conexus wireless timer operation

Once you initiate wireless telemetry, a 5 min timer begins. The device sends a signal to the programmer and remains active for 5 min. A response from the programmer establishes communication, and the device appears in the Find Patient window when that window is open. If the programmer touch pen is not used within 5 min, the Find Patient window closes and the Select Model screen appears.

When you end a session, a final 5 min timer begins; you can re-interrogate the device during this time before the session ends completely.

As long as wireless telemetry with the device is maintained, there is no time limit during a wireless telemetry session.

If electrical interference disrupts a session, the programmer attempts to re-establish communication with the device for 5 min. If you do not re-establish communication between the device and the programmer during this time, use the Conexus Activator or programming head to reactivate wireless telemetry in the device to resume or start a session.

2.1.1.3 How to maintain reliable telemetry

You can expect reliable wireless telemetry between the implanted device and the programmer in a typical examination room or operating room. If other electrical equipment is in the area, the system is designed to maintain effective communication between the device and the programmer at distances up to 2 m (6.5 feet). The system should not interfere with other electronic equipment in the area.

If you are having trouble maintaining consistent, reliable telemetry, take one or more of the following actions:

- Adjust the angle of the programmer screen. The telemetry antenna is part of the programmer display screen structure; slight movements of the screen may improve the telemetry link.
- Change the position of the programmer so that the space between the programmer screen and the patient is relatively free of obstruction. Make sure that nothing is between the programmer and the patient.
- Shorten the distance between the programmer and the patient.
- Remove any sources of electromagnetic interference (EMI) that may be affecting the telemetry signal.

2.1.1.4 Session inactivity safeguards

If you or the patient moves away from the programmer, the system guards against unintentional programming in the following ways:

- After 2 min of programmer inactivity, the system displays the patient's name or ID number, if available, and device information. You are then required to confirm that the correct patient is in the follow-up session before you can process a programming command.
- The device transitions to Standby mode after a period of programmer inactivity in an implant session or a follow-up session, as follows:
 - At implant and in the first 7 days after implant: The device transitions to Standby mode after 2 hours of programmer inactivity.

- 7 days after implant: The device transitions to Standby mode after 5 min of programmer inactivity.

Note: To extend the wireless telemetry session to 2 hours, select Session > Extend Wireless Telemetry Session and select [Continue]. When the session is ended, the timer reverts to 5 min.

2.1.1.5 Device standby mode

When the device is in standby mode, live waveforms are turned off, the programmer telemetry status indicator shows no telemetry link, and programmer functions are limited. You can use standby mode when you need a period of inactivity in a patient session.

To activate and deactivate Standby mode in the device manually:

- To activate Standby mode, select the wireless telemetry icon on the task bar.
- To deactivate Standby mode and reactivate wireless telemetry with the programmer, select the wireless telemetry icon on the task bar or place either the Conexus Activator or the programming head over the device.

After 5 min in Standby mode, wireless telemetry is deactivated within the device. To recover the wireless telemetry session, use either the Conexus Activator or the programming head.

Standby mode is also deactivated when you attempt to program parameters, interrogate the device, or conduct testing or emergency operations. The programmer screen displays the Verify Patient warning. To deactivate Standby mode and resume a patient session, verify that the session is with the intended patient, select the “Allow communication with” check box, and select [Continue].

Note: To use Holter telemetry to transmit EGM and Marker Channel data during a Conexus telemetry session, you first must activate Standby mode.

2.1.1.6 How to maintain patient safety and privacy

During a wireless telemetry session, all other programmers are blocked from communicating or initiating a session with the patient's implanted device. Implanted devices in other patients are locked out from any communication or programming occurring during the patient's session.

When you are using wireless telemetry, the patient's name is displayed on the Command bar of the programmer screen. If you have not entered the patient's name, the patient's ID number appears. If the patient's name or ID has not been entered, then “Patient name is not entered” appears on the Command bar. Enter the patient's name and ID number as early as possible to assist with patient identification when using wireless telemetry.

2.1.2 Using nonwireless telemetry

Some Medtronic programmers feature only nonwireless telemetry. If your Medtronic programmer features both Conexus wireless telemetry and nonwireless telemetry, you must choose to use nonwireless telemetry.

You must have a Medtronic programming head to use nonwireless telemetry.

2.1.2.1 How to establish nonwireless telemetry

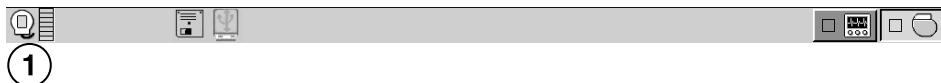
1. Turn on the programmer.

If you are using a programmer with Conexus wireless telemetry, make sure the “Allow wireless communication” check box in the Find Patient window is not selected. The check box does not appear if you are using a programmer without Conexus wireless telemetry.

2. Place the programming head over the device to activate nonwireless telemetry in the device.

When nonwireless telemetry is established during a session, the telemetry status indicator on the task bar displays the programming head icon, as shown in Figure 2.

Figure 2. Programming head icon on the task bar



1 Programming head icon

Note: The magnet in the programming head can suspend tachyarrhythmia detection. However, when telemetry between the device and the programmer is established, detection is not suspended.

When 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. To ensure that the proper telemetry is established, position the programming head over the device so at least 2 of the green lights illuminate. 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.

2.2 Starting 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, start a new session for each patient. End the previous session before starting a session with another patient.

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.

Caution: During a wireless telemetry session, verify that you have selected the appropriate patient before proceeding with the session, and maintain visual contact with the patient for the duration of the session. If you select the wrong patient and continue with the session, you may inadvertently program the wrong patient's device.

Caution: Do not leave the programmer unattended while a wireless telemetry session is in progress. Maintain control of the programmer during the session to prevent inadvertent communication with the patient's device.

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

2.2.1 How to start a patient session using wireless telemetry

1. Select [Find Patient...] from the Select Model window.
2. Select the "Allow wireless communication" check box on the Find Patient window.
3. Use the Conexus Activator, or briefly place the programming head over the device to activate wireless telemetry in the device.

Notes:

- When the Conexus Activator is used to activate telemetry in the device, the programmer launches the patient session without suspending tachyarrhythmia detection. Placing a magnet near the device, however, suspends tachyarrhythmia detection.
- When the programming head is used to activate telemetry in the device, the programmer automatically launches the patient session with tachyarrhythmia detection suspended. Detection remains suspended as long as the programming head is over the device. If tachyarrhythmia detection is programmed on, a warning reminds you that tachyarrhythmia detection is suspended.

4. Select the appropriate patient from the Patient Name list on the Find Patient window.

Note: The programmer lists all patients with wireless-activated implantable devices within telemetry range.

5. Select [Start].

2.2.2 How to start a patient session using nonwireless telemetry

1. Select [Find Patient...] from the Select Model window.
2. If you are using a Medtronic programmer with Conexus wireless telemetry, make sure that the “Allow wireless communication” check box on the Find Patient window is not selected. If you start a session with the programming head over the patient’s device and the “Allow wireless communication” check box is selected, the system initiates a wireless telemetry session and automatically interrogates the device. If you are using a Medtronic programmer without Conexus wireless telemetry, the “Allow wireless communication” check box does not appear on the Find Patient window.
3. Place the programming head over the device and the nonwireless session automatically begins.

2.2.3 Device and telemetry effects during a patient session

Tachyarrhythmia detection during a wireless telemetry session – If you place a programming head over the device, the magnet in the programming head always suspends tachyarrhythmia detection.

Tachyarrhythmia detection during a nonwireless telemetry session – If you place a programming head over the device and telemetry is established, the magnet in the programming head does not suspend tachyarrhythmia detection.

Episodes in progress during a wireless telemetry session – If you attempt to initiate a patient session when a detected arrhythmia episode is in progress, the device treats the arrhythmia normally. If telemetry has not been established, the magnet inside the programming head causes the device to suspend detection when the programming head is placed over the device.

Episodes in progress during a nonwireless telemetry session – After telemetry has been established and you position the programming head over the device when a detected arrhythmia episode is in progress, the device treats the arrhythmia normally. If telemetry has not been established and you position the programming head over the device, the magnet inside the programming head causes the device to suspend detection.

Capacitor charging during a wireless telemetry session – Interference caused by capacitor charging may affect telemetry between the device and the programmer. This

interference could result in a temporary loss of telemetry indicator lights as shown on the programmer task bar and a temporary loss in Marker transmissions. It could also temporarily affect the ability to send programming commands. Ensure that the greatest number of telemetry strength indicator lights are illuminated on the programmer task bar to help improve telemetry reliability before any manual or automatic capacitor charging.

Capacitor charging during a nonwireless telemetry session – Interference caused by capacitor charging may affect telemetry between the device and the programmer. The programming head indicator lights may turn off during charging periods. It is normal for the lights to turn off on the programming head.

Note: The programming head “P” button is disabled during all EP study and manual system tests. During tachyarrhythmia inductions, the programming head “I” button is also disabled.

Marker transmissions during a wireless telemetry session – The device continuously transmits Marker Channel and supplementary marker data while telemetry is established. The device stops these transmissions when telemetry is interrupted. If Holter telemetry is programmed to On, the device transmits telemetry at all times except during a Conexus wireless telemetry session. To use Holter telemetry during a Conexus wireless telemetry session, you must first activate Standby mode.

Marker transmissions during a nonwireless telemetry 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.

Device longevity and wireless telemetry – In typical patient session and device operation scenarios, wireless telemetry has no significant effect on device longevity.

2.2.4 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. In a nonwireless session, you can 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. To gather all of the information from the device, select the All option.
3. Select [Start].

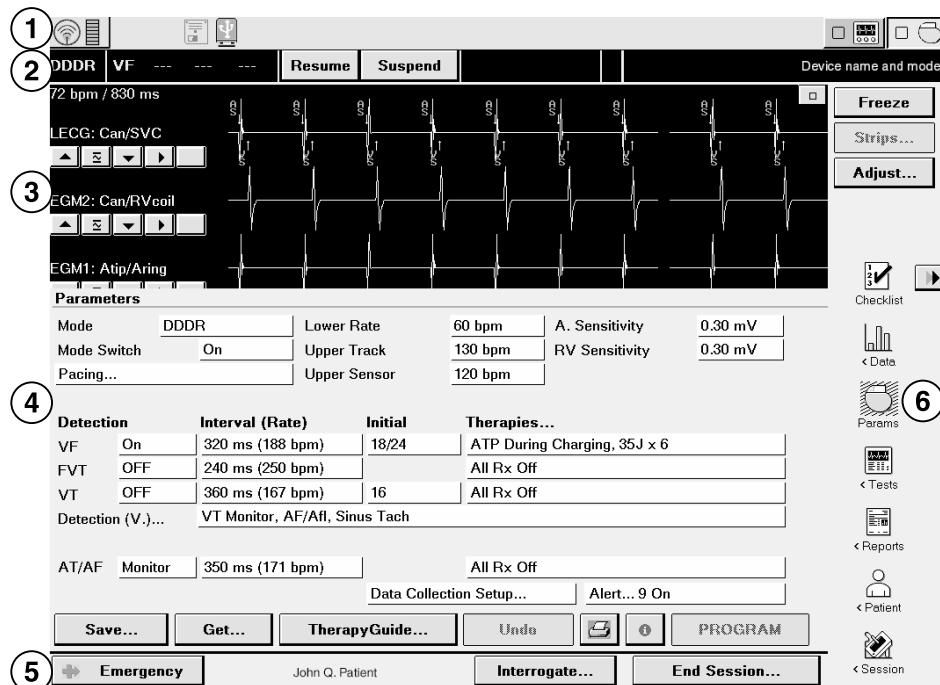
Note: You cannot manually interrogate the device during an emergency programmer operation. You must select [Exit Emergency] before you can manually interrogate the device.

2.3 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 3.

Figure 3. Main elements of a display screen



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

If the SessionSync feature is installed on the programmer, the programmer task bar displays an icon that indicates the status of the SessionSync feature. For complete information on viewing the status of the SessionSync feature from the programmer task bar, see Section 2.14, “Transferring data to Paceart with SessionSync”, page 51.

2.3.1 Task bar

The display screen features a task bar at the 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 indicator. In a wireless telemetry session, selecting the wireless telemetry icon breaks the telemetry link. Selecting it again restores the telemetry link. If you are conducting a nonwireless telemetry session, the task bar includes a graphical representation of the telemetry strength light array on the programming head.

Figure 4. Task bar display

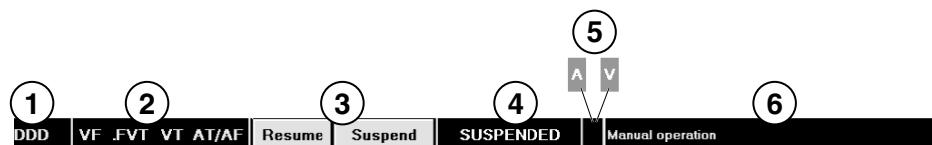


- | | |
|--|-----------------|
| 1 Telemetry icon and telemetry strength indicator (wireless telemetry shown) | 4 USB icon |
| 2 SessionSync icon | 5 Analyzer icon |
| 3 Disk icon (for some Medtronic programmer models) | 6 Device icon |

2.3.2 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 5. 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 a tachyarrhythmia episode is in progress
 - 6 Either the current episode, therapy, or manual operation status, or the device name and model number

2.3.3 Live Rhythm Monitor window

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

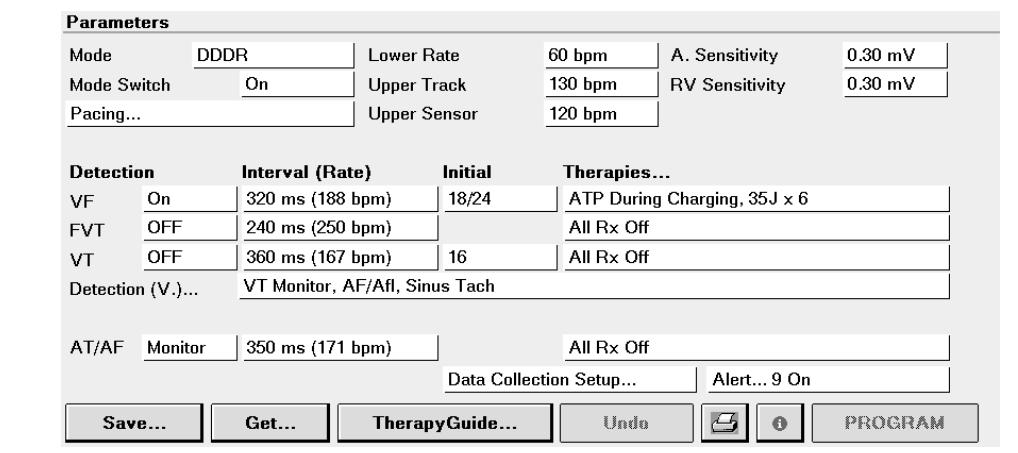
- The heart rate and the rate interval appear if telemetry has been established with the device.
- The annotations above the waveform trace show the point at which parameters are programmed.

The Live Rhythm Monitor window appears in the partial view by default. 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...]. For more information, see Section 2.7, “Monitoring cardiac activity with the Live Rhythm Monitor”, page 28.

2.3.4 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 2.9, “Programming device parameters”, page 40.

Figure 6. Task area of the screen

2.3.5 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 3.

Table 3. Tool palette options

Freeze	The [Freeze] button captures a segment of the Live Rhythm Monitor display.
Strips...	The [Strips...] button accesses the waveform strips saved since the start of the session.
Adjust...	The [Adjust...] button opens a window of options for adjusting the Live Rhythm Monitor display.
Checklist	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.
< Data	The Data icon displays options for viewing device information and diagnostic data.

Table 3. Tool palette options (continued)

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

2.3.6 Buttons

Buttons, such as those shown in Figure 7, respond when you “select” them by touching them with the tip of the touch pen.

Figure 7. 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.

2.3.7 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.

If the programmer is using wireless telemetry, the patient may be identified on the command bar of the programmer screen. Depending on the programmed patient information, one of the following text fields appears:

- the patient name
- the patient ID, if the patient name was not entered
- the message “(Patient name not entered)”, if neither the name nor the ID was entered

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

Figure 8. Command bar



2.4 Delivering an emergency tachyarrhythmia therapy

You can use emergency defibrillation, cardioversion, and fixed burst pacing therapies to quickly treat ventricular tachyarrhythmia episodes during a patient session. Emergency defibrillation therapy delivers a high-voltage biphasic shock at the selected energy level. Emergency cardioversion therapy also delivers a high-voltage biphasic shock, but it must be synchronized to a ventricular event. Emergency fixed burst pacing therapy delivers maximum output pacing pulses to the ventricle at the selected interval.

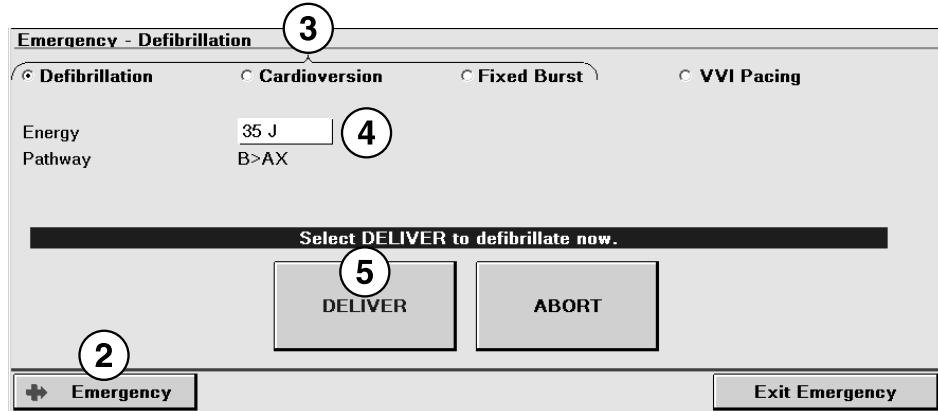
2.4.1 Considerations for emergency tachyarrhythmia therapies

Tachyarrhythmia detection during emergency tachyarrhythmia therapies – The device suspends the tachyarrhythmia detection features when emergency defibrillation, cardioversion, or fixed burst pacing therapies are delivered. Select [Resume] to re-enable tachyarrhythmia detection.

Temporary parameter values – Emergency tachyarrhythmia therapies use temporary parameter values that do not change the programmed parameters of the device. After the tachyarrhythmia therapy is complete, the device reverts to its programmed parameter values.

Aborting an emergency tachyarrhythmia therapy – You can immediately terminate an emergency defibrillation or emergency cardioversion therapy by selecting [ABORT]. To stop an emergency fixed burst therapy, remove the touch pen from [BURST Press and Hold].

2.4.2 How to deliver an emergency tachyarrhythmia therapy



1. Establish telemetry with the device.
2. Select [Emergency].
3. Select the type of emergency therapy to deliver: Defibrillation, Cardioversion, or Fixed Burst.
4. Accept the therapy parameters shown on the screen, or select new values.
5. For defibrillation and cardioversion therapy, select [DELIVER]. For fixed burst therapy, select [BURST Press and Hold] and hold the touch pen over the button for as long as you want to deliver the therapy.

2.5 Enabling emergency VVI pacing

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

2.5.1 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 the device manual for the device. To terminate emergency VVI pacing, you must reprogram pacing parameters from the Parameters screen.

2.5.2 How to enable emergency VVI pacing

1. During a patient session, establish telemetry with the device.
2. Press the red VVI button on the programmer to enable emergency VVI pacing.

Depending on your model of Medtronic programmer, the emergency VVI button is:

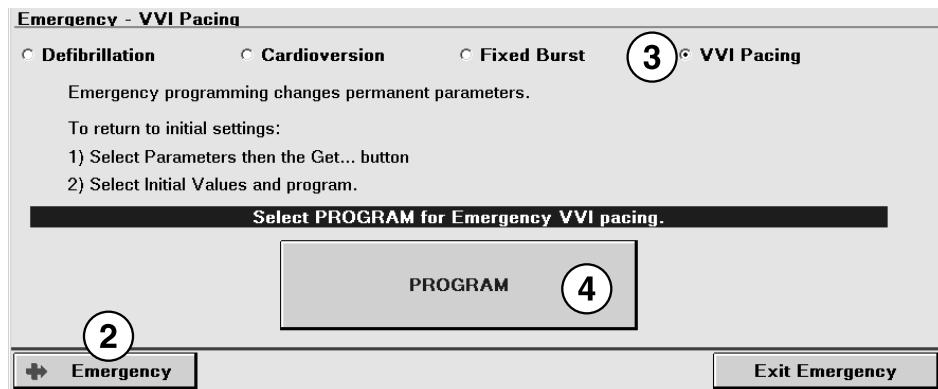
- a mechanical red button to the left of the programmer screen, on the programmer bezel.
- a red button on the programmer button panel, above the programmer screen.

Note: On all programmers, an [Emergency] button is implemented in the software and is available on the display screen (see the following procedure for instructions regarding this button).



How to enable emergency VVI pacing with the on-screen [Emergency] button –
Perform the following steps to enable emergency VVI pacing with the on-screen [Emergency] button:

1. Establish telemetry with the device.



2. Select [Emergency].
3. Select VVI Pacing.
4. Select [PROGRAM].

2.6 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. The Suspend/Resume function applies to both atrial and ventricular tachyarrhythmia detection.

2.6.1 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/FVT/VF episodes – If you suspend detection while a therapy is being delivered, the device finishes delivering the therapy that is in progress but does not redetect until you resume detection. If you resume detection before the episode terminates, the device begins redetection, and the episode is redetected if the programmed Beats to Redetect value is reached.

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.

2.6.2 How to suspend or resume detection with the programmer

Figure 9. [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].

2.6.3 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.

Note: The programming head contains a magnet. When the programmer is using wireless telemetry, you can suspend detection by placing the programming head over the device. For more information, see Section 2.1, “Establishing telemetry between the device and the programmer”, page 11.

2.7 Monitoring cardiac activity with the Live Rhythm Monitor

The Live Rhythm Monitor window displays ECG, Leadless ECG (LECG), Marker Channel with marker annotations, and telemetered EGM waveform traces on the programmer screen. The Live Rhythm Monitor window also displays the patient 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 to the programmer’s strip chart recorder or Electronic Strip Chart (eStrip) recorder, whichever is available, and recall any saved waveform strips prior to ending a patient session.

By default, the Live Rhythm Monitor window 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 the [Adjust...] button. Waveform traces display depending on which waveform source is selected and how waveform traces have been arranged in the full-screen view.

2.7.1 Types of live waveform traces

2.7.1.1 Leadless ECG (LECG) waveform

Leadless ECG simplifies and expedites patient follow-up sessions by providing an alternative to obtaining an ECG signal without the need to connect surface leads to the patient. Leadless ECG is available in the clinic and at remote locations where the CareLink Network is available.

Leadless ECG provides a far-field view of cardiac activity without connecting leads to the patient. The Leadless ECG (LECG) waveform displays an approximation of a surface ECG signal through the Can to SVC source. The Can to SVC source is available only when an SVC coil is present. You can also choose to display the waveform from the RVcoil to Aring source or the Can to Aring source on the LECG channel. This signal is telemetered from the device and is selected from the programmable LECG source when you set up data collection.

2.7.1.2 ECG waveforms

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.

2.7.1.3 EGM waveforms

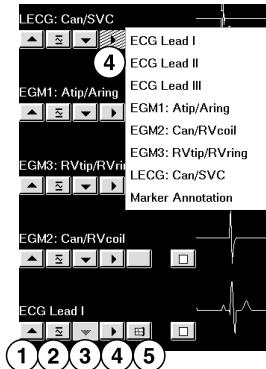
The EGM1, EGM2, and EGM3 signals are telemetered from the device and are selected from programmable EGM sources. You can choose the sources of EGM1, EGM2, and EGM3 when you set up data collection. The programmer cannot display or record an EGM waveform trace until the device has been interrogated.

You can also choose the sources of the LECG waveforms when you set up data collection. For more information, see Section 3.8, “Arrhythmia Episodes data”, page 115. Data collection parameters are provided in the device manual.

2.7.2 Viewing live waveform traces

2.7.2.1 How to select and adjust the waveforms

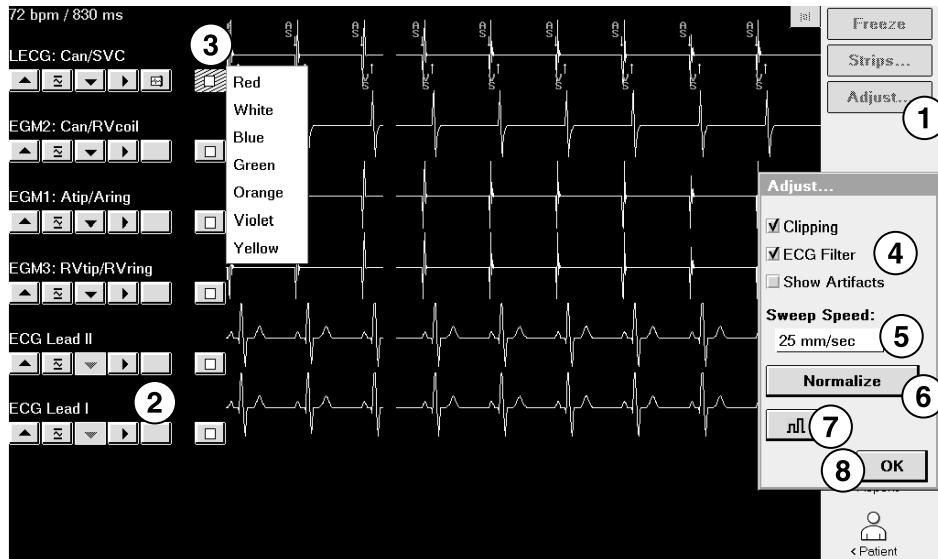
You can use the waveform adjustment button bar to change the appearance of the waveforms in view.



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.

2.7.2.2 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 finish making adjustments, select [OK].

2.7.2.3 How to interpret Marker Channel annotations and symbols

Marker Channel annotations appear as 2 characters above or below the Marker Channel waveform trace. 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 when printed, depending on the printout speed of the programmer strip chart recorder, if available.

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.

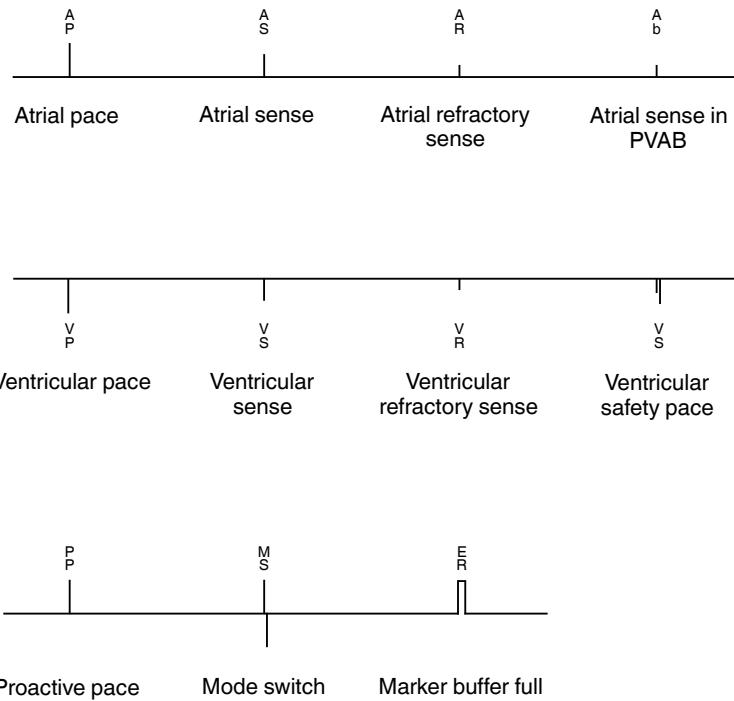
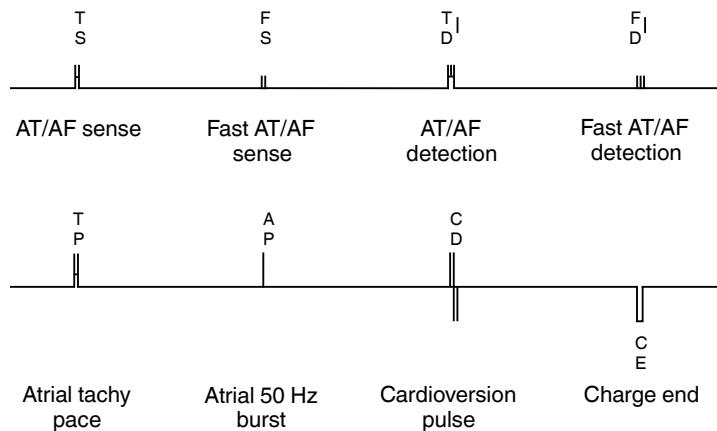
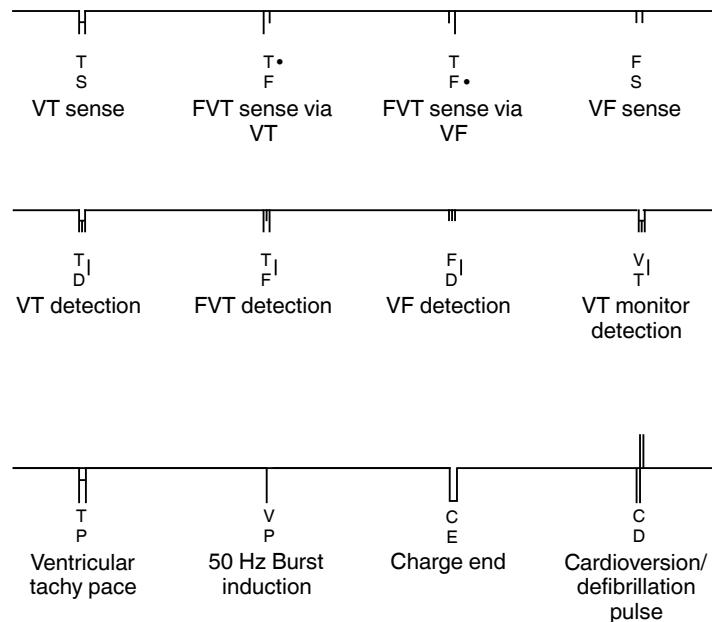
Figure 10. Pacing Marker Channel annotations and symbols

Figure 11. Atrial detection and therapies Marker Channel annotations and symbols**Figure 12.** Ventricular detection and therapies Marker Channel annotations and symbols

2.7.3 Recording live waveform traces

At any time during a patient session, you can record a continuous, live waveform trace of the patient's ECG, LECG, and EGM in either of two ways:

1. on an internal strip chart recorder, if available on your Medtronic programmer.

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.

2. on an Electronic Strip Chart (eStrip) recorder, if available on your Medtronic programmer.

Depending on the Medtronic programmer model used, a printout or a recording of the live waveform trace includes the following information:

- ECG, LECG, and EGM traces²,
- 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. For more information, see Section 3.8, "Arrhythmia Episodes data", page 115.

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. 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, if available with your Medtronic programmer. Printing to an external printer is not affected.

EGM or LECG Range – The programmer cannot display or record an EGM or LECG waveform trace until the current EGM Range or LECG Range setting has been interrogated from the device. If you program an EGM Range or LECG Range setting during a recording, the programmer marks the change with a vertical dotted line on the paper recording.

² Programmers that feature a strip chart recorder cannot display or record an EGM or LECG trace until the device has been interrogated.

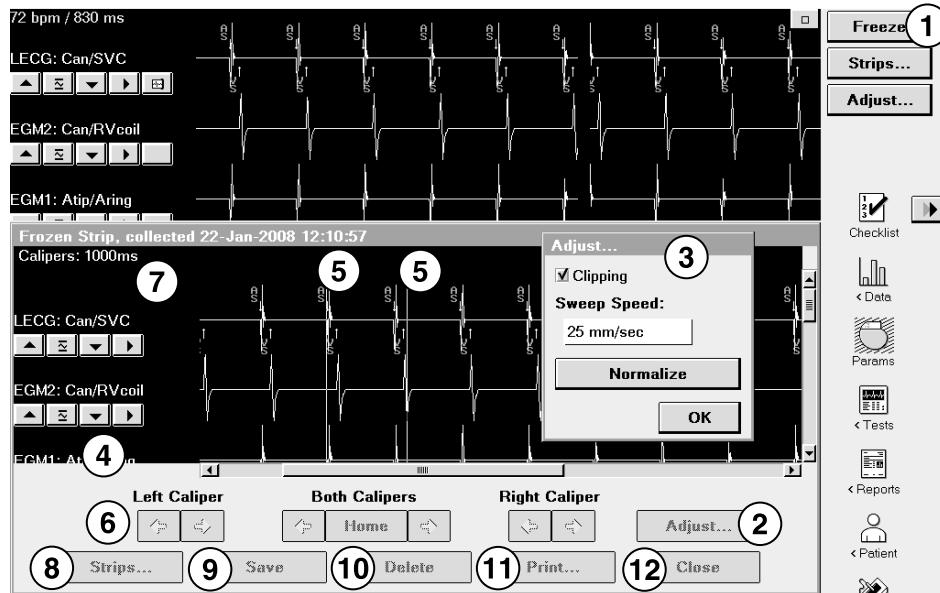
2.7.4 Freezing live waveform traces

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 13. Interpreting the frozen strip viewing window



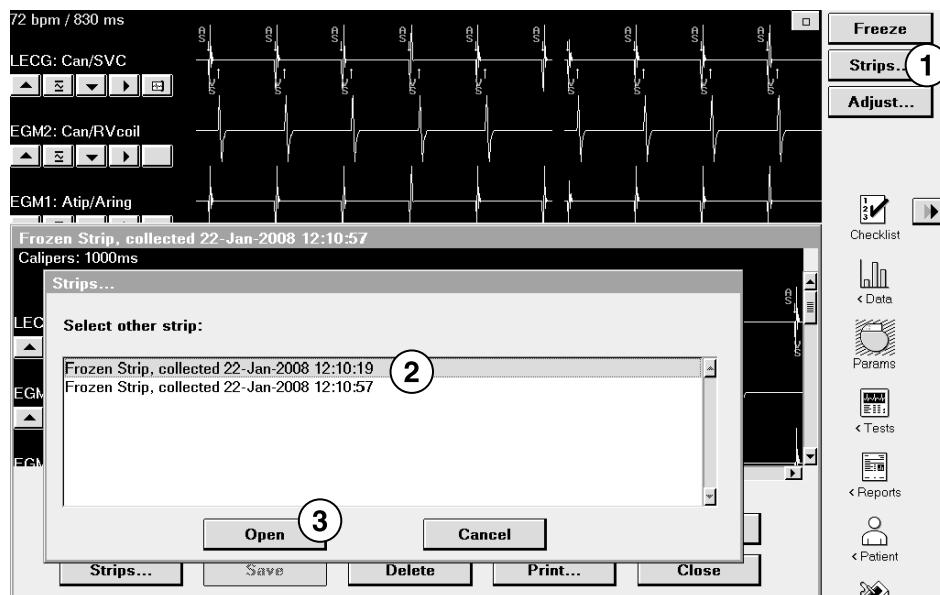
- 1 The [Freeze] button freezes a live waveform trace and displays it in the frozen strip viewing window on the programmer screen.
- 2 The [Adjust...] button opens the Adjust window for the strip viewer.
- 3 The Adjust window offers display options for the strip viewer, which is similar to the Adjust 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.

2.7.5 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.

2.7.5.1 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.

2.8 Navigating a patient session 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.

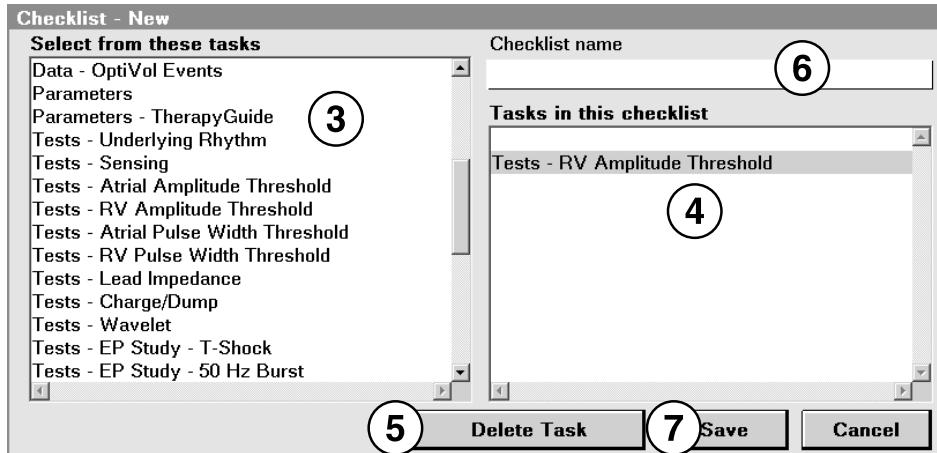
2.8.1 How to use a standard checklist

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.

2.8.2 How to create and use 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.

2.9 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.

2.9.1 Understanding the symbols used on the Parameters screen

The following symbols can appear next to a parameter value.

Table 4. Symbols that appear with parameter values

Symbol	Definition
	This symbol indicates that the value is the Medtronic nominal value.
	This symbol indicates that the value is the programmed value.
	This symbol indicates that the programmed value can be changed automatically by the device. The adaptive symbol does not necessarily indicate that the parameter value has been adapted from a previously programmed value. It only indicates that it is able to be adapted.
	This symbol indicates that the parameter value conflicts with the setting of another present or pending value. A parameter interlock exists.
	This symbol indicates that a warning message is available about the value. A parameter warning exists.

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. If a parameter interlock symbol appears, select another value or resolve the conflicting parameter value before programming the parameter. If a parameter warning exists, select the message button to read the warning and view recommendations.

The programmer may display a message button next to the [PROGRAM] button that accesses additional information about the pending parameters. When the message button is selected, the programmer opens a second window displaying one or more messages. The message button has one of the symbols described in Table 5.

Table 5. Symbols that appear on the message button

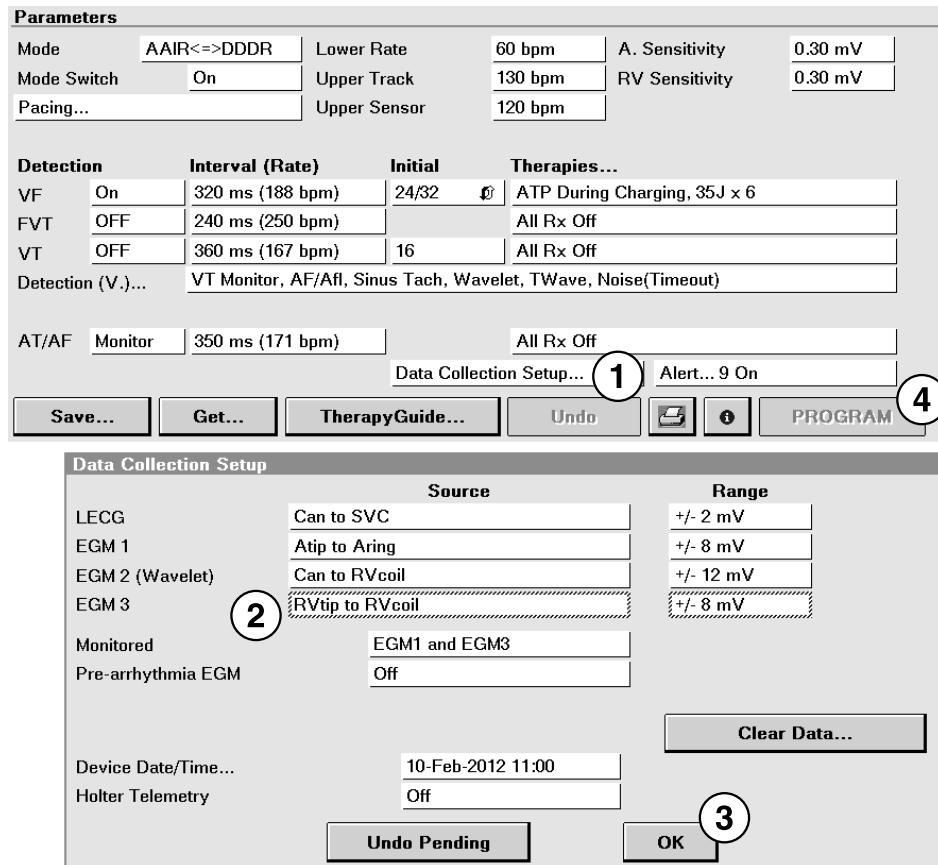
Symbol	Explanation
 PROGRAM	Interlock – Indicates that a parameter interlock exists. Programming is restricted until you resolve the conflict. Select this button for a message that describes the conflict.
 PROGRAM	Warning – Indicates that there is a warning associated with programming one or more of the pending parameter values. Select this button to view the warning message and recommendations.
 PROGRAM	Informational – Indicates that there is an informational message about 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.

2.9.2 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.

2.9.3 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.

2.10 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.

2.10.1 How to save a set of parameter values

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

2.10.2 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. Select [PROGRAM] to apply the pending values.

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.

To remove a parameter set from the list, choose the parameter set and select [Delete].

2.11 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.

2.11.1 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 14. TherapyGuide window

TherapyGuide		
VT/VF	Spontaneous Sustained VT	
Slowest VT	330 ms (182 bpm)	
Atrial Status	AT/AF + Normal Sinus	
AV Conduction	Normal AV Conduction	
Heart Failure	No Heart Failure	
Date of Birth	01-Jan-1937	
Activity Level	Average Activity	
Last Update	10-Feb-2012	
Note: Information is stored in device only after selecting PROGRAM on the Parameters screen.		
Rationale...	Get Suggestions	Close

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 6. 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 clinical conditions do not influence a parameter, TherapyGuide may either recommend the Medtronic nominal value for that parameter or make no recommendation.

If the suggested value for a parameter is different from 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 6. How programming suggestions are determined

Programming suggestions	Clinical conditions
VF Detection	VT/VF Slowest VT
VT Detection	VT/VF Slowest VT
VT Monitor	Atrial Status AV Conduction Date of Birth Treated Cutoff ^a
Pacing Mode	Atrial Status AV Conduction
Lower Rate	Atrial Status Date of Birth
Upper Tracking Rate	AV Conduction Date of Birth Treated Cutoff ^a
Rate Drop Response	Atrial Status
Rate Response (including Upper Sensor Rate)	Atrial Status Heart Failure Date of Birth Activity Level

^aThe Treated Cutoff equals the VT detection interval if VT Detection Enable is On. Otherwise, the Treated Cutoff is the VF detection interval.

2.11.2 Considerations for TherapyGuide

TherapyGuide and the Patient Information screen – The clinical conditions can also be programmed into device memory from the Patient Information screen. For more information, see Section 2.12, “Storing patient information”, page 47.

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 10 days after implant.

2.11.3 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.

2.11.4 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.

2.12 Storing 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. Likewise, this same information programmed through the TherapyGuide feature appears in the Patient Information screen. For more information, see Section 2.11, "Using TherapyGuide to select parameter values", page 44.

The patient's name and ID and the device serial number are printed on all full-size and strip chart reports. If the programmer is using wireless telemetry, the patient is also identified at the bottom of the programmer screen, either by the patient's name or by the patient ID (if the patient's name was not entered).

Note: The Patient Information screen should not be used in the place of the patient's medical chart.

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 Model 2290 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.

2.12.1 How to view and enter patient information

Select Patient > Patient Information. The Patient Information screen appears. Select each text field to enter or change its content.

Patient Information	
Patient	1 John Q. Patient
ID	2 123-45-6789
Date of Birth	3 02-Feb-1947
Serial Number	4 BLC012345R
Lead 1...	5 []
Lead 2...	5 []
Lead 3...	5 []
Implant...	6 14-Feb-2012
Notes	7 []
History...	8 Spontaneous Sustained VT, 3
EF, on	9 30 % 11-Apr-2012
Physician	10 Dr. McMurray
Phone	10 763-555-1234
Hospital	10 Redwing General
Last Update	10 11-Apr-2012
<input type="button" value="Undo Pending"/> <input type="button" value="Print..."/> 11 <input type="button" value="PROGRAM"/>	

1. Enter the patient's name (29 character maximum).
2. Enter the patient's ID (15 character maximum).
3. Select the patient's date of birth.
4. The serial number of the implanted device.
5. Enter the information for up to 3 leads. Select the model, position, and manufacturer from the lists of options. Enter the serial number and implant date.

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 2.12.2 for instructions. Otherwise, select a value for each parameter.

6. Export lead data from the analyzer, or enter lead data using the submenus. Enter the results of defibrillation testing.
7. Enter notes about the patient.
8. Select the patient's clinical conditions. This information is made available to TherapyGuide.
9. Select the ejection fraction from a table of values in the first field, and enter the date in the second field.
10. Select the physician's name, phone number, and hospital from the lists. If information is not on the list, add the information to the list and then select.
11. When you have entered the information in all fields, select [PROGRAM].

The date of the last Patient Information update appears automatically.

2.12.2 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 task bar.



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 2.12.1, 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.

2.13 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.

2.13.1 Setting preferences for printing, reports, and tests

Preferences allows you to choose the printer you want to use, the number of copies to print, and whether you want to print now or later. You can choose to print reports anytime during a patient session. Your printing preferences are then applied automatically whenever you select the [Print...] button.

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".

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

2.13.1.1 How to set preferences

1. After starting a patient session, select Reports > Preferences....
2. From the Index selection box, select the option you want: Printing, Initial Report, Final Report, or Tests.
3. Select your preferences.
4. Select [OK].

Basic printing preferences take effect immediately and are applied at the end of the current patient session. 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. The preferences you select for Final Report persist between sessions and across most applications.

The Session Summary report always prints when you request a Final Report.

The Tests preference 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 keep the waveform arrangement unchanged. For more information on tests, see Chapter 7, “System test and EP Study features”, page 333.

2.13.1.2 How to print an Initial Interrogation Report

The Initial Interrogation Report includes the Quick Look II report and the other reports you selected from the preferences on the Initial Report window. If you select the check box next to “Print Initial Interrogation Report after first interrogation” as a preference for the Initial Report, the programmer automatically prints the reports after the first interrogation in a patient session.

To print an Initial Interrogation Report for a patient session that is in progress, select the check box next to “Print Initial Interrogation Report after first interrogation”. Then end the current patient session and restart the patient session. If you have selected this option, the Initial Interrogation Report prints automatically after interrogation.

2.13.2 Printing reports during and after 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.

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

2.13.2.1 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 unavailable.
3. Select [Print Options...]. Enter number of copies and select printer preference.
4. Select [Print Now] for immediate printing, or select [Print Later] to add the print request to the print queue.

2.13.2.2 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.

2.13.3 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. 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. You can print or delete a print job from the queue. A report cannot be deleted if its status is “printing” or “waiting”.

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

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 sessions.

2.14 Transferring data to Paceart with SessionSync

The SessionSync feature enables you to transfer device data through your clinic network between the Medtronic programmer and the Medtronic Paceart data management system, if Paceart is available in your locale. Transferred device data can be stored and used for later analysis and patient management.

The SessionSync status icon indicates network connectivity and shows data transfer when the SessionSync feature is enabled. The SessionSync Status screen provides information about the connection status of the programmer to the data management system. Details about the SessionSync status icon and connection status are provided in Section 2.14.4.2.

Notes:

- For information about searching, viewing, and printing data from the patient records stored on the Medtronic Paceart data management system, consult the Paceart documentation.
- For information about saving data to media and retrieving, viewing, and printing data from media, see Section 2.15, “Saving and retrieving device data”, page 58.
- The SessionSync feature operates within the context of a patient session. For information about patient sessions, see Section 2.2, “Starting a patient session”, page 16 and Section 2.16, “Ending a patient session”, page 61.

2.14.1 Enabling and disabling the SessionSync feature

Typically, the SessionSync feature is enabled only once when it is first installed. Once the SessionSync feature is enabled, any device application on the programmer that can use the SessionSync feature has SessionSync functionality.

The SessionSync status icon indicates network connectivity and shows data transfer when SessionSync is enabled. The SessionSync status icon is unavailable when the feature is disabled, for example, during a patient session.

2.14.1.1 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.

2.14.2 Configuring the SessionSync network connection

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

2.14.2.1 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 – Before configuring the network connection, you 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.

2.14.2.2 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].

2.14.3 Transferring device data

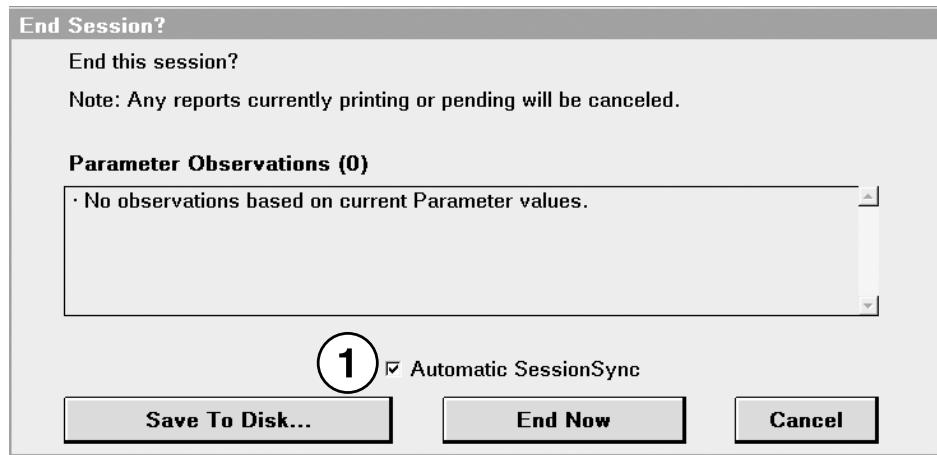
Device data is transferred to the Medtronic Paceart data management system using either Automatic SessionSync or Manual SessionSync.

2.14.3.1 Transferring session data with Automatic SessionSync

Perform the following steps to end the current session and use Automatic SessionSync to transfer session data between the Medtronic programmer and the Medtronic Paceart data management system.

1. Select [End Session...].

The End Session window is displayed.

Figure 15. End Session window

1 Automatic SessionSync check box

2. Make sure that the Automatic SessionSync check box is selected.

Notes:

- The Automatic SessionSync check box is not visible in the End Session window if device interrogation is not successful.
- The Automatic SessionSync check box is not visible in the End Session window if SessionSync is not enabled on the programmer.

3. Select [End Now].

The following actions occur:

- a. Data transfer begins immediately.
- b. The SessionSync – Saving Session Data on Programmer window is displayed to show the progress of the data transfer.
- c. The programmer side of the SessionSync status icon turns blue after the data has been saved on the programmer's hard disk.
- d. If the subsequent transfer is successful, the data management system side of the SessionSync status icon turns blue.

See Section 2.14.4, “Viewing the SessionSync data transfer status”, page 56, for more details about status icon indications.

Note: If error messages appear during the data transfer process, see Section 2.14.5, SessionSync error messages for a list of message descriptions.

2.14.3.2 Transferring session data with Manual SessionSync

You can use Manual SessionSync at any time during a patient session to transfer session data between the Medtronic programmer and the Medtronic Paceart data management system.

To use Manual SessionSync, select Session > SessionSync.... The following events occur during the data transfer process:

1. The SessionSync – Saving Session Data on Programmer window opens to show the progress of session data being saved automatically on the programmer's hard disk.
2. The programmer side of the SessionSync status icon turns blue after the data has been saved on the programmer's hard disk.
3. If the subsequent transfer is successful, the data management system side of the SessionSync status icon turns blue.

See Section 2.14.4.2, "States of the SessionSync status icon", page 57 for more details.

Notes:

- SessionSync may have been disabled outside the patient session. If so, SessionSync... is not listed in the Session menu and the SessionSync status icon is unavailable.
- The procedure in Section 2.14.3.1, "Transferring session data with Automatic SessionSync", page 53 allows you to transfer session data automatically, but it requires that you end the current session to do so.
- If error messages appear during the data transfer process, see Section 2.14.5, "SessionSync error messages", page 58 for a list of message descriptions.

2.14.3.3 Transferred data

The following table lists the device data that is transferred with Automatic SessionSync or Manual SessionSync to the Medtronic Paceart data management system.

Table 7. Data transferred with SessionSync

Feature name	Information exported
Therapy Parameters	Initial interrogated values Last programmed values
Patient Information	Last programmed values
Battery and Lead Measurements	Last measured values

Table 7. Data transferred with SessionSync (continued)

Feature name	Information exported
Threshold Tests ^a	Last results for each test type conducted (for each chamber tested)
Sensing Tests ^a	Last results for each test type conducted (for each chamber tested)
Automatic Diagnostics	Event Counters Atrial Arrhythmia Episodes Ventricular Arrhythmia Episodes Mode Switch Episodes Rate Drop Response Episodes
Device Memory	Retrieved from interrogation performed only for saving session data

^aManual test results are saved only if the user has saved the results.

2.14.4 Viewing the SessionSync data transfer status

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

When all components of the SessionSync status icon are unavailable on 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 update dynamically when the SessionSync Status window is open. To update the status, select the [Update Status] button.

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

The programmer task bar displays a SessionSync status 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 16. SessionSync status icon on the programmer task bar

Figure 17. SessionSync status icon indicators

1 Data management system status

2 Connection status

3 Programmer status

2.14.4.2 States of the SessionSync status icon

The following table lists the states of the SessionSync status icon that appears in the programmer task bar.

Table 8. SessionSync status icon states

Part of SessionSync status icon	Color	What the color indicates
Data management system status	Gray	No session data has been transferred to the data management system
	Blue	All session data has been successfully transferred to the data management system
Connection status	Not visible	No valid connection between the programmer and the data management system
	Green	Valid connection between the programmer and the data management system
Programmer status	Red circle with a line through it	A device application in use that does not support SessionSync
	Gray	No session data files in the Transfer Queue
	Blue	Session data files in the Transfer Queue

2.14.4.3 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.

Note: Events displayed on the SessionSync Status screen are not automatically updated when SessionSync Status is selected from the menu. The user must manually select the [Update Status] button to refresh the events that are displayed.

2.14.5 SessionSync error messages

Table 9. SessionSync error messages

Error Message	What this means
Ending a Session without Automatic SessionSync	You have deselected the Automatic SessionSync check box on the End Session window before selecting the [End Now] button.
Interrogation Required	You must conduct an interrogation.
Data Transfer Failed	The data cannot be transferred to the data management system. The session data has been successfully saved on the programmer's hard disk but cannot be transferred to the data management system. Select [Retry] to retry the SessionSync operation. - or - Select [Cancel] to close the window.
Unable to Save Session Data	The session data cannot be saved on the programmer's hard disk. Select [Save to Disk...] to save the session data on a floppy disk. - or - Select [End Now] to end the session without saving the device data. - or - Select [Cancel] to close the window without saving the device data.

2.15 Saving and retrieving device data

The programmer allows you to save interrogated device data from a patient session to a disk 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.

Note: Medtronic programmers are equipped either of two ways: with a disk drive for 3.5 inch disks plus a USB port for USB flash drives, or with a USB port only. If your programmer has a USB port only, please disregard content in this section that documents the use of disk drives.

2.15.1 Saving device data

Any programmer equipped with a disk drive can read device data from or write device data to a disk. However, if a USB flash drive is inserted into the programmer, it overrides the disk drive for saving and retrieving device data. Disks may be used only when no USB flash drive is inserted.

Storage requirements – To ensure the integrity and security of patient information, use a 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 to a disk because the programmer saves only the data it has interrogated. If the Interrogate How Much? window is displayed, select Interrogate 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.

2.15.1.1 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-disk
- performing a reload session data operation
- saving a report as a PDF file

2.15.1.2 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...].

2.15.1.3 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.

2.15.1.4 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...].

2.15.2 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.

2.15.2.1 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.

2.16 Ending a patient session

2.16.1 How to end a patient session

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

2.17 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.

2.17.1 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 2.13, “Printing reports”, page 49. 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 2.8, “Navigating a patient session with Checklist”, page 38.

Leadless ECG (LECG) – Leadless ECG is designed to simplify and expedite patient follow-up sessions by providing an alternative to obtaining an ECG signal without the need to connect surface leads to the patient. You can view the Leadless ECG waveform trace on the Live Rhythm Monitor window. Leadless ECG is available at clinic and remote locations. For more information, see Section 2.7, “Monitoring cardiac activity with the Live Rhythm Monitor”, page 28.

Cardiac Compass Trends – Cardiac Compass Trends provides a picture of the patient's condition during the last 14 months. The report includes graphs that show trends in the frequency of arrhythmias, the amount of physical activity, heart rates, and device therapies. Dates and event annotations allow you to correlate trends from different graphs. The trends can also help you to assess whether device therapies or drug therapies is effective. For more information, see Section 3.6, “Cardiac Compass Trends”, page 102.

2.17.2 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.

2.17.3 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 3.1, "Quick Look II summary data", page 69.

2.17.3.1 How to review the Remaining Longevity estimate 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.

Review the displayed Remaining Longevity estimate. If the programmer displays the RRT indicator, contact your Medtronic representative and schedule an appointment to replace the device. For more information, see Section 3.4, "Device and lead performance data", page 88.

2.17.3.2 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 3.4, "Device and lead performance data", page 88.

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 7.4, “Lead Impedance Test”, page 339.
- Sensing Test: Compare the test results to previous P-wave and R-wave amplitude measurements. For more information, see Section 7.5, “Sensing Test”, page 340.
- 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 device longevity. For more information, see Section 7.2, “Pacing Threshold Test”, page 334.

2.17.4 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.

2.17.4.1 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 Rate Histograms.
3. Review the Cardiac Compass Trends for comparison to 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 3.6, “Cardiac Compass Trends”, page 102.

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

2.17.4.2 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 3.8, “Arrhythmia Episodes data”, page 115.

Episode misidentification – If the episode records indicate that the device has misidentified the patient’s rhythm, carefully review the tachyarrhythmia episode and sensing

integrity data, the Cardiac Compass trend data, and the data stored for other episodes. Consider adjusting the detection parameters and the SVT detection criteria as needed. For more information about how to view sensing integrity data, see Section 4.1, “Sensing”, page 140.

Caution: Use caution when reprogramming the detection or sensing parameters to ensure that changes do not adversely affect VF detection. Ensure that appropriate sensing is maintained. For more information, see Section 4.1, “Sensing”, page 140.

2.17.4.3 How to assess appropriate tachyarrhythmia therapy

1. Review any Medtronic CareAlert Notifications in the Quick Look II Observations section that relate to therapy delivery. To see detailed information about Medtronic CareAlert Notifications, select Data > Alert Events.
2. Check tachyarrhythmia episode records to determine the effectiveness of therapies that have been delivered.
3. Adjust the therapy parameters as needed.

2.18 Optimizing device longevity

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

To view the Remaining Longevity estimate for the device, refer to the Quick Look II screen. The following sections describe strategies that may help reduce the energy requirements placed on the battery.

2.18.1 Promoting intrinsic AV conduction

Managed Ventricular Pacing (MVP) – MVP promotes AV conduction by reducing unnecessary right ventricular pacing. The primary benefit of MVP is therapeutic, but it may also preserve device longevity as a result of a decrease in the percentage of pacing. For more information about MVP, see Section 4.3, “Managed Ventricular Pacing (MVP)”, page 160.

Promoting AV conduction with longer AV intervals – Another method of promoting AV conduction is to increase the Paced AV and Sensed AV intervals. This allows intrinsic conduction to occur before a ventricular pace. Fewer pacing pulses may help to preserve device longevity. For more information, see Section 4.2, “Basic pacing”, page 150.

2.18.2 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 right 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, see Section 4.5, “Capture Management”, page 173.

Manual optimization of amplitude and pulse width – If you choose to program Capture Management to Off, you can optimize the patient’s pacing output parameters manually. Perform a pacing threshold test to determine the patient’s pacing thresholds. Select amplitude and pulse width settings that provide an adequate safety margin above the patient’s pacing threshold. These actions decrease the pacing outputs and preserve battery energy. For more information, see Section 7.2, “Pacing Threshold Test”, page 334.

Pacing rate – The more paced events that are delivered, the more device longevity is reduced. Make sure that you have not programmed an unnecessarily high pacing rate for the patient. Carefully consider using features that increase bradycardia pacing rate. Use features such as Atrial Preference Pacing (APP), Conducted AF Response, and Rate Response only for patients who can receive therapeutic benefit from the feature.

2.18.3 Optimizing tachyarrhythmia therapy settings

Defibrillation – To treat ventricular fibrillation episodes, the device may deliver defibrillation therapy to terminate the episode and restore the patient’s normal sinus rhythm. The device can be programmed to deliver a sequence of up to 6 defibrillation therapies. Although defibrillation therapy expends a high level of energy, VF therapies should be programmed to the maximum energy level. For more information about defibrillation energy, see Section 6.5.2, “Programming VF therapies”, page 311.

Atrial cardioversion – You can program the device to deliver automatic atrial cardioversion (CV) therapies to treat atrial tachyarrhythmia episodes. If you choose to treat the patient with atrial CV therapies, you can extend device longevity by carefully considering how you program the following parameters: the number of shocks delivered during a 24-hour cycle and the Episode Duration before CV. It is recommended that CV therapy be set to full energy to terminate the arrhythmia. For more information, see Section 6.3, “Atrial cardioversion”, page 292.

Patient-activated cardioversion is another way to provide atrial cardioversion therapy. The patient can use the InCheck Patient Assistant to signal the device to deliver atrial cardioversion therapy as needed. Counsel the patient on the potential inappropriate overuse of patient-activated cardioversion that can result in decreased device longevity. For more information, see Section 6.4, “Patient-activated atrial cardioversion”, page 298.

Ventricular cardioversion – If you are providing ventricular cardioversion therapies for the patient, consider programming the therapy energy to a value lower than the maximum energy but high enough to terminate the VT. However, at least one VT therapy and one FVT therapy in a sequence should be programmed to the maximum energy level. For more information, see Section 6.7, “Ventricular cardioversion”, page 323.

FVT via VF detection – An FVT detection zone may be used to detect and treat a VT episode that is in the rate zone for VF. This approach may help maintain reliable detection of VF while allowing ATP to be delivered for fast VT episodes. For more information, see Section 5.2, “VT/VF detection”, page 230.

Antitachycardia pacing (ATP) – ATP therapies interrupt the tachycardia episode and restore the patient’s normal sinus rhythm. ATP therapies deliver pacing pulses instead of high-voltage shocks that are delivered in cardioversion therapy and defibrillation.

ATP therapy requires less battery energy than cardioversion or defibrillation. For some patients, you may be able to program the device to deliver ATP therapies before delivering high-voltage therapies.

For more information about ATP and atrial episodes, see Section 6.2, “Atrial ATP therapies”, page 282. For more information about ATP and ventricular episodes, see Section 6.6, “Ventricular ATP therapies”, page 313.

Delivering ATP before the first defibrillation – You can program the device to deliver ATP therapy before delivering the first defibrillation therapy by enabling ATP During Charging or ATP Before Charging. This action can prevent delivery of high-voltage therapy for rhythms that can be terminated by ATP (rapid, monomorphic VT, for example).

If you program the ChargeSaver feature to On, the device can also automatically switch to ATP Before Charging operation. This switch allows the device to attempt a sequence of ATP therapy before charging the capacitors to treat a detected VF episode. For more information, see Section 6.5, “VF therapies”, page 303.

2.18.4 Considering how diagnostic features with data storage impact longevity

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

When Pre-arrhythmia EGM storage is on, the device collects up to 10 s of EGM data before the onset of VT/VF, VT Monitor, or the detection of SVT 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:

- Set Pre-arrhythmia EGM storage to On to capture possible changes in the tachyarrhythmia onset mechanism following significant clinical adjustments such as device implant, medication changes, and surgical procedures. Pre-arrhythmia EGM storage may be set to On - 1 month, On - 3 months, or On Continuous. Select the setting for the shortest time period that will provide the necessary data.
- Set Pre-arrhythmia EGM storage to Off after you have obtained the data of interest.

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

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

Medtronic CareLink remote transmissions – When scheduling Medtronic CareLink remote transmissions, be aware that increasing the frequency of remote transmissions reduces implanted device service life by approximately 1 day for each additional transmission. To conserve battery energy, schedule the lowest frequency of remote transmissions that still allows for the desired monitoring of your patient's device.

2.18.5 Managing wireless telemetry session duration

Reducing wireless telemetry session duration may help reduce the energy requirements placed on the battery.

- At implant and in the first 7 days after implant, the wireless telemetry session duration is 2 hours to provide time for implant, programming, and patient follow-up tasks. The device transitions to Standby mode after 2 hours of programmer inactivity.
- 7 days after implant, the wireless telemetry session duration is reduced automatically to 5 min to help preserve device longevity. The device transitions to Standby mode after 5 min of programmer inactivity. If patient follow-up tasks require it, you can optionally extend the wireless telemetry for a patient session to 2 hours by selecting Session > Extend Wireless Telemetry Session and then selecting [Continue]. At the end of the session, the wireless telemetry session duration for the patient reverts automatically to 5 min.

3 Diagnostic data features

3.1 Quick Look II summary data

At the start of a patient session, it is useful to quickly view summary information about device operation and the patient's condition over the period since the last follow-up appointment. 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.

3.1.1 How to view the Quick Look II screen

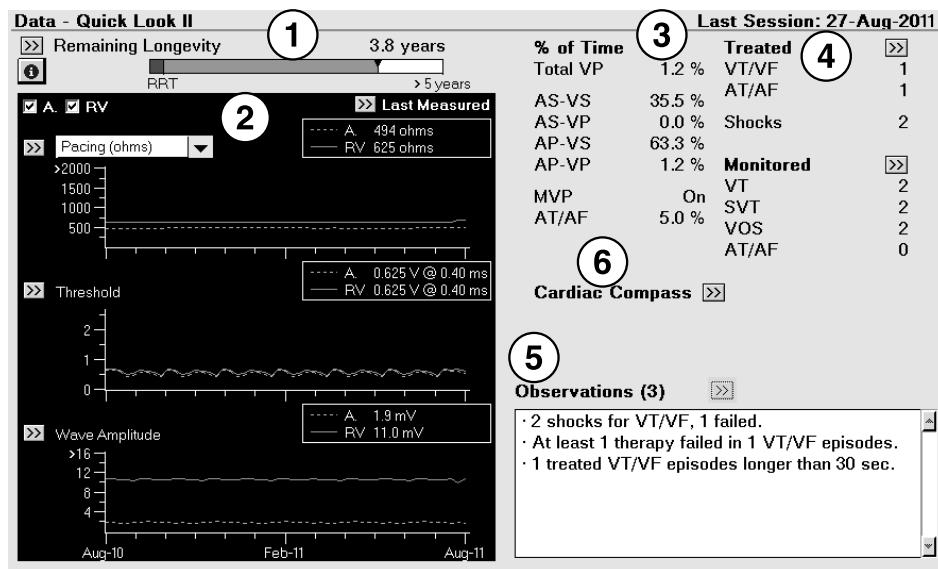
The Quick Look II screen is automatically displayed after the patient session is started. You can also access the Quick Look II screen by selecting Data > Quick Look II.

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

3.1.2 Information provided by the Quick Look II screen

The Quick Look II screen shows information in 6 sections.

Figure 18. Quick Look II screen



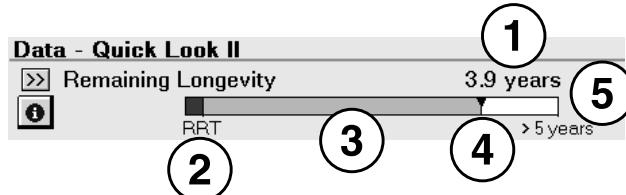
- 1 Remaining Longevity estimate
- 2 Lead status and trends
- 3 Pacing and sensing information

- 4 Arrhythmia episode information
- 5 Observations
- 6 Cardiac Compass Trends

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.

3.1.2.1 Assessing the device and lead status

Remaining Longevity estimate – The device automatically calculates the estimated time remaining until Recommended Replacement Time (RRT) based on automatic daily battery voltage measurements, time since implant, programmed parameter settings, and device recorded events. Remaining Longevity displays the estimated time remaining and a graphic that shows the RRT period in red and the estimated remaining longevity in green.

Figure 19. Remaining Longevity estimate

- 1 Estimated remaining longevity to RRT (years or months)
- 2 RRT (red bar)
- 3 Estimated remaining longevity to RRT (green bar)
- 4 Remaining Longevity marker
- 5 If estimated remaining longevity to RRT is greater than 5 years, the green bar is full

Select the Remaining Longevity [>>] button to see more detailed battery and lead measurement data. The Battery and Lead Measurements screen and its associated printed report provide the most recent Remaining Longevity estimates, battery voltage measurement, and RRT indicator with date and time, if applicable. For more information, including the date when the battery reaches RRT, see Section 3.4, “Device and lead performance data”, page 88.

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 3.4, “Device and lead performance data”, page 88.

3.1.2.2 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 5.1, “AT/AF detection”, page 224.

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. It also shows the number of shocks that were delivered since the last session. In addition, it shows the number of episodes for which ventricular oversensing (VOS) was detected by the TWave Discrimination feature or the RV Lead Noise Discrimination feature.

Select the [>>] button to review details of all arrhythmia episodes. For more information, see Section 3.8, “Arrhythmia Episodes data”, page 115.

3.1.2.3 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 charge circuit irregularity or 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. One example is if certain parameter settings result in a therapy being disabled.

- Diagnostic data observations report noteworthy arrhythmia episodes. Examples include arrhythmias of different types occurring together and episodes for which therapies were unsuccessful. Conditions that prevent diagnostic data from being collected effectively are also reported.
- Medtronic CareAlert observations can report system or device performance conditions and certain heart rhythm conditions. For more information, see Section 3.2, “Medtronic CareAlerts and notifications”, page 73.
- Clinical status observations alert you to abnormal patient conditions, such as low activity rates, unexpectedly high heart rates, high arrhythmia burden, or fluid accumulation.

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.

3.2 Medtronic CareAlerts and notifications

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

The device continuously monitors for a specified set of clinical management and system performance events that may occur between scheduled follow-up sessions. If the device detects that such an event has occurred and if alerting parameters are turned on, it responds in the following ways:

- Wireless signal and network transmission of event information

Medtronic CareAlert Monitoring continuously monitors for alert events. If an event occurs, CareAlert Monitoring sends a wireless alert signal to your patient’s Medtronic patient monitor. Upon receiving a signal, the monitor transmits the alert data to the Medtronic CareLink Network, if programmed to do so.

- Notification of alert event

Depending on the severity of the alert condition, you can set up Medtronic CareAlert Notifications through the CareLink Network (if available) to hold the alert for routine review at your office via email or the CareLink website or to immediately notify you via voice message, text message, or pager.

- Patient alert

The device emits 1 of 2 tones to alert your patient, depending on the type and urgency of the event that has occurred. The patient then responds according to your instructions.

3.2.1 Clinical management and system performance event alerts

3.2.1.1 Clinician-defined alerts (programmable)

Clinical Management Alerts

Possible Fluid Accumulation	This alert indicates that the OptiVol 2.0 Fluid Index has met or exceeded the programmed OptiVol Threshold. Note that the OptiVol Alert Enable parameter is permanently programmed to "Off (Observation only)", but the OptiVol Threshold parameter is programmable. If the OptiVol 2.0 Fluid Index has exceeded the programmed threshold, the fluid accumulation event is listed on the OptiVol Events screen and is provided as an observation on the Quick Look II screen.
AT/AF Daily Burden > Threshold	This alert indicates that the cumulative time in AT/AF exceeds the programmed threshold.
Avg. V. Rate During AT/AF > Threshold	This alert indicates that the average ventricular rate during a selectable duration of AT/AF exceeds the programmed threshold.
Number of Shocks Delivered in an Episode	This alert indicates that the number of shocks delivered in a VT/VF episode is greater than or equal to the programmed Number of Shocks Threshold.
All Therapies in a Zone Exhausted	This alert indicates that a specific VF, VT, or FVT episode was re-detected after all programmed therapies for that type of episode were delivered.

Lead and Device Integrity Alerts

RV Lead Integrity	This alert indicates that an RV lead problem is suspected, which could indicate lead fracture. The device immediately sounds an alert tone that lasts for 30 s. This tone repeats every 4 hours, beginning at the next scheduled 4-hour time interval, and at the programmed Daily Alarm Time.
RV Lead Noise	This alert indicates that noise was detected on the RV lead, which could indicate lead fracture, breached lead insulation, lead dislodgement, or improper lead connection. The device sounds an alert tone 3 min after a lead noise episode is detected. This tone repeats every 4 hours, beginning at the next scheduled 4-hour time interval, and at the programmed Daily Alarm Time.
VF Detection/Therapy Off	This alert indicates that one or more of the following conditions has occurred for at least 6 hours since the last programming: VF detection has been turned off; 3 or more VF therapies have been turned off; or FVT detection is programmed to FVT via VF and 3 or more FVT therapies have been turned off. Note that this alert sounds immediately and then every 6 hours until cleared.
Low Battery Voltage Recommended Replacement Time	This alert indicates that the daily automatic battery voltage measurement has been at or below the Recommended Replacement Time voltage level for 3 consecutive days.

Excessive Charge Time End of Service	This alert indicates that the charging period equals or exceeds the charge time threshold.
(Lead Name) Impedance Out of Range	This alert indicates that the daily lead impedance measurement for the (lead name) is out of range. This could indicate that the lead has dislodged or is improperly connected. For all leads, the device sounds an alert tone at the programmed Daily Alarm Time. For the RV Pacing, RV Defibrillation and SVC leads, the device also immediately sounds an alert tone and repeats this tone every 4 hours, beginning at the next scheduled 4-hour time interval.

For details about programmable settings for a particular parameter, see the device manual for the specific device.

3.2.1.2 System-defined alerts (non-programmable)

Electrical Reset	This alert indicates that the device has been reset and may require reprogramming. The device immediately sounds a high-urgency alert tone that repeats every 20 hours or every 9 hours, depending on the type of electrical reset. Immediately contact your Medtronic representative if an Electrical Reset alert occurs. For electrical reset parameter values, see the device manual for the specific device. ^a
Pacing Mode DOO, VOO, or AOO	This alert indicates that the device is programmed to DOO, VOO, or AOO pacing mode and, as such, does not deliver tachyarrhythmia therapy. The device sounds a high-urgency tone daily at the programmed time.
Active Can Off without SVC	This alert indicates that the Active Can feature is disabled without an SVC lead in place, which does not provide a viable defibrillation pathway. The device sounds a high-urgency tone daily at the programmed time.
Charge Circuit Timeout	This alert indicates that a charging period has exceeded the maximum time allowed for capacitor charging. The device immediately sounds a high-urgency alert tone that repeats every 20 hours. Contact your Medtronic representative if a Charge Circuit Timeout alert occurs.
Unsuccessful Wireless Transmission	This alert indicates that the device attempted a wireless transmission, but that the transmission was still unsuccessful after a 72-hour period during which the device retried the transmission every 3 hours.

^aAn Electrical Reset alert sounds immediately and then every 20 hours thereafter. However, if the electrical reset disables tachyarrhythmia detection and therapy, the alert sounds immediately and then every 9 hours thereafter. Contact your Medtronic representative if an electrical reset alert sounds.

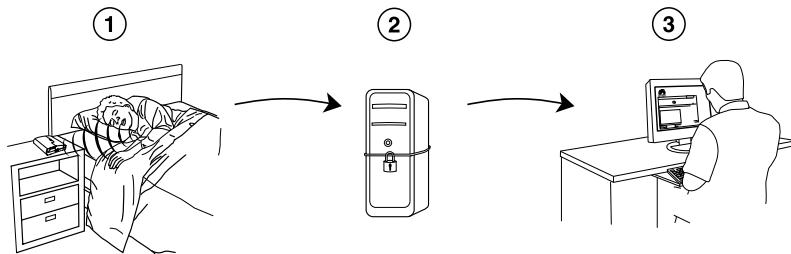
3.2.2 Operation of Medtronic CareAlert Monitoring and Medtronic CareAlert Notifications

If a clinical or system performance event occurs and the device is programmed to notify you over the CareLink Network, CareAlert Monitoring automatically attempts to establish wireless communication between the device and the monitor. Once communication is established, the monitor receives the alert data from the device. The monitor then transmits the alert data to the CareLink Network. The CareLink Network records the alert, and you are notified based on your preferences. The monitor communicates back to the device when the data transmission is successful. If a data transmission is unsuccessful at first, CareAlert Monitoring attempts to establish wireless communication with the monitor every 3 hours until the transmission is successful. If a transmission is still unsuccessful after 72 hours, the device emits a backup tone at the Alert Time that you select for your patient or at intervals unique to some alerts as described in Section 3.2.1.1 and Section 3.2.1.2. A transmission includes data for all active alerts.

Note: After a wireless alert signal has been successfully transmitted, the device does not retransmit data for that particular alert until the alert is cleared, even if the threshold for the alert is met again in the interim. However, the device continues to emit alert tones each day for active alerts that have Device Tone set to On. There are no such tones emitted for alerts that have Device Tone set to Off.

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

Figure 20. Process for transmitting Medtronic CareAlert Notifications



- 1 The device detects an alert condition and establishes wireless communication with the monitor.
 - 2 The monitor sends the alert data to a secure server via the patient's telephone land line or cellular telephone connection.
 - 3 If the CareLink Network is configured to do so, the clinician is notified via voice message, text message, pager, email, or website. The clinician can then consult the network for detailed information.
-

3.2.3 Operation of Medtronic CareAlert events

Medtronic CareAlert events trigger patient alerts that are clinician-defined or system-defined and emit tones that can be differentiated using 2 levels of urgency:

- Clinician-defined alerts may be programmed as high-urgency or low-urgency and may be turned on or off.
- System-defined alerts are high-urgency, and they are always on.

High-urgency alerts emit a dual, high-low tone. Low-urgency alerts emit an intermittent on-off tone. High-urgency tones may indicate that there is a device problem that needs immediate attention. Alerts are displayed in the Observations window on the Quick Look II and Alert Events screens of the Medtronic programmer.

When an alert is initiated, the device emits the tone pattern either at a selected time of day or at a fixed time interval. The tone then sounds each day at the selected time or interval until the alert is cleared (or until Device Tone is set to Off). Active tones also sound when the patient magnet is placed over the device. You can view alert details on a programmer during a patient session.

Notes:

- A CareLink transmission does not clear an alert tone from sounding. The tone will continue to sound until the alert is cleared (or until the Device Tone is set to Off).
- Once an alert has been successfully transmitted over the CareLink Network (if available), further transmissions for that alert condition will not occur until the alert is cleared.
- All alerts are cleared automatically when the device is interrogated with a programmer.

3.2.3.1 Patient alert process

If a clinical management or system performance event occurs and the device is programmed to sound a patient alert, the device emits alert tones at any or all of the following times, depending on the event: when the event occurs, at a programmed time of day, at fixed intervals. Instruct your patient to call the clinic if the patient hears tones coming from the device. Alert tones last for up to 30 s and are slightly louder than typical living room noise. If both high-urgency and low-urgency alerts are active at the same time, the high-urgency alert is given priority and sounds at the appropriate time or interval.

Although the system provides 2 types of alert tones for high-urgency and low-urgency clinical scenarios, it is important to remember that the patient may hear identical tones whether the alert is caused by a system performance issue or by a significant clinical event. Because the tones may be identical, a patient may not be able to distinguish between a system performance alert and a clinical event alert. The patient alert tone is only intended to prompt the patient to contact you. You should be aware that a patient who hears an alert tone will contact you to determine the type of alert that has occurred, the information the device has recorded, and how you interpret the data to assist in a plan of care. The details related to the alert, including the type of alert and detailed findings, are only available to the patient through discussion with you.

3.2.3.2 Selecting a patient alert time

The system allows you to select the time of day that a patient alert sounds. The alert tone continues to sound each day at the selected time until the alert is cleared (or until Device Tone is set to Off). Select a time when the patient or a companion is most likely to hear the tone. The following patient factors may influence your selection of the alert time:

- when the patient will be in a predictably quiet setting
- the patient's daily schedule; for example, medication routines that may affect alertness
- the patient's hearing acuity
- the presence or absence of companions who might also hear the tones

Note: Some patient alerts will also sound at times other than the programmed alert time. See Section 3.2.1.1 and Section 3.2.1.2 for exceptions.

If the conditions that trigger an alert are intermittent, the alert event may not actually be present when the alert tone sounds. Also, the alert time is based on the internal device clock. It does not adjust for time zone changes.

3.2.3.3 Programming a patient alert time

Tones for some system alerts are synchronized to the time you program tones for clinician-defined alerts. To program an alert time, select Params > Alert... > Alert Time....

However, if you program all clinician-defined alerts to Off, the Alert Time field is not shown. In this situation, perform the following steps to program the Alert Time for these system alert tones:

1. Program one of the programmable alerts to On to display the Alert Time field.
2. Select an alert time to apply to system alerts.
3. Reprogram the alert to Off.

3.2.3.4 Instructing the patient

It is important that patients understand that they may hear alert tones emitted from implanted devices. They must know what to do when an alert sounds.

Warning: Make sure that patients understand that they must not carry, store, or leave the patient magnet positioned over the device. Device operation is temporarily impaired when the magnet is placed over the device and it must be moved away from the device to restore normal operation.

- Instruct patients to contact you immediately if they hear ANY tones from the device.
- Advise patients of the time of day that you have programmed an alert tone to sound. If a tone sounds, they should expect it to sound every day at that time until the alert is cleared (or until the Device Tone is set to Off).
- For patients with a Medtronic monitor, advise them that if an alert is not successfully transmitted to the monitor within 72 hours, a high-urgency tone sounds each day at the programmed alert time.
- Make sure patients know that the alert time does not adjust for time zone changes.

- Advise patients that they may hear a steady test tone or any active alert tones if they are in the presence of a strong electromagnetic field, such as the field within a store theft detector. Advise patients that the device operation is temporarily impaired in these situations and that they should move away from the source of the interference to restore normal device operation.

Patients should also understand the purpose of the patient magnet and how and when to use it. Make sure that they know that current patient alerts sound when the patient magnet is placed over the device. Demonstrate how to place the patient magnet over the device to replay the alert tones, and review the patient magnet manual with them. Patients can use a folded patient magnet manual as a reference card.

3.2.3.5 Demonstrating alert tones

During a patient session, you can demonstrate high-urgency tones, low-urgency tones, and the test tone from the programmer as follows:

1. Select the Params icon.
2. Select Alert....
3. Select [Demonstrate Tones...].
4. Select [High-Urgency Condition Met], [Low-Urgency Condition Met], or [No Conditions Met].

Note: Any active alert tones will sound when the patient magnet is placed over the device. If there are no active alerts, the steady test tone will sound.

3.2.4 Programming Alerts

Note: The Medtronic CareAlert Setup screen shows either a Lead/Device Integrity Alerts view or a Clinical Management Alerts view. To switch between views, select either [Clinical Management Alerts...] or [Lead/Device Integrity Alerts...].

Note: Programming each Device Tone alert includes setting the alert urgency. Alerts for the Patient Home Monitor do not have an urgency setting.

Table 10. How to navigate to parameters for Lead/Device Integrity Alerts

Parameters	Path
Patient Home Monitor (Yes, No) Alert Time...	Params > Alert... > Lead/Device Integrity Alerts...
Alert Urgency (High, Low)	Params > Alert... > Lead/Device Integrity Alerts... > RV Lead...
RV Lead Integrity (On, Off)	
RV Lead Noise (On, Off)	

Table 10. How to navigate to parameters for Lead/Device Integrity Alerts (continued)

Parameters	Path
Lead Impedance Out of Range	Params > Alert... > Lead/Device Integrity
Alert Urgency (High, Low)	Alerts... > Lead Impedance Out of Range... >
A. Pacing (On, Off [Observation only])	Lead Impedance > Enable
RV Pacing (On, Off [Observation only])	
RV Defibrillation (On, Off [Observation only])	
SVC Defibrillation (On, Off [Observation only])	
Low Battery Voltage RRT	Params > Alert... > Lead/Device Integrity
Alert Enable – Urgency (On-High, On-Low, Off)	Alerts... > Low Battery Voltage RRT...
Excessive Charge Time EOS	Params > Alert... > Lead/Device Integrity
Alert Enable – Urgency (On-High, On-Low, Off)	Alerts... > Excessive Charge Time EOS...
VF Detection OFF, VF or FVT Therapies Off (On-High, Off)	Params > Alert... > Lead/Device Integrity
(On-High, Off)	Alerts... > VF Detection OFF, 3+ VF or 3+ FVT Rx Off.

Table 11. How to navigate to parameters for Clinical Management Alerts

Parameters	Path
Patient Home Monitor (Yes, No)	Params > Alert...
Alert Time...	
OptiVol 2.0 Fluid Settings (Off [Observation only])	Params > Alert... > OptiVol 2.0 Fluid Settings...
OptiVol Threshold	
Adjust Thoracic Reference Impedance	Params > Alert... > OptiVol 2.0 Fluid Settings... > Additional Settings...
AT/AF Daily Burden (On, Off [Observation only])	Params > Alert... > AT/AF Burden and Rate Settings...
Burden	
V. Rate	
Avg. V. Rate During AT/AF (On, Off [Observation only])	
Burden	
V. Rate	
Number of Shocks Delivered in an Episode (On, Off)	Params > Alert... > Number of Shocks Delivered in an Episode...
Alert Enable – Urgency (On-High, On-Low, Off)	
Number of Shocks Threshold	
All Therapies in a Zone Exhausted for an Episode	Params > Alert... > All Therapies in a Zone
Alert Enable – Urgency (On-High, On-Low, Off)	Exhausted for an Episode.

Transmitting alerts – The ability to transmit Medtronic alerts to the CareLink Network is programmable only when the Patient Home Monitor field on the programmer screen is programmed to Yes.

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

3.2.5 Evaluation of alert events

The device stores alert events in the Medtronic CareAlert Events log. The programmer screen refers to alert events as Alert Events and OptiVol Events. For each alert event, a log entry includes the date and time of the alert, a description of the event, and the measurement or information that caused the event. Up to 15 Alert Events and the last 7 OptiVol Events are stored. Alert data is cleared only when you clear all device data from the Data Collection Setup screen.

Caution: Verify lead integrity when evaluating OptiVol Events. Loss of RVcoil integrity due to lead fracture or insulation defect may adversely affect OptiVol Events.

To access alert events, select Data > Alert Events > Alert Events, or select Data > Alert Events > OptiVol Events.

3.3 RV Lead Integrity Alert

RV lead fractures can cause oversensing, which can lead to inappropriate tachyarrhythmia detection and shock. While some lead fractures occur suddenly and provide little warning, other fractures are preceded by rapid, unexpected changes in lead impedance and short episodes of oversensing. Monitoring for these changes may provide patients with enough advance warning of a potential lead problem to avoid an inappropriate shock.

Medtronic leads – When used with Medtronic Fidelis leads, the RV Lead Integrity Alert feature is designed to extend the advance warning time of a potential lead-related issue, improve opportunities for more patients to recognize the audible alert, and reduce inappropriate shocks. The RV Lead Integrity Alert feature is intended for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930), based on performance data.

St. Jude Riata/Durata lead families – A retrospective analysis of data from the CareLink system was performed to evaluate the performance of RV LIA compared to pace/sense monitoring in St. Jude Riata/Durata lead families (n=6,123 as of October 2011).

Boston Scientific Endotak lead families – A retrospective analysis of data from the CareLink system was performed to evaluate the performance of RV LIA compared to pace/sense monitoring in Boston Scientific Endotak lead families (n=5,114 as of October 2011).

The RV LIA feature may not perform as well with a St. Jude Riata/Durata lead or a Boston Scientific Endotak lead as it does with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature. The RV Lead Integrity Alert feature detects issues with the pace/sense conductor only, and does not provide warning of issues related to the high voltage conductor.

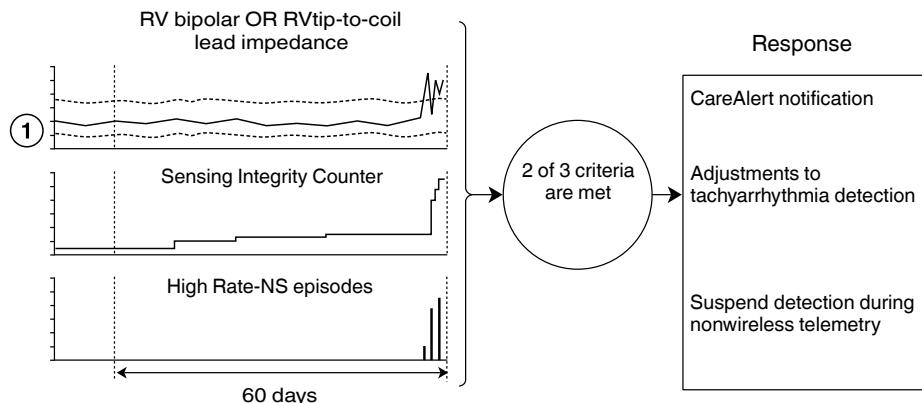
The RV Lead Integrity Alert feature is not intended to withhold therapy for true VT or VF. To identify a potential lead issue, the RV Lead Integrity Alert monitors RV pacing lead impedance measurements, the frequency of rapid non-sustained VT episodes, and the frequency of short ventricular intervals counted on the Sensing Integrity Counter.

If the possibility of an impending RV lead fracture is indicated by the data, the RV Lead Integrity Alert feature can trigger a Medtronic CareAlert Notification and an alert tone to warn the patient. In addition, the RV Lead Integrity Alert feature automatically adjusts tachyarrhythmia detection settings and diagnostic settings to avoid the delivery of an inappropriate shock.

The RV Lead Integrity Alert feature is only one part of an overall monitoring and diagnostic plan. Consequently, if the Medtronic ICD or CRT-D device is sounding an audible alert tone or if the programmer indicates that an alert event has occurred, review the alert messages and evaluate the diagnostic data to determine the likelihood of a lead integrity issue.

3.3.1 Operation of RV Lead Integrity Alert

Figure 21. Operation of RV Lead Integrity Alert



1 Lead Integrity Alert impedance is evaluated for both RV bipolar and RV tip-to-coil pacing polarities. If either measurement goes out of range, the impedance criterion is met.

The device continually monitors for a potential RV lead fracture using lead impedance measurements for both RV pacing lead polarities, the Sensing Integrity Counter, and High Rate-NS episode data. It identifies a potential lead fracture if at least 2 of the following criteria have been met within the past 60 days:

- An RV pacing lead impedance measurement for either polarity is less than 50% or greater than 175% of the baseline impedance. The baseline measurement is the median of the previous 13 daily measurements. A separate baseline is calculated for each RV pacing vector. The RV bipolar and RV tip-to-coil impedance measurements are taken at the same time each day.
- The ventricular Sensing Integrity Counter is incremented by at least 30 within a period of 3 consecutive days or less.

Note: The Sensing Integrity Counter total displayed on the Battery and Lead Measurements screen is the number of short ventricular intervals that occurred since the last patient session. Therefore, the total could exceed 30 without satisfying the alert criteria if the total was reached during a period of more than 3 consecutive days.

- The device senses 2 High Rate-NS episodes with a 4-beat average R-R interval of less than 220 ms.

If either the Device Tone or the Patient Home Monitor alert parameter for the RV Lead Integrity Alert is programmed to On, the device responds to a potential RV lead fracture with an alert tone, a Medtronic CareAlert Notification, and automatic adjustments to tachyarrhythmia detection. When at least 1 High Rate-NS episode occurs or if the alert criteria are met, the device automatically adjusts EGM storage operation.

If both the Device Tone and the Patient Home Monitor alert parameters for the RV Lead Integrity Alert are programmed to Off, the device does not trigger a Medtronic CareAlert Notification or an alert tone, and it does not adjust tachyarrhythmia detection parameters. However, it records a Quick Look II observation for the lead warning, and it makes adjustments to EGM storage.

3.3.1.1 RV Lead Integrity Alert tones and CareAlert Notifications

When the criteria for the RV Lead Integrity Alert are met, the device immediately sounds an alert tone. The tone sounds again every 4 hours beginning at the next scheduled 4-hour time interval (00:00, 04:00, 08:00...). The tone also sounds at the programmed Alert Time and when a magnet is placed over the device. The tone continues to sound until the alert is cleared (or until Device Tone is set to Off). If the Patient Home Monitor alert for the RV Lead Integrity Alert is programmed to On, the device also attempts to send a wireless transmission to the Medtronic patient monitor.

3.3.1.2 Automatic adjustments to tachyarrhythmia detection

When the RV Lead Integrity Alert is triggered, the device automatically programs the VF Initial Beats to Detect parameter to 30/40 (if it was less). If necessary, the device automatically adjusts the Monitored VT Beats to Detect parameter and sets AT/AF Detection to Monitor.

In addition, after the RV Lead Integrity Alert has been triggered, the device automatically suspends tachyarrhythmia detection when it is interrogated using nonwireless telemetry by a programmer or a Medtronic patient monitor. The device suspends detection to prevent inappropriate therapy delivery during the telemetry session when a lead issue is suspected.

During a monitor session, tachyarrhythmia detection resumes automatically when the interrogation is complete. During a programmer session, tachyarrhythmia detection can be resumed by selecting [Resume] at the top of the programmer screen, by removing the programming head, or by ending the session and removing the programming head.

Note: This suspension behavior occurs for all nonwireless sessions until 3 days have passed since the alert was cleared.

3.3.1.3 EGM storage changes

When at least 1 High Rate-NS episode occurs, the device automatically adjusts EGM storage operation in order to provide more diagnostic data to help identify a lead-related issue. The device programs the Pre-arrhythmia EGM parameter to On - 1 month (unless the previous setting provided more than 30 days of Pre-arrhythmia EGM storage remaining).

Notes:

- The Pre-arrhythmia EGM parameter displays the programmed setting even when the device adjusts EGM storage automatically after a High Rate-NS episode has occurred.
- The changes to EGM storage occur even when the Device Tone and Patient Home Monitor alert parameters for RV Lead Integrity Alert are programmed to Off.

If the Lead Impedance and Sensing Integrity Counter criteria are met, the device also changes the criteria for storing High Rate-NS episodes, allowing a High Rate-NS episode with EGM data to be recorded if a single ventricular interval less than 200 ms occurs. This condition persists until a High Rate-NS episode occurs or until you interrogate the device.

3.3.2 Programming RV Lead Integrity Alert

Note: The Medtronic CareAlert Setup screen shows either a Lead/Device Integrity Alerts view or a Clinical Management Alerts view. To switch between views, select either [Clinical Management Alerts...] or [Lead/Device Integrity Alerts...].

Note: Programming each Device Tone alert includes setting the alert urgency. Alerts for the Patient Home Monitor do not have an urgency setting.

To navigate to the RV Lead Integrity Alert parameter, select Params > Alert... > Lead/Device Integrity Alerts... > RV Lead....

VF Detection and VF therapies – If you program VF Detection or all of the VF therapies to Off, the RV Lead Integrity Alert does not operate. The RV Lead Integrity Alert operation resumes when you program VF Detection and the VF therapies to On, and only the data collected after that time are applied to the alert criteria.

3.3.3 Evaluation of RV Lead Integrity Alert

If the device is sounding an alert tone or if the programmer indicates that an alert event has occurred, review the alert messages and evaluate the diagnostic data to determine the likelihood of a lead integrity issue.

3.3.3.1 CareAlert window

When the device is interrogated, a CareAlert window notifies you that an alert condition exists, including the RV Lead Integrity Alert.

3.3.3.2 Quick Look II observations

Check the Quick Look II Observations list to verify that there is an RV Lead Integrity warning by selecting Data > Quick Look II.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

3.3.3.3 Medtronic CareAlert Events

Check the CareAlert Events list to verify that there is an RV Lead Integrity warning by selecting Data > Alert Events.

3.3.3.4 Sensing Integrity Counter

To access the Sensing Integrity Counter, select Data > Device/Lead Diagnostics > Battery and Lead Measurements > [Open Data].

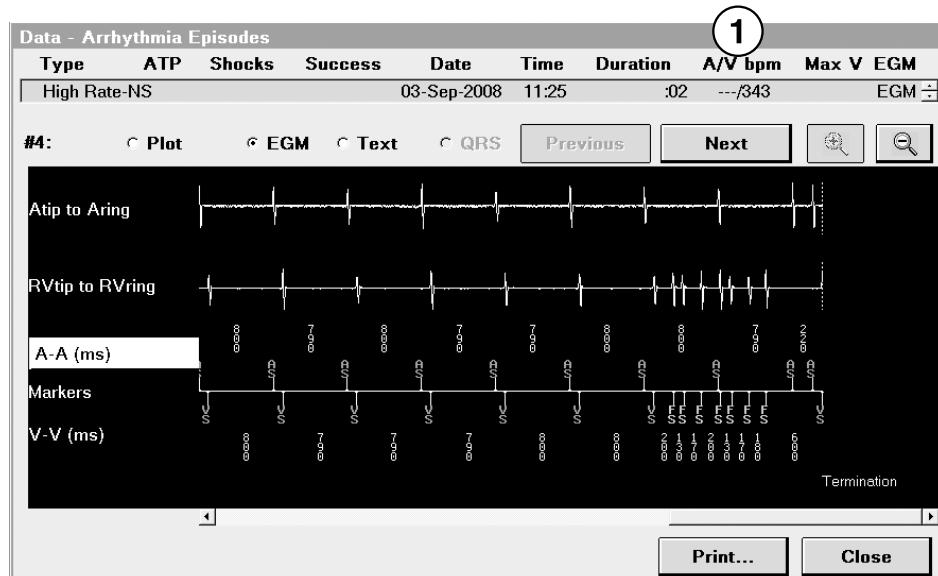
Sensing Integrity Counter – Check the Sensing Integrity Counter section of the Battery and Lead Measurements screen for evidence of oversensing. For more information, see Section 3.4, “Device and lead performance data”, page 88.

3.3.3.5 Arrhythmia Episodes (High Rate-NS)

If an RV Lead Integrity warning is present in Quick Look II Observations, select the Observations [>>] button on the Quick Look II screen, or select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data].

Check the High Rate-NS episodes in the Arrhythmia Episodes window. A High Rate-NS episode has an average ventricular rate greater than 273 bpm (less than 220 ms). If there are 2 or more High Rate-NS episodes, lead noise oversensing may have occurred. Review the stored EGM to determine the cause of the oversensing.

Figure 22. High Rate-NS episode record

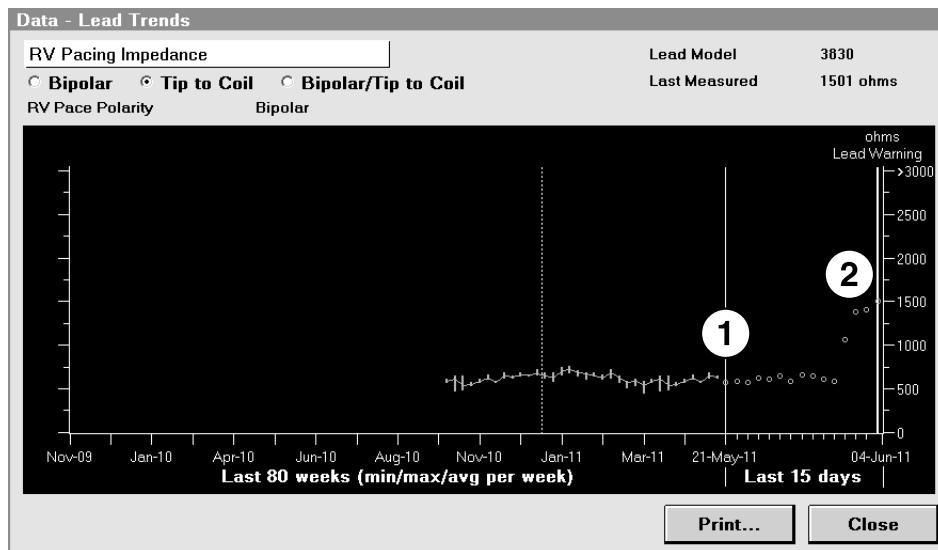


1 Average rate information

3.3.3.6 Lead Trends

To access lead impedance trends, select Data > Device/Lead Diagnostics > Lead Impedance Trends > [Open Data].

Check the Lead Impedance Trends for a sudden change in either the RV bipolar impedance or the RV tip-to-coil impedance measurement. If at least 1 measurement is greater than 175% of the baseline value or is less than 50% of the baseline value, then the lead impedance should be considered abnormal.

Figure 23. RV Lead Impedance Trend data

1 Baseline value

2 Abnormal impedance measurements

3.4 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.

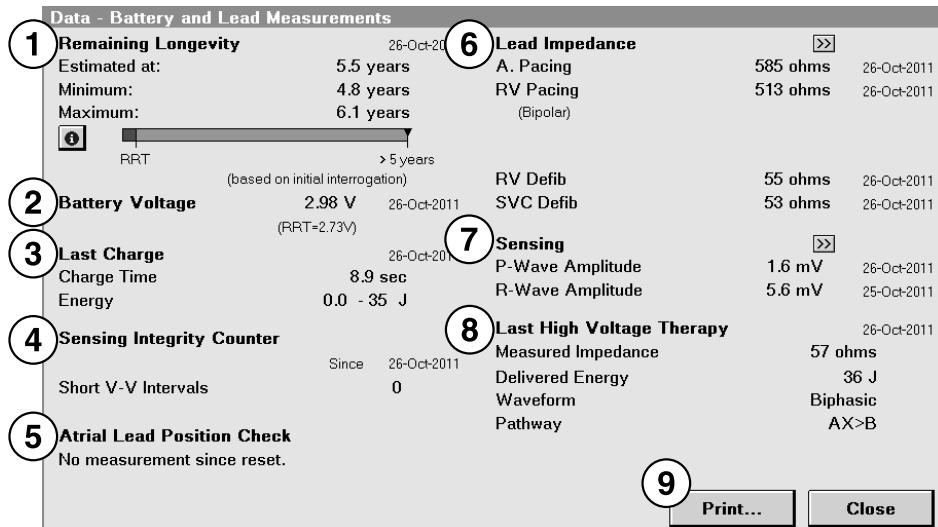
3.4.1 Viewing battery and lead measurement data

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.

3.4.1.1 How to view battery and lead measurement data

To access battery and lead measurement data, select Data > Device/Lead Diagnostics > Battery and Lead Measurements > [Open Data].

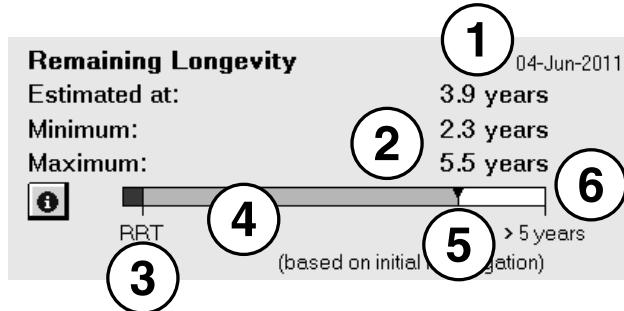
Figure 24. Battery and Lead Measurements screen



- 1 Remaining Longevity information
- 2 Battery Voltage information
- 3 Capacitor charging information
- 4 Sensing Integrity Counter
- 5 Result of the last Atrial Lead Position Check
- 6 Most recent lead impedance measurements
- 7 Most recent daily automatic sensing amplitude measurements
- 8 Information about the last delivered high-voltage therapy
- 9 Select [Print...] to print a Battery and Lead Measurements Report

3.4.1.2 Remaining Longevity estimate

The device automatically calculates the estimated time remaining until RRT based on automatic daily battery voltage measurements, time since implant, programmed parameter settings, and device recorded events. The estimated Remaining Longevity, minimum longevity, and maximum longevity are reported in years or months. The estimated Remaining Longevity is also reported in a graphic for easy reference with the RRT period in red and the estimated remaining longevity in green.

Figure 25. Remaining Longevity estimate

- 1 Estimated remaining longevity to RRT (years or months)
- 2 Minimum and Maximum remaining longevity to RRT (years or months)
- 3 RRT (red bar)
- 4 Estimated remaining longevity to RRT (green bar)
- 5 Remaining Longevity marker
- 6 If estimated remaining longevity to RRT is greater than 5 years, the green bar is full

Table 12. Remaining Longevity examples

Device Scenario	Device Status	Remaining Longevity Information
Before implant - VF detection Off	Pre-Implant	The bar on the graphic is green and the estimated remaining longevity to RRT is > 5 years.
Before implant - the device may have been exposed to cold temperatures	Pre-Implant	The bar on the graphic is gray and estimated remaining longevity to RRT is not reported.
Immediately after implant - VF detection On	Initializing	Remaining longevity estimator is initializing. Longevity estimate will be available within 24 hours.
Recommended Replacement Time (RRT)	Replace Device RRT	RRT and the RRT date are displayed.
End of Service (EOS)	Replace Device EOS	EOS and the RRT date are displayed.
Device Electrical Reset	Re-Initializing	The bar on the graphic is gray and estimated remaining longevity values will be available within 1 week.

3.4.1.3 Battery voltage and replacement indicators

The device measures the battery voltage automatically when telemetry is initiated at the start of a session, when a lead impedance test is performed, and every day at 02:15 as part of the automatic daily measurements. The battery voltage measurement at the start of a session is displayed on the Battery and Lead Measurements screen. The automatic daily battery voltage measurements are used in the calculation of Recommended Replacement Time (RRT).

Note: You may see a temporary drop in the displayed battery voltage if high-voltage charging has occurred within the past 7 days.

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 indicator and the date when the battery reached RRT. If the programmer displays the RRT indicator, 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 3 months (90 days).³ After the 90-day PSP has expired, the device reaches End of Service (EOS) and the programmer displays the EOS indicator.⁴

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.

3.4.1.4 Capacitor charging and high-voltage therapy information

The Battery and Lead Measurements screen reports information about the last high-voltage charge and the last delivered high-voltage therapy. The Last Charge section displays the date, charge time, and energy range from the last time the high-voltage capacitors were charged (from any starting energy to any final energy). This information includes periodic charging (if necessary) to condition the battery. The Last High Voltage Therapy section reports the date, measured impedance, delivered energy, waveform, and pathway for the last delivered high-voltage therapy.

³ EOS may be indicated before the end of 90 days if the actual battery usage exceeds the expected conditions during the Prolonged Service Period.

⁴ EOS may also be indicated if an excessive charge time occurs.

3.4.1.5 Sensing Integrity Counter

When the device senses high-frequency electrical noise, the result is often a large number of ventricular sensed events with intervals near the programmed value for ventricular blanking after a ventricular sense (V. Blank Post VS). The Sensing Integrity Counter records the number of ventricular events with intervals that are within 20 ms of the V. Blank Post VS parameter value. A large number of short ventricular intervals may indicate oversensing, lead fracture, or a loose setscrew. If the Sensing Integrity Counter reports more than 300 short ventricular intervals, investigate potential sensing and lead integrity issues. For more information, see Section 3.3, “RV Lead Integrity Alert”, page 82, and Section 5.9, “RV Lead Noise Discrimination”, page 270.

3.4.1.6 Atrial Lead Position Check results

The device can be programmed to automatically disable atrial tachyarrhythmia therapies if the daily Atrial Lead Position Check identifies a potential problem with the lead position. The Battery and Lead Measurements screen displays the result of the most recent Atrial Lead Position Check. For more information, see Section 6.1, “Atrial therapy scheduling”, page 275.

3.4.1.7 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 manual 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 7.4, “Lead Impedance Test”, page 339. For more information about performing manual sensing amplitude measurements, see Section 7.5, “Sensing Test”, page 340.

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. In addition, if the Lead Trends screen is displayed, you can select any measurement trend data from the menu on the Lead Trends screen.

3.4.2 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.

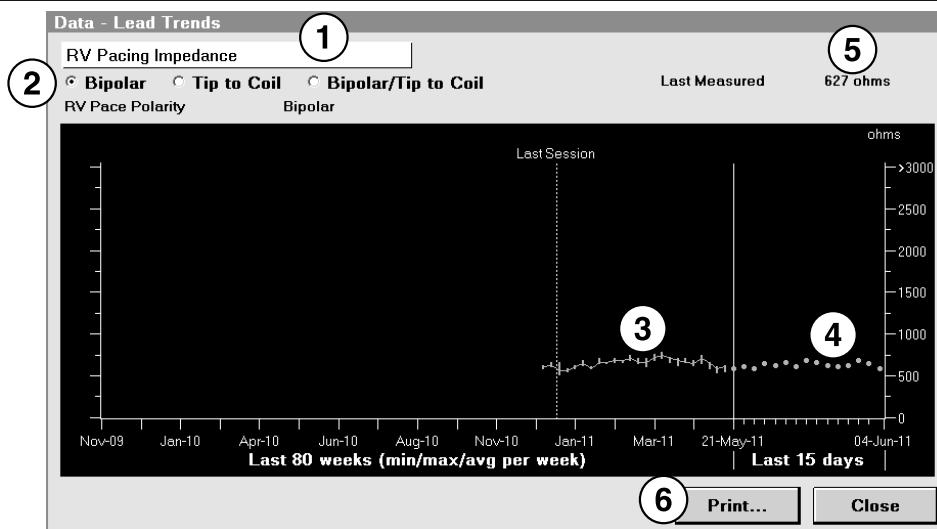
If the device is unable to perform automatic lead impedance measurements, gaps are present in the trend graph.

Note: The RV Defib impedance is measured and displayed for the currently programmed defibrillation pathway only. Reprogramming the Active Can/SVC Coil parameter changes the electrodes included in the defibrillation pathway and affects which of the collected measurements are displayed in the trend graph.

3.4.2.1 How to view lead impedance trends

To access lead impedance trends, select the Lead Impedance [>>] button or Sensing [>>] button on the Battery and Lead Measurements screen, or select Data > Device/Lead Diagnostics > Lead Impedance Trends > [Open Data].

Figure 26. Lead Trends screen showing the RV Pacing Impedance trend



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

3.4.3 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 24:00, no measurement is recorded. The sensing amplitude trend graph shows a gap for that day.

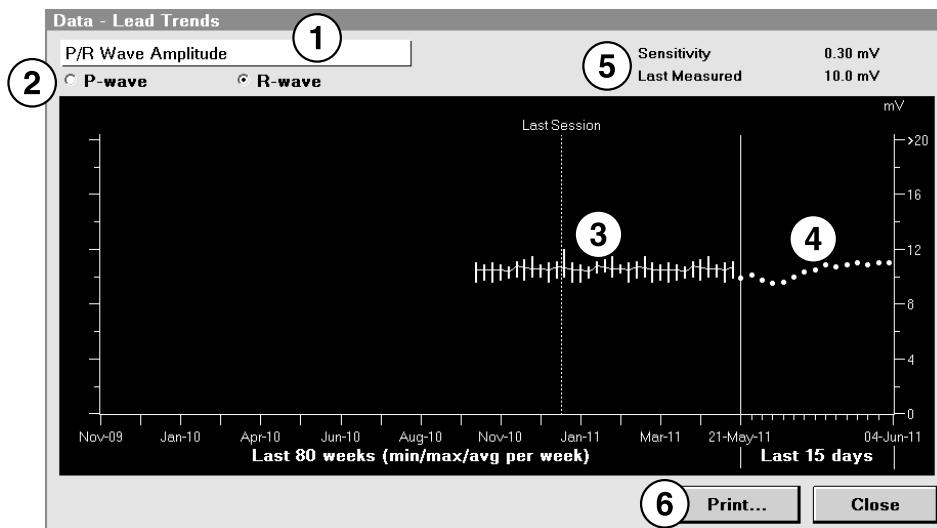
The daily automatic sensing amplitude measurements are displayed on the Lead Trends screen, which plots the data as a graph. The graph displays up to 15 of the most recent measurements and up to 80 weekly summary measurements (showing minimum, maximum, and average values for each week). Significant or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

Note: The sensing amplitude trend data is intended to show changes in sensing amplitude measurements that may be used to assess lead integrity. The adequacy of the ventricular sensing safety margin cannot be determined by the R-wave trend measurement and should be based on VF induction testing.

3.4.3.1 How to view sensing amplitude trends

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

Figure 27. Lead Trends screen showing the R-wave Amplitude trend



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

3.4.4 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, see Section 4.5, “Capture Management”, page 173.

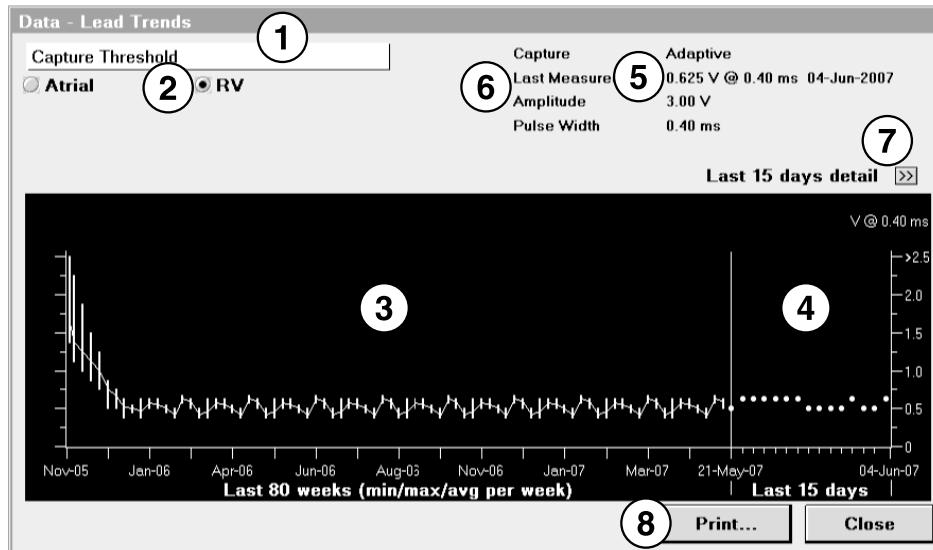
The results of the daily pacing threshold measurements are displayed on the Lead Trends screen in the Capture Threshold trend graph. The graph displays up to 15 of the most recent measurements and up to 80 weekly summary measurements, showing minimum, maximum, and average values for each week.

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.

3.4.4.1 How to view capture threshold trends

To access Capture Threshold Trends, select the Threshold [>>] button on the Quick Look II screen, or select Data > Device/Lead Diagnostics > Capture Threshold Trends > [Open Data].

Figure 28. 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 29. RV Capture Threshold trend detail

Capture Management (Last 15 days detail)					
RV Capture		Adaptive	Programmed Safety Margin		2.0 X
Amplitude		3.00 V	Min. Adapted Amplitude		1.00 V
Pulse Width		0.40 ms			
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	2.0	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

Print... **Close**

3.5 OptiVol 2.0 fluid status monitoring

Clinical studies have shown that lung congestion is a primary complication associated with heart failure and is a frequent cause of repeated hospital admissions.

Patients with moderate to severe heart failure are at risk of further cardiac decompensation as a result of total body and thoracic fluid accumulation. Early detection of thoracic fluid accumulation may enable more timely treatment adjustments.

Clinical data suggest that changes in thoracic impedance and fluid accumulation in the thoracic cavity or lungs are inversely correlated. As the patient's lungs become congested, thoracic impedance tends to decrease. Similarly, an increase in thoracic impedance may indicate the patient's lungs are becoming drier.

The OptiVol 2.0 Fluid Status Monitoring feature measures the patient's thoracic impedance using the RVcoil to Can pathway, which passes through the tissue within the thoracic cavity. Increases in thoracic fluid cause a decrease in impedance for this pathway. Decreases in thoracic fluid cause an increase in impedance for this pathway.

Notes:

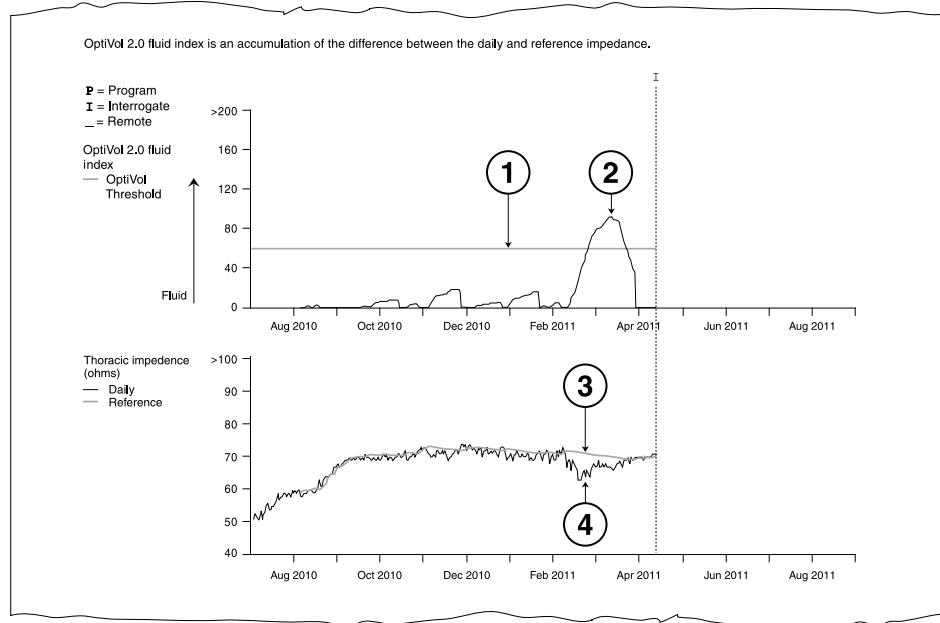
- The OptiVol Fluid Status Monitoring feature has been updated to OptiVol 2.0 to account for individual patient variation, including allowing the Fluid Index to increase or decrease based on recent thoracic impedance measurements.
- The OptiVol 2.0 Fluid Status Monitoring feature may not provide early warning for all fluid-related decompensations. Therefore, patients should be instructed to seek medical attention immediately any time they feel ill and need help, even if the OptiVol fluid monitoring features of their device or monitor indicate acceptable pulmonary fluid status conditions.
- The OptiVol 2.0 Fluid Status Monitoring feature is an additional source of information for patient management and does not replace assessments that are part of standard clinical practice.
- The clinical value of the OptiVol 2.0 Fluid Status monitoring feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.

3.5.1 Operation of OptiVol 2.0 Fluid Status Monitoring

3.5.1.1 Daily and Reference Impedances

Thoracic impedance measurements are made at regular intervals between 12:00 and 17:00. After all of the impedance measurements for a day have been made, the average impedance value is calculated for that day. This Daily Impedance value is used to update a slowly adapting trend known as the Reference Impedance, which is calculated by the device. In this way, a control value for each individual patient is calculated. The device uses this control value to assess impedance variations.

The system provides a diagnostic plot that illustrates a patient's fluid status over time. The plot is part of Cardiac Compass Trends and the Heart Failure Management Report. See Section 3.7, "Heart Failure Management Report", page 108.

Figure 30. OptiVol 2.0 Fluid Trends

- 1 OptiVol Threshold
- 2 OptiVol 2.0 Fluid Index: accumulation of the difference between the Daily Impedance and the Reference Impedance, adjusted for individual patient variation
- 3 Reference Impedance adapts slowly to daily impedance changes
- 4 Daily Impedance is the average of each day's multiple impedance measurements

OptiVol 2.0 Fluid Index – If the Daily Impedance falls below the Reference Impedance, this may indicate that fluid is accumulating in the patient's thoracic cavity. If the Daily Impedance remains below the Reference Impedance, the difference between the Daily Impedance and Reference Impedance values, adjusted for individual patient variation, is added to the OptiVol 2.0 Fluid Index.

While there is a difference between the Daily Impedance and the Reference Impedance, the fluid index may continue to increase. If the Daily Impedance begins to rise, this may be an indication that the thoracic fluid accumulation is resolving and the fluid index may decrease. When the Daily Impedance returns to the Reference Impedance, the fluid event is considered to have ended and the OptiVol 2.0 Fluid Index resets to 0.

OptiVol Threshold – If the Daily Impedance remains below the Reference Impedance on consecutive days, the OptiVol 2.0 Fluid Index may rise above the programmed OptiVol Threshold. This triggers an OptiVol clinical status observation.

3.5.2 Programming OptiVol 2.0 Fluid Status Monitoring

Note: The Medtronic CareAlert Setup screen shows either a Lead/Device Integrity Alerts view or a Clinical Management Alerts view. To switch between views, select either [Clinical Management Alerts...] or [Lead/Device Integrity Alerts...].

Note: Programming each Device Tone alert includes setting the alert urgency. Alerts for the Patient Home Monitor do not have an urgency setting.

Table 13. How to navigate to parameters for OptiVol 2.0 fluid status monitoring

Parameters	Path
OptiVol 2.0 Fluid Settings (Off [Observation only]) OptiVol Threshold	Params > Alert... > OptiVol 2.0 Fluid Settings...
Adjust Thoracic Reference Impedance	Params > Alert... > OptiVol 2.0 Fluid Settings... > Additional Settings...

Setting the OptiVol Threshold – The OptiVol Threshold is nominally programmed to 60. Medtronic recommends that you use this setting until you have clinical experience using OptiVol 2.0 Fluid Status Monitoring with individual patients.

If the patient is experiencing too many OptiVol observations, the OptiVol Threshold may be set at too sensitive (low) a level, and you should consider increasing the OptiVol Threshold.

If OptiVol observations are absent or are delayed when the patient has thoracic fluid accumulation, the OptiVol Threshold may be set at too insensitive (high) a level, and you should consider decreasing the OptiVol Threshold.

Reference Impedance initialization period – The Reference Impedance is first calculated on the thirty-fourth day of impedance measurements after implant. If the patient's lead is still maturing, the patient is retaining lung fluid, or there is tissue swelling around the device pocket, the Reference Impedance may require more time to adapt to the patient's normal Daily Impedance.

Adjusting the Reference Impedance – Under appropriate circumstances, you can adjust the Reference Impedance so that it more closely matches the patient's Daily Impedance measurements. This should be done only in rare cases and when the patient has stable pulmonary fluid status. The adjustment process takes several days. The Reference Impedance is set to the average of the last Daily Impedance measurement and the next 3 Daily Impedance measurements.

Notes:

- You should adjust the Reference Impedance only when all of the following conditions hold: the patient has stable pulmonary fluid status, OptiVol trends show that the patient's Daily Impedance is stable, and the Reference Impedance has not already adjusted to the patient's Daily Impedance.
- The Reference Impedance adjustment cannot be performed during the Reference Impedance Initialization period.
- The OptiVol observation is suspended for the first few days after an adjustment.

3.5.3 Evaluation of OptiVol 2.0 Fluid Status Monitoring

Caution: Verify lead integrity when evaluating OptiVol 2.0 Fluid Status Monitoring. Loss of RVcoil integrity due to lead fracture or insulation defect may adversely affect the results of OptiVol 2.0 Fluid Status Monitoring.

3.5.3.1 Viewing OptiVol 2.0 Fluid Trends

To view OptiVol 2.0 Fluid Trends, select the Cardiac Compass [>>] button on the Quick Look II screen, or select Data > Clinical Diagnostics > Cardiac Compass Trends.

Cardiac Compass Trends and the Heart Failure Management Report display up to 14 months of OptiVol 2.0 Fluid Trends patient data.

The OptiVol 2.0 Fluid Index is a plot of the accumulation of differences, adjusted for individual patient variation, between the Daily thoracic impedance value and the Reference thoracic impedance value.

The Thoracic Impedance trend plots the Daily and Reference Impedance values.

3.5.3.2 Viewing OptiVol observations

To access OptiVol observations, select Data > Quick Look II.

A clinical status observation appears on the Quick Look II screen and on the Heart Failure Management Report when the OptiVol 2.0 Fluid Index has reached or exceeded the OptiVol Threshold since the last session. If the OptiVol 2.0 Fluid Index is still greater than 0, the observation displays the date of the first day that the OptiVol 2.0 Fluid Index was equal to or greater than the threshold and "ongoing". If the OptiVol 2.0 Fluid Index has since reset to 0, the observation displays the date of the first day that the OptiVol 2.0 Fluid Index was equal to or greater than the threshold and the date that the OptiVol 2.0 Fluid Index reset to 0.

3.5.3.3 Viewing the OptiVol event log

To access the OptiVol event log, select Data > Alert Events > OptiVol Events.

The OptiVol event log reports the last 7 OptiVol Events. For OptiVol 2.0 Fluid Status Monitoring, an event log entry is recorded the first time that the patient's OptiVol 2.0 Fluid Index has reached or exceeded the OptiVol Threshold.

3.6 Cardiac Compass Trends

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

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

The Cardiac Compass trends are based on data and measurements collected daily. Data storage for Cardiac Compass trends 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 in the trends are based on the device clock.
- You cannot manually clear the Cardiac Compass trend data.

3.6.1 How to view and print Cardiac Compass Trends

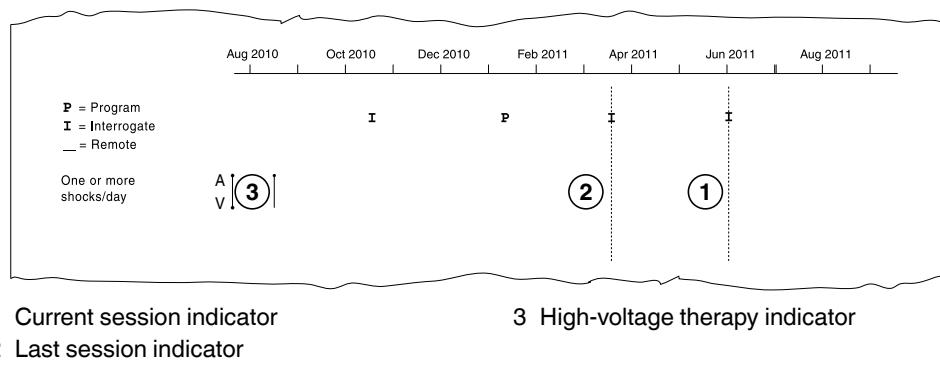
Cardiac Compass trend data is available on the Cardiac Compass Trends programmer screen and in a printed report. To view Cardiac Compass Trends on the programmer screen, select the Cardiac Compass [>>] button on the Quick Look II screen, or select Data > Clinical Diagnostics > Cardiac Compass Trends > [Open Data]. To print Cardiac Compass Trends, select the [Print...] button if you are already viewing Cardiac Compass Trends on the programmer screen, or select Reports > Available Reports...> Cardiac Compass Trends.

3.6.2 Information provided by Cardiac Compass Trends

Cardiac Compass Trends shows events that have occurred during the reporting period. It also provides trend graphs that can help you to assess the frequency of VT/VF arrhythmias, AT/AF arrhythmias, pacing and rate response, and information related to heart failure.

3.6.2.1 Event information

Figure 31. Event annotations



Programming and interrogation events – Cardiac Compass Trends 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.

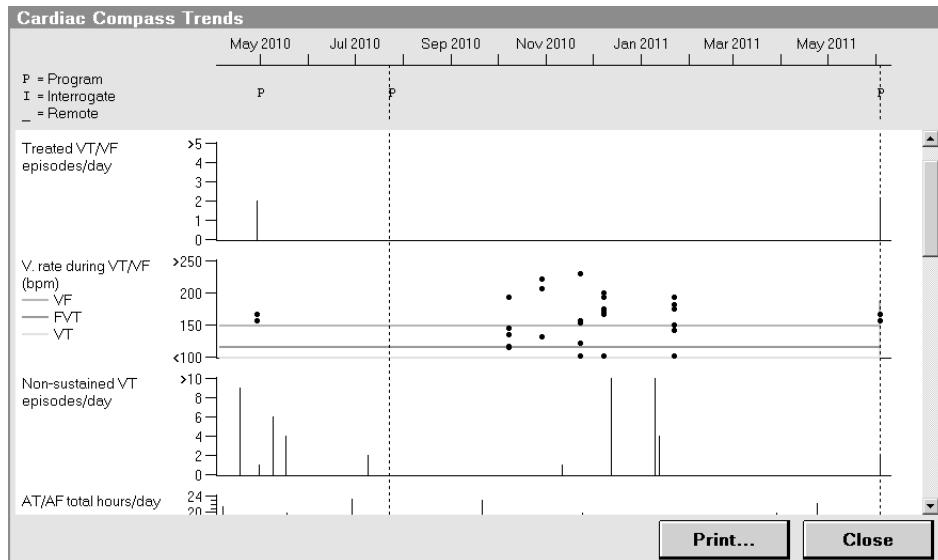
When the patient is evaluated during a Medtronic patient monitor session, the report records an "I" with a line beneath it.

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.

One or more shocks per day – Cardiac Compass Trends indicates a shock for any day on which the device delivered a high-voltage therapy (an automatic defibrillation therapy, cardioversion therapy, or atrial shock therapy). Each annotation indicates delivery of one or more ventricular (V) or atrial (A) high-voltage therapies on a single day.

3.6.2.2 Assessing VT/VF arrhythmia information

Figure 32. VT/VF arrhythmia trend graphs



Treated VT/VF episodes per day – The history of ventricular tachyarrhythmias may be helpful in revealing correlations between clusters of episodes and other clinical trends.

Each day, the device records the total number of spontaneous VT and VF episodes for which a therapy was started. This count may include therapies that were started and aborted. It does not include episodes that were only monitored.

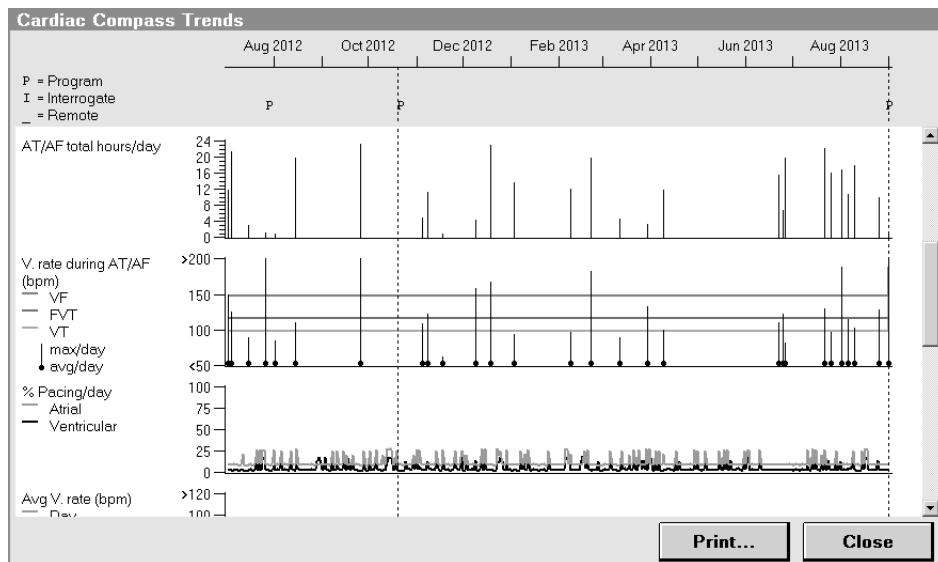
Ventricular rate during VT/VF – This trend may provide an indication of the effects of antiarrhythmic drugs on VT and VF rates and gives a better understanding of the safety margins for detection.

The graph displays the median ventricular rate during spontaneous VT and VF episodes. Multiple points on one day represent multiple episodes with different median rates. The horizontal lines indicate the programmed VF, VT, and FVT detection rates, if applicable.

Non-sustained VT episodes per day – This trend may help you to correlate patient symptoms (such as palpitations) to non-sustained VT episodes and may indicate a need for further investigation of the status of the patient.

3.6.2.3 Assessing AT/AF arrhythmia information

Figure 33. AT/AF arrhythmia trend graphs



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

The device records a daily total for the time the patient spent in atrial arrhythmia. The time in AT/AF is calculated from the point of AT/AF Onset. This trend may be reported in hours (0 to 24) or minutes (0 to 60) per day depending on the maximum duration per day. For more information, see Section 5.1, “AT/AF detection”, page 224.

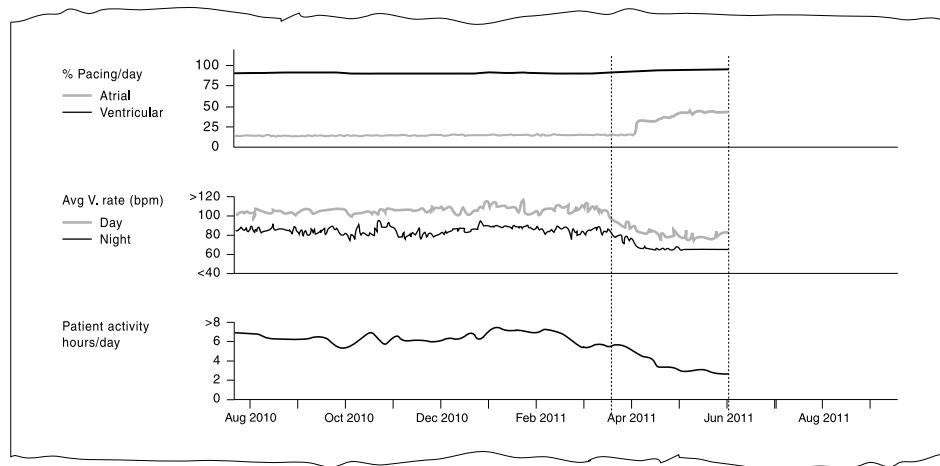
Ventricular rate during AT/AF – You can use this trend to perform the following assessments:

- Correlate patient symptoms to rapid ventricular responses to AT/AF.
- Assess VT/VF detection safety margins and modify programming to avoid treating rapidly conducted AT/AF as VT/VF.
- 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. The horizontal lines indicate the programmed VF, VT, and FVT detection rates, if applicable.

3.6.2.4 Assessing pacing and rate response information

Figure 34. 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 24:00 and 04:00 (as indicated by the device clock).

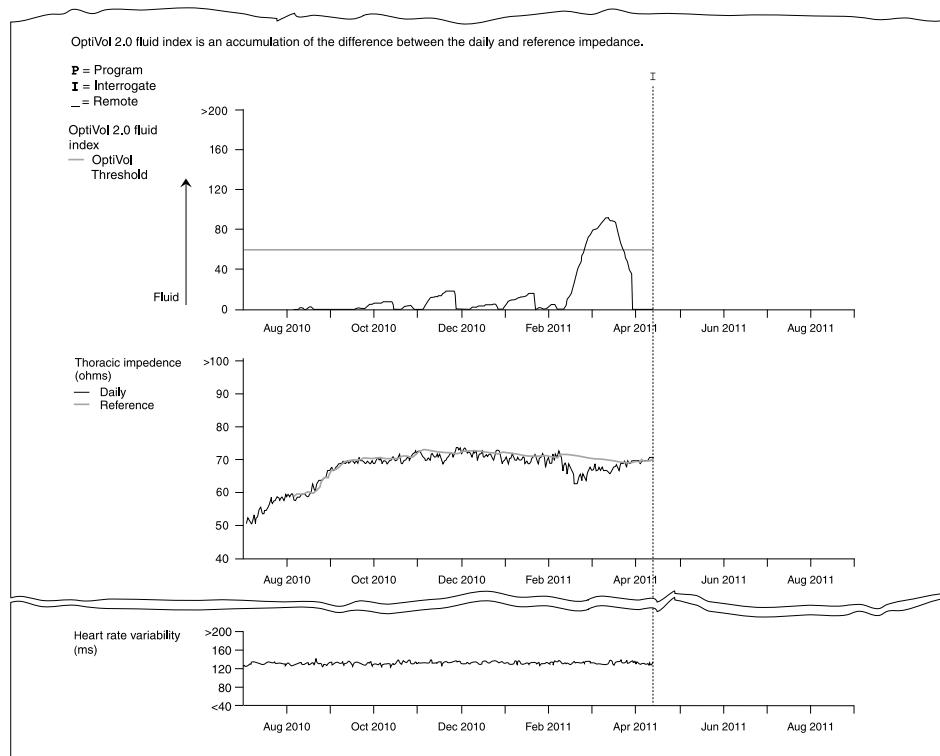
Patient activity – The patient activity trend may provide the following information:

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

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

3.6.2.5 Assessing heart failure information

Figure 35. Heart failure trend graphs



OptiVol 2.0 Fluid Index – A decrease in thoracic impedance may be an early indicator of fluid accumulation associated with heart failure. The OptiVol 2.0 Fluid Index trend displays the accumulated difference between the measured daily thoracic impedance and the Reference Impedance, adjusted for individual patient variation. If the Daily Impedance is

less than the Reference Impedance, this may indicate that the patient's thoracic fluid has increased. The horizontal line shows the programmed value of the OptiVol threshold.

Caution: Verify lead integrity when evaluating the OptiVol 2.0 Fluid Index trend. Loss of RVcoil integrity due to lead fracture or insulation defect may adversely affect the results of the OptiVol 2.0 Fluid Index trend.

Note: The OptiVol Fluid Status Monitoring feature has been updated to OptiVol 2.0 to account for individual patient variation, including allowing the Fluid Index to increase or decrease based on recent thoracic impedance measurements.

For more information, see Section 3.5, "OptiVol 2.0 fluid status monitoring", page 97.

Note: The OptiVol fluid monitoring feature provides an additional source of information for patient management and does not replace assessments that are part of standard clinical practice.

Thoracic impedance – The Thoracic impedance trend allows you to compare the daily average measured thoracic impedance to the Reference Impedance values. The Reference Impedance changes slightly from day to day to adapt slowly to the Daily Impedance.

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

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

3.7 Heart Failure Management Report

An analysis of clinical information related to heart failure 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 Heart Failure Management Report provides a picture of the patient's condition over the short and long term, with a focus on heart failure management. A summary of clinical data recorded since the last follow-up appointment shows information about arrhythmia episodes and therapies. Clinical trend graphs show long-term trends in heart rates, arrhythmias, and fluid accumulation indicators over the last 14 months.

The Heart Failure Management Report is based on data and measurements displayed on the Patient Information and Quick Look II screens and on Cardiac Compass Trends. Data storage for the Heart Failure Management Report is automatic. No setup is required.

Note: The time annotations displayed on the report are based on the device clock.

3.7.1 How to print the Heart Failure Management Report

Heart failure management data is available only as a printed report.

To access the Heart Failure Management Report, select Reports > Heart Failure...

3.7.2 Information provided by the Heart Failure Management Report

The Heart Failure Management Report provides information about the patient and the patient's clinical status since the last follow-up appointment. It displays events that have occurred during the reporting period and provides graphs that can help you to assess OptiVol 2.0 Fluid Trends and clinical trends related to heart failure.

Figure 36. Patient information, clinical status, and observations

The screenshot shows a report with the following sections:

Patient Information:

Date of Birth	29-Sep-1950	EF, on	---
Implant	13-Jan-2009	Hospital	

Clinical Status (01-Jan-2010 to 13-Apr-2011):

Treated VT/VF	0 episodes	V. Pacing	99.5%	Lower Rate	50 bpm
AT/AF	0 episodes	Atrial Pacing	99.1%	Upper Rate	130 bpm
Time in AT/AF	0.0 hr/day (0.0%)			Battery	OK

Observations (2) (01-Jan-2010 to 13-Apr-2011):

- Possible OptiVol fluid accumulation: 24-Feb-2011 -- 28-Mar-2011.
- Patient Activity less than 1 hr/day for 40 weeks.

3.7.2.1 Patient information

Patient information is based on data entered in the Patient Information screen. It includes any medical history and dates of measurements that have been recorded in the Patient Information screen.

3.7.2.2 Clinical Status and Observations

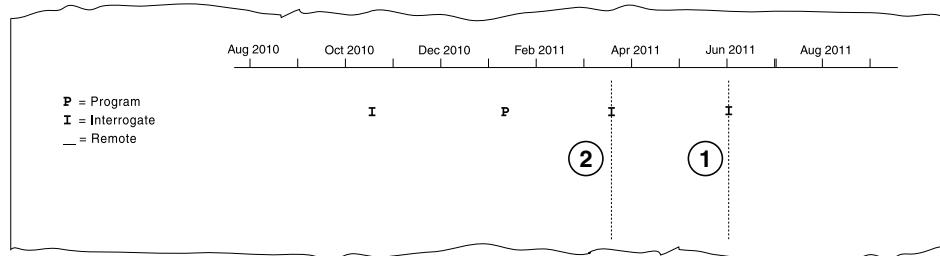
The Clinical Status and the Observations sections of the Heart Failure Management Report include information that can be useful for managing heart failure. This information is also available on the Quick Look II screen. For more information about Quick Look II data, see Section 3.1, "Quick Look II summary data", page 69.

The Heart Failure Management Report shows the following information:

- Arrhythmia episode information shows the number of Treated VT/VF episodes and the number of treated and monitored AT/AF episodes recorded since the last follow-up appointment.
- Ventricular and atrial pacing are shown as the percentage of the total time during the reporting period.
- The battery status at the start of the session can be OK, RRT (Recommended Replacement Time), or EOS (End of Service).
- System-defined observations alert you to conditions that may be related to heart failure.

3.7.2.3 Event information

Figure 37. 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.

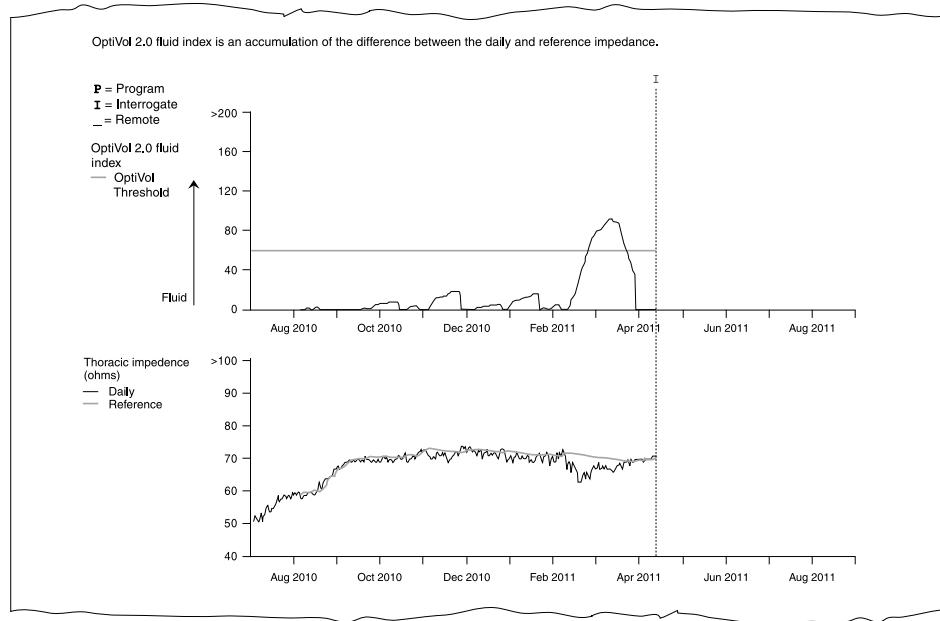
3.7.2.4 Assessing OptiVol 2.0 Fluid Trends

OptiVol 2.0 Fluid Index and Thoracic impedance graphs show data about thoracic impedance collected over the previous 14 months.

For more information, see Section 3.5, “OptiVol 2.0 fluid status monitoring”, page 97.

Note: The OptiVol fluid monitoring feature provides an additional source of information for patient management and does not replace assessments that are part of standard clinical practice.

Figure 38. OptiVol 2.0 Fluid Trends



OptiVol 2.0 Fluid Index – A decrease in thoracic impedance may be an early indicator of fluid accumulation associated with heart failure. The OptiVol 2.0 Fluid Index trend displays the accumulated difference between the measured daily thoracic impedance and the Reference Impedance, adjusted for individual patient variation. If the Daily Impedance is less than the Reference Impedance, this may indicate that the patient's thoracic fluid has increased. The horizontal line shows the programmed value of the OptiVol threshold.

Caution: Verify lead integrity when evaluating the OptiVol 2.0 Fluid Index trend. Loss of RVcoil integrity due to lead fracture or insulation defect may adversely affect the results of the OptiVol 2.0 Fluid Index trend.

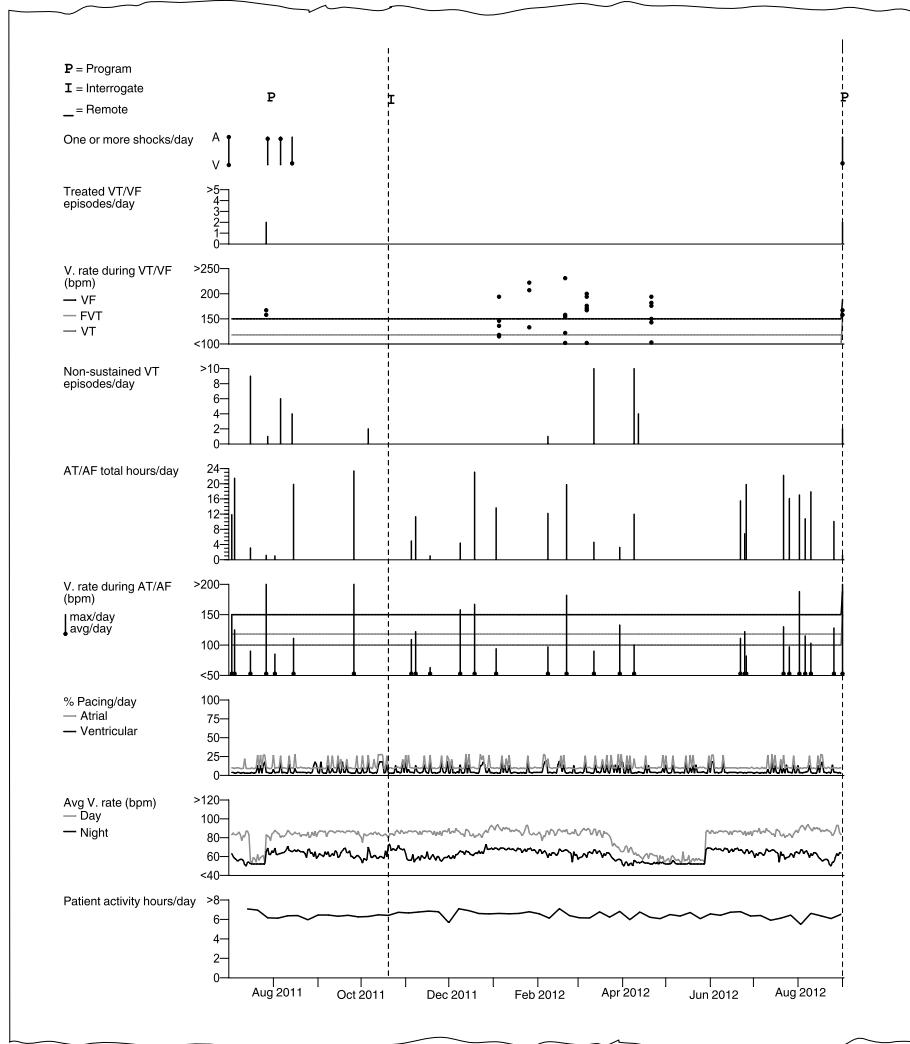
Note: The OptiVol Fluid Status Monitoring feature has been updated to OptiVol 2.0 to account for individual patient variation, including allowing the Fluid Index to increase or decrease based on recent thoracic impedance measurements.

Thoracic impedance – The Thoracic impedance trend allows you to compare the daily average measured thoracic impedance to the Reference Impedance values. The Reference Impedance changes slightly from day to day to adapt slowly to the Daily Impedance.

3.7.2.5 Assessing clinical trends

Clinical trend graphs show information collected over the previous 14 months that can be useful for heart failure management. Dates and event annotations allow you to correlate trends from different graphs.

The trend graphs that appear in both the Heart Failure Management Report and Cardiac Compass Trends are identical. For more information, see Section 3.6, “Cardiac Compass Trends”, page 102.

Figure 39. Clinical trend graphs

One or more shocks per day – The report indicates a shock for any day on which the device delivered a high-voltage therapy (an automatic defibrillation therapy, cardioversion therapy, or atrial shock therapy). Each annotation indicates delivery of one or more ventricular (V) or atrial (A) high-voltage therapies on a single day.

Treated VT/VF episodes per day – The history of ventricular tachyarrhythmias may be helpful in revealing correlations between clusters of episodes and other clinical trends.

Each day the device records the total number of spontaneous VT and VF episodes for which a therapy was started. This number may include therapies that were started and aborted. It does not include episodes that were only monitored.

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

The device records a daily total for the time the patient spent in atrial arrhythmia. The time in AT/AF is calculated from the point of AT/AF Onset. This trend may be reported in hours (0 to 24) or minutes (0 to 60) per day depending on the maximum duration per day. For more information, see Section 5.1, "AT/AF detection", page 224.

Ventricular rate during AT/AF – The graph plots average ventricular rates during episodes of AT and AF each day. The vertical lines show the difference between the average rate and the maximum sensed ventricular rate each day. The horizontal lines indicate the programmed VF, VT, and FVT detection rate, if applicable.

Patient activity – The patient activity trend can be an early indicator of symptoms due to progressive heart failure, which causes fatigue and a consequent reduction in patient activity. The trend can also provide an objective measurement of patient response to changes in therapy and can help you to monitor the patient's exercise regimen. The patient activity trend is a 7-day average of data derived from the device rate response accelerometer. It is reported only after 14 days of data have been collected.

Average ventricular rate – The day and night heart rates provide information that may indicate autonomic dysfunction related to heart failure. Gradual increases in heart rate may indicate decompensation, a symptom of heart failure. For this trend, "day" is defined as the 12-hour period between 08:00 and 20:00 and "night" as the 4-hour period between 24:00 and 04:00 (as indicated by the device clock).

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

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

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.

3.8 Arrhythmia Episodes data

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.

3.8.1 How to view the Arrhythmia Episodes data

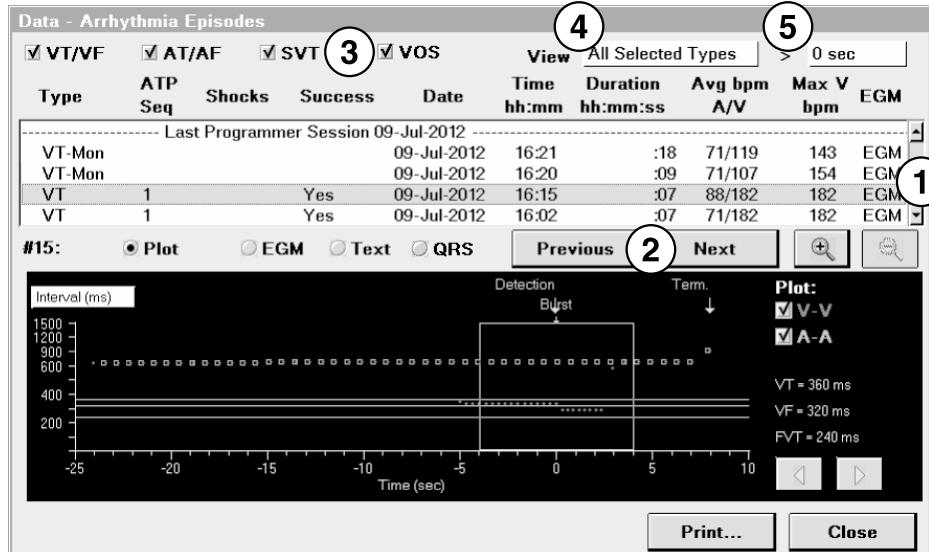
Table 14. How to access Arrhythmia Episodes data

Episodes	Path
All Arrhythmia Episodes	Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data]
Treated Arrhythmia Episodes	Data > Quick Look II > Treated [>>]
Monitored Arrhythmia Episodes	Data > Quick Look II > Monitored [>>]

3.8.2 Viewing the episode log

The episode log is displayed in the upper portion of the Arrhythmia Episodes screen. 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)
- the number of shocks or the energy 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 40. Episode log

- 1 Use the scroll buttons on the right side of the log area to scroll through the list of stored episodes.
- 2 Use the [Next] and [Previous] buttons to view the next or previous episode on the episode log.
- 3 Use the VT/VF, AT/AF, SVT, and VOS check boxes to select the types of episodes you want displayed.
- 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, and VT-NS episodes, the Avg bpm A/V is an average of A/V cycle length throughout the entire episode. For VT/VF, SVT, and VOS 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 Max V bpm value appears in the log as VP. For VT-NS episodes, the Max V bpm value is not displayed.

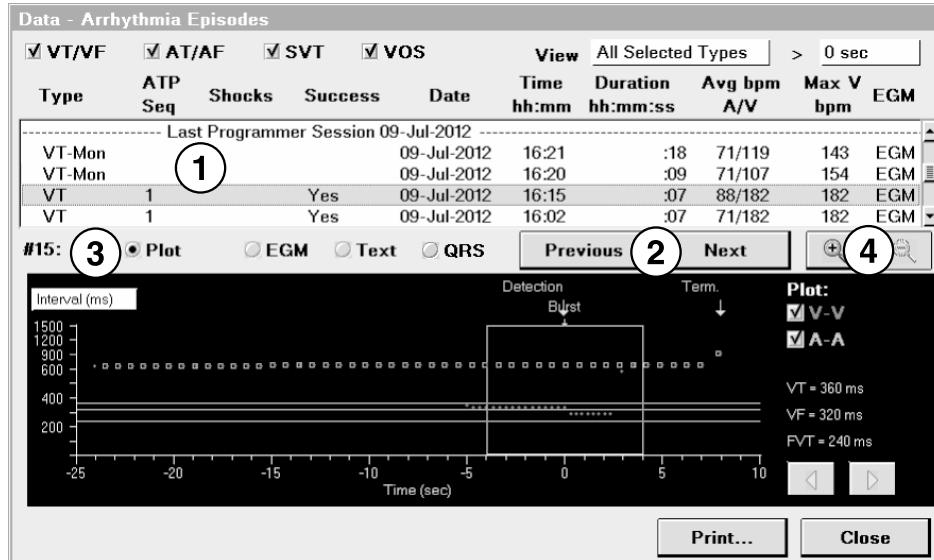
Notes:

- Episodes that occur during a device session are not available to view in the episode records until an interrogation is performed. To view the episode information, interrogate the device after episode termination.
- If an interrogation is performed while an episode is in progress, the type, date, and time of the episode are provided. To view additional episode information, interrogate the device after episode termination.
- For most episode types, when the log capacity is reached, data from the most recent episode will overwrite the oldest episode data in the log. For High Rate-NS episodes, if the log capacity has been reached and an RV Lead Integrity Alert is triggered, no new episodes will be added to the High Rate-NS log and no existing episodes will be overwritten until the alert is cleared. This allows the episodes that triggered the alert to be viewed. Overwriting of the oldest High Rate-NS episode data with new data resumes after the alert is cleared.

3.8.3 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 screen 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
- a QRS display showing Wavelet template match scores. For more information, see Section 5.4, “Wavelet”, page 248.

Figure 41. Arrhythmia episode record

- 1 Select an episode record in the upper portion of the Arrhythmia Episodes screen.
- 2 Use the [Previous] and [Next] buttons to navigate from record to record.
- 3 Use the Plot, EGM, Text, and QRS option buttons to display the selected episode data in one of the available formats.
- 4 Use the [+] button to maximize the plot, EGM, text, or QRS 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. At 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 Medtronic patient monitor reads the data from device memory, and the clinician can view the EGM and markers on the CareLink Network.

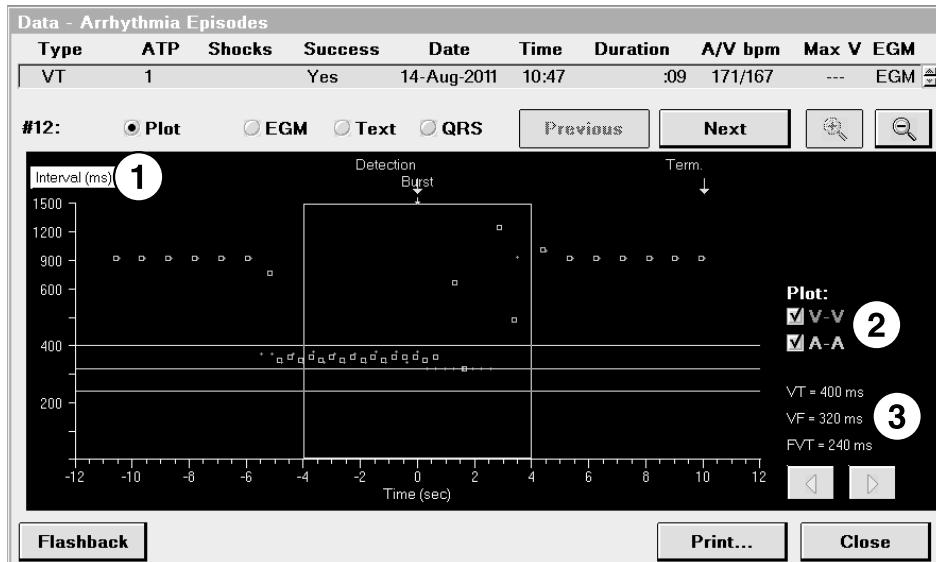
Notes:

- The Model 2696 InCheck Patient Assistant cannot communicate with the implanted device if the device is already in a wireless telemetry session.
- Patient-Activated Symptom Log entries are not collected when tachyarrhythmia episodes are being detected by the device.
- If the patient uses the activator during an episode, the device check marks the episode log entry and records the following in the episode text: "Patient Symptom detected during episode". However, a separate patient-activated record is not created.

3.8.3.1 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
- point of episode termination

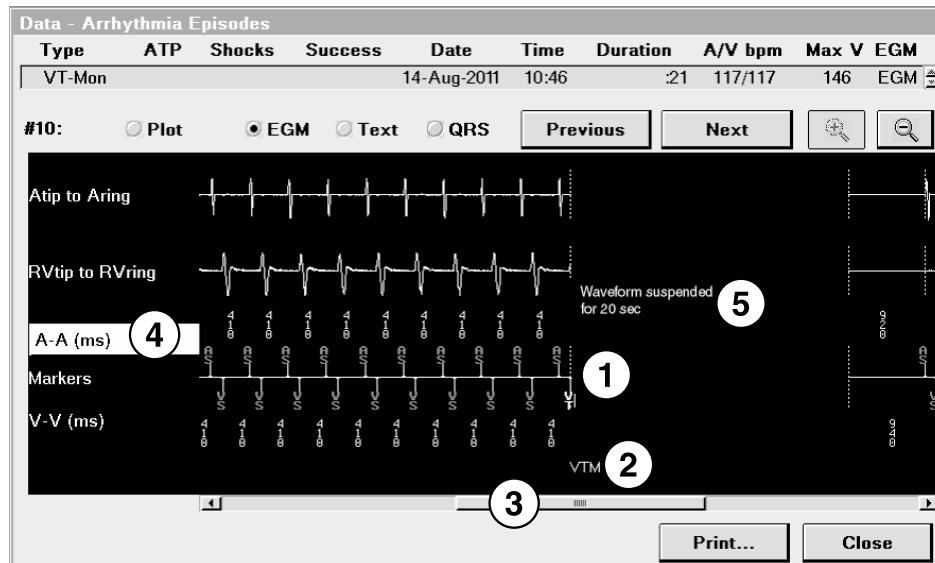
Figure 42. Episode Plot

- 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. If so, the programmer may display time labels on the horizontal axis of the interval plot following the truncation as asterisks (*).

3.8.3.2 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 43. 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 VT Monitor). 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 VT/VF or VT Monitor episodes, the device begins to store ventricular EGM data when 3 consecutive intervals have occurred in the VT, VT Monitor, or VF zone.

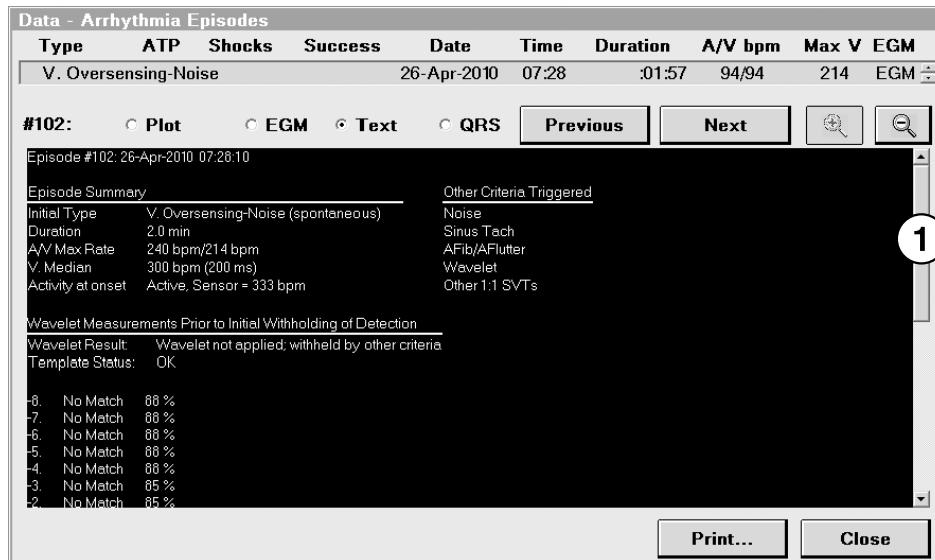
For AT/AF episodes, the device begins to store atrial EGM data when the device detects AT/AF Onset. The device stores up to 5 s of EGM data before AT/AF detection, regardless of whether a Pre-arrhythmia EGM storage option is selected.

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 storage memory.

3.8.3.3 Viewing the episode text

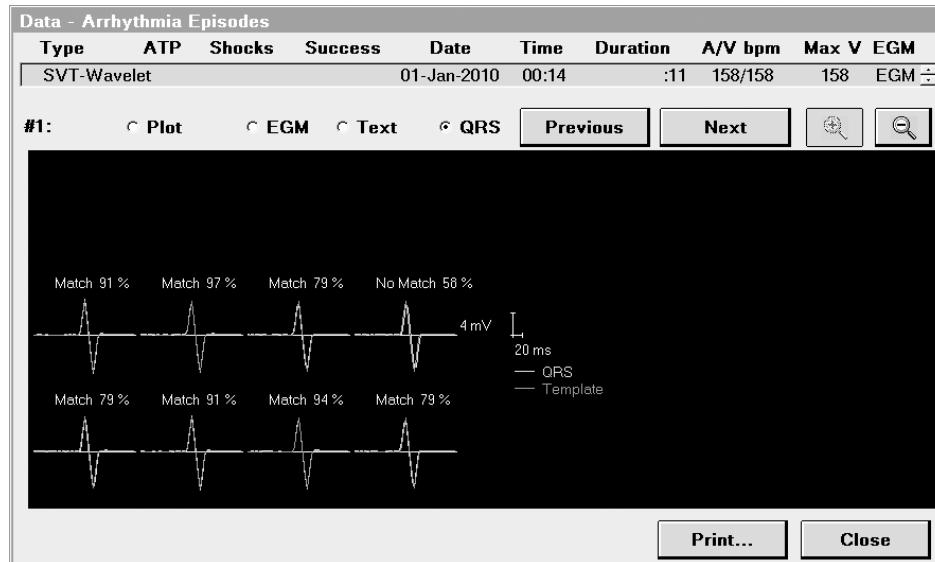
When you select an episode from the episode log and then select the Text option, the programmer displays a text summary of the episode.

Figure 44. Episode Text

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

3.8.3.4 Viewing the episode QRS data

When you select an episode from the episode log and then select the QRS option, the programmer displays the QRS data stored by the Wavelet feature.

Figure 45. Episode QRS

The QRS screen is available for SVT, VF, VT, VT Monitor, FVT, and VOS episodes if the Wavelet criterion is programmed to On or Monitor at the time when the episodes occur.

The QRS screen displays waveform diagrams of up to 8 recorded QRS complexes, with the current template overlaid on each waveform. For each QRS complex, the match percentage and classification (Match or No Match) are also displayed. For more information, see Section 5.4, “Wavelet”, page 248.

Note: If no template was available at the time the episode was recorded, the QRS complexes appear with no match percentages or classifications.

3.8.4 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.

LECG source – You can choose to display the Leadless ECG waveform on the LECG channel. Leadless ECG is an approximation of a surface ECG signal through the Can to SVC source and is available only when an SVC coil is present. You can also choose to display the waveform from the RVcoil to Aring source or the Can to Aring source on the LECG channel.

Note: The Leadless ECG option cannot be removed from the Live Rhythm Monitor.

For more information, see Section 2.7, “Monitoring cardiac activity with the Live Rhythm Monitor”, page 28.

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, your selection of EGM sources does not affect tachyarrhythmia interval criteria, synchronization, and therapy.

EGM and LECG range – Select a range for each EGM channel and the LECG channel. The range setting affects the resolution of the signal; the lower the setting, the higher the resolution. If the signal is illegible or clipped, consider changing the range selection.

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

Pre-arrhythmia EGM – Indicate whether you want to store EGM data collected prior to an episode. When Pre-arrhythmia EGM storage is on, the device collects up to 10 s of EGM data before the onset of VT/VF, VT Monitor, or the detection of SVT episodes. If Pre-arrhythmia EGM is programmed to Off, the episode record stores only intervals and no EGM at the beginning of each VT/VF, VT Monitor, or SVT episode. The device stores up to 5 s of EGM before AT/AF detection regardless of the Pre-arrhythmia EGM storage setting.

Note: 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.

3.8.4.1 Programming data collection preferences

Table 15. How to navigate to parameters for data collection preferences

Parameters	Path
LECG Source	Params > Data Collection Setup...
LECG Range	
EGM1 Source	
EGM1 Range	
EGM2 (Wavelet) Source	
EGM2 (Wavelet) Range	
EGM3 Source	
EGM3 Range	

Table 15. How to navigate to parameters for data collection preferences (continued)

Parameters	Path
Monitored EGM and LECG signals	
Pre-arrhythmia EGM	

3.9 Episode and therapy counters

The programmer allows you to view stored data about the number of times VT/VF and AT/AF episodes and therapies have occurred.

The count data for ventricular episodes includes the number of premature ventricular contractions (PVCs), Ventricular Rate Stabilization (VRS) paces, and monitored and non-sustained episodes. The count data for ventricular episodes also includes the number of episodes for which detection and therapy were withheld due to the application of supraventricular tachycardia (SVT) and ventricular oversensing (VOS) discrimination features.

The count data for atrial episodes includes the number of monitored, non-sustained, treated, and pace-terminated episodes.

3.9.1 How to view the counters

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

3.9.2 VT/VF episode counters

Figure 46. VT/VF episode counters

<input checked="" type="radio"/> VT/VF Episodes	<input type="radio"/> VT/VF Rx	<input type="radio"/> AT/AF Episodes	<input type="radio"/> AT/AF Rx
	Prior Session 15-Oct-2010 to 28-Dec-2010	Last Session 28-Dec-2010 to 04-Jun-2011	Device Lifetime Total (Since 01-Oct-2010)
VT/VF Counters			
VF	1	2 ↑	5
FVT	1	3 ↑	6
VT	1	4 ↑	7
Monitored VT (133 - 150 bpm)	2	4 ↑	
VT-NS (>4 beats, >150 bpm)	4	26 ↑	
High Rate-NS	3	12 ↑	
PVC Runs (2-4 beats)	<0.1 per hour	<0.1 per hour	
PVC Singles	0.0 per hour	<0.1 per hour	↑
Runs of VRS Paces	<0.1 per hour	<0.1 per hour	
Single VRS Paces	<0.1 per hour	<0.1 per hour	
SVT: VT/VF Rx Withheld			
AFib/AFlutter	0	1	9
Sinus Tach	1	6	9
Other 1:1 SVTs	3	5	10
Wavelet	2	0	2
V. Stability	5	26	32
Onset	2	2	6
V. Oversensing: VT/VF Rx Withheld			
V. Oversensing-TWave	2	4	7
V. Oversensing-Noise	1	7	9
Print...		Close	

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

VF, FVT, and VT – The number of episodes of each tachyarrhythmia.

Monitored VT – The number of VT Monitor episodes.

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

High Rate-NS – The number of high rate non-sustained ventricular tachyarrhythmia 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.

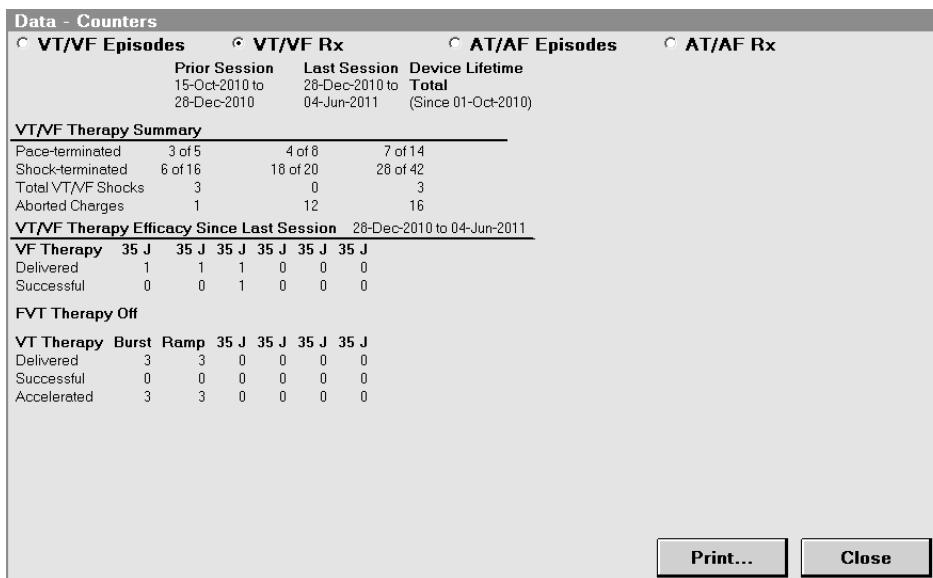
SVT: VT/VF Rx Withheld – The number of episodes initially detected for each supraventricular tachycardia (SVT) discrimination feature, causing withholding of VT/FVT/VF detection and therapy.

Note: Only SVTs with rates in the treated zones are included.

V. Oversensing: VT/VF Rx Withheld – The number of episodes initially detected as TWave Discrimination or RV Lead Noise Discrimination (ventricular oversensing discrimination features) for which VT/FVT/VF detection and therapy were withheld.

3.9.3 VT/VF therapy counters

Figure 47. VT/VF therapy counters



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

VT/VF Therapy Summary – The number of pace-terminated tachyarrhythmias, shock-terminated tachyarrhythmias, total VT/VF shocks, and aborted charges.

VT/VF Therapy Efficacy Since Last Session – The number and types of VF, FVT, and VT therapies delivered, whether they were successful (if no redetection occurred), and, for VT and FVT therapies, whether redetected episodes had accelerated (and were redetected as faster tachyarrhythmias). The 6 listed therapies refer to Rx1 through Rx6 for each episode type.

3.9.4 AT/AF episode counters

Figure 48. AT/AF episode counters

Data - Counters																																																																	
<input checked="" type="radio"/> VT/VF Episodes	<input type="radio"/> VT/VF Rx	<input checked="" type="radio"/> AT/AF Episodes	<input type="radio"/> AT/AF Rx																																																														
	Prior Session 15-Oct-2010 to 28-Dec-2010	Last Session 28-Dec-2010 to 04-Jun-2011																																																															
AT/AF Summary																																																																	
<table> <tr> <td>% of Time AT/AF</td> <td>0.1</td> <td>%</td> <td>1.7</td> <td>%</td> <td>↑</td> </tr> <tr> <td>Average AT/AF time/day</td> <td><0.1</td> <td>hours/day</td> <td>0.4</td> <td>hours/day</td> <td>↑</td> </tr> <tr> <td>Monitored AT/AF Episodes</td> <td><0.1</td> <td>per day</td> <td><0.1</td> <td>per day</td> <td></td> </tr> <tr> <td>Treated AT/AF Episodes</td> <td><0.1</td> <td>per day</td> <td><0.1</td> <td>per day</td> <td></td> </tr> <tr> <td>Pace-Terminated Episodes</td> <td>23.8</td> <td>%</td> <td>16.6</td> <td>%</td> <td>↓</td> </tr> <tr> <td>% of Time Atrial Pacing</td> <td>53.5</td> <td>%</td> <td>62.3</td> <td>%</td> <td>↑</td> </tr> <tr> <td>% of Time Atrial Intervention</td> <td>15.2</td> <td>%</td> <td>9.2</td> <td>%</td> <td>↓</td> </tr> <tr> <td>AT-NS (>6 beats)</td> <td>0.2</td> <td>per day</td> <td>0.9</td> <td>per day</td> <td>↑</td> </tr> </table>						% of Time AT/AF	0.1	%	1.7	%	↑	Average AT/AF time/day	<0.1	hours/day	0.4	hours/day	↑	Monitored AT/AF Episodes	<0.1	per day	<0.1	per day		Treated AT/AF Episodes	<0.1	per day	<0.1	per day		Pace-Terminated Episodes	23.8	%	16.6	%	↓	% of Time Atrial Pacing	53.5	%	62.3	%	↑	% of Time Atrial Intervention	15.2	%	9.2	%	↓	AT-NS (>6 beats)	0.2	per day	0.9	per day	↑												
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Since Last Session 28-Dec-2010 to 04-Jun-2011																																																																	
<table> <thead> <tr> <th>AT/AF Durations</th> <th>Episodes*</th> <th>AT/AF Start Times</th> <th>Episodes*</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>>72 hr</td> <td>806</td> <td>09:00 - 12:00</td> <td>355</td> <td></td> <td></td> </tr> <tr> <td>48 hr to 72 hr</td> <td>715</td> <td>12:00 - 15:00</td> <td>445</td> <td></td> <td></td> </tr> <tr> <td>24 hr to 48 hr</td> <td>625</td> <td>15:00 - 18:00</td> <td>535</td> <td></td> <td></td> </tr> <tr> <td>12 hr to 24 hr</td> <td>535</td> <td>18:00 - 21:00</td> <td>0</td> <td></td> <td></td> </tr> <tr> <td>4 hr to 12 hr</td> <td>445</td> <td>21:00 - 00:00</td> <td>715</td> <td></td> <td></td> </tr> <tr> <td>1 hr to 4 hr</td> <td>355</td> <td>00:00 - 03:00</td> <td>85</td> <td></td> <td></td> </tr> <tr> <td>10 min to 1 hr</td> <td>265</td> <td>03:00 - 06:00</td> <td>175</td> <td></td> <td></td> </tr> <tr> <td>1 min to 10 min</td> <td>175</td> <td>06:00 - 09:00</td> <td>265</td> <td></td> <td></td> </tr> <tr> <td><1 min</td> <td>85</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>						AT/AF Durations	Episodes*	AT/AF Start Times	Episodes*			>72 hr	806	09:00 - 12:00	355			48 hr to 72 hr	715	12:00 - 15:00	445			24 hr to 48 hr	625	15:00 - 18:00	535			12 hr to 24 hr	535	18:00 - 21:00	0			4 hr to 12 hr	445	21:00 - 00:00	715			1 hr to 4 hr	355	00:00 - 03:00	85			10 min to 1 hr	265	03:00 - 06:00	175			1 min to 10 min	175	06:00 - 09:00	265			<1 min	85				
AT/AF Durations	Episodes*	AT/AF Start Times	Episodes*																																																														
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4 hr to 12 hr	445	21:00 - 00:00	715																																																														
1 hr to 4 hr	355	00:00 - 03:00	85																																																														
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<1 min	85																																																																
*Includes AT-NS episodes																																																																	
<input type="button" value="Print..."/> <input type="button" value="Close"/>																																																																	

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 percentage is of total time, not 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 AT-NS and detected AT/AF 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 AT-NS and detected AT/AF episodes falling into each of a series of 3-hour periods of the day.

3.9.5 AT/AF therapy counters

Figure 49. AT/AF therapy counters

Data - Counters		VT/VF Episodes		VT/VF Rx		AT/AF Episodes		AT/AF Rx	
<input type="radio"/> Since Last Session		09-Dec-2011 to 10-Dec-2011							
<hr/>									
Fast AT/AF Rx		Rx1:Ramp	Rx2:Burst+	Rx3:50 Hz					
Treated episodes		1	0	0					
% Terminated		100.0 %	0.0 %	0.0 %					
AT/AF Rx		Rx1:Ramp	Rx2:Burst+	Rx3:50 Hz					
Treated episodes		2	1	1					
% Terminated		50.0 %	0.0 %	0.0 %					
ATP Rx versus		100-149	150-199	200-249	250-299	300-349	350-399	400-449	ms
ms		401-600	301-400	241-300	201-240	172-200	151-171	133-150	bpm
Treated episodes		0	0	0	0	2	1	0	
% Terminated		0.0 %	0.0 %	0.0 %	0.0 %	50.0 %	0.0 %	0.0 %	
<hr/>									
Fast AT/AF Zone 100-199 ms: 1 treated episodes, 100.0 % terminated									
Note: Above table does not include Fast AT/AF therapies.									
ATP Sequences: 0 delivered, 0 aborted									
Automatic Shocks: 0 delivered, 0 failed									
Patient Activated Shocks: 0 delivered, 0 failed									
<input type="button" value="Print..."/>							<input type="button" value="Close"/>		

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

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

ATP treated episodes by cycle length – The number of ATP 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.

Automatic Shocks – The number of automatic atrial defibrillation therapies that were delivered and the number of episodes that were not terminated.

Patient Activated Shocks – The number of patient-activated atrial defibrillation therapies that were delivered and the number of episodes that were not terminated.

3.10 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 VF episode
- the most recent VT 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.

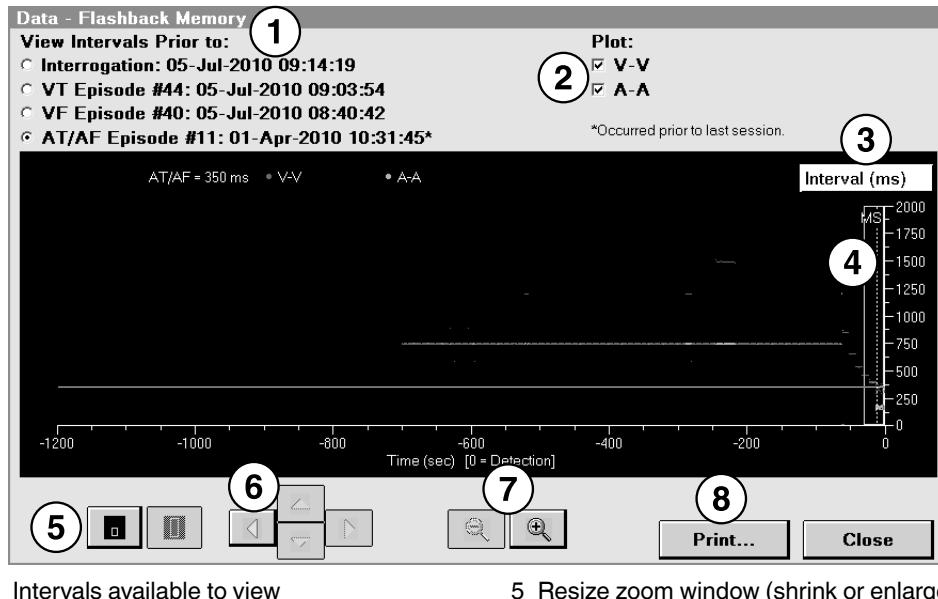
Note: When an episode is detected, Flashback Memory storage is suspended until the episode terminates.

3.10.1 How to view Flashback Memory data

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

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

Figure 50. Flashback Memory screen



1 Intervals available to view

5 Resize zoom window (shrink or enlarge)

2 Plot intervals

6 Reposition zoom window

3 Interval or Rate

7 Zoom in (+); zoom out (-)

4 Zoom window

8 Print

3.11 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 4.8, “Rate Drop Response”, page 188.

When Rate Drop Response is programmed to 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).

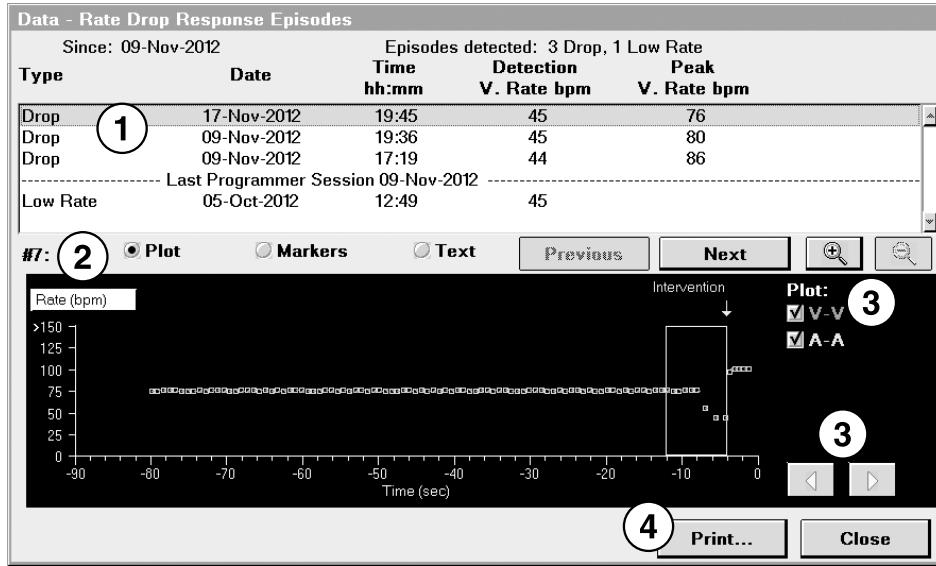
Available views – The Rate Drop Response Episodes screen allows you to select from different views of the episode. Selecting Plot shows the beat-to-beat data for the selected episode. Selecting Markers provides the data as annotated marker channels. Selecting Text allows you to review Rate Drop Response 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.

3.11.1 How to view Rate Drop Response episode data

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

Figure 51. 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.

3.12 Rate Histograms

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

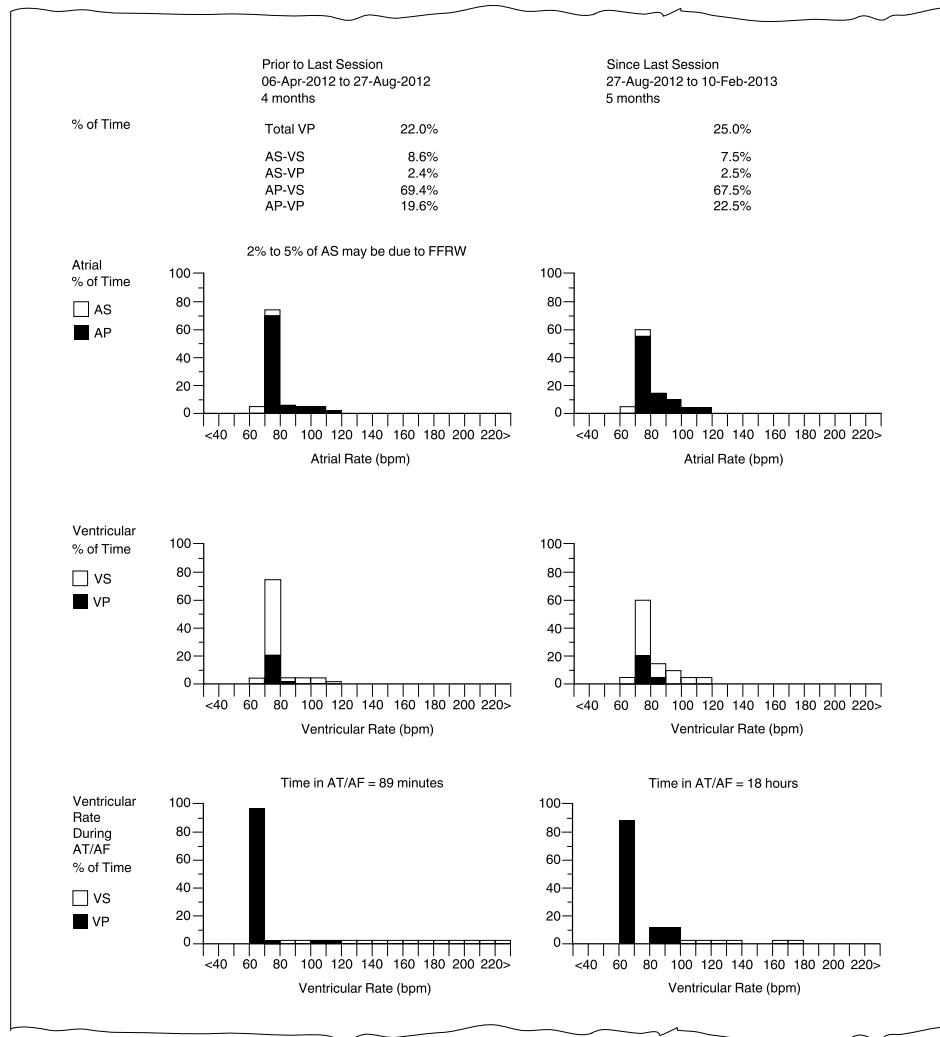
3.12.1 How to view and print Rate Histograms

You can view Rate Histograms starting from the Data icon. Select Data > Clinical Diagnostics > Rate Histograms.

You can print Rate Histograms starting from either the Reports icon or the Rate Histograms screen. Select Reports > Available Reports...> Rate Histograms, or select [Print...] from the Rate Histograms screen.

3.12.2 Information provided by Rate Histograms

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

Figure 52. Rate Histograms

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

% of Time – This section shows the 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 total daily counts of VP and 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/AF⁵. This histogram may be used to monitor the effectiveness of ventricular rate control therapy and drug titration.

3.13 Automatic device status monitoring

The device automatically and continuously monitors for adequate charge time performance, 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. A device status indicator warning is displayed as a window on the programmer screen and is displayed also 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 3.13.2, “How to respond to the device status indicator warning for electrical reset”, page 138.

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 window that displays the device status indicator warning.

3.13.1 Definitions of device status indicator warnings

Warning - Charge Circuit Timeout – Indicates that the charging period has exceeded 30 s. The charge circuit is still active. Inform a Medtronic representative if this device status

⁵ The time in AT/AF is calculated from the point of AT/AF Onset. For more information, see Section 5.1, “AT/AF detection”, page 224.

indicator is displayed on the programmer screen. **Immediate replacement of the device is recommended.**

Warning - Charge Circuit Inactive – Indicates that 3 consecutive charging periods have each exceeded 30 s. The charge circuit is inactive, and all automatic therapy functions, EP study functions, and manual system tests are disabled except for Emergency VVI pacing. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen. **Immediate replacement of the device is recommended.**

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 reset settings, see the device manual for the specific device. 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 warning 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. In most electrical reset situations, VF detection is enabled. In rare cases, an electrical reset may disable tachyarrhythmia detection and therapy. If this occurs, the Medtronic CareAlert alarm for electrical reset sounds every 9 hours, and the device operates as a simple bradycardia pacing device (in VVI mode, 65 bpm). Tachyarrhythmia detection and therapy can be reprogrammed after the electrical reset indicator has been cleared.

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 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 before 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, see Section 6.1, “Atrial therapy scheduling”, page 275.

3.13.2 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 window to clear the reset indicator and the Medtronic CareAlert alarm. A confirmation window appears indicating that all previously interrogated data in the programmer has been 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. You should give a copy of this saved data file to your Medtronic representative; it can be helpful in determining the events leading up to the reset.
6. Verify the programmed device parameters. If a full reset occurred, the reprogrammed values are displayed in the warning message. If a full electrical reset occurred, reprogram the device parameters.

After this type of reset, the device operates as a simple defibrillator (in VOE-VVI mode) until it is reprogrammed. For a list of electrical reset parameter settings, see the device manual for the specific device.
7. Verify that the device time and date are correct. If necessary, reprogram the time and date.

8. Check the Battery and Lead Measurements screen to verify that the battery voltage and charge time are acceptable.
9. Conduct lead impedance and pacing threshold tests as desired.

4 Pacing features

4.1 Sensing

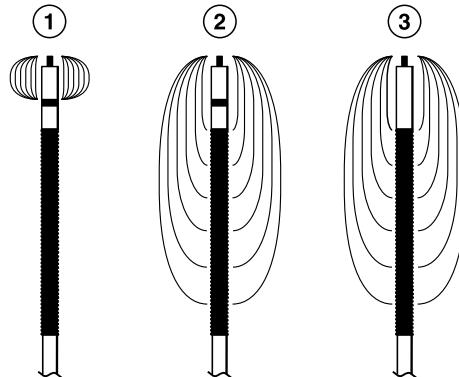
The device must sense the occurrence of intrinsic cardiac events while avoiding oversensing so that it can deliver therapies appropriately. Effective sensing can reduce the effects of long depolarizations after paced events, oversensing the same event, cross-chamber sensing, sensing far-field R-waves,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

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

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

Programmable blanking periods and refractory periods help to screen out extraneous sensing or to prevent the device from responding to it. Blanking periods follow pacing pulses, sensed events, and shocks. Sensing is inhibited during blanking periods. Refractory periods follow pacing pulses and sensed events. 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.

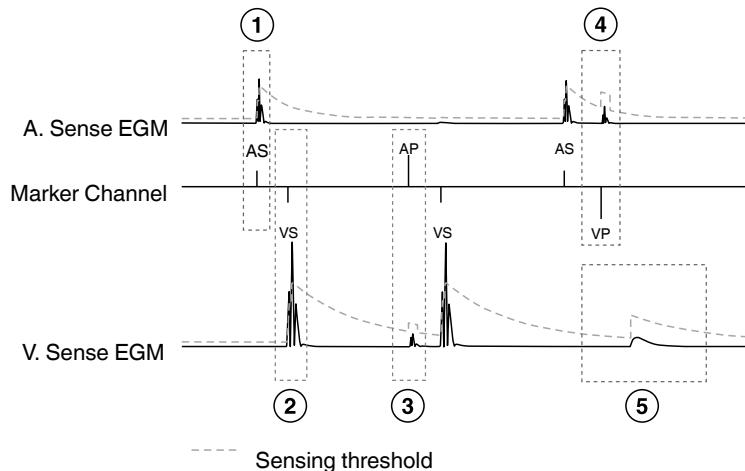
The sensing polarity is bipolar in the atrium and either bipolar or tip-to-coil in the right ventricle. The device can use either a true bipolar lead or an integrated bipolar lead for right ventricular sensing. With a true bipolar lead, right ventricular sensing can occur between the RV tip and RV ring electrodes (bipolar), or between the RV tip and RV coil electrodes (see Figure 53). The sensing vector is programmable via the RV Sense Polarity parameter. With an integrated bipolar lead, right ventricular sensing occurs between the RV tip and RV coil electrodes. In this case, the RV Sense Polarity parameter has no effect on the sensing vector. The sensing and blanking functions are identical in these lead configurations.

Figure 53. Ventricular sensing with a true bipolar or an integrated bipolar lead

- 1 Sensing with a true bipolar lead and RV Sense Polarity programmed to Bipolar
- 2 Sensing with a true bipolar lead and RV Sense Polarity programmed to Tip to Coil
- 3 Sensing with an integrated bipolar lead and RV Sense Polarity programmed to either Bipolar or Tip to Coil

4.1.1 Operation of sensing thresholds

The device automatically adjusts sensing thresholds after certain paced and sensed events to help reduce the oversensing of T-waves, cross-chamber events, and pacing pulses. 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 with nominal settings is shown in Figure 54.

Figure 54. Automatic adjustment of sensing thresholds

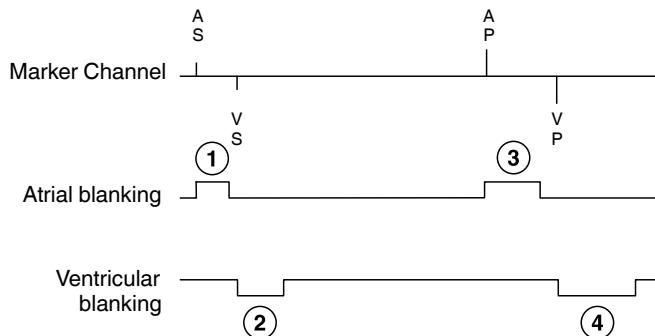
- 1 After an atrial sensed event, the device is temporarily less sensitive to atrial events.
- 2 After a ventricular sensed event, the device is temporarily less sensitive to ventricular events.
- 3 After an atrial paced event, the device is temporarily less sensitive to ventricular events, but the sensitivity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

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

4.1.2 Operation of blanking periods

Blanking periods follow paced events, sensed events, and shocks. Blanking periods help to prevent the device from sensing pacing pulses, cardioversion and defibrillation 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, paced events, and post-shock paced events.

Figure 55. 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 16 are nonprogrammable.

Table 16. Cross-chamber blanking periods

Parameter	Value
Atrial blanking after a ventricular pacing pulse	30 ms
Ventricular blanking after an atrial pacing pulse	30 ms ^a

^aIf the RV pacing amplitude is programmed at 8 V, this value is 35 ms.

The post-shock blanking periods are also nonprogrammable. After a cardioversion or defibrillation therapy is delivered, the atrial and ventricular blanking is 520 ms.

4.1.3 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.

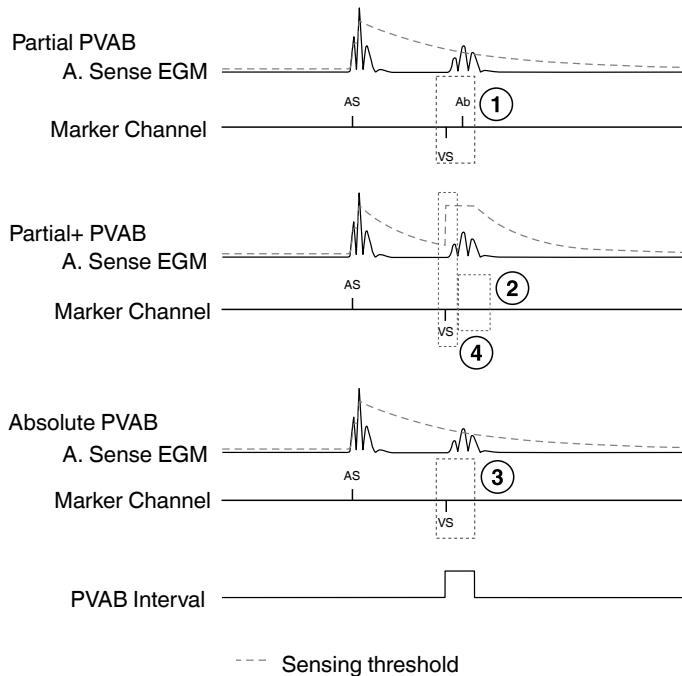
The 3 programmable values of PVAB Method are Partial, Partial+, and Absolute. This parameter determines whether atrial events that occur during PVAB interval are sensed by the device. It also controls how the atrial sensing threshold is adjusted after a ventricular event. Refer to Figure 56 for a comparison of the PVAB methods.

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

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

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

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

Figure 56. Comparison of the PVAB methods

- 1 When the Partial PVAB method is used, if the far-field R-wave exceeds the atrial threshold, an Ab marker indicates that the event is sensed during the PVAB interval.
- 2 With the Partial+ PVAB method, after a ventricular sensed or paced event, the atrial sensing threshold increases, and the device is less sensitive to atrial events.
- 3 When the Absolute PVAB method is used, an atrial event is blanked in the PVAB interval whether or not the far-field R-wave exceeds the atrial threshold.
- 4 Except for the change in the atrial sensing threshold, the Partial+ PVAB and Partial PVAB methods are similar. With either method, atrial events sensed in the PVAB interval are used by the tachyarrhythmia detection features.

4.1.4 Operation of refractory periods

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

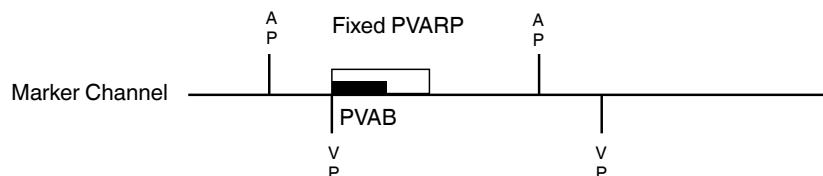
The availability of refractory periods depends on the programmed pacing mode. The Post Ventricular Atrial Refractory Period (PVARP) is available in dual chamber pacing modes, and the Atrial Refractory Period is available in atrial pacing modes.

4.1.4.1 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 57. Timing for fixed PVARP



The PVARP parameter may be programmed to Auto instead of a fixed value. Auto PVARP adjusts PVARP in response to changes in the patient's intrinsic rate or pacing rate. During a Mode Switch episode, the device enables Auto PVARP. For more information, see Section 4.7, "Auto PVARP", page 186.

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

4.1.4.2 Atrial Refractory Period

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

4.1.5 Programming sensing

Table 17. How to navigate to sensing parameters

Parameters	Path
Sensitivity and polarity parameters	Params > Pacing...
Refractory period parameters	Params > Pacing... > PVARP...
Blanking parameters	Params > Pacing... > Blanking...

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.

Detection when pacing at high rates – Undersensing may occur if the value for RV Sensitivity is 0.3 mV or higher and the value for Upper Tracking Rate (or Upper Sensor Rate) is greater than 150 bpm.

High ventricular sensing threshold – Setting RV Sensitivity to a value greater than 0.6 mV is not recommended except for testing purposes. Doing this may cause undersensing, which may result in the following situations:

- asynchronous pacing
- underdetection of tachyarrhythmias
- delayed or aborted cardioversion therapy
- delayed defibrillation therapy (when VF confirmation is active)

Sensing during VF – Always verify that the device senses properly during VF. If the device is not sensing or detecting properly, disable detection and therapies and evaluate the system (making sure to monitor the patient for life-threatening tachyarrhythmias until you enable detection and therapies again). You may need to reposition or replace the ventricular sensing lead to achieve proper sensing.

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 4.11, “Non-Competitive Atrial Pacing”, page 197.

Low sensing threshold – 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.

Recommended ventricular sensing threshold – Setting RV Sensitivity to 0.3 mV is recommended to maximize the probability of detecting VF and to limit the possibility of oversensing and cross-chamber sensing.

Recommended atrial sensing threshold – Setting A. 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.

Testing sensitivity after reprogramming – If you change the ventricular sensing threshold or the ventricular sensing polarity, evaluate for proper sensing. If appropriate, test for proper detection by inducing VF and allowing the device to automatically detect and treat the tachyarrhythmia.

4.1.6 Evaluation of sensing

4.1.6.1 Using the Sensing Test to evaluate sensing

The Sensing Test allows you to measure P-wave and R-wave amplitudes. These measurements may be useful for assessing lead integrity and sensing performance. After the Sensing Test is complete, the test results are displayed on the test screen. You may view and print the results when desired. For more information, see Section 7.5, “Sensing Test”, page 340.

4.1.6.2 Viewing the Sensing Integrity Counter

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

Figure 58. Battery and Lead Measurements screen

Data - Battery and Lead Measurements					
Remaining Longevity	26-Oct-2011	Lead Impedance		[>>]	
Estimated at:	5.5 years	A. Pacing	585 ohms	26-Oct-2011	
Minimum:	4.8 years	RV Pacing	513 ohms	26-Oct-2011	
Maximum:	6.1 years	(Bipolar)			
 RRT	> 5 years (based on initial interrogation)				
Battery Voltage	2.98 V (RRT=2.73V)	26-Oct-2011	RV Defib	55 ohms	26-Oct-2011
			SVC Defib	53 ohms	26-Oct-2011
Last Charge	26-Oct-2011	Sensing	[>>]		
Charge Time	8.9 sec	P-Wave Amplitude	1.6 mV	26-Oct-2011	
Energy	0.0 - 35 J	R-Wave Amplitude	5.6 mV	25-Oct-2011	
Sensing Integrity Counter		Last High Voltage Therapy		26-Oct-2011	
	Since 26-Oct-2011	Measured Impedance	57 ohms		
Short V-V Intervals	0	Delivered Energy	36 J		
		Waveform	Biphasic		
		Pathway	AX>B		
Atrial Lead Position Check					
No measurement since reset.					
				Print...	Close

The Sensing Integrity Counter records the following information:

- the number of short ventricular intervals that occurred since the last patient session
- the date of the first of these intervals, if any occurred

A large number of short ventricular (more than 300) intervals may indicate oversensing, lead fracture, or a loose setscrew.

Note: The number of short ventricular intervals is an input to the RV Lead Integrity Alert. For more information, see Section 3.3, “RV Lead Integrity Alert”, page 82.

4.1.6.3 Viewing P-wave and R-wave amplitude trends

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

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). You can compare recent amplitude measurements to the trends of daily automatic measurements. Significant or sudden changes in sensing amplitude may indicate a problem with a lead.

Note: The sensing amplitude trend data is intended to show changes in sensing amplitude measurements that may be used to assess lead integrity. The adequacy of the ventricular sensing safety margin cannot be determined by the R-wave trend measurement and should be based on VF induction testing.

4.2 Basic pacing

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

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.

4.2.1 Operation of pacing and sensing

The output energy for pacing pulses in each chamber is determined by individually programmed amplitude and pulse width parameters. Although you can program these parameters manually, the Capture Management feature is available to manage pacing output energies in the atrium and right ventricle. For more information, refer to Section 4.5, “Capture Management”, page 173.

The device provides sensing in both the atrium and right ventricle. For information about sensing thresholds, lead polarities, blanking periods, and refractory periods, see Section 4.1, “Sensing”, page 140.

4.2.2 Operation of dual chamber pacing

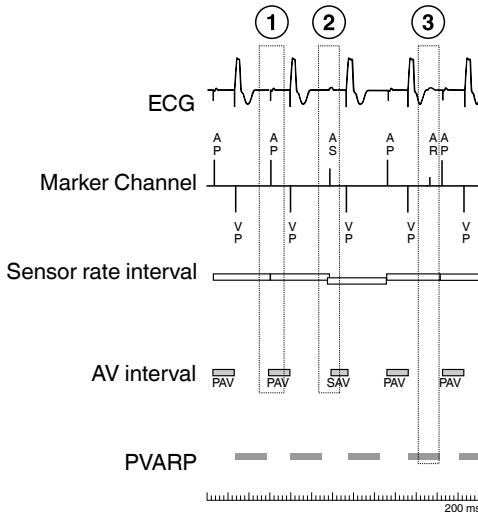
In dual chamber modes, pacing and sensing occur in the atrium and ventricle. The dual chamber pacing modes include DDDR, DDD, DDIR, and DDI. In the DDD mode, pacing occurs at the programmed Lower Rate in the absence of intrinsic atrial activity. In the DDI mode, pacing occurs at the programmed Lower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

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

For information about the AAIR<=>DDDR and AAI<=>DDD modes (MVP modes), see Section 4.3, “Managed Ventricular Pacing (MVP)”, page 160.

4.2.2.2 DDDR and DDD modes

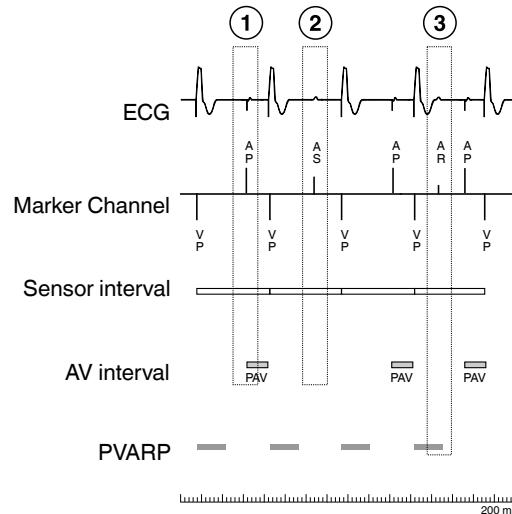
DDDR and DDD are atrial tracking pacing modes. Atrial tracking means that when the device senses an intrinsic atrial event, it schedules a ventricular paced event in response (see Figure 59). The delay between the sensed atrial event and the corresponding ventricular paced event is the Sensed AV (SAV) 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 4.1.4.1, “Post Ventricular Atrial Refractory Period (PVARP)”, page 146.

Figure 59. Operation of dual chamber pacing in DDDR

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

4.2.2.3 DDIR and DDI modes

In the DDIR and DDI modes, sensed atrial events are not tracked. When an atrial event is sensed, atrial pacing is inhibited, but a SAV interval is not started (see Figure 60). Instead, ventricular pacing is delivered at the current pacing rate (for example, at the Lower Rate or sensor rate). If the current pacing interval ends before the device senses an atrial event, the device paces the atrium and then schedules a ventricular paced event to occur at the end of the PAV interval. If a ventricular sensed event occurs during the PAV interval, ventricular pacing is inhibited. A sensed atrial event that occurs during PVARP is classified as refractory and does not inhibit atrial pacing. For more information, see Section 4.1.4.1, “Post Ventricular Atrial Refractory Period (PVARP)”, page 146.

Figure 60. Operation of dual chamber pacing in DDIR

- 1 An atrial paced event starts a PAV interval.
- 2 An atrial sensed event inhibits the scheduled atrial paced event but does not start an SAV interval (is not tracked).
- 3 An atrial event that is sensed during PVARP does not inhibit the scheduled atrial paced event.

4.2.2.4 ODO mode (bradycardia pacing off)

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

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

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

4.2.2.5 D00 mode

The D00 mode provides AV sequential pacing at the programmed Lower Rate with no inhibition by intrinsic events.

Warning: The device provides no sensing or detection in either chamber when it is programmed to D00 mode. Use D00 mode only in situations in which asynchronous pacing is warranted.

To program the device to the D00 mode, VT Detection and VF Detection must be programmed to Off, and AT/AF Detection must be programmed to Monitor.

4.2.3 Operation of single chamber pacing

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

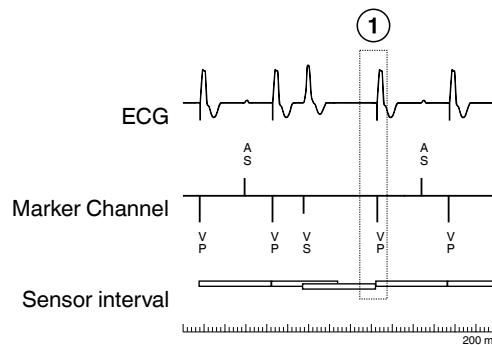
4.2.3.1 AAIR<=>DDDR and AAI<=>DDD modes

For information about the AAIR<=>DDDR and AAI<=>DDD modes (MVP modes), see Section 4.3, “Managed Ventricular Pacing (MVP)”, page 160.

4.2.3.2 VVIR and VVI modes

In the VVIR and VVI modes, the ventricle is paced if no intrinsic ventricular events are sensed. Pacing occurs at the programmed Lower Rate in the VVI mode and at the sensor rate in the VVIR mode (see Figure 61). In VVIR and VVI modes, the device continues sensing atrial events for tachyarrhythmia detection purposes.

Figure 61. Operation of single chamber ventricular pacing in VVIR



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

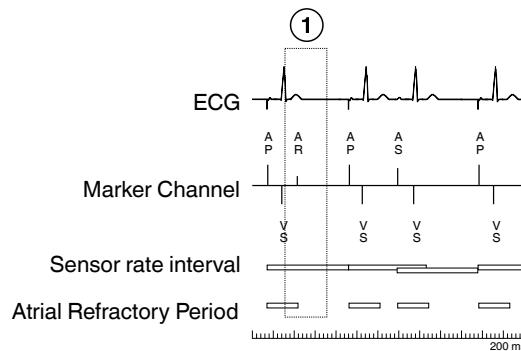
4.2.3.3 AAIR and AAI modes

In the AAIR and AAI modes, the atrium is paced if no intrinsic atrial events are sensed. Pacing occurs at the programmed Lower Rate in the AAI mode and at the sensor rate in the AAIR mode (see Figure 62).

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

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

Figure 62. Operation of single chamber atrial pacing in AAIR



1 An atrial event during the Atrial Refractory Period does not restart the A-A pacing interval.

4.2.3.4 VOO mode

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

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

4.2.3.5 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 even though it offers ventricular sensing. AT/AF Detection must be programmed to Monitor and VT Detection and VF Detection must be programmed to Off to program the device to the AOO mode.

4.2.4 Programming pacing therapies

Table 18. How to navigate to basic pacing parameters

Parameters	Path
Mode and rates	Params > Pacing...
Pacing amplitudes and pulse widths	
Pacing and sensing polarities	
AV Intervals	Params > Pacing... > Paced AV...
Paced AV	
Sensed AV	
Rate Adaptive AV	

TherapyGuide – It is suggested that you use TherapyGuide to determine the pacing mode for a particular patient. For more information, see Section 2.11, “Using TherapyGuide to select parameter values”, page 44.

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

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

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

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

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

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

4.2.5 Evaluation of pacing therapies

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

Percentage of Time (% of Time) – For single chamber modes, the % of Time section reports the patient's pacing 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).

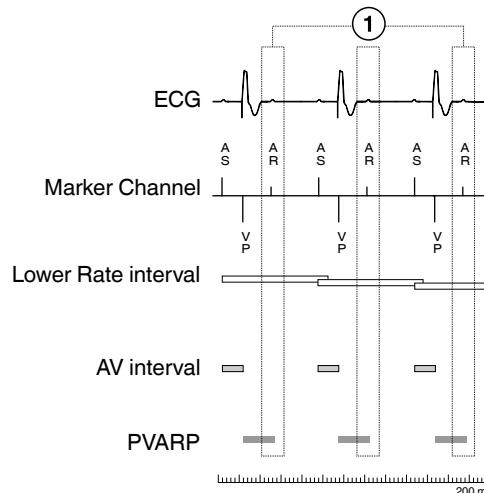
For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

4.2.6 Tracking rapid atrial rates

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

4.2.6.1 2:1 block

2:1 block occurs when the intrinsic atrial interval is so short that every other atrial sensed event occurs during PVARP (see Figure 63). 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 63. Example of pacing at the 2:1 block rate

1 One of every 2 atrial sensed events occurs during PVARP and is not tracked.

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

A common method to prevent 2:1 block at elevated exercise rates (for example, above 150 bpm) is to program shorter than nominal values for SAV and PVARP. Use of the Rate Adaptive AV and Auto PVARP features dynamically shortens the operating SAV and PVARP values during exercise. For more information, see Section 4.7, “Auto PVARP”, page 186. These features can prevent symptomatic 2:1 block during exercise while allowing nominal or longer SAV and PVARP values at resting rates to help prevent rapid ventricular pacing rates during the onset of AT/AF.

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

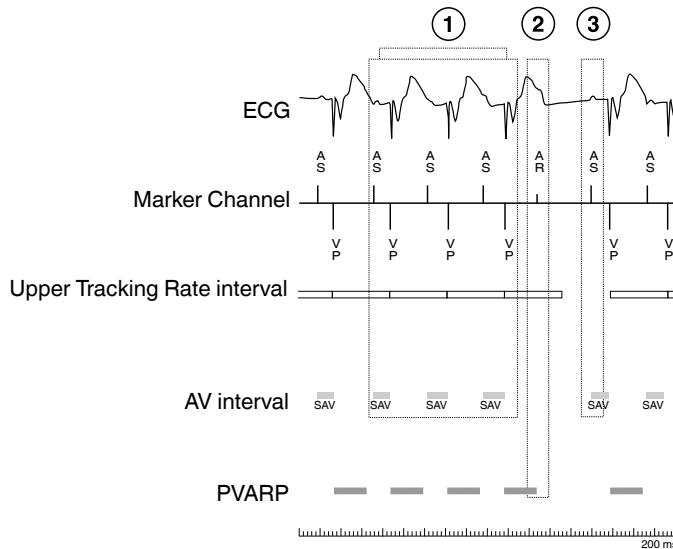
4.2.6.2 Upper Tracking Rate

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

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

This Upper Tracking Rate behavior is known as pacemaker Wenckebach (see Figure 64). 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 64. Example of Wenckebach pacing



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

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

4.3 Managed Ventricular Pacing (MVP)

Unnecessary right ventricular pacing may be associated with an increased risk of atrial fibrillation, left ventricular dysfunction, and congestive heart failure, especially in patients with intact or intermittent AV conduction.^{6,7,8}

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.

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

- AAI(R) mode pacing when AV conduction is intact
- the ability to switch to DDD(R) pacing during AV block
- periodic conduction checks while operating in DDD(R) mode, with the ability to switch back to AAI(R) mode when AV conduction resumes
- backup ventricular support for transient loss of AV conduction

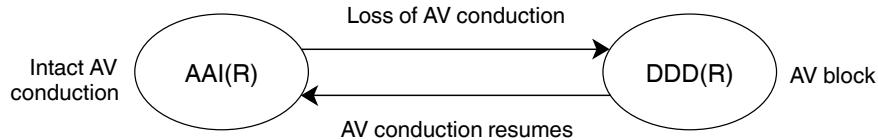
⁶ Sweeney M, Hellkamp A, Ellenbogen K, et al. Adverse effect of ventricular pacing on heart failure and atrial fibrillation among patients with normal baseline QRS duration in a clinical trial of pacemaker therapy for sinus node dysfunction. *Circulation*. 2003;107:2932-2937.

⁷ 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.

⁸ Andersen H, Nielsen J, Thomsen P, et al. Long-term follow-up of patients from a randomised trial of atrial versus ventricular pacing for sick-sinus syndrome. *Lancet*. 1997;350:1210-1216.

4.3.1 Operation of MVP mode

Figure 65. Overview of MVP mode



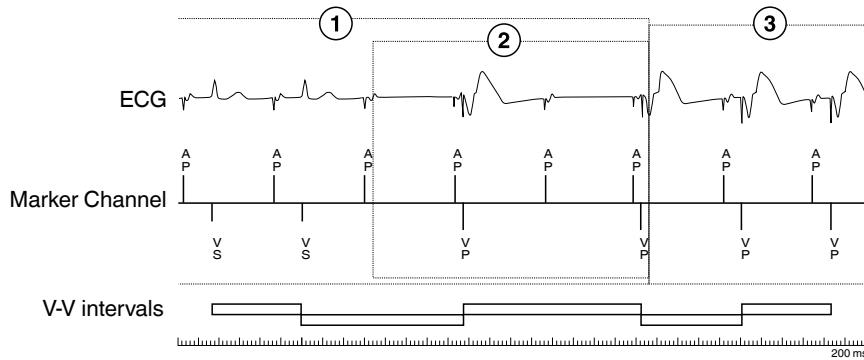
4.3.1.1 Intact AV conduction

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

4.3.1.2 Loss of AV conduction

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

Figure 66. Switching from AAIR mode to DDDR mode



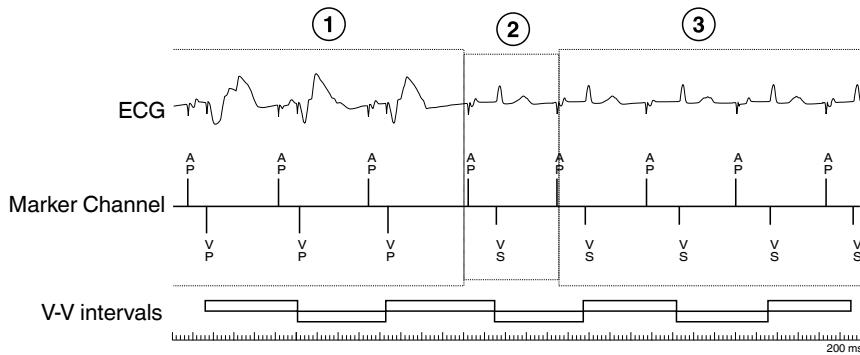
- 1 The device operates in AAIR mode.
- 2 At the onset of AV block, the device supplies ventricular backup pacing pulses.
- 3 The device switches to DDDR mode.

4.3.1.3 AV conduction resumes

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

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

Figure 67. Switching from DDDR mode to AAIR mode after AV conduction resumes

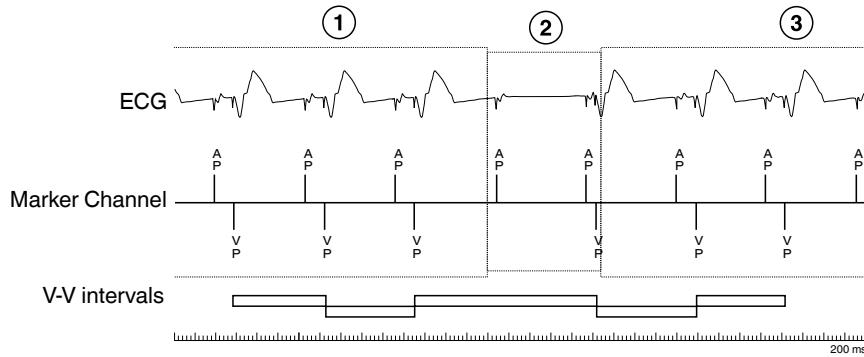


- 1 The device operates in DDDR mode.
- 2 The device performs an AV conduction check. AV conduction is detected.
- 3 The device operates in AAIR mode.

4.3.1.4 Complete AV block

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

Figure 68. Remaining in DDDR mode after an AV conduction check



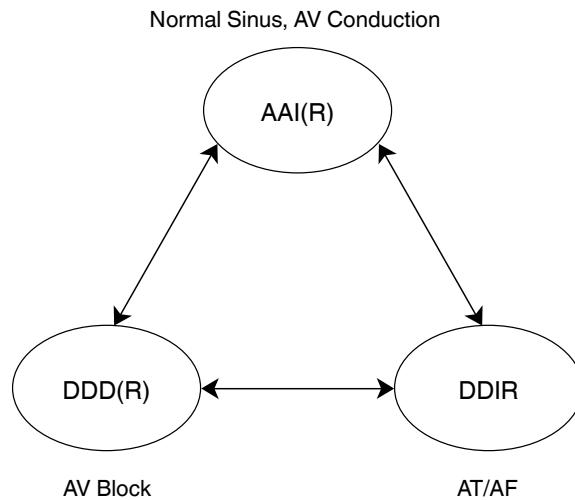
- 1 The device operates in DDDR mode.
- 2 The device checks for AV conduction, but conduction is not detected.
- 3 The device continues to operate in DDDR mode.

4.3.1.5 Transient loss of conduction

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

4.3.1.6 Interactions with MVP mode

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

Figure 69. Operation of MVP mode and Mode Switch

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

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

After cardioversion or defibrillation therapy – After cardioversion or defibrillation therapy, the device operates in the DDDR or DDD mode for 1 min. If an AV conduction check was scheduled to occur during this time, the check is postponed until after 1 min has passed.

4.3.2 Programming MVP mode

To access MVP mode, select Params > 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.

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

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

Complete heart block – For patients with complete heart block, the device drops 1 beat every 16 hours (AV conduction check). See Section 4.3.1.4. If this is undesirable, permanent DDDR or DDD modes may be more appropriate.

Long PR intervals – For patients with long PR intervals, the device remains in the AAIR or AAI mode. Permanent DDDR or DDD modes may be more appropriate for patients with symptomatic first-degree AV block.

Operation immediately after implant – The device is shipped in MVP mode, initially operating in DDD mode. Approximately 30 min after implant, the device checks for AV conduction and switches to AAIR or AAI mode if the next A-A interval includes a sensed ventricular beat. See Section 4.3.1.3 for more information.

4.3.3 Evaluation of MVP mode

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

4.3.3.1 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 70. Pacing mode on the status bar



4.3.3.2 Quick Look II screen

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

The Quick Look II screen shows the percentages of atrial and ventricular pacing since the last 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.”

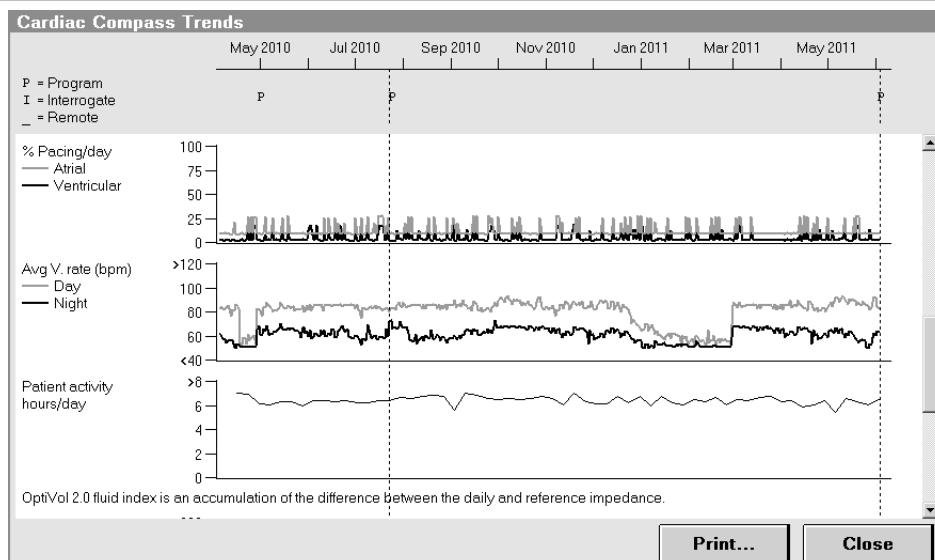
For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

4.3.3.3 Cardiac Compass Trends

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

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

Figure 71. % Pacing/day trend graph



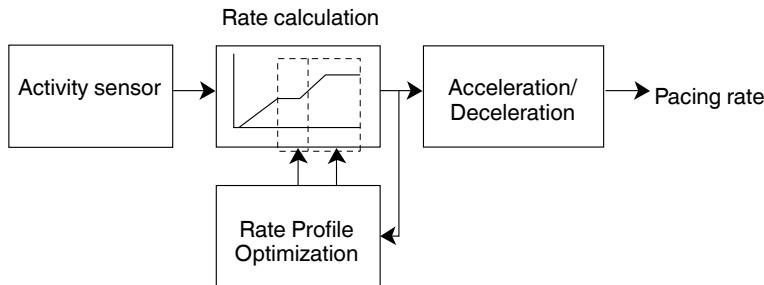
4.4 Rate Response

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

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

4.4.1 Operation of Rate Response

Figure 72. Overview of Rate Response



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

4.4.1.1 Activity sensing

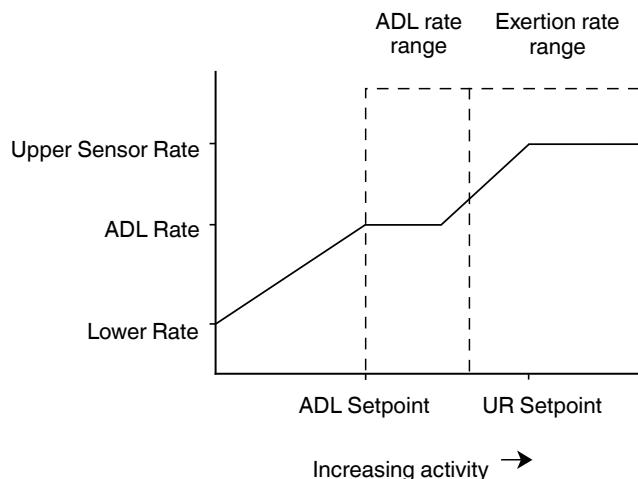
The activity sensor is an accelerometer in the device that detects the patient's body movements. Because activity detection varies from patient to patient, the sensitivity to motion can be adjusted by reprogramming the Activity Threshold parameter. If the Activity Threshold is lowered, smaller body movements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

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

4.4.1.2 Rate calculation

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

Figure 73. 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.

4.4.1.3 Rate Profile Optimization

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

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

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

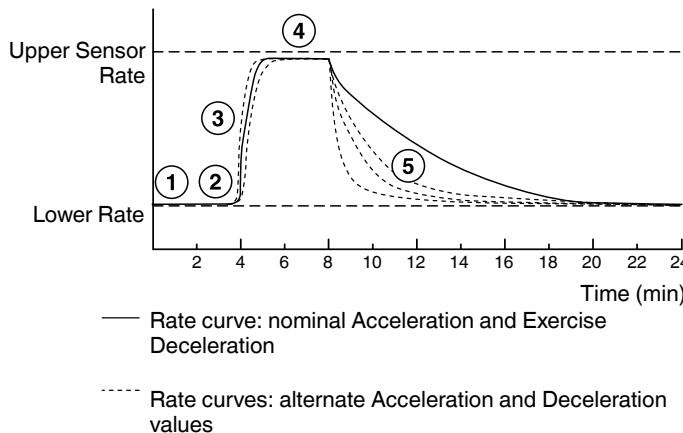
Note: Because the device is automatically changing the setpoint values, if you manually program the setpoint values, Rate Profile Optimization is disabled.

4.4.1.4 Activity Acceleration and Activity Deceleration

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

As shown in Figure 74, changing the values of the Activity Acceleration and Activity Deceleration parameters affects the pacing rate during and after exertion.

Figure 74. Activity Acceleration and Deceleration curves for rate response



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

4.4.1.5 Rate Response during implant

Rate Response does not operate during an implant procedure to avoid increased pacing caused by handling. Rate Response and Rate Profile Optimization begin operating after implant, when VF Detection is programmed to On.

4.4.1.6 Rate Response parameters screen

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

4.4.2 Programming Rate Response

Table 19. How to navigate to Rate Response parameters

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

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

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

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

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

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

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

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

4.4.3 Evaluation of Rate Response

4.4.3.1 Rate Histograms

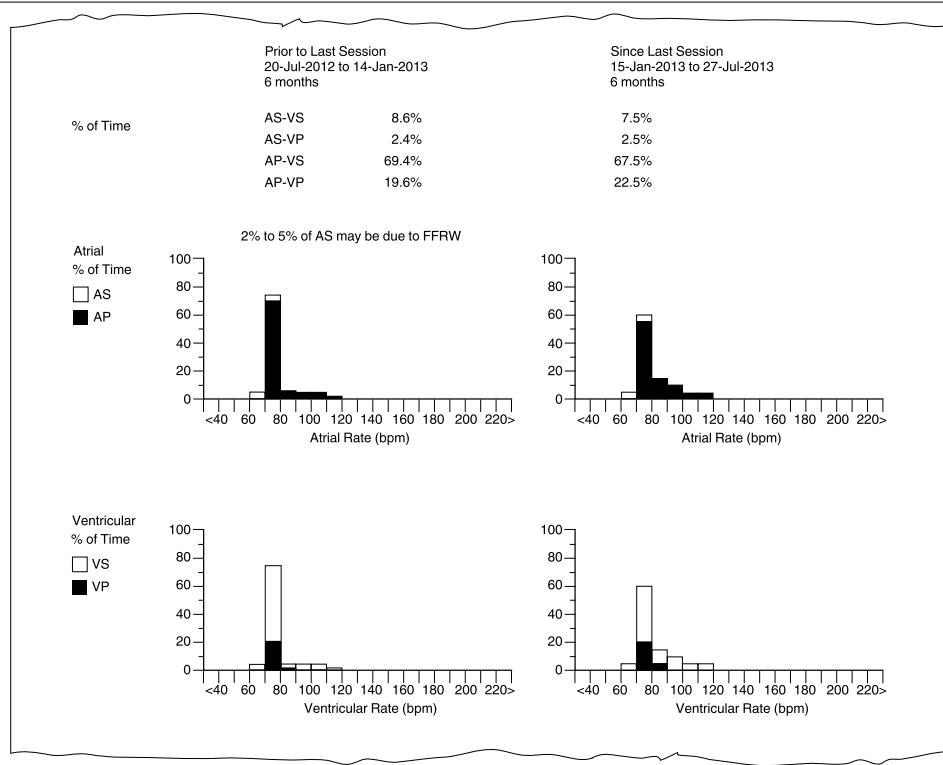
To access Rate Histograms, select Data > Clinical Diagnostics > Rate Histograms > [Open Data].

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

In Figure 75, 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 75. Rate Histograms Report



4.4.3.2 Flashback Memory

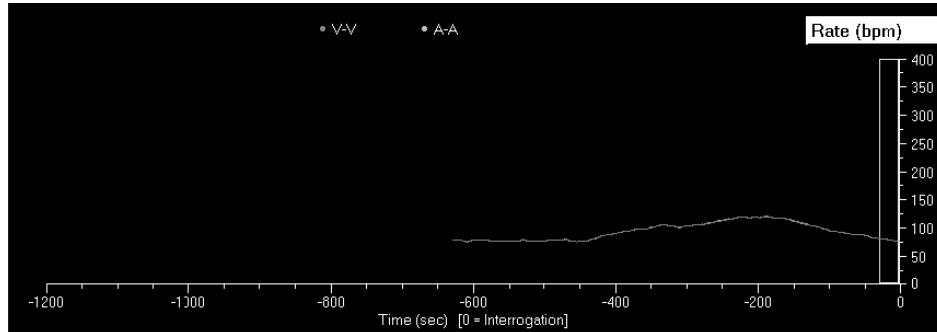
Flashback Memory provides a rate trend based on the initial interrogation.

To access Flashback Memory data, select Data > Clinical Diagnostics > Flashback Memory > [Open Data] > View Intervals Prior to: Interrogation.

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

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 76. Rate trend in Flashback Memory



4.5 Capture Management

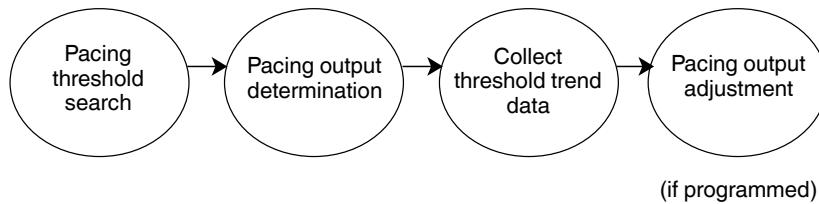
Maintaining adequate safety margins for pacing output energies and optimizing device longevity are critical to patient care. As the patient's condition changes, pacing thresholds may change, requiring pacing outputs to be monitored regularly and modified, if necessary, to capture the myocardium.

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

4.5.1 Operation of Capture Management

Capture Management is a programmable feature that is available for the right atrium (ACM) and right ventricle (RVC). 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 Capture Management is programmed to Adaptive, the device may automatically adjust the pacing outputs. If Capture Management is programmed to Monitor, no adjustments occur.

Figure 77. Overview of Capture Management



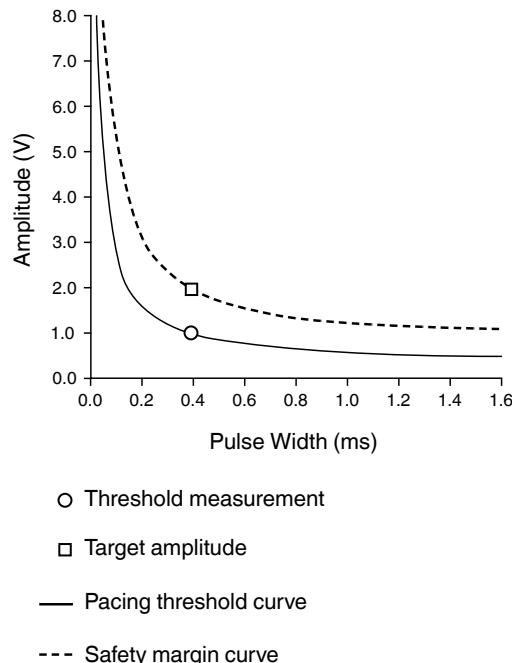
4.5.1.1 Manual adjustment of pacing outputs

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, see Section 4.2, “Basic pacing”, page 150.

4.5.1.2 Pacing thresholds and safety margins

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

Both a threshold curve and a safety margin curve are shown in Figure 78. 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 78. Threshold and safety margin curves

4.5.2 Operation of Atrial Capture Management

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

4.5.2.1 Preparing for an atrial pacing threshold search

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

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

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

4.5.2.2 Searching for and determining the atrial pacing threshold

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

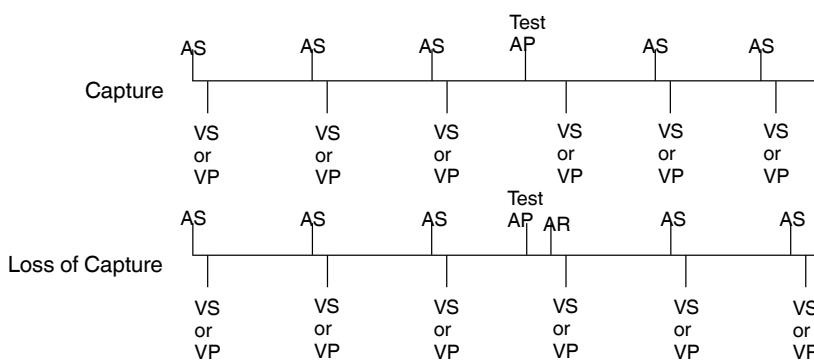
If the right atrium responds to a test pace, the result is "Capture". If no response is detected, the result is "Loss of capture". The result of a test pace is ignored if the device cannot determine whether the test pace captures the myocardium. In this case, testing may continue with additional test paces at the same test amplitude. If there are too many inconclusive results, the device stops the pacing threshold search and retries it at the next scheduled period. See Section 4.5.2.4.

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

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

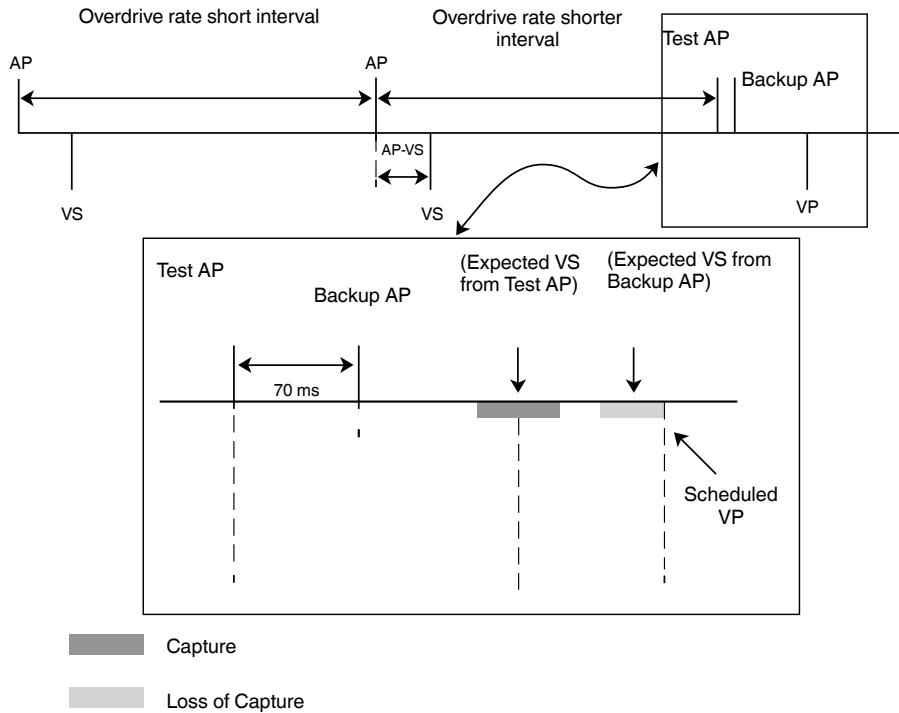
Atrial Chamber Reset (ACR) method – In the ACR method, each test pace is preceded by 3 support cycles and followed by 2 extra support cycles. The 3 support cycles monitor AS-AS intervals to ensure that the patient's rhythm is stable before the test pace is delivered. The 2 extra support cycles provide time after the test pace for the atrial rhythm to stabilize. ACR evaluates capture based on the response of the intrinsic rhythm to the atrial test pace. “Loss of capture” is characterized by an atrial event that follows the test pace but occurs within the atrial refractory period. As shown in Figure 79, this event is indicated by an AR marker.

Figure 79. 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 80. 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 80. AV Conduction test method

4.5.2.3 Adjusting atrial pacing outputs

If ACM is programmed to the Adaptive setting, the device automatically adjusts the Atrial Amplitude based on the pacing threshold search results. After a successful pacing threshold search, the device calculates a target amplitude by multiplying the programmed Atrial Amplitude Safety Margin by the amplitude threshold measured at a pulse width of 0.4 ms. The device calculation for the target amplitude is rounded up to the next programmable amplitude setting. For information about target amplitudes and safety margins, see Section 4.5.1.2.

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

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

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

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

4.5.2.4 Stopping an atrial pacing threshold search in progress

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

When a pacing threshold search cannot be completed, the device automatically schedules another search within 30 min. If 5 more search attempts are stopped during a day, the pacing threshold test is suspended until the following day. Whenever this happens, a device check occurs again, and the process is repeated. The reasons for stopping a pacing threshold search are noted in the Capture Threshold trends diagnostic. See Section 4.5.5.

4.5.3 Operation of Right Ventricular Capture Management

Right Ventricular Capture Management (RVC) is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI, VVIR, VVI, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD), and it functions when the device is operating in one of these modes. If RVC is programmed to the Monitor or Adaptive setting, the device conducts a pacing threshold search to determine the RV pacing threshold. If RVC 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, RVC may not prevent loss of capture.

Note: If the battery reaches the Recommended Replacement Time (RRT), the device aborts RVCM. No additional RV pacing threshold searches will be conducted.

4.5.3.1 Preparing for an RV pacing threshold search

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

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

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

4.5.3.2 Searching for and determining the RV pacing threshold

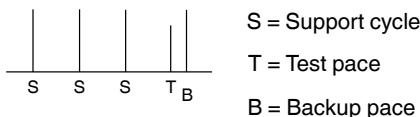
The device conducts a pacing threshold search to determine the RV pacing amplitude threshold at a fixed pulse width of 0.4 ms. RVCM varies the amplitude of test paces to find the lowest amplitude that consistently captures the right ventricular myocardium. The device evaluates capture by detecting the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

If the right ventricle responds to a test pace, the result is "Capture". If no response is detected, the result is "Loss of capture". The result of a test pace is ignored if the device cannot determine whether the test pace captures the myocardium. In this case, testing may continue with additional test paces at the same test amplitude. If there are too many inconclusive results, the device stops the pacing threshold search and retries it at the next scheduled period. See Section 4.5.3.4.

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 RV pacing threshold.

In each threshold measurement, the test pace is part of a test sequence (see Figure 81). 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 90 ms after the test pace at the programmed amplitude and a 1.0 ms pulse width.

Figure 81. 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.

4.5.3.3 Adjusting the RV pacing outputs

If RVCm is programmed to the Adaptive setting, the device automatically adjusts the RV Amplitude based on the pacing threshold search results. After a successful pacing threshold search, the device calculates a target amplitude by multiplying the programmed RV Amplitude Safety Margin by the amplitude threshold measured at a pulse width of 0.4 ms. The device calculation for the target amplitude is rounded up to the next programmable amplitude setting. See Section 4.5.1.2.

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

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

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

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

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

4.5.3.4 Stopping an RV pacing threshold search in progress

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

When a pacing threshold search cannot be completed, the device automatically schedules another search within 30 min. If 5 more search attempts are stopped during a day, the pacing threshold test is suspended until the following day. Whenever this happens, a device check occurs again, and the process is repeated. The reasons for stopping a pacing threshold search are noted in the Capture Threshold trends diagnostic. See Section 4.5.5.

4.5.4 Programming Capture Management

For information about programming amplitude and pulse width parameters manually, see Section 4.2, "Basic pacing", page 150.

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

Table 20. How to navigate to Capture Management parameters

Parameters	Path
Atrial Capture Management (Adaptive, Monitor, Off) Atrial Amplitude Safety Margin Atrial Minimum Adapted Amplitude	Params > Pacing... > Atrial Amplitude...
RV Capture Management (Adaptive, Monitor, Off) RV Amplitude Safety Margin RV Minimum Adapted Amplitude	Params > Pacing... > RV Amplitude...
Atrial Acute Phase Remaining RV Acute Phase Remaining	Params > Pacing... > Atrial Amplitude... > Additional Parameters...

Warning: Capture Management 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 RVCN 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 RVCN:

- With poor lead fixation, modulations in pacing timing and rate could influence thresholds.
- In rare instances, combinations of morphology and rhythm may result in a low threshold measurement. This may occur if the pacing threshold search is unable to differentiate between myocardial contractions caused by the pacing pulse and those caused by physiologic means.

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

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

4.5.5 Evaluation of Capture Management

4.5.5.1 Quick Look II

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

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

Quick Look II Observations – If there are significant observations about ACM or RVCN, they are shown in the Quick Look II Observations window.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

4.5.5.2 Capture Threshold trends

To access Capture Threshold Trends, select the Threshold [>>] button on the Quick Look II screen, or select Data > Device/Lead Diagnostics > Capture Threshold Trends > [Open Data].

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). When either the Pulse Width parameter or the Pace Polarity parameter has been reprogrammed, a line appears on the graph to show when the reprogramming occurred.

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.

4.6 Rate Adaptive AV

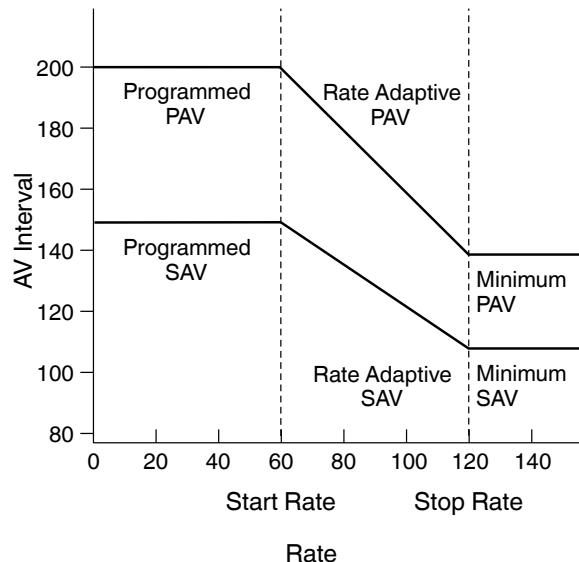
A fixed AV interval makes it difficult to select the optimal AV interval value that meets all of the patient's needs. A short AV interval is desirable at higher rates to avoid symptomatic 2:1 block during exercise and to avoid asynchronous pacing. A long AV interval is desirable at lower rates to promote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

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

4.6.1 Operation of Rate Adaptive AV

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

The way in which Rate Adaptive AV adjusts the operating AV intervals in a linear manner as the heart rate changes in bpm is shown in Figure 82.

Figure 82. Operation of Rate Adaptive AV in DDDR mode

The Start Rate determines the heart rate at which the AV intervals begin to shorten. The Stop Rate determines the heart rate at which the Minimum PAV intervals and Minimum SAV intervals are applied.

Note: The device may occasionally display behavior that mimics Rate Adaptive AV but is not Rate Adaptive AV. If the device suspects that a tachyarrhythmia is in progress, it shortens the PAV interval to allow observation of the rhythm. This occurs even when Rate Adaptive AV is off.

4.6.2 Programming Rate Adaptive AV

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 2.11, "Using TherapyGuide to select parameter values", page 44.

To access Rate Adaptive AV parameters, select Params > Pacing...> Paced 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.

4.7 Auto PVARP

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

For more information, see Section 4.1, “Sensing”, page 140 and Section 4.2, “Basic pacing”, page 150.

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

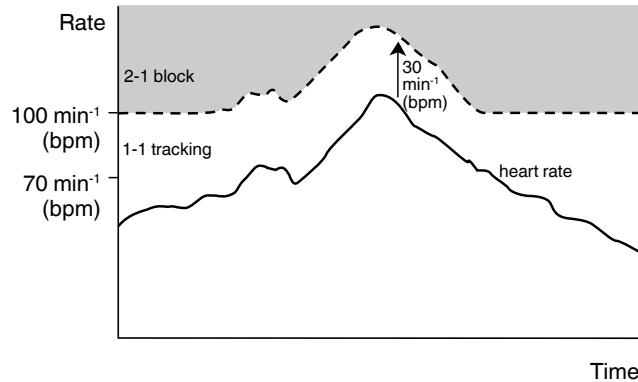
4.7.1 Operation of Auto PVARP

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

In a tracking mode (DDDR or DDD), 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.

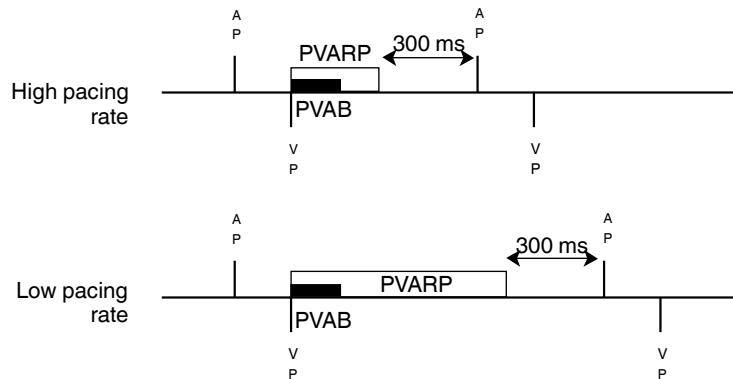
The programmable Minimum PVARP parameter value sets a limit on the shortest PVARP that is allowed. If the programmed Minimum PVARP value is reached and the Rate Adaptive AV (RAAV) parameter is programmed to On, the Sensed AV (SAV) interval is shortened to help maintain 1:1 tracking.

For more information, see Section 4.6, “Rate Adaptive AV”, page 184.

Figure 83. Operation of Auto PVARP in the DDDR or DDD mode

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

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

Figure 84. Operation of Auto PVARP in the DDIR or DDI mode

4.7.2 Programming Auto PVARP

To access PVARP, select Params > Pacing... > PVARP.

Minimum PVARP value selection – When programming a higher value for the Upper Tracking Rate, you may have to program a lower Minimum PVARP value to achieve 1:1 tracking up to the higher rate. An alternative is to use the Rate Adaptive AV feature, or a combination of Rate Adaptive AV and a lower Minimum PVARP value. For more information, see Section 4.6, “Rate Adaptive AV”, page 184.

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.

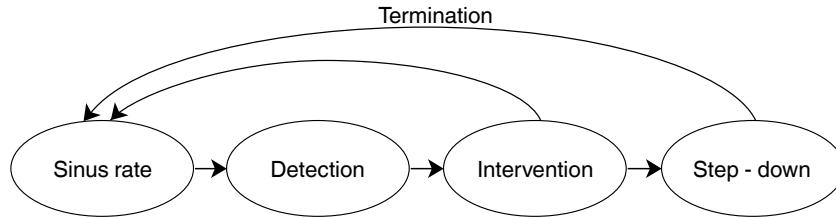
4.8 Rate Drop Response

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

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

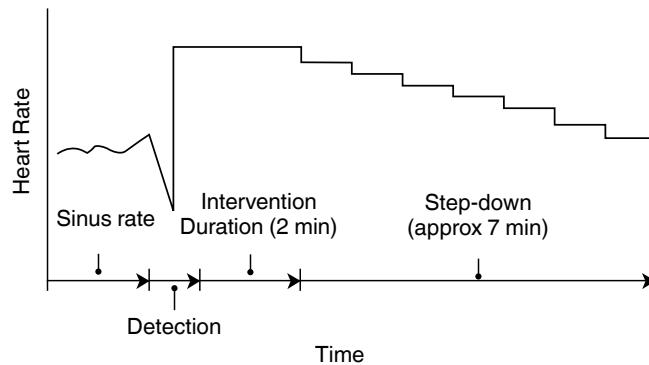
4.8.1 Operation of Rate Drop Response

Figure 85. 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 86. Rate Drop Response Rate and Time



As shown in Figure 86, Rate Drop Response typically operates over several minutes, and most of this time involves the step-down phase.

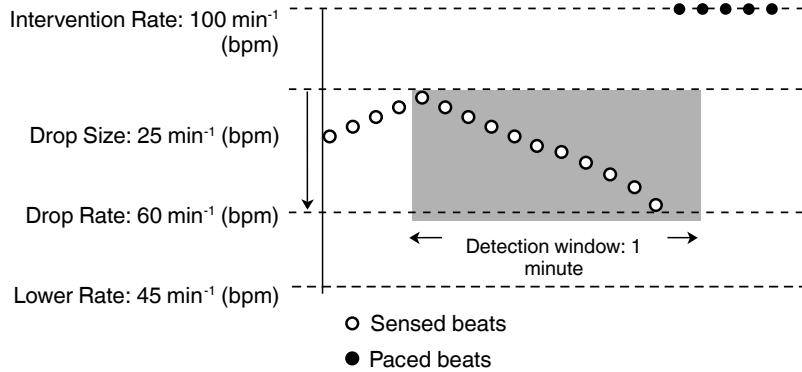
Rate Drop Response is available when the pacing mode is programmed to DDD, DDI, or AAI<=>DDD (MVP mode). Rate Drop Response functions when the device is operating in the DDD or DDI mode. For the MVP mode, the device operates in DDD mode during Rate Drop Response interventions. Rate Drop Response does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

4.8.1.1 Detection

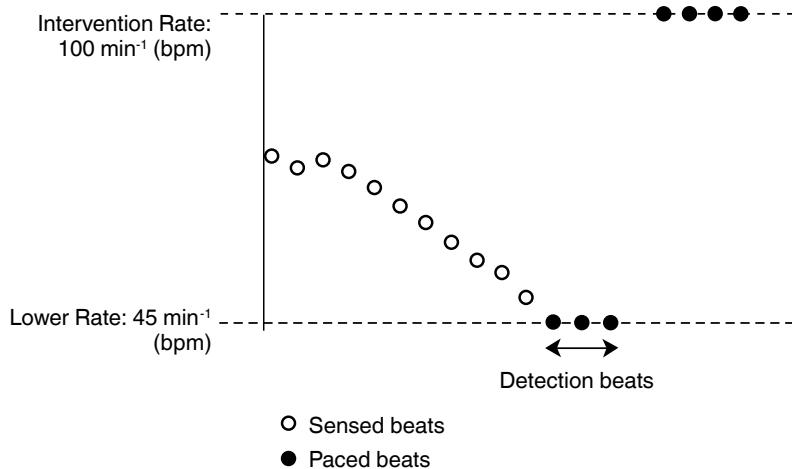
Rate Drop Response provides 2 methods for detecting significant rate drops:

- Drop Detection
- Low Rate Detection

Figure 87. Drop Detection



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

Figure 88. Low Rate Detection

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

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

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

4.8.1.2 Intervention and step-down

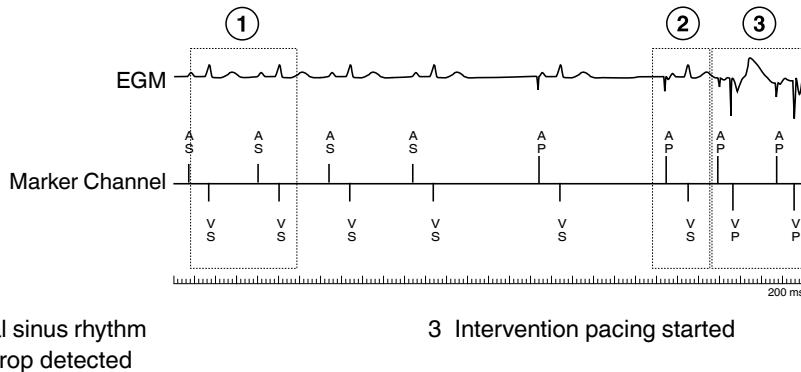
When a rate drop is detected, the device paces the heart at the programmed Intervention Rate for the programmed Intervention Duration. After the Intervention Duration is complete, the device reduces the pacing rate by 5 bpm steps per minute. This step-down process continues until the sinus rate or the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

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

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

See Figure 89 for an example of the device detecting a rate drop and starting to pace the heart at the programmed Intervention Rate.

Figure 89. Example of detection and intervention



4.8.2 Programming Rate Drop Response

Table 21. How to navigate to Rate Drop Response parameters

Parameters	Path
Rate Drop Response (On, Off)	Params > Pacing... > Additional Features... >
Mode	Rate Drop Response...
Lower Rate	
Detection Type	
Drop Size	
Drop Rate	
Detection Window	
Detection Beats	
Intervention Rate	
Intervention Duration	

Symptoms during sleep – During sleep, a patient's sinus rate may fall below the programmed Lower Rate, thereby triggering intervention pacing at an inappropriate time. There are two ways to address this problem. First, you can turn off Low Rate Detection. Second, you can turn on the Sleep feature. The Sleep feature replaces the programmed Lower Rate with a slower pacing rate during the time of day the patient normally sleeps. For more information, see Section 4.10, "Sleep feature", page 196.

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.

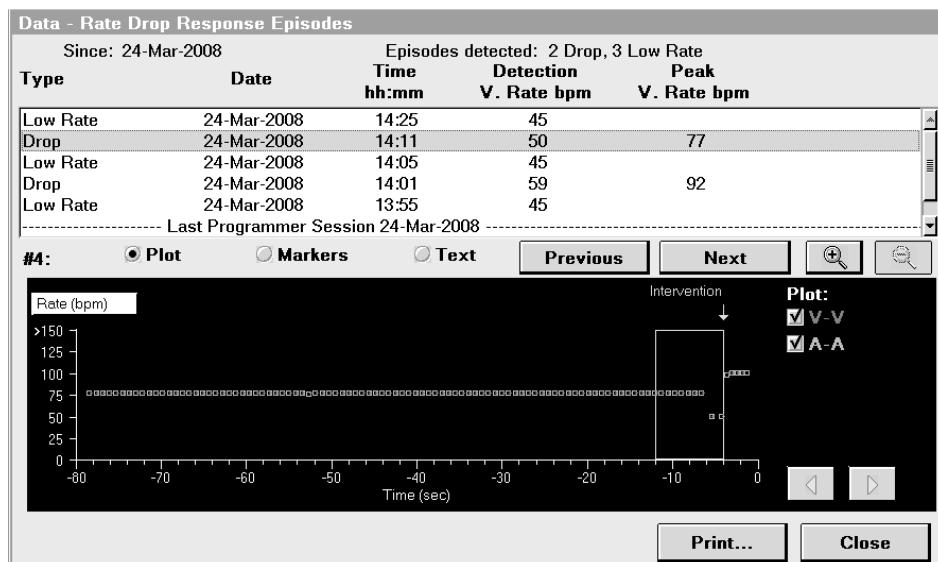
4.8.3 Evaluation of Rate Drop Response

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

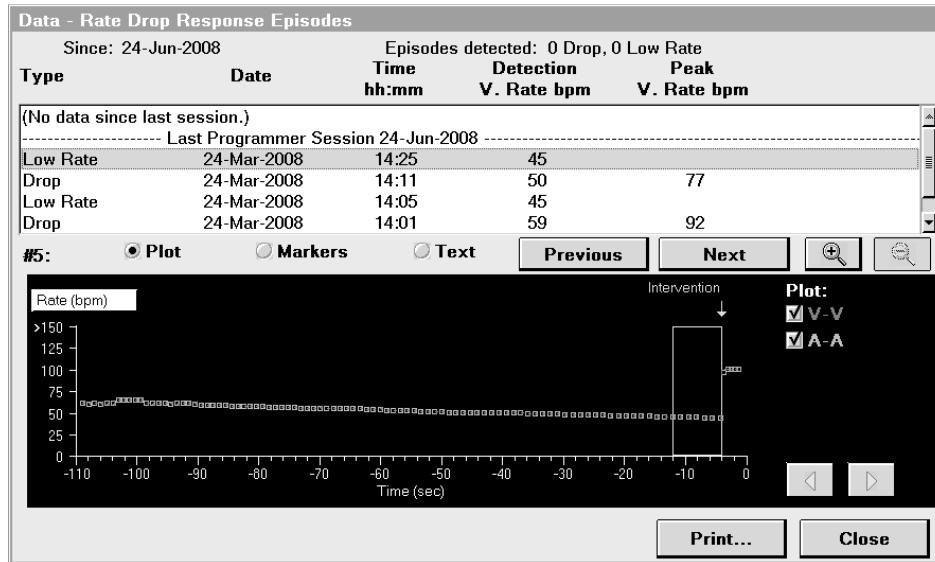
To access Rate Drop Response episode data, select Data > Clinical Diagnostics > Rate Drop Response Episodes.

An example of a sudden rate drop episode is shown in Figure 90.

Figure 90. Drop Episode



An example of a more gradual rate drop episode is shown in Figure 91.

Figure 91. Low Rate Episode

4.9 Rate Hysteresis

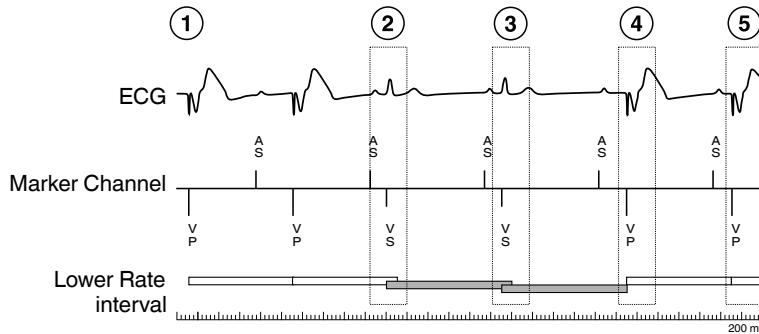
The patient's intrinsic heart rate is preferable to pacing during extended periods of patient inactivity, such as when the patient is sleeping.

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

4.9.1 Operation of Rate Hysteresis

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

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

Figure 92. 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 reapplys the Lower Rate interval.
- 5 The ventricle is paced at the Lower Rate.

4.9.2 Programming Rate Hysteresis

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

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

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

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

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

4.9.3 Evaluation of Rate Hysteresis

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

4.9.3.1 Viewing the Ventricular Rate Histogram

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

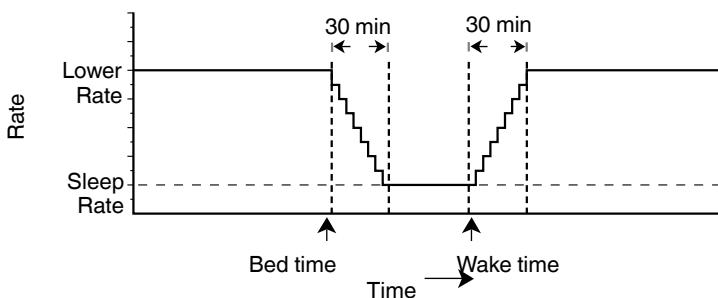
4.10 Sleep feature

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

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

4.10.1 Operation of the Sleep feature

Figure 93. Overview of the Sleep feature



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

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

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

If the patient experiences an AT/AF episode and the Mode Switch feature is operating during the Sleep period, the device does not pace below the Lower Rate until the AT/AF episode has ended. For more information, see Section 4.15, “Mode Switch”, page 204.

4.10.2 Programming the Sleep feature

To access Sleep feature parameters (Sleep Rate, Bed Time, and Wake Time), select Params > Pacing... > Additional Features... > Sleep....

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.

To set the device clock, select Params > Data Collection Setup... > Device Date/Time....

4.10.3 Evaluation of the Sleep feature

The Ventricular Rate Histogram shows heart rates below the Lower Rate but above the Sleep Rate for the percentage of time that correlates to the Sleep period. For more information, see Section 3.12, “Rate Histograms”, page 134.

Cardiac Compass Trends shows the average ventricular rate during the day and night, which should indicate that the device is allowing a slower heart rate at night. For more information, see Section 3.6, “Cardiac Compass Trends”, page 102.

4.11 Non-Competitive Atrial Pacing

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

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

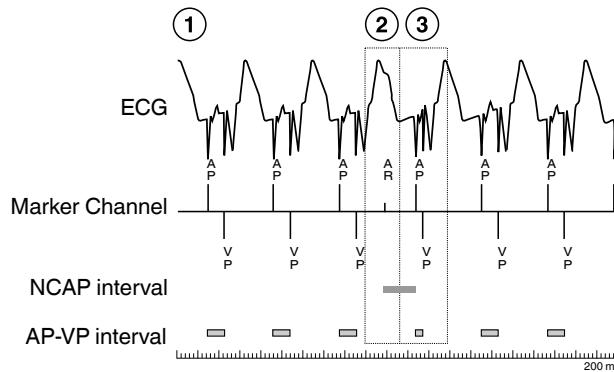
4.11.1 Operation of NCAP

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

Whenever an atrial refractory sense occurs, the device starts a programmable NCAP interval. If an atrial pace is scheduled to occur during the NCAP interval, the atrial pace is delayed until the NCAP interval expires. When an atrial pace is delayed by the NCAP feature, the AP-VP interval decreases (but not 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 94. Operation of NCAP



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

4.11.2 Programming NCAP

To access NCAP parameters, select Params > Pacing... > Additional Features....

4.11.3 Evaluation of NCAP

When evaluating an ECG strip, you will notice that the AP-VP interval has been shortened and the NCAP interval can be seen as the time between the AR and AP events (see Figure 94).

4.12 PMT Intervention

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

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

4.12.1 Operation of PMT Intervention

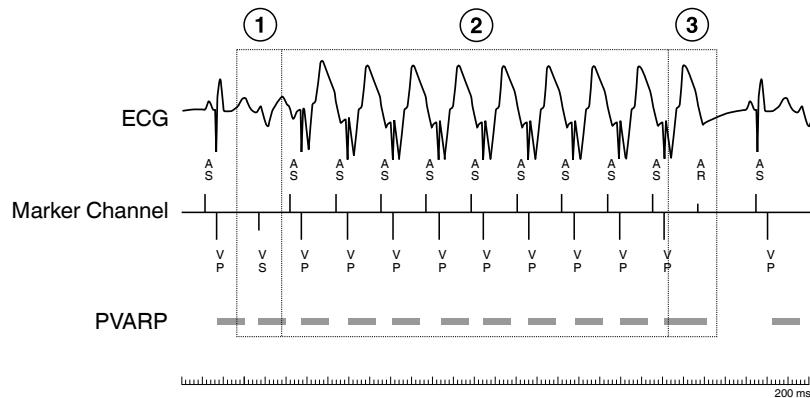
PMT Intervention is available when the pacing mode is programmed to DDDR, DDD, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). PMT Intervention functions when the device is operating in the DDDR or DDD mode.

The device 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 95. 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.

4.12.2 Programming PMT Intervention

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

4.13 PVC Response

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

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

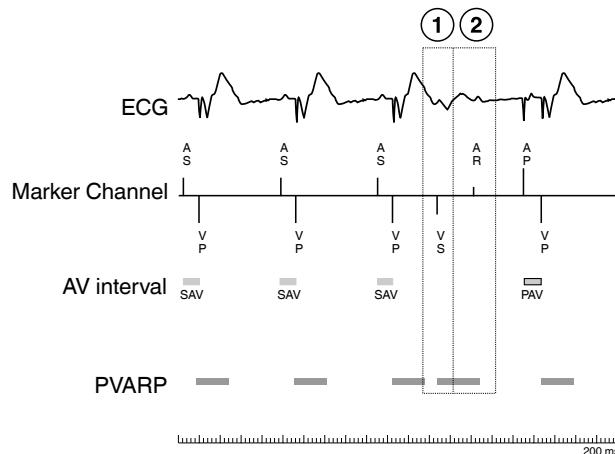
4.13.1 Operation of PVC Response

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

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

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

Figure 96. PVC Response starts an extended PVARP



- 1 A PVC occurs.
- 2 The device extends the PVARP to 400 ms, and the subsequent atrial event is classified as refractory.

4.13.2 Programming PVC Response

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

4.14 Ventricular Safety Pacing

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

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

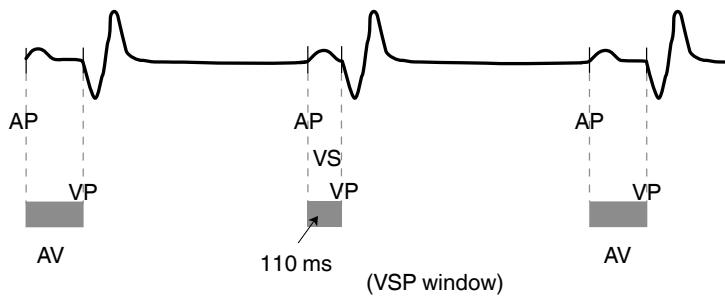
4.14.1 Operation of VSP

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

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

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

Figure 97. VSP pulse delivered at the end of the VSP window (110 ms)



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

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

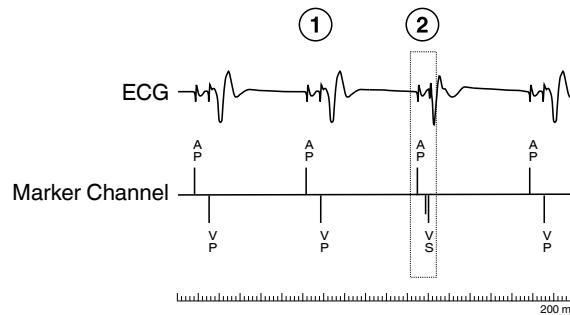
4.14.2 Programming VSP

To access VSP, select Params > Pacing... > Additional Features....

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

4.14.3 Evaluation of VSP

Figure 98. 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 usually does not appear on a printed real-time ECG strip due to the limited space after the “VS” annotation. Both the “VP” and the “VS” annotations appear in the Live Rhythm Monitor, on frozen strips, and on printed frozen strips.

4.15 Mode Switch

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

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

4.15.1 Operation of Mode Switch

Figure 99. Overview of Mode Switch operation

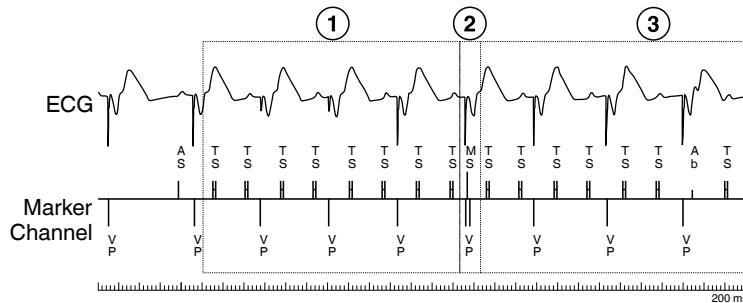


Mode Switch is available when the pacing mode is programmed to DDDR, DDD, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). Mode Switch functions when the device is operating in the DDDR or DDD mode.

Mode Switch operation starts when the device detects the onset of an atrial tachyarrhythmia episode. The detection of AT/AF onset is based on the programmed AT/AF Interval and the accumulation of additional evidence of atrial tachyarrhythmia based on the number and timing of atrial events within the ventricular intervals. For more information, see Section 5.1, "AT/AF detection", page 224.

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

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

Figure 100. Example of a Mode Switch episode

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

4.15.1.1 Interactions with other device operations

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

Mode Switch and MVP modes – Mode Switch and MVP modes (AAIR<=>DDDR or AAI<=>DDD) interact to adjust the pacing mode according to the patient's atrial rhythm and AV conduction status. For more information, see Section 4.3, “Managed Ventricular Pacing (MVP)”, page 160.

4.15.2 Programming Mode Switch

To access Mode Switch, select Params.

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

Post Mode Switch Overdrive Pacing – You can program Post Mode Switch Overdrive Pacing (PMOP) to extend pacing in the DDIR mode when the atrial tachyarrhythmia ends. For more information, see Section 4.19, “Post-Mode Switch Overdrive Pacing”, page 216.

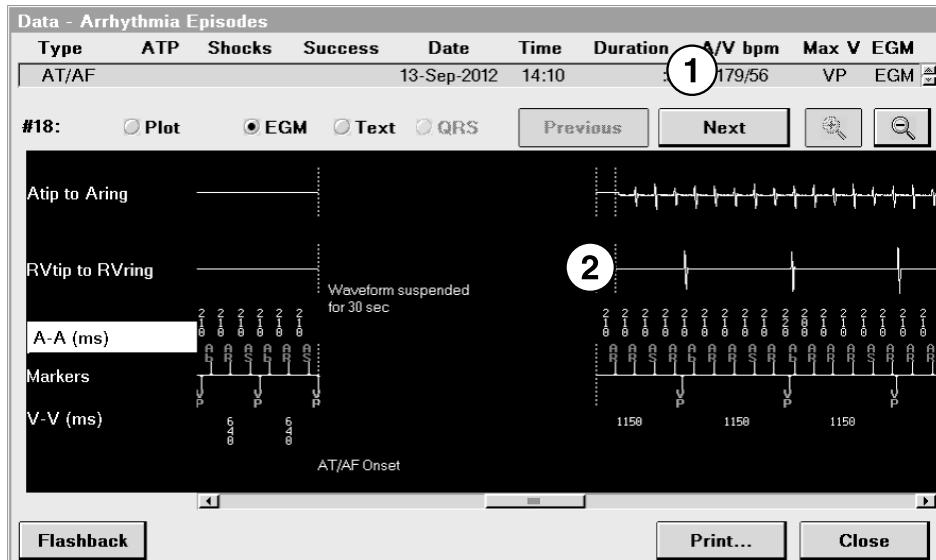
4.15.3 Evaluation of Mode Switch performance

4.15.3.1 EGM strip

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

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

Figure 101. 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.

4.15.3.2 Mode Switch transitions

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

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

4.16 Conducted AF Response

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

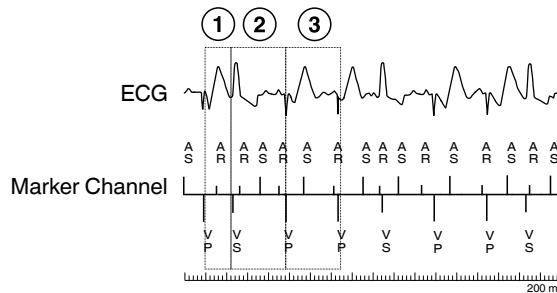
The Conducted AF Response feature helps promote a regular ventricular rate during conducted AT/AF episodes.

4.16.1 Operation of Conducted AF Response

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

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

Figure 102. Operation of Conducted AF Response



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

Note: Conducted AF Response operation is suspended during tachyarrhythmia therapies, system tests, EP study inductions, manual therapies, and emergency fixed burst, cardioversion, and defibrillation therapies. Conducted AF Response operation is not suspended during an impedance test or a Charge/Dump Test.

4.16.2 Programming Conducted AF Response

Table 22. How to navigate to Conducted AF Response parameters

Parameters	Path
Conducted AF Response (On, Off)	Params > Pacing... > Arrhythmia/Post Shock...
Response Level	Params > Pacing... > Arrhythmia/Post Shock... > Additional V Settings...
Maximum Rate	

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

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

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

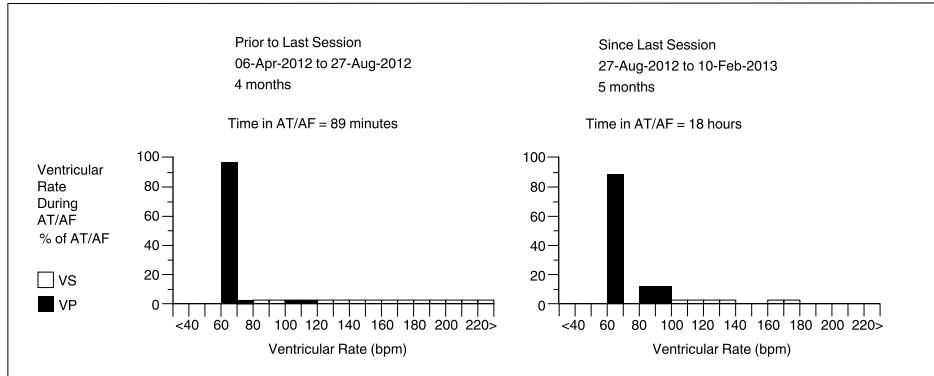
Conducted AF Response and VRS – In DDIR and VVIR modes, Conducted AF Response and VRS cannot be programmed to On at the same time.

4.16.3 Evaluation of Conducted AF Response

4.16.3.1 Rate Histograms

Select Data icon > Clinical Diagnostics > Rate Histograms.

Figure 103. Rate Histograms



This report shows the distribution of ventricular rates during AT/AF episodes. For more information, see Section 3.12, "Rate Histograms", page 134.

4.17 Atrial Rate Stabilization

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

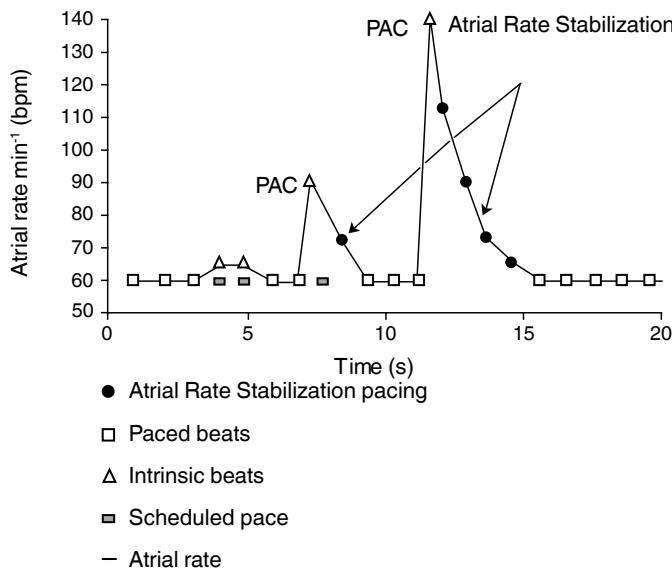
The system provides overdrive pacing techniques that are designed to counteract potential atrial tachyarrhythmia initiating mechanisms.

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

4.17.1 Operation of ARS

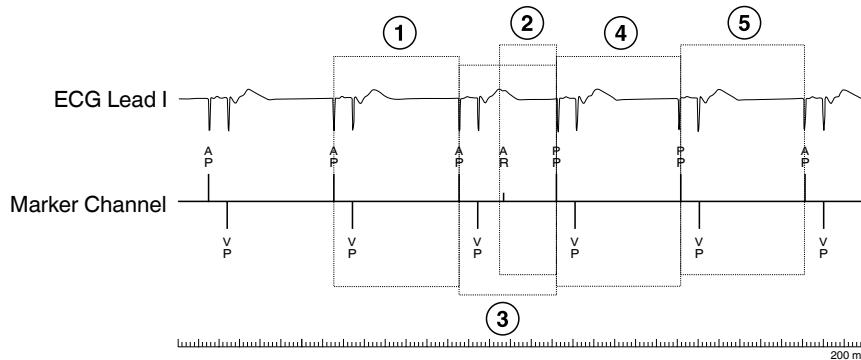
Atrial Rate Stabilization (ARS) is available when the pacing mode is programmed to DDDR, DDD, AAIR, AAI, or MVP (AAIR<=>DDDR or AAI<=>DDD) mode, and it functions when the device is operating in one of these modes.

Figure 104. 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 and then smoothly slowing the rate back to the intrinsic rate or the programmed pacing rate (whichever is faster). When activated by a PAC, the device delivers a pacing pulse at the premature interval increased by a percentage of that interval (defined by a programmed Interval Percentage Increment parameter). For each subsequent atrial paced or atrial sensed event, the device continues to increase each pacing interval by the programmed percentage of the previous interval. In this way, ARS prevents the “short-long-short” sequences of atrial intervals that may precede the onset of some atrial tachyarrhythmias. The Maximum Rate parameter sets an upper rate limit for ARS.

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

Figure 105. Example of ARS operation

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

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

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

4.17.2 Programming ARS

Table 23. How to navigate to ARS parameters

Parameters	Path
A. Rate Stabilization (On, Off)	Params > Pacing... > Arrhythmia/Post Shock...
Maximum Rate Interval Percentage Increment	Params > Pacing... > Arrhythmia/Post Shock... > Additional A Settings...

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

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

4.17.3 Evaluation of ARS

The device collects and stores AT/AF episode summary data that includes the total percentage of time that the device provided atrial intervention pacing. To access AT/AF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Episodes. You can view the AT/AF summary data on the programmer screen and print the data in report form. For more information, see Section 3.9, “Episode and therapy counters”, page 125.

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

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

4.18 Atrial Preference Pacing

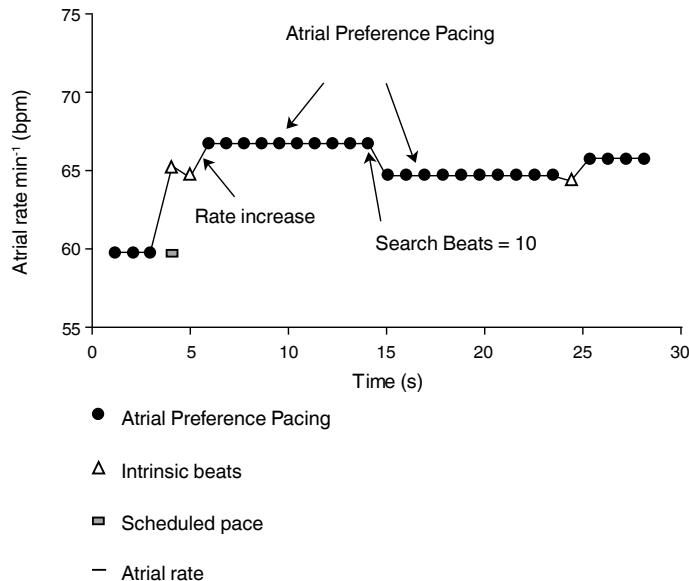
The management of patients with atrial tachyarrhythmias is made more challenging by the different types of mechanisms known to initiate atrial tachyarrhythmias. It is also made more challenging by the high incidence of tachyarrhythmia recurrences following both therapeutic and spontaneous terminations.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

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

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

4.18.1 Operation of APP

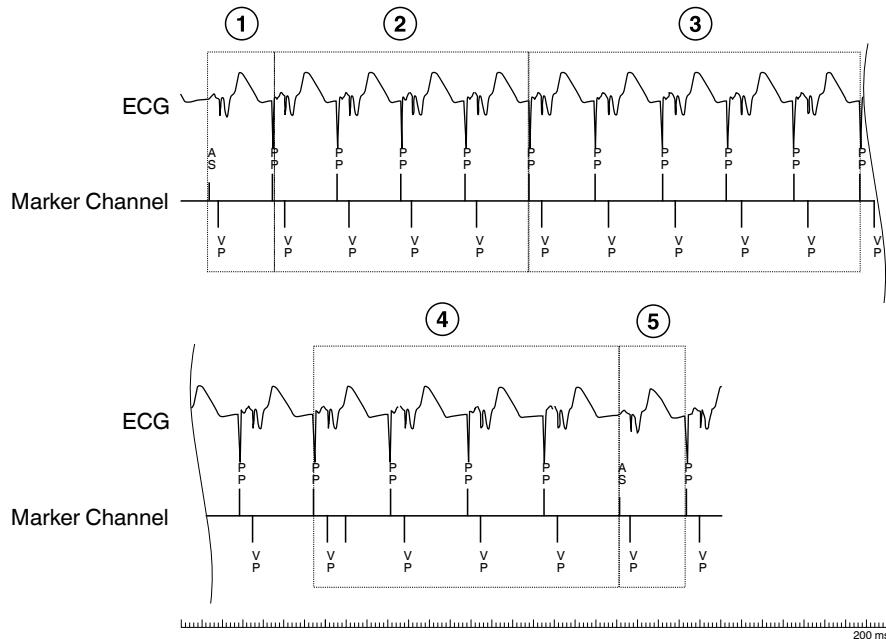
Atrial Preference Pacing (APP) is available when the pacing mode is programmed to DDDR, DDD, AAIR, AAI, or MVP (AAIR<=>DDDR or AAI<=>DDD) mode, and it functions when the device is operating in one of these modes.

Figure 106. Atrial Preference Pacing (APP)

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

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

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

Figure 107. Example of APP operation

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

Notes:

- APP is suspended during mode switching (including PMOP operation) and during detected tachyarrhythmia episodes.
- Generally, when multiple device features attempt to control the pacing rate, the feature with the fastest rate takes precedence.

4.18.2 Programming APP

Table 24. How to navigate to APP parameters

Parameters	Path
A. Preference Pacing (On, Off)	Params > Pacing... > Arrhythmia/Post Shock...
Maximum Rate	Params > Pacing... > Arrhythmia/Post Shock...
Interval Decrement	Params > Pacing... > Arrhythmia/Post Shock... > Additional A Settings...
Search Beats	

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

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

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

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

4.18.3 Evaluation of APP

The device collects and stores AT/AF episode summary data that includes the total percentage of time that the device provided atrial intervention pacing. To access AT/AF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Episodes. You can view the AT/AF summary data on the programmer screen and print the data in report form. For more information, see Section 3.9, “Episode and therapy counters”, page 125.

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

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

4.19 Post-Mode Switch Overdrive Pacing

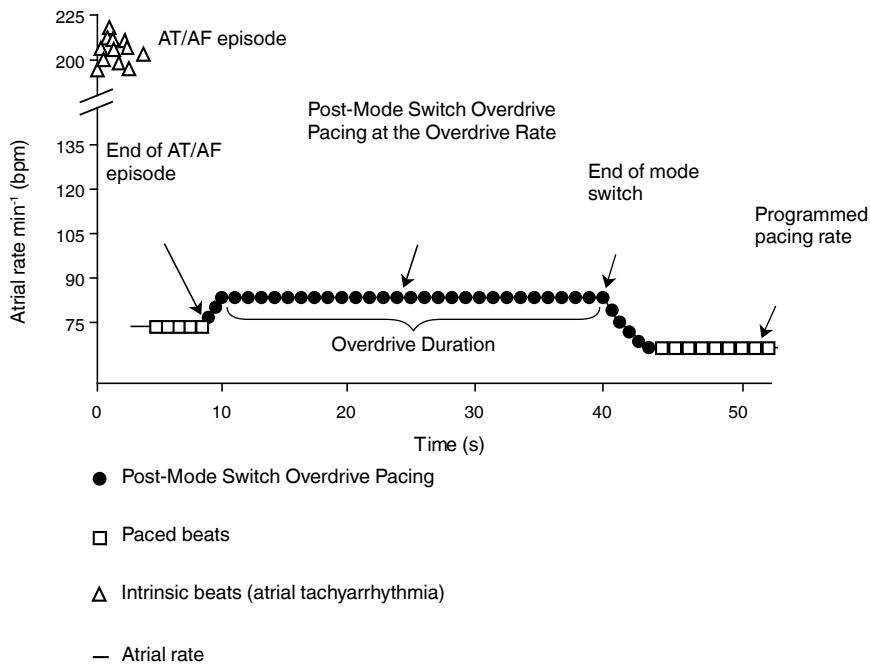
The management of patients with atrial tachyarrhythmias is made more challenging by the different types of mechanisms known to initiate atrial tachyarrhythmias. It is also made more challenging by the high incidence of tachyarrhythmia recurrences following both therapeutic and spontaneous terminations.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

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

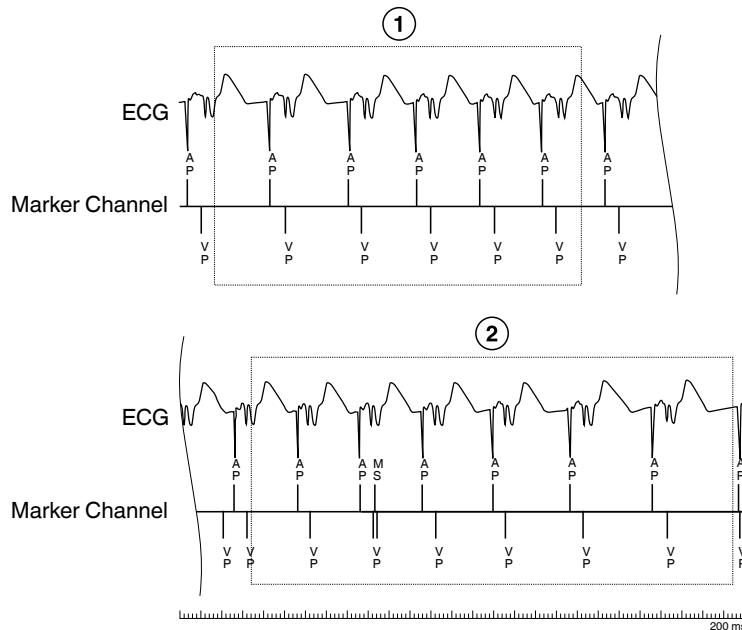
Post Mode Switch Overdrive Pacing (PMOP) works with the Mode Switch feature to deliver overdrive atrial pacing during the vulnerable phase following an AT/AF episode termination.

4.19.1 Operation of PMOP

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

Figure 108. 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 109. Example of PMOP operation

- 1 Following a mode switch, the device gradually increases the pacing rate to the programmed Overdrive Rate.
- 2 After pacing for the programmed Overdrive Duration, the device indicates the end of the mode switch and gradually slows the pacing rate to the programmed rate.

For more information, see Section 4.15, “Mode Switch”, page 204.

4.19.2 Programming PMOP

Table 25. How to navigate to PMOP parameters

Parameters	Path
Post Mode Switch (On, Off)	Params > Pacing... > Arrhythmia/Post Shock...
Overdrive Rate	
Overdrive Duration	

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

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

4.19.3 Evaluation of PMOP

The device collects and stores AT/AF episode summary data that includes the total percentage of time that the device provided atrial intervention pacing. To access AT/AF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Episodes. You can view the AT/AF summary data on the programmer screen and print the data in report form. For more information, see Section 3.9, “Episode and therapy counters”, page 125.

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

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

4.20 Post Shock Pacing

After the heart receives a high-voltage therapy, there may be a temporary rise in the pacing thresholds. The rise in the pacing threshold may result in loss of capture.

Post Shock Pacing increases the pacing amplitude and pulse width following a high-voltage therapy.

4.20.1 Operation of Post Shock Pacing

The device allows you to program separate Post Shock Pacing amplitude and pulse width settings that apply after any high-voltage therapy. These parameters remain in effect for 25 pacing cycles.

Note: If the programmed pacing mode is an MVP mode (AAIR<=>DDDR or AAI<=>DDD), the device operates in DDDR or DDD mode for 1 min after a high-voltage therapy. For more information, see Section 4.3, “Managed Ventricular Pacing (MVP)”, page 160. For all other modes, the device operates in the programmed pacing mode.

4.20.2 Programming Post Shock Pacing

Table 26. How to navigate to Post Shock Pacing parameters

Parameters	Path
A. Amplitude and A. Pulse Width	Params > Pacing... > Arrhythmia/Post Shock...
V. Amplitude and V. Pulse Width	

4.21 Post VT/VF Shock Overdrive Pacing

After a VT/VF episode is successfully terminated by a high-voltage therapy, there may be a temporary reduction in cardiac output.

Post VT/VF Shock Pacing provides overdrive pacing that may improve cardiac output.

4.21.1 Operation of Post VT/VF Shock Pacing

Post VT/VF Shock Pacing provides programmable parameters for the Overdrive Rate and Overdrive Duration after a VT/VF episode is treated with a shock. The pacing mode remains at the programmed setting. Pacing continues at the Overdrive Rate through the Overdrive Duration unless a test or another therapy occurs first. At the conclusion of the Overdrive Duration, the pacing rate transitions smoothly back to normal pacing rates.

Note: The first 25 pacing cycles use the Post Shock Pacing settings for amplitude and pulse width.

Note: If the programmed pacing mode is an MVP mode (AAIR<=>DDDR or AAI<=>DDD), the device operates in DDDR or DDD mode for 1 min after a high-voltage therapy. For more information, see Section 4.3, “Managed Ventricular Pacing (MVP)”, page 160. For all other modes, the device operates in the programmed pacing mode.

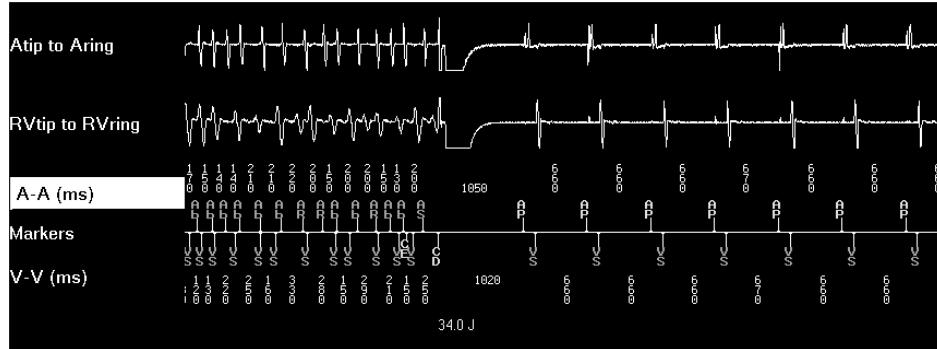
4.21.2 Programming Post VT/VF Shock Pacing

Table 27. How to navigate to Post VT/VF Shock Pacing parameters

Parameters	Path
Post VT/VF Shock Pacing (On, Off)	Params > Pacing... > Arrhythmia/Post Shock...
Overdrive Rate	
Overdrive Duration	

4.21.3 Evaluation of Post VT/VF Shock Pacing

To observe pacing at the Overdrive Rate, go to Arrhythmia Episodes and look at the pacing markers. To access Arrhythmia Episodes EGM data, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] > EGM.

Figure 110. Post VT/VF shock pacing after the delivery of high-voltage therapy

4.22 Ventricular Rate Stabilization

When a patient experiences a PVC, it is often followed by a long pause in the cardiac cycle. This pause is sometimes associated with the onset of pause-dependent ventricular tachyarrhythmias.

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

4.22.1 Operation of VRS

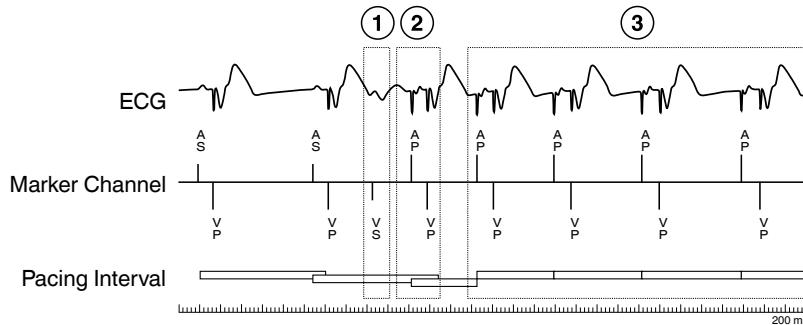
VRS operates as a constant rate-smoothing function by adjusting the ventricular intervals that may follow a PVC. The following programmable parameters control the pacing rate determined by VRS:

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

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

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

Figure 111. Operation of VRS



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

Notes:

- An upper limit is placed on the operation of VRS because it is intended as a response to a premature ventricular beat. VRS does not respond to sustained high heart rates.
- In dual chamber pacing modes, VRS automatically shortens the atrial pacing interval so that the ventricular pacing pulse is delivered at the required pacing interval.
- Generally, when multiple device features attempt to control the pacing rate, the feature with the fastest rate takes precedence.

4.22.2 Programming VRS

Table 28. How to navigate to VRS parameters

Parameters	Path
V. Rate Stabilization (On, Off)	Params > Pacing... > Arrhythmia/Post Shock...
Maximum Rate Interval Increment	Params > Pacing... > Arrhythmia/Post Shock... > Additional V Settings...

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

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

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

4.22.3 Evaluation of VRS performance

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

Figure 112. Example of PVC and VRS counter data

Data - Counters			
<input checked="" type="radio"/> VT/VF Episodes	<input type="radio"/> VT/VF Rx	<input type="radio"/> AT/AF Episodes	<input type="radio"/> AT/AF Rx
Prior Session 06-Apr-2012 to 27-Aug-2012	Last Session 27-Aug-2012 to 10-Dec-2012	Device Lifetime Total (Since 13-Jan-2011)	
VT/VF Counters			
VF	1	2 ↑	5
FVT	1	3 ↑	6
VT	1	4 ↑	7
Monitored VT (133-150 bpm)	2	4 ↑	
VT-NS (>4 beats, >150 bpm)	4	26 ↑	
High Rate-NS	3	12 ↑	
PVC Runs (2-4 beats)	<0.1 per hour	<0.1 per hour	
PVC Singles	0.0 per hour	<0.1 per hour ↑	
Runs of VRS Paces	<0.1 per hour	<0.1 per hour	
Single VRS Paces	<0.1 per hour	<0.1 per hour	

- 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.

5 Tachyarrhythmia detection features

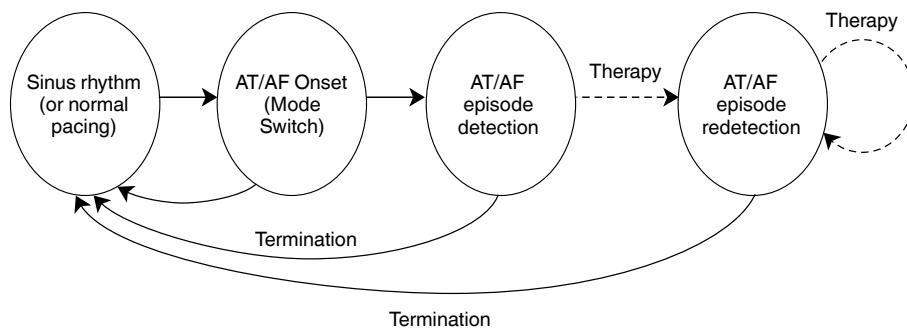
5.1 AT/AF detection

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

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

5.1.1 Operation of AT/AF detection

Figure 113. Overview of AT/AF detection



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

5.1.1.1 Identifying atrial tachyarrhythmia onset

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

- There are at least 2 atrial sensed events per ventricular interval for a sufficient number of ventricular intervals (at least 3 ventricular intervals must have passed since the beginning of the episode).
- The median of the 12 most recent atrial intervals is shorter than the programmed AT/AF (or Fast AT/AF) interval.

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

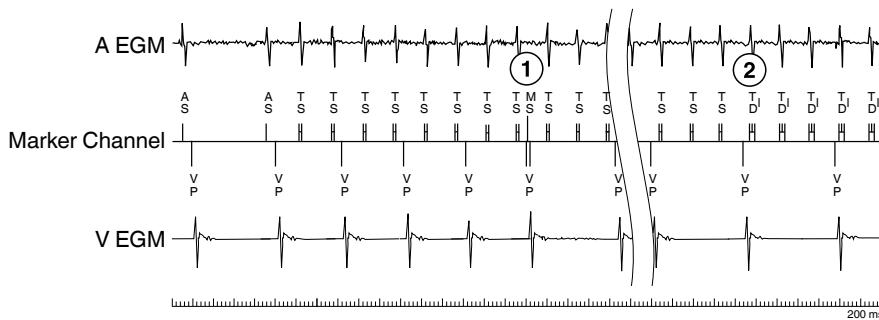
Note: The system begins to calculate the percentage of time the patient spends in AT/AF when the conditions for AT/AF onset are met. This information is used in Cardiac Compass Trends.

5.1.1.2 Detecting an atrial tachyarrhythmia episode

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

- There are at least 2 atrial sensed events per ventricular interval for a sufficient number of ventricular intervals (at least 40 ventricular intervals must have passed since the beginning of the episode).
- The median of the 12 most recent sensed atrial intervals is shorter than the programmed AT/AF (or Fast AT/AF) interval.

Episode record storage occurs when the conditions for AT/AF detection are met. In the episode record, AT/AF detection is marked with the annotation, AT/AF Detection. For more information, see Section 5.1.3, “Evaluation of AT/AF detection”, page 228.

Figure 114. AT/AF onset and AT/AF detection

- 1 The MS marker indicates that Mode Switch has taken place. This marker appears only if Mode Switch has been programmed to On.
- 2 The TD marker indicates that AT/AF episode detection has taken place.

Notes:

- When AT/AF detection occurs, the system creates an episode record marking the AT/AF onset and detection points. If onset is reached but detection never occurs, there will not be an episode record 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/VF detection takes priority over AT/AF detection. When VT/VF is detected, any ongoing AT/AF detection process is postponed until after the VT/VF episode terminates.

5.1.1.3 Classifying atrial tachyarrhythmia episodes for treatment

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

Figure 115. AT/AF and Fast AT/AF detection parameters

Detection	Zones	A. Interval (Rate)
On	2	Fast AT/AF AT/AF

200 ms (300 bpm)
350 ms (171 bpm)

200 ms
350 ms

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

5.1.1.4 Redetecting an atrial tachyarrhythmia

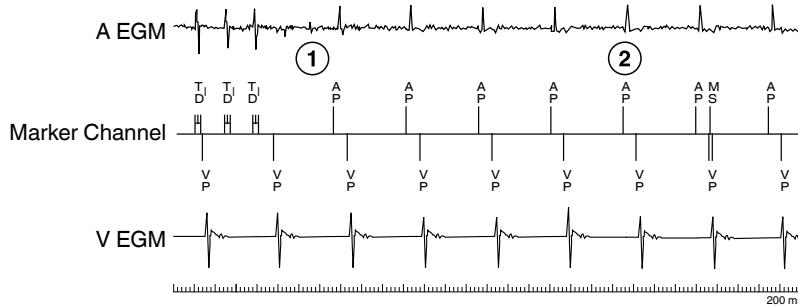
After a therapy sequence is delivered, the device must redetect the atrial tachyarrhythmia before applying another therapy sequence. The device applies a subsequent therapy sequence only when both of the following conditions are met:

- There are at least 2 atrial sensed events per ventricular interval for a sufficient number of ventricular intervals (at least 32 ventricular intervals must have passed since therapy delivery).
- The median of the 12 most recent sensed atrial intervals is shorter than the programmed AT/AF (or Fast AT/AF) interval.

5.1.1.5 Identifying atrial tachyarrhythmia termination

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

Figure 116. AT/AF termination



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

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

5.1.1.6 Monitoring an atrial tachyarrhythmia without delivering therapy

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

5.1.2 Programming AT/AF detection

Table 29. How to navigate to AT/AF detection parameters

Parameters	Path
AT/AF Detection (On, Monitor)	Params
AT/AF A. Interval (Rate) Zone 1	Params > AT/AF Therapies...
Fast AT/AF A. Interval (Rate) Zone 2	

VF detection backup during AT/AF – For AT/AF Detection to be programmed to On, VF Detection must be programmed to On. This ensures VF detection backup during AT/AF episodes.

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

5.1.3 Evaluation of AT/AF detection

5.1.3.1 Quick Look II screen

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

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

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

5.1.3.2 Arrhythmia Episodes screen

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

The Arrhythmia Episodes screen displays recorded tachyarrhythmia episodes and triggered therapies. The Plot option displays a diagram of the episode and shows the times of onset, detection, therapy delivery, and termination. The EGM option displays the episode information in the context of an EGM strip.

5.1.3.3 Flashback Memory

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

The Flashback Memory screen shows interval and marker data before the most recent occurrence of an AT/AF episode. Total elapsed time is plotted against interval length in ms.

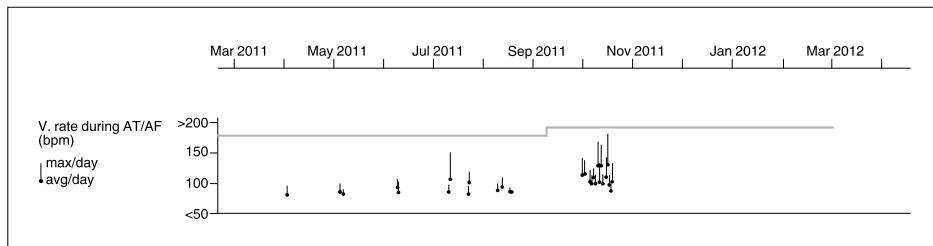
5.1.3.4 Cardiac Compass Trends

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

Cardiac Compass Trends provides information about AT/AF episodes and ventricular rhythms and how much time the patient has spent in AT/AF.

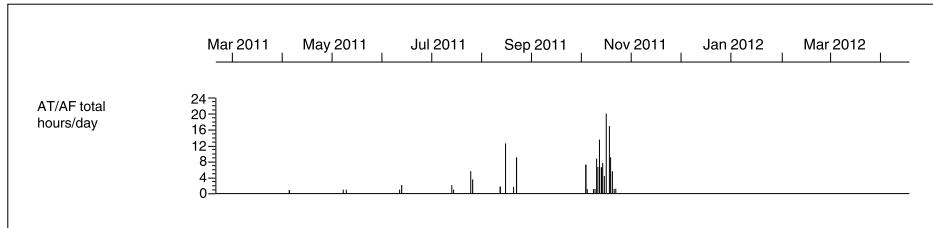
The V. rate during AT/AF trend in Cardiac Compass Trends displays information about ventricular response during atrial tachyarrhythmias.

Figure 117. Cardiac Compass V. Rate during AT/AF



The AT/AF total hours/day trend in Cardiac Compass Trends provides information about the amount of time the patient has spent in AT/AF.

Figure 118. Cardiac Compass AT/AF total hours/day

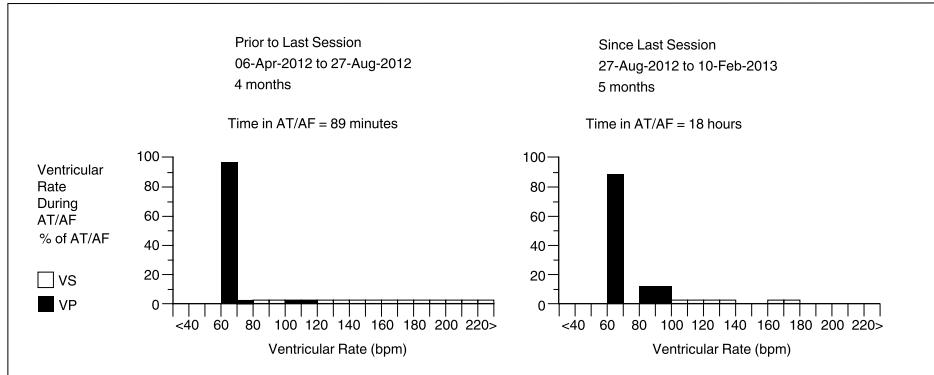


5.1.3.5 Rate Histograms

To access Rate Histograms, select Data > Clinical Diagnostics > Rate Histograms > [Open Data], or select Reports > Available reports... > Rate Histograms.

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

Figure 119. Ventricular Rate During AT/AF Histogram



5.1.3.6 AT/AF episode counters

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

The AT/AF episode counters provide a summary of AT/AF activity, including the percentage of time spent in AT/AF, and the number of AT/AF episodes since the last session. For more information, see Section 3.9, "Episode and therapy counters", page 125.

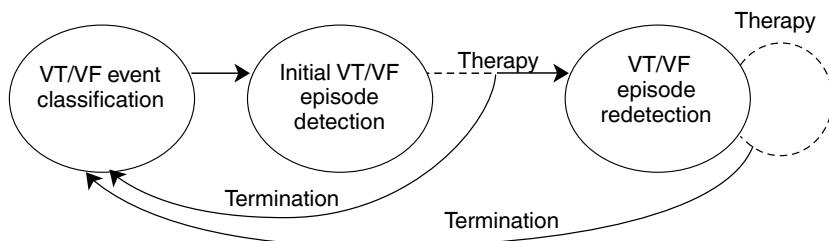
5.2 VT/VF detection

To provide the appropriate therapies for the patient, the device must first detect the presence of a tachyarrhythmia and classify it accurately. The device must be capable of detecting several types of ventricular tachyarrhythmia with differing characteristics. After delivering a therapy, the device must evaluate the effectiveness of the therapy and deliver additional therapy if the arrhythmia persists. Following episode termination, the device must continue to monitor for recurrence of the tachyarrhythmia. If an arrhythmia terminates spontaneously following detection or if a fast ventricular rate is due to oversensing, therapy should be withheld.

Ventricular tachyarrhythmia detection is an ongoing process of classifying sensed ventricular events for tachyarrhythmia episode detection. Based on the results of the detection process, the device may deliver programmed therapy to the patient or withhold therapy from the patient. After delivering a therapy, the device continues to monitor the patient's rhythm to determine whether the tachyarrhythmia has terminated or whether it persists or changes. The device can be programmed to monitor for slower, non-life-threatening VTs without providing therapy.

5.2.1 Operation of VT/VF detection

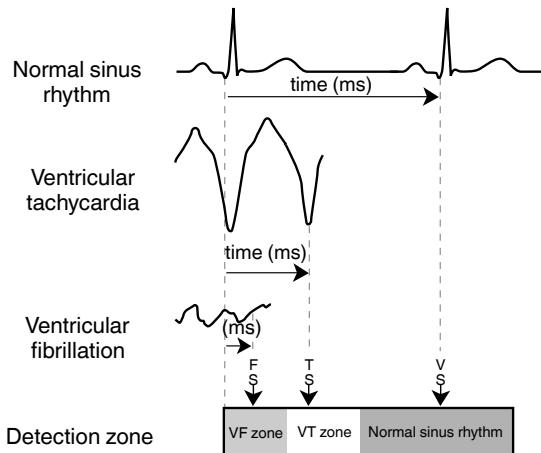
Figure 120. Overview of VT/VF detection



The device classifies the patient's heart rhythm by measuring each interval and counting the number of tachyarrhythmia events that occur within programmed tachyarrhythmia "detection zones". There are 4 programmable detection zones: VF, Fast VT, VT, and Monitor. If the number of tachyarrhythmia events in a zone exceeds a programmed threshold, the device detects a ventricular tachyarrhythmia episode. Upon detection, the device may deliver a scheduled therapy, after which it reevaluates the patient's heart rhythm for episode termination or redetection.

5.2.1.1 Classifying ventricular events

Figure 121. VF and VT detection zones



The system uses programmable “detection zones” to classify ventricular events for tachyarrhythmia detection and therapy. A detection zone is a range of cycle lengths used to classify a sensed ventricular tachyarrhythmia event as VF or VT.

Figure 122. VF and VT detection intervals

	Initial	Redetect	V. Interval (Rate)	
VF	On	30/40	320 ms (188 bpm)	
FVT	OFF		240 ms (250 bpm)	
VT	OFF	16	360 ms (167 bpm)	
Monitor	Monitor	32	450 ms (133 bpm)	

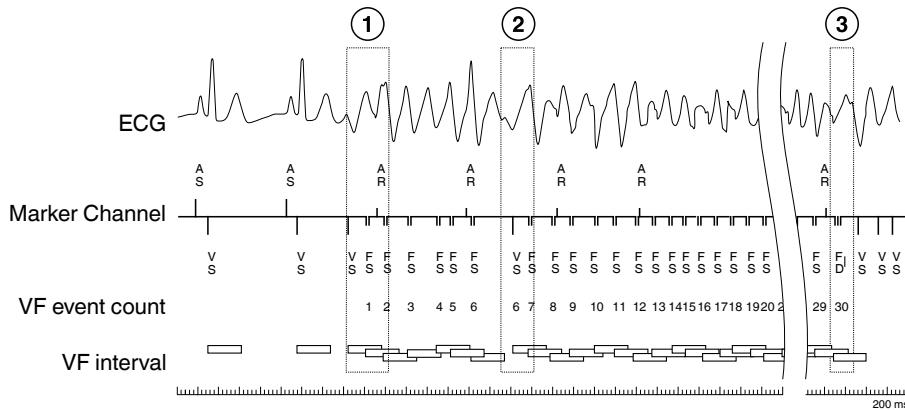
You program the detection zones by selecting a detection interval for each type of tachyarrhythmia that you want the device to detect. (The detection interval is called V. Interval (Rate) on the Parameters screen.) When you program a detection interval for VF, you are defining a zone for VF events. Intervals that are shorter than the VF detection interval fall in the VF detection zone and are classified as ventricular fibrillation events. In addition, when you program a VT detection interval, you are defining a zone for VT events. Intervals that are shorter than the VT detection interval and longer than or equal to the VF detection interval fall into the VT detection zone and are classified as ventricular tachycardia events.

5.2.1.2 Detecting VF and VT episodes

The system uses a programmable Initial Beats to Detect value to define how many beats a tachyarrhythmia must continue to be detected as an episode. The Initial Beats to Detect value operates differently for events in the VF zone as compared to events in the VT zone.

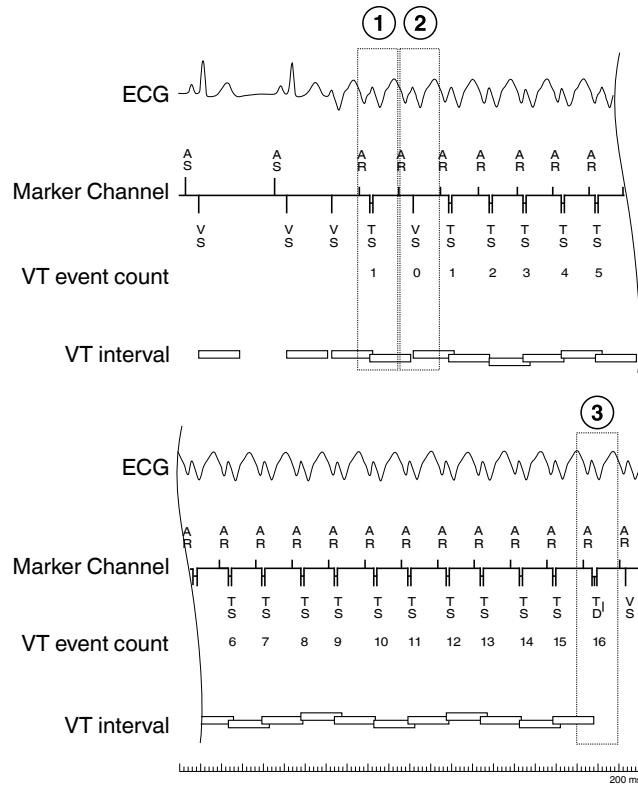
VF episodes have very fast, irregular intervals as a result of the chaotic nature of VF depolarizations. Some smaller VF signals may not be sensed and counted. Because of this, the system uses a ratio of VF events to consecutive events for VF detection. For example, if you program the VF Initial Beats to Detect value to 30/40, the device detects VF when at least 30 of the most recent 40 intervals have been classified as VF events.

Figure 123. Initial Beats to Detect calculation for VF



- 1 Ventricular fibrillation starts, and sensed intervals in the VF detection zone are classified as VF events (marked FS).
- 2 A sensed ventricular interval occurs outside the VF detection zone. This event is not classified as a VF event.
- 3 The programmed VF Initial Beats to Detect value of 30 events out of 40 is reached, and the device detects a VF episode (indicated by the FD marker).

VF detection uses a probabilistic counter to ensure that undersensing does not prevent detection. However, since VT rhythms are not as prone to undersensing, the system uses a count of consecutive events for VT detection. For example, if you program the VT Initial Beats to Detect value to 16, the device detects VT when 16 consecutive intervals have been classified as VT events. If an interval is longer than the VT zone, the detection process is restarted. If the interval is shorter than the VT detection interval and occurs in the VF zone, the device holds the count of consecutive VT events (neither resets nor increments it).

Figure 124. Initial Beats to Detect calculation for VT

- 1 Ventricular tachycardia starts, and sensed ventricular intervals in the VT detection zone are classified as VT events (marked TS).
- 2 A sensed ventricular interval occurs outside the VT detection zone. VT detection restarts.
- 3 The programmed VT Initial Beats to Detect value of 16 events is reached, and the device detects VT (indicated by the TD marker).

5.2.1.3 Detecting 2 clinical VTs

A fast ventricular tachyarrhythmia (FVT) detection zone may be used to allow different therapeutic approaches for a patient who exhibits 2 VTs of different rates. To detect 2 clinical VTs, program FVT Detection to via VT and select a V. Interval (Rate) value for FVT. To help ensure that the patient's fast ventricular tachycardia is classified as FVT, select a value that matches the longest ventricular interval that typically occurs during the patient's fast VT.

Figure 125. FVT via VT detection parameters

		Initial	Redetect	V. Interval (Rate)	
VF	On	30/40	0	320 ms (188 bpm)	
FVT	via VT			350 ms (171 bpm)	
VT	On	16	12	400 ms (150 bpm)	
Monitor	Off	32		450 ms (133 bpm)	

The device detects a tachyarrhythmia episode when the number of consecutive VT or FVT events reaches the programmed Initial Beats to Detect value for VT. If any of the 8 most recent intervals have occurred in the FVT zone, the device detects an FVT episode. If all of the 8 most recent intervals are longer than the FVT detection interval, the device detects a VT episode.

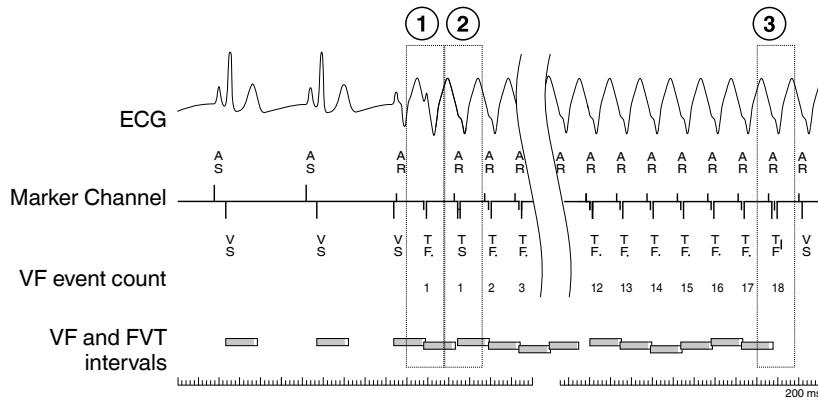
5.2.1.4 Detecting a VT in the VF zone

An FVT detection zone may also be used to detect and treat a VT episode that is in the VF zone. This approach may help to ensure reliable detection of VF, while providing the ability to deliver a less aggressive therapy such as antitachycardia pacing for the patient's fast VT. To detect a VT in the VF zone, program FVT Detection to via VF and select a V. Interval (Rate) value for FVT. To help ensure that the patient's fast ventricular tachycardia is classified as FVT, select a value that matches the shortest ventricular interval that typically occurs during the patient's fast VT.

Figure 126. FVT via VF detection parameters

		Initial	Redetect	V. Interval (Rate)	
VF	On	30/40	0	320 ms (188 bpm)	
FVT	via VF			240 ms (250 bpm)	
VT	OFF	16	12	360 ms (167 bpm)	
Monitor	Off	32		450 ms (133 bpm)	

The device detects a tachyarrhythmia episode when the number of recent VF or FVT events reaches the programmed Initial Beats to Detect value for VF. If all of the 8 most recent intervals were classified as FVT events, the device detects an FVT episode. If 1 or more of the 8 most recent intervals were classified as VF events, the device detects a VF episode.

Figure 127. Detecting an FVT via VF episode

- 1 Fast ventricular tachycardia starts. The first event has a cycle length in the FVT detection zone and is counted toward FVT or VF detection.
- 2 The second event has a cycle length that is longer than the VF detection interval. This event is not counted toward FVT or VF detection.
- 3 The programmed VF Initial Beats to Detect value is reached. Because all of the previous 8 events were classified as FVT events, the device detects a fast ventricular tachyarrhythmia episode (marked TF followed by a vertical bar).

5.2.1.5 Detecting ventricular tachyarrhythmia that fluctuates between zones: Combined Count detection

Combined Count detection is designed to prevent VF detection from being delayed when ventricular tachyarrhythmia fluctuates between the VF and VT zones. Combined Count detection occurs if the sum of the VT and VF events reaches 7/6 of the programmed VF Initial Beats to Detect value. For example, if the programmed VF Initial Beats to Detect value is 30/40, Combined Count detection takes place when the count reaches 7/6 of 30, which is 35. After Combined Count detection takes place, the last 8 events are examined. If any of the 8 events is classified as a VF event, VF is detected; otherwise, VT (or FVT) is detected. Combined Count detection also applies to redetection.

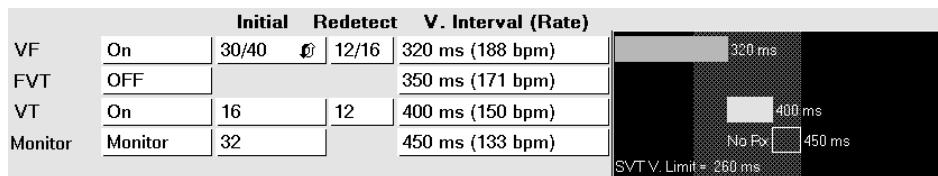
Notes:

- Combined Count detection is not programmable. It is automatically enabled when VT Detection is programmed to On. Combined Count detection begins when at least 6 VF events have occurred.
- Events in the Monitor zone are not included in Combined Count detection.

5.2.1.6 Monitoring ventricular tachyarrhythmias without delivering therapy

The Monitor zone may be used to program a range of rates for detecting ventricular tachycardia without delivering therapies.

Figure 128. VT Monitor Detection parameters



When VT Detection is programmed to On, the Monitor zone can function as a diagnostic zone to monitor for non-life-threatening VTs with cycle lengths longer than or equal to the VT detection interval (see Figure 128).

When VT Detection is not programmed to On, a Monitor zone may be programmed to monitor any ventricular tachyarrhythmia with a cycle length longer than or equal to the VF detection interval.

Notes:

- Detection of a VF, VT, or FVT episode terminates a VT monitor episode and suspends the VT monitoring operation until termination of the tachyarrhythmia.
- The programmed SVT discrimination features (Onset, Stability, PR Logic, and Wavelet) are applied in the VT monitor zone.

5.2.1.7 Detecting non-sustained ventricular tachyarrhythmia episodes

If at least 5 beats fall within any programmed ventricular tachyarrhythmia detection zone (but fewer than the programmed Initial Beats to Detect), the episode is classified as a non-sustained VT (VT-NS). For example, if 5 or more intervals occur in the VT zone, but not enough to detect a VT episode, a VT-NS is detected.

After the device has been interrogated, VT-NS episodes can be selected from the Episode Log. For more information about the Episode Log, see Section 3.8, "Arrhythmia Episodes data", page 115.

5.2.1.8 Evaluating the ventricular rhythm after therapy

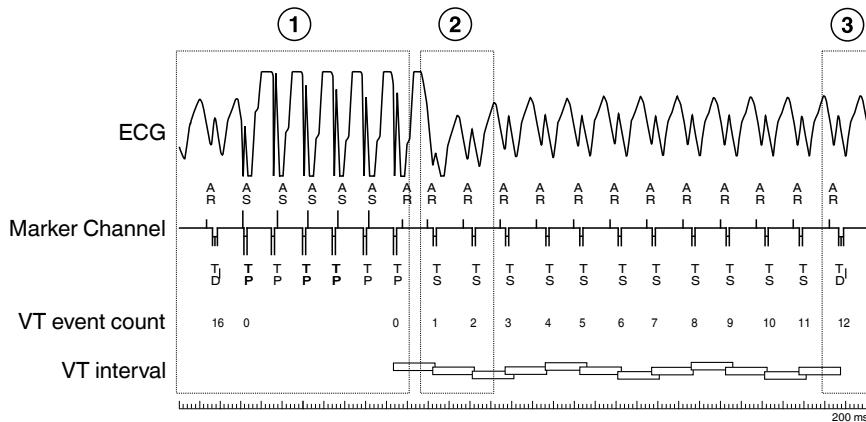
After delivering a therapy, the device evaluates the ventricular rhythm to determine if the episode is continuing.

Redetection – The device redetects the ventricular tachyarrhythmia if the programmed VF Beats to Redetect value or the programmed VT Beats to Redetect value is reached. The device then delivers the next programmed therapy sequence for the redetected ventricular tachyarrhythmia and again evaluates the rhythm for redetection or termination.

Notes:

- You can expedite redetection by programming the VF and VT Beats to Redetect values to values that are lower than the VF and VT Initial Beats to Detect value.
- The SVT discrimination features are not applied during redetection with the exception of the TWave Discrimination feature and the Stability feature, which are always applied after 3 consecutive VT events.

Figure 129. Redetecting a VT episode after therapy



- 1 A VT episode is detected, and the device delivers a Burst ATP therapy.
- 2 After the Burst ATP therapy, the device continues to identify VT events.
- 3 When the number of VT events reaches the programmed VT Beats to Redetect value, the device redetects the VT.

Zone merging – To ensure that the device delivers sufficiently aggressive therapies when FVT Detection is programmed, the device merges detection zones during redetection as follows:

- If FVT Detection is programmed to FVT via VT and an FVT or VF episode is detected, the VT zone merges with the FVT zone. After the zones have merged, the episode cannot be classified for redetection as the slower VT rhythm.
- If FVT Detection is programmed to FVT via VF and a VF episode is detected, the FVT zone merges with the VF zone. After the zones have merged, the episode cannot be classified for redetection as the slower FVT rhythm.

The merged zone configuration remains in effect until the episode terminates.

5.2.1.9 Evaluating the ventricular rhythm for termination

The device determines that a VT episode has terminated if 8 consecutive ventricular intervals are longer than or equal to the programmed VT detection interval or if 20 s elapse during which the median of the last 12 ventricular intervals is always longer than the VT detection interval.

If VT detection is off but VF detection is on, the device uses the programmed VF interval to terminate a VF episode. The episode is terminated when 8 consecutive ventricular intervals are longer than or equal to the programmed VF detection interval or when 20 s elapse during which the median of the last 12 ventricular intervals is always longer than the VF detection interval.

5.2.1.10 SVT discrimination features for ventricular tachyarrhythmia detection

The device provides the following features designed to help prevent conducted supraventricular tachycardias (SVTs) from being treated as ventricular tachyarrhythmias:

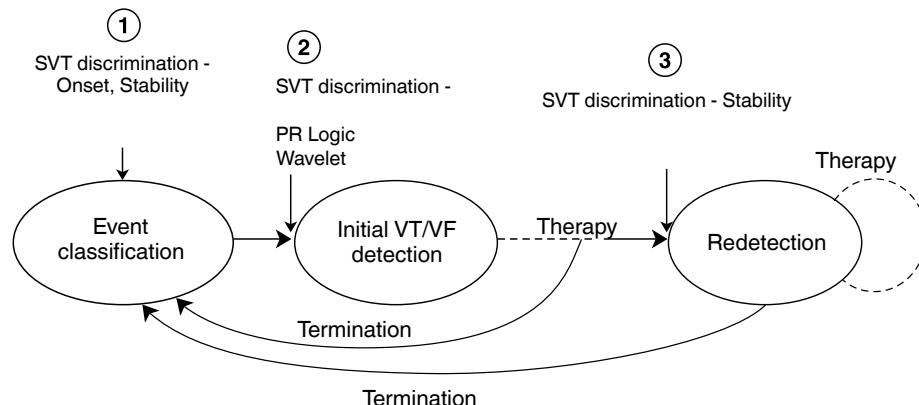
PR Logic – PR Logic is a set of SVT discrimination functions that withhold VT/VF detection if the rhythm displays characteristics of an SVT origin. For more information, see Section 5.3, “PR Logic”, page 245.

Wavelet – The Wavelet feature withholding VT/VF detection if the rhythm displays characteristics of an SVT origin. For more information, see Section 5.4, “Wavelet”, page 248.

Onset – The Onset feature is designed to prevent sinus tachycardia from being treated as ventricular tachycardia. For more information, see Section 5.5, “Onset”, page 256.

Stability – The Stability feature is designed to prevent conducted atrial fibrillation episodes from being treated as ventricular tachycardia. For more information, see Section 5.6, “Stability”, page 262.

Figure 130. Overview of SVT discrimination



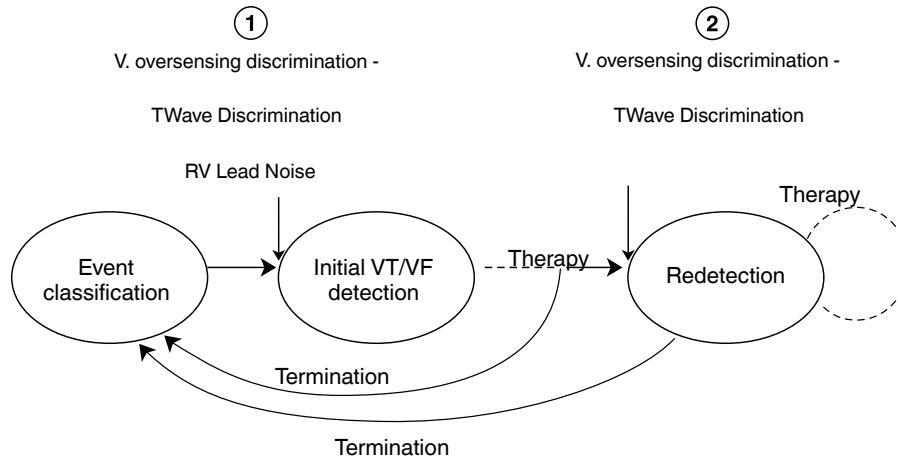
- 1 Onset and Stability withhold detection by preventing the programmed Initial Beats to Detect value from being reached.
- 2 PR Logic and Wavelet withhold detection and therapy after the programmed Initial Beats to Detect value has been reached.
- 3 Stability also applies to the Redetection phase.

5.2.1.11 Ventricular oversensing (VOS) discrimination features for ventricular tachyarrhythmia detection

The device provides the following features designed to help prevent inappropriate ventricular tachyarrhythmia detection and therapy caused by ventricular oversensing (VOS).

TWave Discrimination – The TWave Discrimination feature withholds inappropriate ventricular tachyarrhythmia detection caused by the oversensing of T-waves. For more information, see Section 5.8, “TWave Discrimination”, page 266.

RV Lead Noise Discrimination – The RV Lead Noise Discrimination feature withholds inappropriate ventricular tachyarrhythmia detection caused by the oversensing of noise from the right ventricular lead. For more information, see Section 5.9, “RV Lead Noise Discrimination”, page 270.

Figure 131. Overview of ventricular oversensing (VOS) discrimination

- 1 The TWave Discrimination and RV Lead Noise Discrimination features withhold ventricular tachyarrhythmia detection and therapy after the programmed Initial Beats to Detect value has been reached.
- 2 The TWave Discrimination feature also applies to the Redetection phase.

5.2.2 Programming ventricular tachyarrhythmia detection

Table 30. How to navigate to VT/VF detection parameters

Parameters	Path
VF Detection (On, Off)	Params > Detection (V)...
VF Initial	
VF Redetect	
VF V. Interval (Rate)	
FVT Detection (via VF, via VT, Off)	
FVT V. Interval (Rate)	
VT Detection (On, Off)	
VT Initial	
VT Redetect	
VT V. Interval (Rate)	
Monitor (Monitor, Off)	
Monitor Initial	
Monitor V. Interval (Rate)	

VF, FVT, and VT detection intervals – To allow for normal variations in the patient's tachycardia interval, you should program the VF, FVT, and VT detection intervals at least 40 ms apart.

Tachyarrhythmia detection and bradycardia pacing – To diminish the possibility that bradycardia pacing will interfere with ventricular tachyarrhythmia detection, the programmer restricts the parameter values available for pacing rates, pacing intervals, and detection intervals.

VF detection interval minimum setting – Programming the VF detection interval to a value less than 300 ms may increase the chance of underdetection of VF.

VF detection interval maximum setting – Programming the VF detection interval to a value greater than 350 ms may increase the chance of inappropriate detection of rapidly conducted atrial fibrillation as VF or FVT via VF.

VF detection, AF/Afl, Sinus Tach, and Wavelet – When VF Detection is set to On, the AF/Afl, Sinus Tach, and Wavelet features are also set to On automatically. For more information about the AF/Afl and Sinus Tach features, see Section 5.3, “PR Logic”, page 245. For more information about the Wavelet feature, see Section 5.4, “Wavelet”, page 248.

AT/AF detection – If AT/AF Detection is programmed to On, VF Initial Beats to Detect must be less than or equal to 30/40; Monitored VT Beats to Detect must be less than or equal to 36; and VT Initial Beats to Detect must be less than or equal to 36.

VF detection backup – To ensure VF detection backup during VT, FVT, and VT Monitor episodes, if VT, FVT, or VT Monitor is programmed to On, VF Detection must also be programmed to On.

Monitored VT Beats to Detect – The Monitored VT Beats to Detect value must be greater than the VF and VT Initial Beats to Detect.

5.2.3 Evaluation of VT/VF detection

5.2.3.1 Quick Look II screen

To access Quick Look II VT/VF detection information, select Data > Quick Look II. The Quick Look II screen shows the number of monitored and treated VT, FVT, and VF episodes since the last session.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

5.2.3.2 Arrhythmia Episodes screen

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

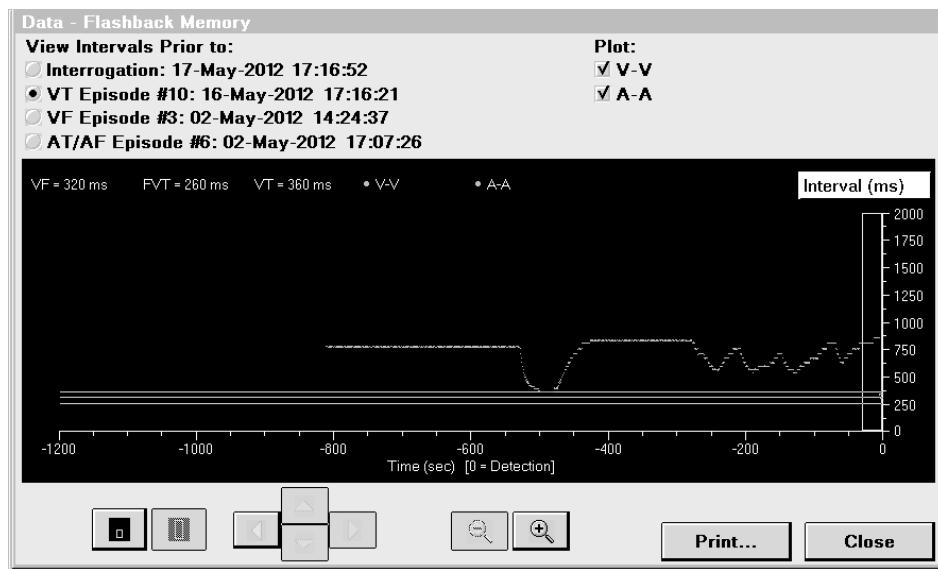
The Plot option displays a plot diagram of the episode intervals and shows the detection and termination points. The EGM option displays EGM traces leading up to the detection point and through therapy and termination. The Text option provides a text summary of the episode.

5.2.3.3 Flashback Memory

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

The Flashback Memory screen shows interval and marker data prior to the most recent occurrence of a VT or VF episode. Total elapsed time is plotted against interval length in milliseconds.

Figure 132. Flashback Memory screen

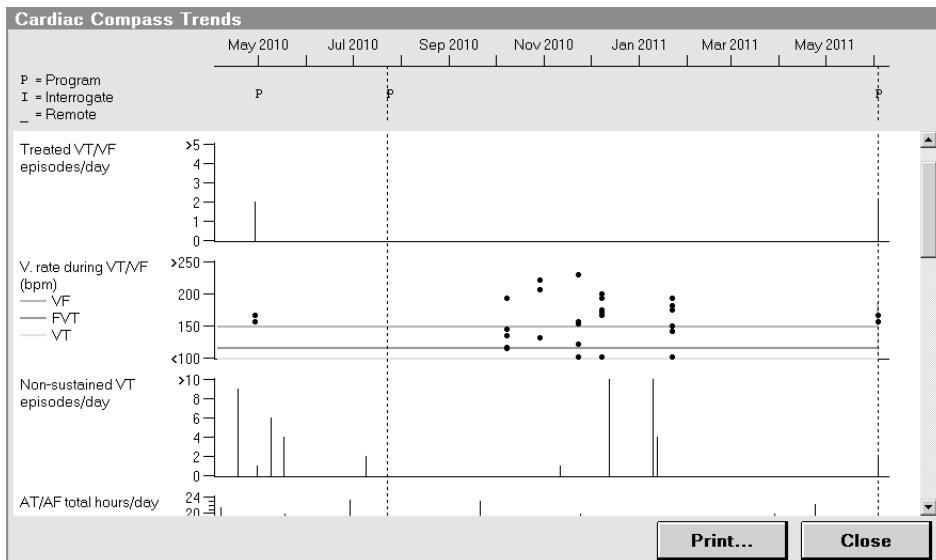


5.2.3.4 Cardiac Compass Trends

To view Cardiac Compass Trends data, select Data > Clinical Diagnostics > Cardiac Compass Trends > [Open Data]. To print Cardiac Compass Trends, select Reports > Available Reports... > Cardiac Compass Trends or select [Print...] directly from the Cardiac Compass Trends screen.

Cardiac Compass Trends data includes information about treated VT/VF episodes per day; ventricular rate during VF, FVT, or VT; and non-sustained VT episodes per day.

Figure 133. Cardiac Compass Trends data



5.2.3.5 VT/VF episode counter

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

The VT/VF episode counter provides a summary of VT/VF activity for last session, prior session, and device lifetime, including the number of VF, FVT, and VT episodes and the instances of therapy withheld by SVT and ventricular oversensing discrimination features.

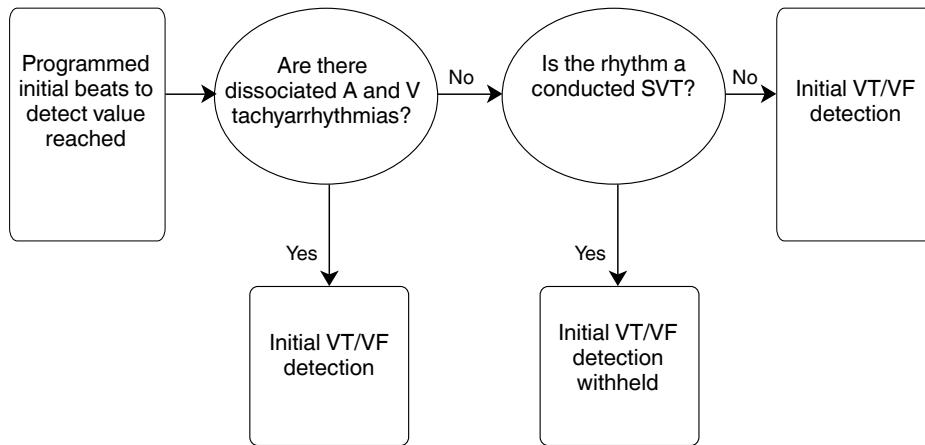
5.3 PR Logic

Patients who are experiencing supraventricular tachycardia (SVT) may exhibit ventricular rates in the VT/VF detection zone. If sustained, such fast ventricular rates may cause an inappropriate delivery of a tachyarrhythmia therapy. Identifying and withholding detection for conducted SVT reduces the chance of delivering an inappropriate therapy for high ventricular rates that are not ventricular in origin.

PR Logic uses pattern and rate analysis to discriminate between SVTs and true ventricular tachyarrhythmias and to withhold inappropriate VT/VF detection and therapy during episodes of rapidly conducted SVT.

5.3.1 Operation of PR Logic

Figure 134. Overview of PR Logic



When the programmed Initial Beats to Detect is reached, PR Logic analyzes the activation patterns and timing in both cardiac chambers to obtain the following information:

- the atrial and ventricular rates
- the number and position of atrial events relative to ventricular events
- the association or dissociation of the atrial and ventricular events
- the regularity or irregularity of the ventricular rhythm

If the analysis indicates that there are dissociated supraventricular and ventricular tachyarrhythmias, the device detects and treats the ventricular tachyarrhythmia. If the analysis determines that the ventricular tachyarrhythmia is a conducted SVT such as atrial fibrillation, atrial flutter, sinus tachycardia, or junctional tachycardia, the device withholds ventricular tachyarrhythmia detection and therapy.

Note: As part of its processing, PR Logic evaluates whether atrial events may be far-field R-waves.

There are 3 distinct PR Logic features that can be programmed to On: AF/Afl, Sinus Tach, and Other 1:1 SVTs.

AF/Afl (Atrial Fibrillation/Atrial Flutter) – The AF/Afl feature is designed to withhold ventricular tachyarrhythmia detection when the ratio of sensed atrial to ventricular events is greater than 1:1 and the ventricular cycle length is not regular, indicating irregularly conducted atrial fibrillation. The AF/Afl feature is also designed to withhold ventricular tachyarrhythmia detection when A:V pattern information shows regular 2:1 or 3:2 conduction, indicating atrial flutter.

Sinus Tach (Sinus Tachycardia) – The Sinus Tach feature is designed to withhold ventricular tachyarrhythmia detection when there is sensed 1:1 atrial to ventricular conduction of rhythms that exhibit a gradual increase in rate into the detection zone and a similar PR interval to normal antegrade conduction.

Other 1:1 SVTs (Other 1:1 Supraventricular Tachycardias) – The Other 1:1 SVTs feature is designed to discriminate between ventricular tachyarrhythmias and rhythms that are the result of closely coupled atrial and ventricular depolarizations (for example, junctional rhythms such as AV-nodal reentrant tachycardia). The Other 1:1 SVTs feature withholds ventricular tachyarrhythmia detection when AV pattern information indicates a 1:1 SVT in which there are consistent, near-simultaneous depolarizations of the chambers.

5.3.1.1 Limits for withholding therapy

Dissociated supraventricular and ventricular tachyarrhythmia – If both supraventricular and ventricular tachyarrhythmias occur at the same time and the PR Logic analysis shows that the rhythms are dissociated and that the ventricular rhythm is not a conducted SVT, the device detects ventricular tachyarrhythmia and delivers the zone-appropriate ventricular therapy. In the episode text, the detected VT, VF, or FVT is recorded as VT (+SVT), VF (+SVT), or FVT (+SVT).

Note: If Wavelet is programmed to On, the PR Logic features do not indicate SVT, and the atrial rate is faster than or equal to the ventricular rate, the device performs a Wavelet QRS waveform analysis. If the Wavelet analysis indicates that the rhythm is an SVT, the device withholds detection and therapy. For more information, see Section 5.4, “Wavelet”, page 248.

High Rate Timeout – The High Rate Timeout parameters allow you to program maximum durations for which PR Logic and the other SVT discrimination features can withhold detection and therapy. You can program 2 separate timeout periods: one for the VF zone, and one for all zones. For more information, see Section 5.7, “High Rate Timeout”, page 264.

SVT V. Limit – The SVT V. Limit parameter allows you to program a highest rate for which PR Logic and Wavelet can withhold detection and therapy. When the median of the 12 most recent sensed ventricular intervals is shorter than the programmed SVT V. Limit, the SVT discrimination features do not withhold detection and therapy. The SVT V. Limit can be programmed to a value between 240 ms and the longest detection zone interval.

Note: The SVT V. Limit cannot be programmed longer than the VT detection interval.

5.3.2 Programming PR Logic

Table 31. How to navigate to PR Logic parameters

Parameters	Path
AF/Afl	Params > Detection (V)...
Sinus Tach	
Other 1:1 SVTs	
SVT V. Limit	

Warning: Do not program the Other 1:1 SVTs feature to On until the atrial lead has matured (approximately 1 month after implant). If the atrial lead dislodges and migrates to the ventricle, the Other 1:1 SVTs feature could inappropriately withhold detection and therapy.

Caution: Use caution when programming the Other 1:1 SVTs feature in patients who exhibit slow 1:1 retrograde conduction during VF or VT. This feature could inappropriately withhold VT/VF therapy in such patients.

PR Logic criteria and detecting VF – If VF Detection is programmed to On, the device also enables the PR Logic features, AF/Afl and Sinus Tach.

Detection intervals and the SVT V. Limit – The SVT V. Limit value must be less than the VT detection interval. If VT Detection is programmed to Off, the SVT V. Limit must be shorter than or equal to the VF detection interval for detection enhancements to be in effect in the VF zone.

5.3.3 Evaluation of PR Logic

5.3.3.1 Episode Text display

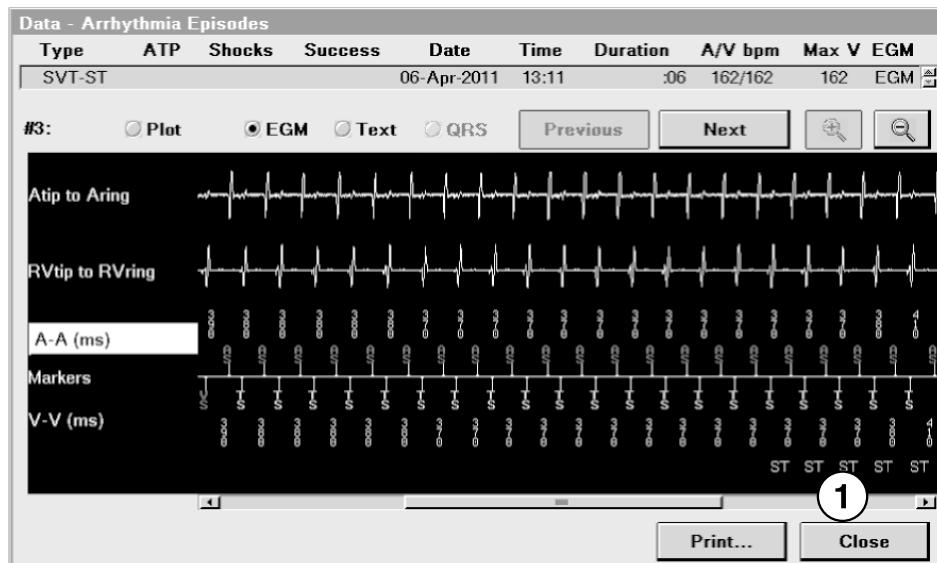
To access information about SVT episodes and PR Logic features that were triggered, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data]> Text.

5.3.3.2 Episode EGM display

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

The following Episode EGM example shows sinus tachycardia, where 1:1 atrial to ventricular conduction is recorded and annotations (ST) indicate that therapy is withheld.

Figure 135. PR Logic Episode EGM



1 ST (Sinus Tach) annotations

There are 3 Decision Channel annotations specific to PR Logic that display when that feature withholds ventricular tachyarrhythmia detection: AF (AF/Afl), ST (Sinus Tach), and SV (Other 1:1 SVTs). Decision Channel annotations are also displayed on the real-time recording when a single annotation is printed and VT/VF detection is first withheld by a PR Logic feature and when a PR Logic feature currently withholding VT/VF detection changes.

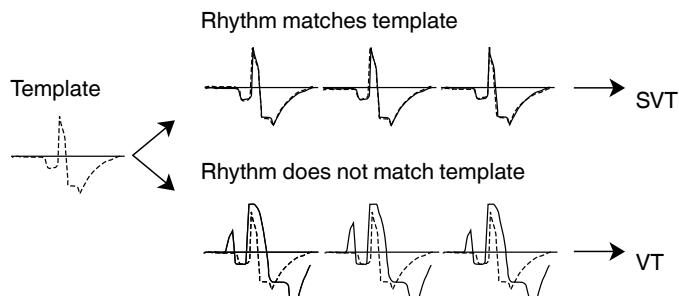
5.4 Wavelet

Patients who are experiencing supraventricular tachycardia (SVT) may exhibit ventricular rates in the VT/VF detection zone. If sustained and not correctly identified, such fast ventricular rates may cause an inappropriate delivery of a VT/VF therapy. Identifying and withholding detection for conducted SVT reduces the chance of delivering an inappropriate therapy for high ventricular rates that are not ventricular in origin.

The Wavelet feature is designed to withhold inappropriate ventricular detection during episodes of rapidly conducted SVT. Tachyarrhythmias of ventricular origin typically have different QRS morphologies than rhythms of supraventricular origin. The Wavelet feature compares the patient's current QRS waveform to a collected and stored template of the patient's QRS waveform in sinus rhythm. VT/VF detection is withheld if the current waveform sufficiently matches the template.

5.4.1 Operation of Wavelet

Figure 136. Using a Wavelet template to discriminate SVT from VT

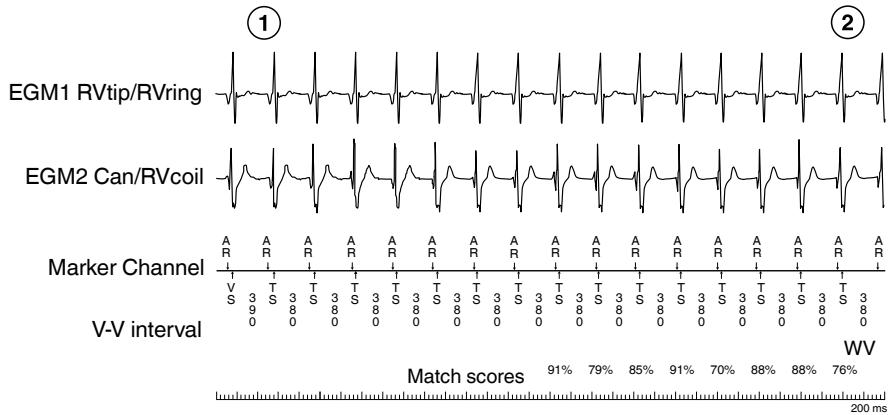


The device collects EGM data for sensed ventricular events and compares it to a stored template using the programmed Match Threshold value (nominally 70%). A QRS complex is classified as a "Match" if its match score is greater than or equal to the programmed Match Threshold value. If at least 3 of the last 8 QRS complexes sufficiently match the stored template, the device withholding detection. If fewer than 3 of the last 8 QRS complexes sufficiently match the stored template, the device allows detection and therapy.

After VT detection is withheld, the ventricular rhythm is continuously evaluated until VT detection occurs or the fast ventricular rate ends.

Notes:

- Wavelet uses the EGM2 channel for template creation and comparison.
- Ventricular events that are paced or that have intervals less than 240 ms are automatically classified as "Not Measured".
- Wavelet applies to initial detection only.

Figure 137. Wavelet withhold detection

- 1 A fast sinus tachycardia begins with sensed ventricular intervals in the VT detection zone.
- 2 The VT Initial Beats to Detect criterion of 16 is reached, but detection is withheld because at least 3 of the previous 8 QRS complexes match the template (in this example, all match).

Using Wavelet with PR Logic – When both Wavelet and PR Logic features are programmed to On, the conditions under which Wavelet withhold detections are as follows:

- The programmed Initial Beats to Detect value is reached.
- The PR Logic features have not indicated that the tachyarrhythmia episode is an SVT.
- The atrial rate is faster than or equal to the ventricular rate.

When Wavelet is programmed to On but all of the PR Logic features are programmed to Off, the device withholds detection when the programmed Initial Beats to Detect value is reached.

Programming an SVT V. Limit – The SVT V. Limit parameter allows you to program a highest rate for which Wavelet and PR Logic withhold therapies. When the median of the 12 most recent sensed ventricular intervals is shorter than the programmed SVT V. Limit, the Wavelet feature does not withhold detection and therapy. The SVT V. Limit can be programmed to a value between 240 ms and the longest detection zone interval.

Note: The SVT V. Limit cannot be programmed longer than the VT detection interval.

5.4.1.1 Collecting the Wavelet template: Auto Collection

You can program automatic device creation and maintenance of the template used to distinguish between VT and SVT. Alternatively, you can collect a template manually using the Wavelet test. For more information, see Section 7.3, "Wavelet Test", page 336.

When Auto Collection is programmed to On and the patient is not being paced, the device collects and confirms a Wavelet template and monitors it for consistency with the patient's QRS complexes in sinus rhythm. When the stored template is no longer consistent with the patient's QRS complexes (for example, due to lead maturation or changes in drug therapy), the device collects and confirms a new template.

After a template is calculated, the device performs a confirmation process before using the template for detection operations. Template confirmation takes a minimum of 12 min. If the intrinsic rhythm changes after the template is collected, template confirmation could take longer.

Notes:

- Pacing prevents a template from being collected. If the patient is being continuously paced, it is recommended that you use the Wavelet test feature to collect a Wavelet template manually. The Wavelet test allows you to change the pacing mode temporarily and then use a manual command to collect a Wavelet template. For more information, see Section 7.3, "Wavelet Test", page 336.
- In creating and maintaining the Wavelet template, the device collects electrogram waveforms only for events with intervals longer than 600 ms or than the VT detection interval plus 60 ms, whichever is longer. It does not collect electrogram waveforms for paced events, for intrinsic events immediately following paced events, or for events classified as PVCs.
- In creating and maintaining the Wavelet template, the device excludes beats where atrial pacing occurs within 130 ms of the ventricular sensed event. This operation avoids corruption of the template by atrial pacing spikes.
- The device stops any template collection or maintenance operations in progress and postpones them for one hour after a tachyarrhythmia episode, a system test, an EP study, or an emergency operation.
- If you clear device data, the number of automatic templates that were collected since the last session (displayed on the Template Details screen) is lost.

5.4.2 Programming Wavelet

Table 32. How to navigate to Wavelet parameters

Parameters	Path
Wavelet (On, Monitor, Off) Match Threshold Auto Collection	Params > Detection (V)... > Wavelet...
SVT V. Limit	Params > Detection (V)...

Wavelet and VF Detection – Wavelet is automatically enabled when VF Detection is set to On.

Concurrent pacemaker – Use caution when programming Wavelet for patients who have a pacemaker concurrently implanted because the ICD cannot distinguish between intrinsic events and paced events from the pacemaker. Program Wavelet to Monitor and evaluate its effectiveness before enabling it for detection. In addition, it is strongly recommended that you disable Auto Collection and collect a template manually with the Wavelet test, making sure that the pacemaker is not pacing the heart during the collection process.

EGM2 Source and Range – It may be necessary to adjust the EGM2 Source and EGM2 Range to optimize Wavelet performance.

Wavelet is less effective at identifying SVTs and withholding detection in the following situations:

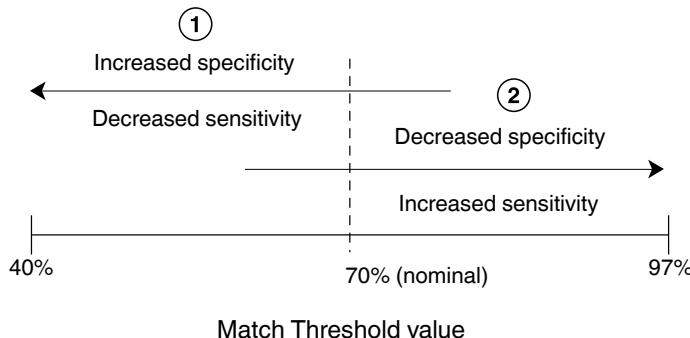
- R-wave amplitudes on the EGM2 signal are too small relative to myopotential interference.
- R-wave amplitudes on the EGM2 signal are so large during intrinsic rhythm or SVT that they exceed the maximum EGM range and are clipped.

You can assess the EGM2 signal using the programmer strip chart recorder or Electronic Strip Chart (eStrip) recorder, whichever is available. If the peak-to-peak R-wave amplitudes on the EGM2 trace are less than 3 mV, consider selecting a different EGM2 source. If the R-wave amplitudes are too large (either clipped or within 1 mV of the EGM2 Range), consider selecting a larger EGM2 Range value. If the R-wave amplitudes are too large at any EGM2 Range, try a different EGM2 Source and assess the R-wave amplitudes starting with an EGM2 Range value of ± 8 mV.

Notes:

- In the Marquis VR Single Chamber ICD clinical study, the EGM sources most commonly used were the Can to RVcoil or RVtip to RVcoil (99% of the episodes in 98% of the patients studied).
- When the EGM2 Source or the EGM2 Range is programmed to a different value, the device clears the current template from memory and starts the template creation process.

Match Threshold – Incorrect programming of the Match Threshold may result in inappropriate therapies or delayed detection of tachyarrhythmias. The diagram in Figure 138 shows the general relationship among Match Threshold, tachyarrhythmia detection, and SVT identification.

Figure 138. Wavelet performance with varying Match Threshold values

- 1 With a decrease in the Match Threshold value, the device is more likely to withhold detection of rapidly conducted SVTs (increased specificity) but is less likely to detect true VT (decreased sensitivity).
- 2 With an increase in the Match Threshold value, the device is less likely to withhold detection of rapidly conducted SVTs (decreased specificity) but is more likely to detect true VT (increased sensitivity).

Note: In the Marquis VR Single Chamber ICD clinical study, the nominal Match Threshold of 70% was used in 99% of episodes in 99% of the patients studied.

Missing template – If Wavelet is enabled but no template is available, detection will occur as if Wavelet were disabled until a new template is stored.

5.4.3 Evaluation of Wavelet

5.4.3.1 Wavelet Test

You can use the Wavelet Test to evaluate the accuracy of the current Wavelet template and, if necessary, to manually collect an updated template.

For a full description of the Wavelet Test, see Section 7.3, “Wavelet Test”, page 336.

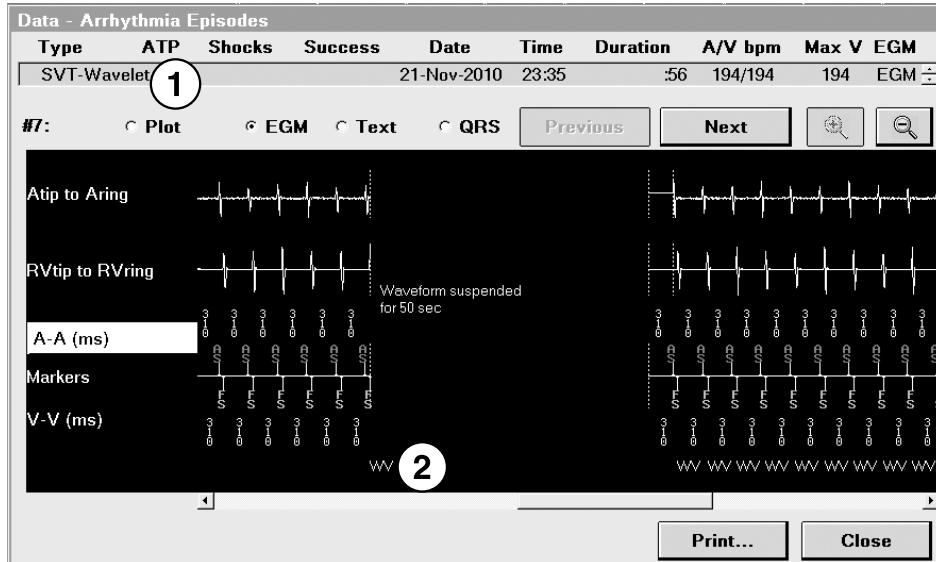
5.4.3.2 Wavelet Monitor

You can use the Wavelet Monitor mode to evaluate the potential effectiveness of Wavelet for the patient without enabling it for detection. When Wavelet has been programmed to Monitor, the device records Wavelet-related data but does not use the Wavelet feature to withhold detection.

5.4.3.3 Arrhythmia Episodes screen

To access stored episode data related to the operation of Wavelet, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data].

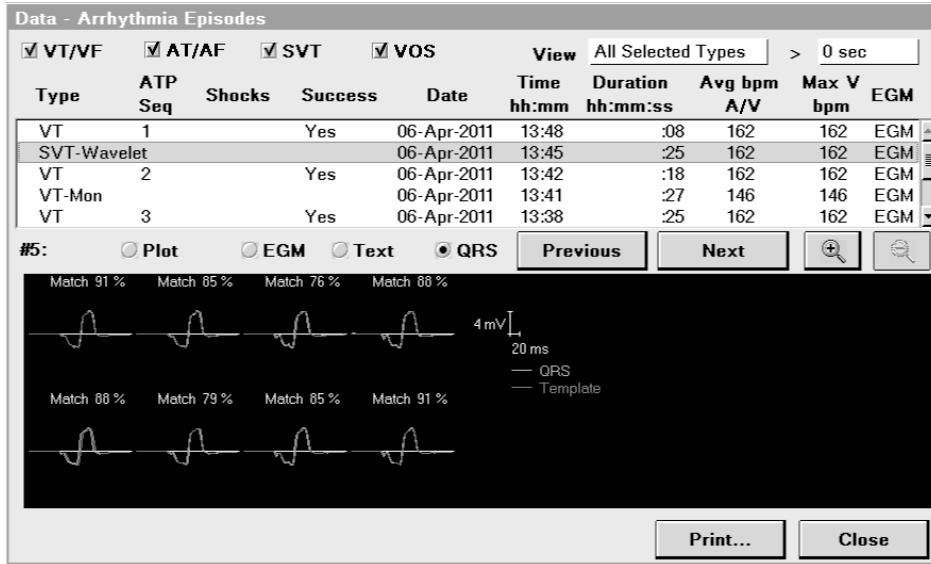
Figure 139. Episode EGM indicating that Wavelet has withheld VT/VF detection



- 1 An episode for which detection is withheld is indicated by “SVT-Wavelet”.
- 2 In the Decision Channel of the EGM display, ventricular events on which VT/VF detection was withheld by the Wavelet feature are indicated by “WV”.

5.4.3.4 QRS complexes with a high match score

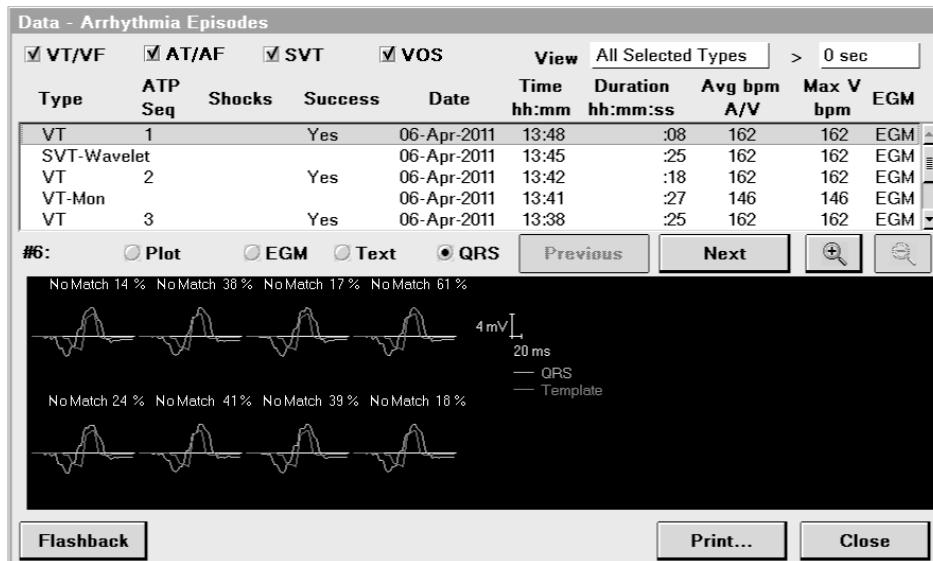
Figure 140. Recorded SVT episode showing QRS complexes that match the template



Note: Wavelet must be programmed to On or Monitor to collect QRS Snapshot data.

5.4.3.5 QRS complexes with a low match score

Figure 141. Recorded VT episode showing QRS complexes that do not match the template



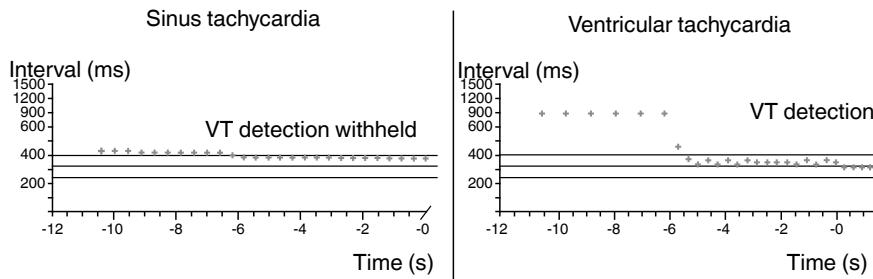
5.5 Onset

Patients experiencing sinus tachycardia may exhibit ventricular rates in the VT detection zone. If sustained, such fast ventricular rates may cause an inappropriate delivery of a ventricular tachyarrhythmia therapy. Sinus tachycardia can generally be distinguished from ventricular tachycardia by the speed of the ventricular rate increase. Typically, sinus tachycardia is characterized by a gradual ventricular rate increase, while ventricular tachycardia exhibits a sudden ventricular rate increase.

The Onset feature may help prevent detection of sinus tachycardia as VT by evaluating the acceleration of the ventricular rate. If the ventricular rate increases gradually, as typically happens during sinus tachycardia, the device does not classify sensed ventricular events that occur in the VT detection zone as VT events. If the ventricular rate increases rapidly, as typically happens during a ventricular tachycardia episode, the device does classify sensed ventricular events that occur in the VT detection zone as VT events.

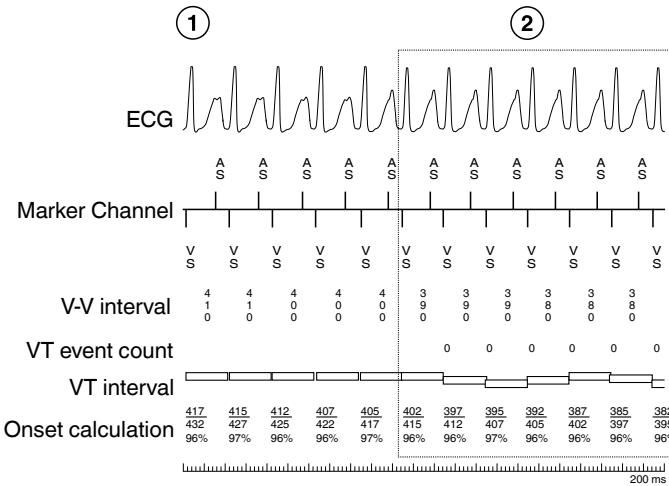
5.5.1 Operation of the Onset feature

Figure 142. Gradual vs sudden rate acceleration



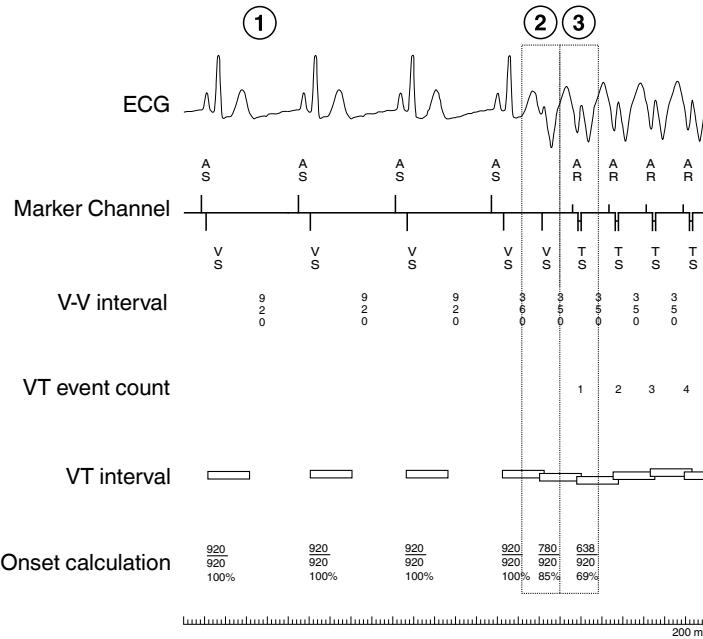
A programmable Onset Percent value is used to evaluate the suddenness or gradualness of the change in average cycle length from one set of 4 intervals to the next. If you program the Onset Percent value lower, a larger rate acceleration is required for the device to detect VT. If you program the Onset Percent value higher, a smaller rate acceleration is required for the device to detect VT.

If the ventricular rate accelerates gradually, as shown in Figure 143, then the Onset feature prevents sensed ventricular intervals that occur in the VT detection zone from being classified as VT events.

Figure 143. Operation of Onset during a gradually accelerating ventricular rate

- 1 The ventricular rate is accelerating (interval cycle lengths are decreasing).
- 2 The ventricular rate is now in the VT detection zone, but the acceleration is gradual. The average cycle length of any set of 4 intervals is never 81% or less of the previous set of 4 intervals. (81% is the Onset Percent value in this example.)

If the ventricular rate accelerates rapidly, as shown in Figure 144, then the Onset feature permits sensed ventricular intervals that occur in the VT detection zone to be classified as VT events.

Figure 144. Operation of Onset during a rapidly accelerating ventricular rate

- 1 The ventricular rate is slow and steady.
- 2 The ventricular rate increases suddenly, with the first interval occurring in the VT detection zone. However, because the average ventricular interval is 85% of the average of the previous 4 intervals (slower than the programmed Onset Percent of 81%), this interval is not classified as a VT event.
- 3 The average ventricular interval is now 69% of the average of the previous 4 intervals (faster than the programmed Onset Percent of 81%), so this interval is classified as a VT event.

5.5.1.1 VT Monitor events and the Onset feature

The Onset feature applies to both VT detection and VT monitoring.

5.5.1.2 Ensuring appropriate detection of VT and VF events

Continuing arrhythmia episodes – The Onset feature does not affect redetection of ventricular tachyarrhythmias. If a VT, FVT, or VF episode is detected, the Onset feature is suspended until the episode is terminated.

VF detection – The Onset feature does not affect VF detection. The Onset feature can prevent sensed ventricular events in the VT detection zone from being classified as VT

events, and therefore it affects VT detection, FVT via VT detection, and Combined Count detection.

5.5.2 Programming the Onset feature

To access Onset parameters, select Params > Detection (V.)...> Onset....

Exercise-induced VT episodes – Onset may delay detection of true VT in patients who experience exercise-induced ventricular tachycardia episodes.

Decreased VT detection sensitivity – With lower settings for the Onset Percent value, the device is less likely to inappropriately detect sinus tachycardia episodes as ventricular tachycardia. However, there may be a reduced likelihood of detecting true ventricular tachycardia.

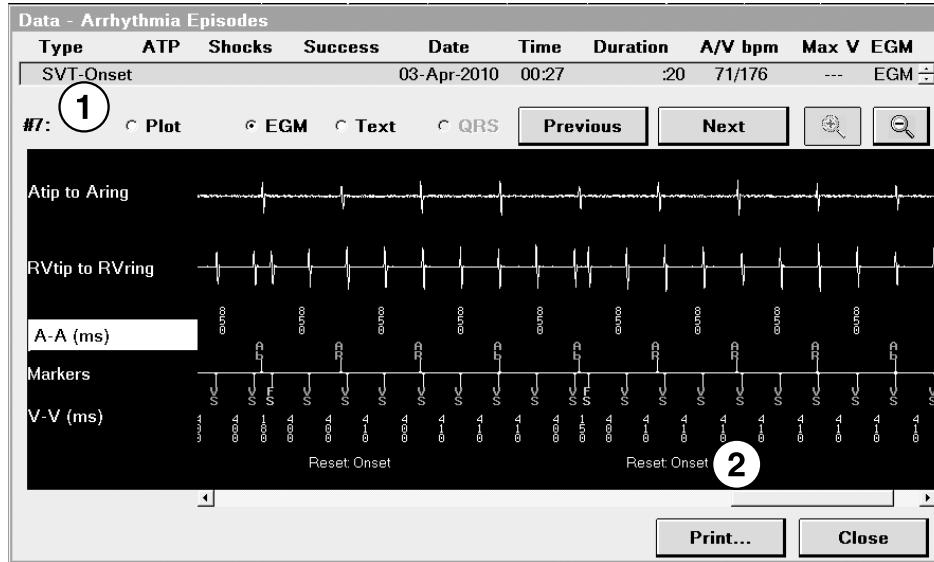
5.5.3 Evaluation of the Onset feature

The Arrhythmia Episodes screen and the Onset Monitor option may help you assess the performance of the Onset feature.

5.5.3.1 Arrhythmia Episodes screen

To access Arrhythmia Episodes EGM data, select Data > Clinical Diagnostics > Arrhythmia Episodes > EGM.

Figure 145. Onset Decision Channel annotation indicating detection withheld



- 1 An episode for which detection is withheld is indicated by "SVT-Onset".
- 2 In the Decision Channel of the EGM display, ventricular events on which VT detection was withheld by the Onset feature are indicated by "Reset: Onset".

5.5.3.2 Onset Monitor option

You can use the Monitor setting to test the potential effectiveness of the Onset feature for the patient without programming it to On.

When the Onset feature is set to Monitor, the device performs all of the calculations associated with the Onset feature, but the calculations do not affect the classification of VT intervals. If the device detects a VT or FVT via VT episode for which detection would have been withheld if the Onset feature had been programmed to On, the episode is noted in the episode text.

5.6 Stability

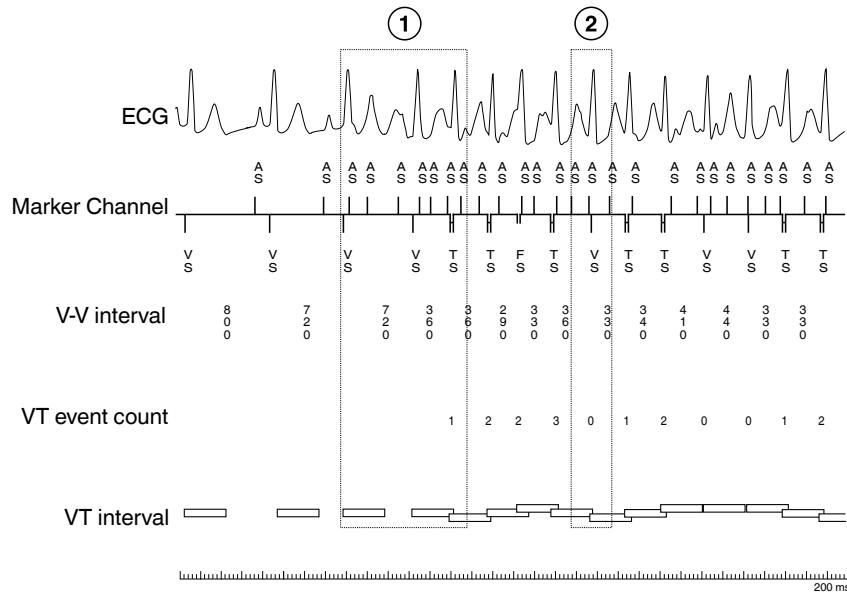
Atrial fibrillation can cause a patient's ventricular rate to accelerate into the VT detection zone, possibly triggering an inappropriate delivery of a ventricular tachyarrhythmia therapy. Atrial fibrillation is typically associated with a fast and irregular (unstable) ventricular rate. True ventricular tachycardia is typically fast but regular (stable).

The Stability feature can help prevent detection of atrial fibrillation as ventricular tachyarrhythmia by evaluating the stability of the ventricular rate. When the device determines that the ventricular rate is not stable, it does not classify ventricular intervals as VT events even if they occur in the VT detection zone.

5.6.1 Operation of the Stability feature

The Stability feature is applied when the device has counted at least 3 consecutive VT events. The device classifies an interval as unstable if the difference between it and any of the 3 previous intervals is greater than the programmed Stability interval. If the device classifies an interval as unstable, the system marks it as a sensed ventricular event and resets the VT event count to zero.

Note: The Stability feature operates throughout initial detection and redetection of VT and FVT via VT.

Figure 146. Operation of Stability during atrial fibrillation

- 1 Atrial fibrillation starts and is conducted into the ventricle at a rapid rate.
- 2 After 3 VT events, the device applies the Stability feature. Because the 360 ms interval differs from the 290 ms interval by more than the programmed Stability interval (50 ms, in this case), the device resets the VT event count.

5.6.1.1 Stability criterion for VT Monitor events

The VT Monitor zone has a non-programmable stability criterion that can reset the VT Monitor event count, but it does so independently from the VT event count. The VT Monitor event count must be at least 3 before this stability criterion is applied to events in the VT Monitor zone. Note that no data is recorded for this operation.

5.6.2 Programming the Stability feature

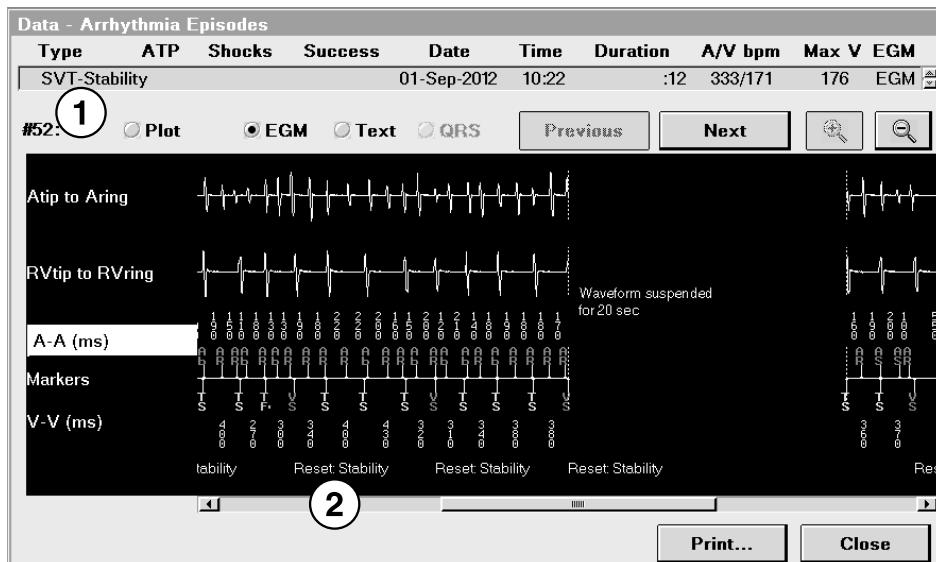
To access the Stability feature, select Params > Detection (V.)....

Stability interval – A small Stability value may not allow for normal VT interval variation and may decrease the sensitivity of the device to detect ventricular tachycardia.

5.6.3 Evaluation of the Stability feature

To access Arrhythmia Episodes EGM data that can help you assess the performance of the Stability feature, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data].

Figure 147. Stability Decision Channel annotation indicating detection withheld



- 1 An episode for which detection is withheld by the Stability feature is indicated by "SVT-Stability".
 - 2 In the Decision Channel of the EGM display, ventricular events on which detection was withheld by the Stability feature are indicated by "Reset: Stability".

5.7 High Rate Timeout

The SVT discrimination features (PR Logic, Wavelet, Onset, and Stability) are designed to withhold detection and therapy for ventricular rates classified by the device as having a supraventricular origin. For some patients, there may be a need to override the SVT discrimination features and allow therapy to be delivered when a ventricular tachyarrhythmia continues beyond a programmed length of time. For some patients, there may be a need for a separate SVT discrimination override for arrhythmias in the VF zone.

The High Rate Timeout feature allows the device to deliver therapy for any ventricular tachyarrhythmia that continues beyond a programmed length of time.

5.7.1 Operation of High Rate Timeout

You can program separate timeout periods for All Zones and for the VF Zone Only.

All Zones – The device starts the programmed High Rate Timeout period when VF, FVT, or VT detection occurs or is withheld by an SVT discrimination feature. If the tachyarrhythmia continues beyond the programmed timeout period, the device suspends all SVT discrimination features and allows the device to deliver therapy.

VF Zone Only – The device starts the programmed High Rate Timeout period when VF or FVT detection occurs or is withheld by an SVT discrimination feature. If the tachyarrhythmia continues beyond the programmed timeout period, the device suspends all SVT discrimination features and allows the device to deliver therapy.

Notes:

- When a VF Zone Only timeout occurs and the tachyarrhythmia leaves the VF zone before the timeout period expires, the timeout period is reset. If the tachyarrhythmia reenters the VF zone, the timeout starts over from the beginning.
- If, during either High Rate Timeout period, the device determines that the SVT discrimination feature no longer applies, detection occurs and therapy is delivered, regardless of the High Rate Timeout feature.
- High Rate Timeout is not applied to rates in the VT Monitor zone.

5.7.2 Programming High Rate Timeout

Table 33. How to navigate to High Rate Timeout parameters

Parameters	Path
VF Zone Only (VF Timeout value, Off) All Zones (All Zones Timeout value, Off)	Params > Detection (V)... > High Rate Timeout...

Programming both High Rate Timeout periods – If both timeout periods are programmed, the shorter timeout is applied first. The VF Zone Only timeout would normally be programmed with the shorter duration.

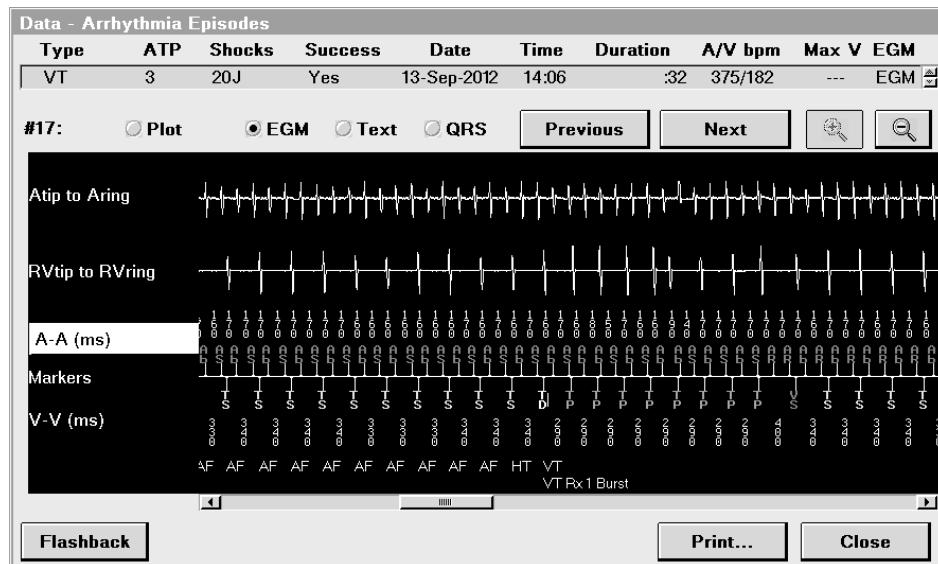
High Rate Timeout and inappropriate therapies – After the programmed High Rate Timeout period elapses and the SVT discrimination features are suspended, it is possible that the device may detect a ventricular tachyarrhythmia that is actually a conducted SVT. If so, inappropriate tachyarrhythmia therapy may be delivered.

5.7.3 Evaluation of High Rate Timeout

5.7.3.1 Arrhythmia Episodes screen

If a High Rate Timeout period expires during an episode, the stored EGM for that episode includes the “HT” Decision Channel annotation at the point when the High Rate Timeout period expired.

Figure 148. Episode EGM



If the High Rate Timeout–All Zones period expires during an episode, the Initial Type field in the episode text includes the text, “High Rate Timeout–All Zones”.

If the High Rate Timeout–VF Zone Only period expires during an episode, the Initial Type field in the episode text includes the text, “High Rate Timeout–VF Zone Only”.

5.8 TWave Discrimination

T-wave oversensing occurs when a device senses T-waves in addition to R-waves. This double-counting of ventricular events can push the ventricular rate into the VT/VF zone, leading to incorrect detection of VT or VF and delivery of inappropriate therapy.

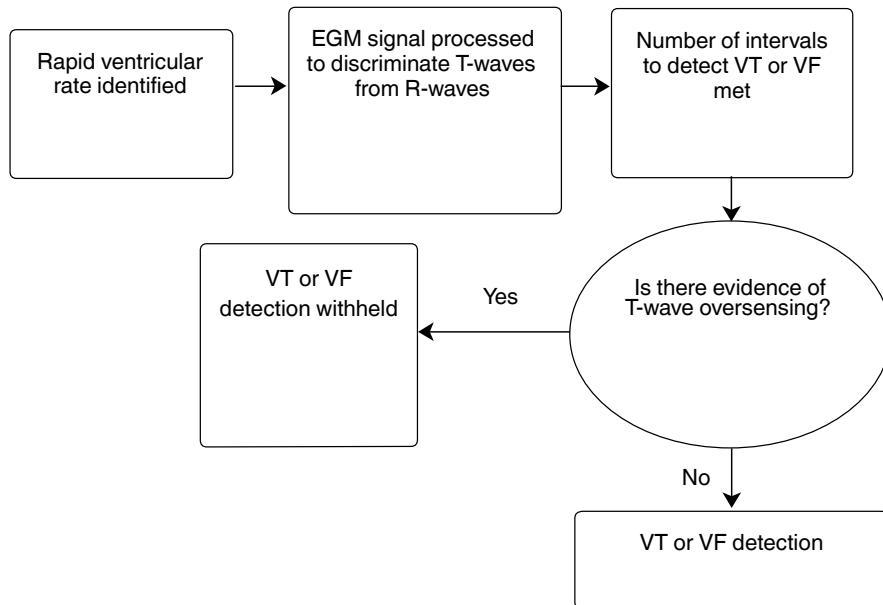
When VT or VF is suspected, TWave Discrimination processes the RV signal to determine if both R-waves and T-waves are being sensed. If both waves are sensed, detection is withheld. If only fast R-waves are sensed, VT or VF detection occurs.

5.8.1 Operation of TWave Discrimination

The TWave Discrimination feature withholds VT/VF detection when a fast ventricular rate is detected due to over-sensed T-waves. The feature operates on the assumption that R-waves and T-waves are clinically different, where R-waves generally have a higher slew rate (higher frequency) than T-waves. The feature uses the right ventricular sensing signal (RVtip to RVring or RVtip to RVcoil, as programmed) to identify T-waves by processing the EGM to highlight differences in frequency between R-waves and T-waves. Also, when T-wave oversensing is present, R- and T-waves alternate, allowing the feature to recognize the 2 waves effectively. It analyzes differences in amplitude, rate, and pattern to differentiate R-waves from T-waves. It then applies additional criteria to distinguish R and T patterns from VT/VF.

This analysis reduces the potential to deliver inappropriate therapy for high rates that are attributable to T-wave oversensing, yet it does not compromise sensitivity to VT/VF detection.

Figure 149. Overview of TWave Discrimination



Note: TWave Discrimination is applied on initial detection and on redetection.

5.8.2 Programming TWave Discrimination

To access TWave Discrimination, select Params > Detection (V)....

VT and VF redetection – If the programmed VT Redetect is less than 12 and VF Redetect values are less than 12/16, TWave Discrimination may not have enough data to distinguish T-waves from R-waves.

5.8.3 Evaluation of TWave Discrimination

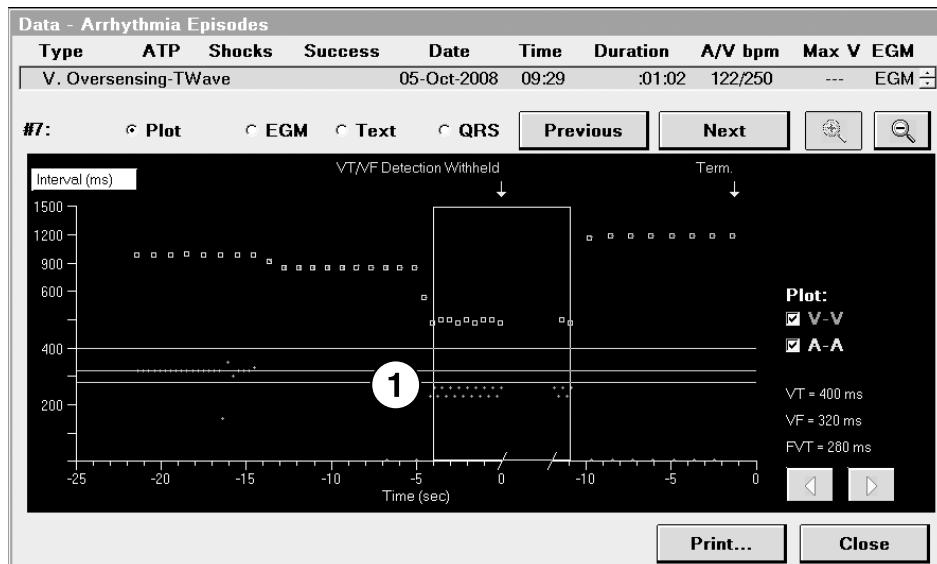
The device stores T-wave oversensing episodes in the V. Oversensing T-wave log. The episode contains the interval plot, EGM detail, episode text, and QRS snapshots. The date, time, duration, and average atrial and ventricular rates, including T-wave oversensing, are also recorded.

5.8.3.1 Episode Plot

To access Arrhythmia Episodes plots, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] > Plot.

The Episode Plot shows a T-wave oversensing episode, indicated by a pattern of 2 V-V events for every A-A event.

Figure 150. Episode Plot of a T-wave oversensing episode



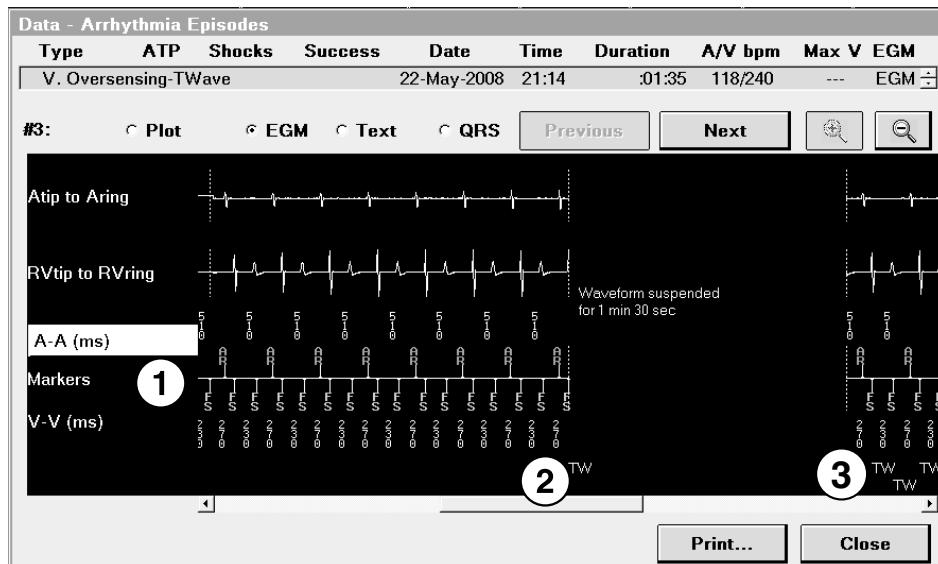
1 V-V events occur at twice the frequency of A-A events.

5.8.3.2 Episode EGM

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

In the EGM view, the annotation TW is displayed in the Decision Channel when the TWave Discrimination feature withholds VT/VF detection.

Figure 151. Episode EGM of a T-wave oversensing episode



- 1 Marker Channel shows each ventricular event is counted twice.
- 2 TW annotated upon initial detection of T-wave oversensing.
- 3 TW annotated to indicate T-wave oversensing on a per-event basis.

5.8.3.3 Episode Text

To access Arrhythmia Episodes text, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] >Text.

For T-wave oversensing episodes, the Episode Text screen lists the following types of information:

- episode summary for V.Oversensing-TWave including:
 - Duration
 - A/V Max Rate

- V. Median rate
- Activity at onset
- list of other detection criteria triggered for this episode and programmed values for all other detection features
- description of Wavelet activity, if triggered
- programmed values for VF, FVT, and VT detection and redetection at time of episode
- status (On/Off) of SVT discrimination features at time of episode

5.8.3.4 Quick Look II observations

Ventricular oversensing episodes since the last session are listed in Observations on the Quick Look II screen. To check the Quick Look II Observations list to verify T-wave oversensing episodes, select Data > Quick Look II.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

5.9 RV Lead Noise Discrimination

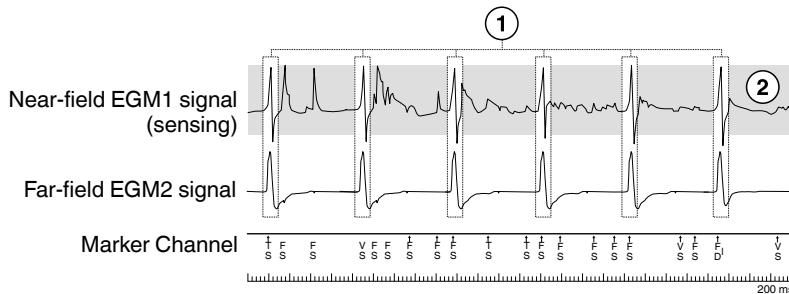
RV lead noise oversensing is caused by lead fracture, breaches in lead insulation, lead dislodgment, or improper lead connection. If the oversensing is not identified, it may cause the device to sense non-physiologic noise as rapid ventricular events. If the oversensing is sustained, such rapid ventricular rates may cause inappropriate delivery of a ventricular tachyarrhythmia therapy.

The RV Lead Noise Discrimination feature compares a far-field EGM signal to the near-field sensing signal to differentiate RV lead noise from VT/VF. If lead noise is identified when these signals are compared, VT/VF detection and therapy are withheld and an RV Lead Noise alert is triggered. This alert issues a tone to warn the patient to contact the patient's clinician, an observation to be viewed by the Medtronic programmer, and a Medtronic CareAlert Notification to warn the clinician that intervention is needed.

5.9.1 Operation of the RV Lead Noise Discrimination feature

When VT or VF is suspected, the device compares the RV sense signal to a far-field EGM signal, seen on the EGM2 channel. When the RV lead functions properly, these signals match. If the RV sense signal shows persistent activity in the VT/VF zone that is not shown on the far-field EGM signal, lead noise is determined and therapy for VT/VF is withheld.

Note: RV Lead Noise Discrimination is applied only to initial detection.

Figure 152. RV Lead Noise Discrimination

1 True events are seen simultaneously by the near-field and far-field signals.

2 Noise (shaded area) is indicated by activity on the near-field signal only.

In Figure 152, noise is identified on the near-field sensing signal when compared to the far-field EGM, which remains at baseline.

5.9.1.1 RV Lead Noise Discrimination timeout

The RV Lead Noise Discrimination feature provides a programmable timeout interval. During an uninterrupted RV lead noise event, the device withholds therapy for the duration of this interval. If the RV lead noise event persists longer than the programmed interval, therapy is delivered. The timeout interval ranges from 15 s to 2 min.

5.9.1.2 Patient alerts and Medtronic CareAlert Monitoring for RV Lead Noise alert

When the RV Lead Noise alert is on, the device sounds a patient alert tone if VF/VT detection is withheld due to lead noise. This tone then sounds every 4 hours beginning at the next scheduled 4-hour time interval (00:00, 04:00, 08:00 ...). The alert tone also sounds at the programmed Alert Time and when a magnet is placed over the device. The alert tone continues to sound until the alert is cleared (or until Device Tone is set to Off). If the Patient Home Monitor alert for the RV Lead Noise alert is programmed to On, the device also attempts to send a wireless transmission to a Medtronic patient monitor. For more information, see Section 3.2, "Medtronic CareAlerts and notifications", page 73.

5.9.2 Programming the RV Lead Noise Discrimination feature

To access RV Lead Noise parameters, select Params > Detection (V.)...> RV Lead Noise....

Note: The RV Lead Noise alert can be programmed on only if the RV Lead Noise Discrimination feature is programmed to On or On+Timeout.

EGM2 programming – If RV Lead Noise is programmed to On or On+Timeout, the EGM2 channel must be programmed to Can to RVcoil or RVcoil to SVC.

5.9.3 Programming the RV Lead Noise alert

Note: The Medtronic CareAlert Setup screen shows either a Lead/Device Integrity Alerts view or a Clinical Management Alerts view. To switch between views, select either [Clinical Management Alerts...] or [Lead/Device Integrity Alerts...].

Note: Programming each Device Tone alert includes setting the alert urgency. Alerts for the Patient Home Monitor do not have an urgency setting.

To access the RV Lead Noise Alert, select Params > Alert...> Lead/Device Integrity Alerts... > RV Lead....

5.9.4 Evaluation of an RV Lead Noise Discrimination event

If the device is sounding an RV Lead Noise alert tone or if the programmer indicates that an RV Lead Noise Discrimination event has occurred, review the alert messages and evaluate the diagnostic data to determine the likelihood of RV lead noise.

Notes:

- The device records RV lead noise oversensing episode summaries only if the RV Lead Noise Discrimination feature is programmed to On or On+Timeout.
- The device sounds an RV Lead Noise alert tone only if the RV Lead Noise Discrimination feature is programmed to On or On+Timeout and the RV Lead Noise alert is programmed to On.

5.9.4.1 Episode Text

To access Arrhythmia Episodes text, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] >Text.

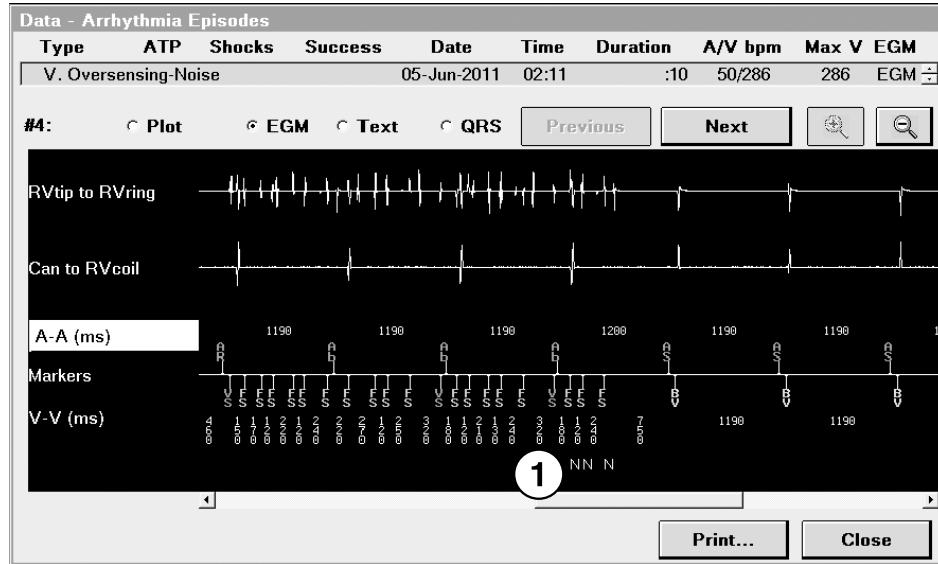
For RV lead noise oversensing episodes, the episode text screen offers the following types of information:

- episode summary for V. Oversensing-Noise including:
 - Duration
 - A/V Max Rate
 - V. Median rate
 - Activity at onset
- list of other detection criteria triggered for this episode and programmed values for all other detection features
- description of Wavelet activity, if triggered
- programmed values for VF, FVT, and VT detection and redetection at time of episode
- status (On/Off) of SVT discrimination features at time of episode

5.9.4.2 Episode EGM

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

The Decision Channel annotation “N”, indicating RV Lead Noise Discrimination, is displayed when the feature withholds ventricular tachyarrhythmia detection. The annotation “NT” is displayed when RV Lead Noise Discrimination times out.

Figure 153. Episode EGM for RV Lead Noise Discrimination event

1 "N" annotated upon detection of RV lead noise.

5.9.4.3 CareAlert pop-up window

When the device is interrogated, a CareAlert window notifies you that an alert condition exists, including the RV Lead Noise alert.

5.9.4.4 Quick Look II observations

To check the Quick Look II Observations list to verify that there is an RV lead noise warning, select Data > Quick Look II.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, "Quick Look II summary data", page 69.

5.9.4.5 Medtronic CareAlert Events

To check the CareAlert Events list to verify that there is an RV lead noise warning, select Data > Alert Events.

6 Tachyarrhythmia therapy features

6.1 Atrial therapy scheduling

An AT/AF episode is detected when a sustained atrial tachyarrhythmia occurs. Treatments for these episodes are intended to interrupt the atrial tachyarrhythmia and restore the patient's normal sinus rhythm. During an episode there may be changes in the atrial rhythm or in the underlying substrate. These changes might make it possible to terminate the episode with a therapy that had been unsuccessful.

Atrial therapies are scheduled for delivery throughout the duration of an AT/AF episode. You have the flexibility to determine how the device delivers the therapies by programming the atrial therapy parameters related to scheduling. Each time that an AT/AF therapy is required, the device schedules one of the available therapies in accordance with your programming.

See the following sections for information about atrial detection and therapies:

- Section 5.1, “AT/AF detection”, page 224
- Section 6.2, “Atrial ATP therapies”, page 282
- Section 6.3, “Atrial cardioversion”, page 292

6.1.1 Operation of atrial therapy scheduling

The device schedules the delivery of automatic atrial therapies. Programmable options allow you to set the conditions for delivering antitachycardia pacing (ATP) and automatic atrial cardioversion (CV) therapies. Reactive ATP is an option that allows the device to deliver ATP therapies that had been unsuccessful earlier in the episode.

Patient-activated atrial cardioversion therapies are delivered, if requested by the patient, provided that an AT/AF episode is in progress. For more information, see Section 6.4, “Patient-activated atrial cardioversion”, page 298.

6.1.1.1 Episode duration

The system allows you to define when atrial ATP and atrial CV 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.
- The programmed Automatic CV value of the Episode Duration Before Rx Delivery parameter determines when automatic atrial CV therapies become available.
- If a time limit is programmed for Duration to Stop, no atrial therapies are scheduled after the episode duration reaches the Duration to Stop value.

6.1.1.2 Requirements for scheduling an automatic atrial therapy

At initial detection and at each subsequent redetection, an atrial therapy is scheduled from the therapies available. For atrial ATP sequences and automatic atrial CV therapies to be scheduled, the following conditions must 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.
- When automatic atrial CV therapies become available, they have priority over the delivery of ATP sequences. After all possible CV therapies have been delivered, the remaining ATP sequences become available again.

Some additional requirements apply to automatic atrial CV therapies.

An automatic atrial CV therapy is scheduled only if the episode duration occurs within a programmable delivery window. The delivery window is determined by 2 parameters listed under Automatic CV Limits. These parameters allow you to program the Start Time and length of the delivery window.

Automatic atrial CV therapies can be delivered only if 10 or more of the 12 most recent ventricular intervals are greater than or equal to the programmed R-R Minimum Interval.

To limit the number of atrial shocks, you can program the Maximum Shocks per Day parameter (listed under Automatic CV Limits). When the total number of automatic atrial shocks and patient-activated atrial shocks reaches the programmed limit, no more automatic atrial CV therapies can be delivered until the next delivery window. Patient-activated atrial CV therapies remain available.

Device longevity is protected by a limit to ineffective atrial cardioversion charges. This limit is not programmable, and it pertains to both automatic and patient-activated atrial CV therapies. Neither type of CV therapy is scheduled during an atrial episode after 15 atrial CV therapies have been aborted within that episode. For more information, see Section 6.3, “Atrial cardioversion”, page 292.

6.1.1.3 Using the Fast AT/AF detection zone

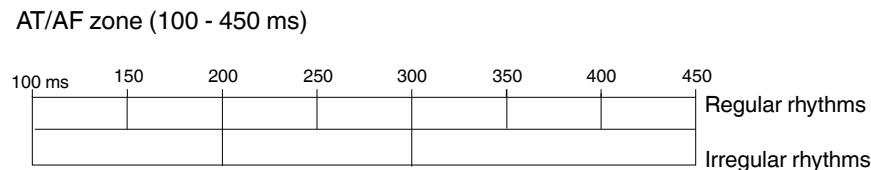
Atrial tachyarrhythmia detection can be programmed for 2 detection zones: AT/AF and Fast AT/AF. Each zone has a unique set of programmed therapies. The device schedules each therapy from the appropriate set for that zone. The availability of individual therapies may depend on the median atrial interval in effect each time that detection occurs.

6.1.1.4 Reactive ATP

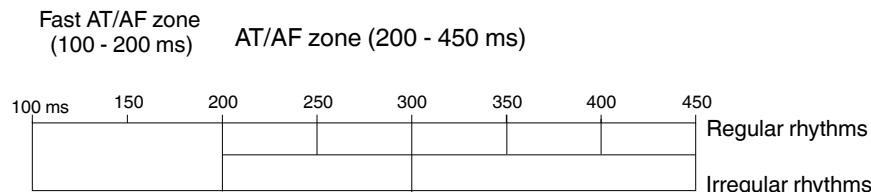
In some cases, the programmed set of atrial ATP therapies may not initially terminate an atrial tachyarrhythmia. Additional attempts at termination with the same set of atrial ATP therapies may be successful, particularly if the atrial rhythm changes. Reactive ATP makes it possible for the device to 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. Refer to Figure 154. 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.

Figure 154. 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 155. The Fast AT/AF zone is not subdivided, and Fast AT/AF ATP therapies are not affected by this type of Reactive ATP.

Figure 155. 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 6.1.4.

Time Interval – Time Interval allows the device to schedule additional ATP therapies regardless of rhythm changes.

All ATP sequences become available when the episode duration value reaches a multiple of the programmed Time Interval. This applies to ATP therapies for both the AT/AF zone and the Fast AT/AF zone. This function is available only within the first 48 hours of an atrial episode.

6.1.1.5 Automatically disabling atrial therapies

In some situations the device may automatically disable or suspend an atrial therapy.

VT/VF detection after an AT/AF therapy delivery – Atrial therapies are disabled if VT/VF is detected immediately after an AT/AF therapy is delivered. In this case, atrial therapies remain disabled until you reprogram them.

VT/VF detection unrelated to AT/AF therapy delivery – If the device detects VT/VF 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/VF 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 but a ventricular tachyarrhythmia episode is not detected, the device immediately disables all atrial ATP therapies for the remainder of the episode. If this type of rate acceleration occurs in 3 episodes, the device disables atrial ATP therapies until the therapies are reprogrammed. You can program this option using the “Disable atrial ATP if it accelerates V. Rate” parameter.

Atrial lead position suspect – The device checks atrial lead position every 24 hours. The Atrial Lead Position Check occurs only if the pacing mode includes atrial pacing. The check is disabled during mode switching, telemetry sessions, and any tachyarrhythmia episodes. The check paces the atrium with a series of high-output pulses. It determines the number of AP-VS intervals in the series that are shorter than 80 ms. A large number of short intervals indicates that the lead may no longer be positioned in the atrium. If the lead check fails, all atrial therapies are disabled until they are reprogrammed. You can program this option using the “Disable all atrial therapies if atrial lead position is suspect” parameter.

6.1.2 Programming considerations for atrial therapy scheduling

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.

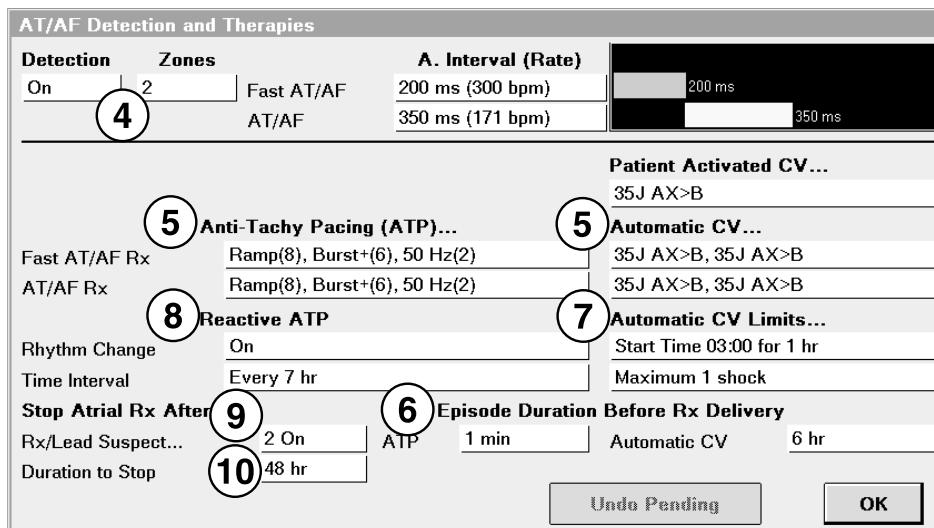
Atrial Lead Position Check and Ventricular Safety Pacing – The lead position check cannot be enabled unless Ventricular Safety Pacing is enabled.

VF detection during AT/AF – To ensure VF detection during AT/AF episodes, AT/AF Detection cannot be programmed to On unless VF Detection is also programmed to On.

Timing for the CV therapy window – Verify that the device clock is accurately set when setting the Start Time for the CV delivery window. The Start Time is set relative to the device clock, which is set on the Data Collection Setup screen.

6.1.3 Programming atrial therapy scheduling

1. Select the Params icon.
2. Set AT/AF Detection to On.
3. Select the Therapies... field for AT/AF to open the AT/AF Detection and Therapies window.

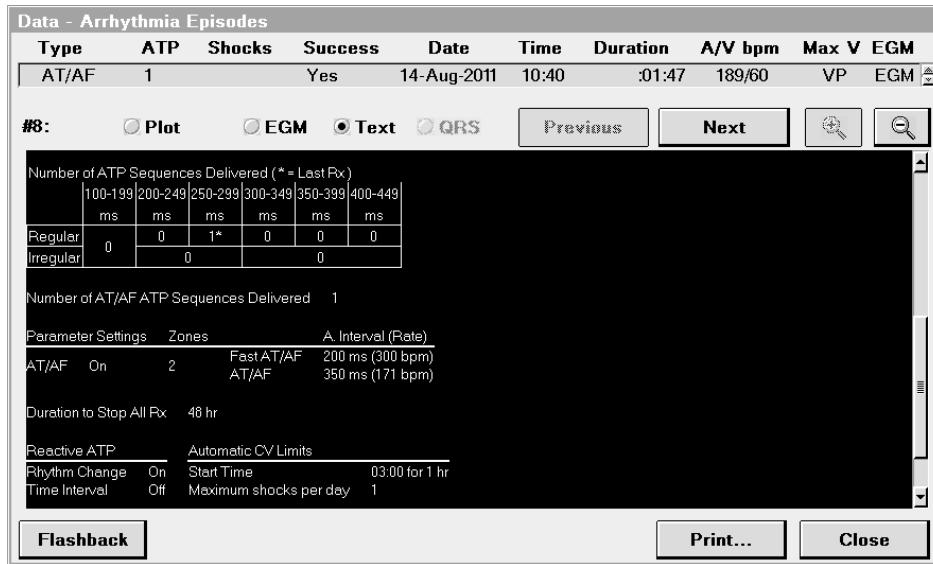


4. Set the number of Zones to 1 or 2 as appropriate for the patient.
5. Select the desired ATP and Automatic CV therapies.
6. Select the desired values for Episode Duration Before Rx Delivery (ATP and Automatic CV).
7. Select the desired Automatic CV Limits (delivery window and maximum shocks per day).
8. Select the desired values for Reactive ATP (Rhythm Change and Time Interval).
9. Select whether atrial therapies should be disabled if rate acceleration occurs or if the lead position is suspect.
10. Select the desired value for Duration to Stop.
11. Return to the Parameters screen and select [PROGRAM].

6.1.4 Evaluation of atrial therapy scheduling

To access Arrhythmia Episodes text, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] >Text.

Figure 156. 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 number of automatic CV shocks that were delivered, if any
- the number of patient-activated shocks that were delivered, if any
- the programmed values for AT/AF Detection, Duration to Stop, Reactive ATP, Automatic CV limits, and the EGM and Sensitivity settings

6.2 Atrial ATP therapies

The device detects sustained atrial tachycardia as an AT/AF episode. Treatments for such episodes are intended to interrupt the atrial tachycardia and restore the patient's normal sinus rhythm. Pacing therapy can be an option for terminating an atrial tachycardia episode.

The device can respond to an AT/AF episode by delivering atrial antitachycardia pacing (ATP) therapies to the patient's heart. Atrial ATP therapies are designed to interrupt the AT/AF reentrant activation pattern and restore the patient's normal sinus rhythm. ATP therapies deliver pacing pulses instead of high-voltage shocks delivered in cardioversion therapy.

For more information, see Section 5.1, "AT/AF detection", page 224 and Section 6.3, "Atrial cardioversion", page 292.

6.2.1 Operation of atrial ATP therapies

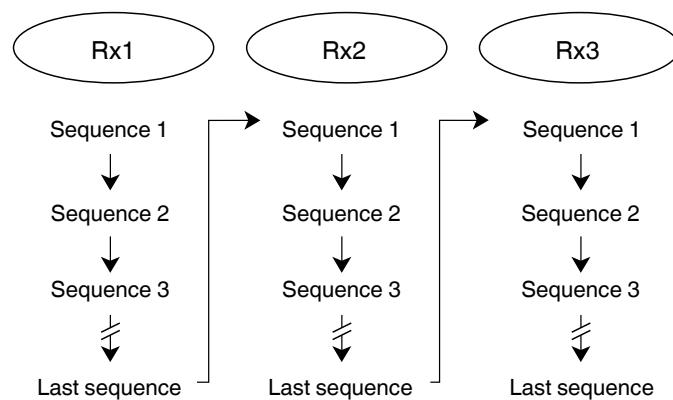
The device can deliver up to 3 ATP therapies to treat an AT/AF or a Fast AT/AF episode. Atrial ATP therapies are Burst+, Ramp, and 50 Hz Burst, each with a programmable number of sequences. All atrial ATP therapies are delivered in the AOO mode.

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 and the next scheduled therapy is an ATP therapy, 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 the device redetects the atrial tachycardia episode and if atrial therapy scheduling has not made a cardioversion therapy available, 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 and an atrial cardioversion therapy is not yet available, the device starts delivering the next scheduled ATP therapy.

Notes:

- When automatic atrial CV therapies become available, they have priority over the delivery of ATP sequences. After all possible CV therapies have been delivered, the remaining ATP sequences become available again.
- 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 an ATP therapy and starts the next scheduled therapy for a Fast AT/AF episode. If the episode then decelerates into AT/AF, this shift is detected, and the device delivers the next sequence of AT/AF therapy.
- The device 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. However, the 10 min delay does not apply if the previous AT/AF therapy is a 50 Hz Burst therapy.
- Atrial detection is suspended during the delivery of an atrial ATP therapy sequence.

Figure 157. Overview of atrial ATP therapy delivery

For an overview of atrial ATP sequence delivery, see Figure 158.

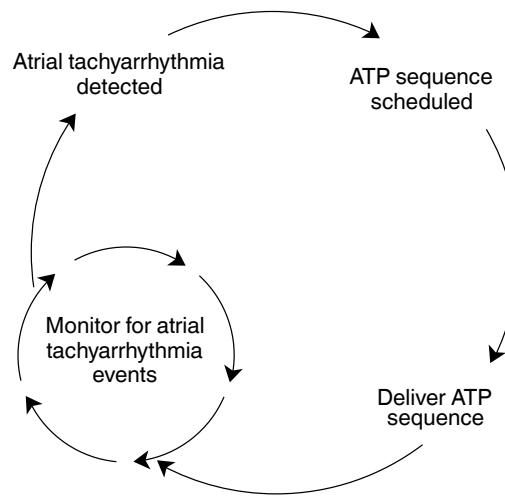
6.2.1.1 Atrial ATP therapy scheduling

The device prepares to deliver an atrial ATP therapy if the following conditions are met:

- An atrial episode is in progress at the time of the scheduled delivery.
- Atrial ATP therapy sequencing indicates that ATP therapies are enabled for the given rhythm classification (AT/AF or Fast AT/AF).
- There is an unused atrial ATP therapy remaining for that classification.

For details about atrial ATP therapy scheduling, see Section 6.1, “Atrial therapy scheduling”, page 275.

Figure 158. Overview of atrial ATP sequence delivery



6.2.1.2 Atrial ATP therapy pacing rate and output

Minimum limit for atrial ATP pacing interval – The Burst+ and Ramp pacing intervals are based on programmed percentages of the atrial tachycardia cycle length, which is calculated as the median of the last 12 atrial intervals prior to therapy delivery. The median atrial tachycardia cycle length can vary from one sequence in a therapy to the next, and the ATP pacing intervals vary accordingly.

The programmable A-A Minimum ATP Interval parameter limits the pacing intervals at which the Burst+ and Ramp pacing pulses are delivered. If some calculated intervals are shorter than the programmed A-A Minimum ATP Interval, the pulses are delivered at the A-A Minimum ATP Interval.

If the median of the last 12 A-A intervals is shorter than the programmed A-A Minimum ATP Interval, the device does not deliver Burst+ or Ramp therapies until the atrial rate slows.

Note: There is no minimum interval limit for the atrial 50 Hz Burst therapy.

Pacing output for ATP therapies – The A. Pacing Amplitude and A. Pacing Pulse Width parameter values are the same for all atrial ATP therapies, but they are programmed separately from the pacing amplitude and pulse width for bradycardia pacing pulses.

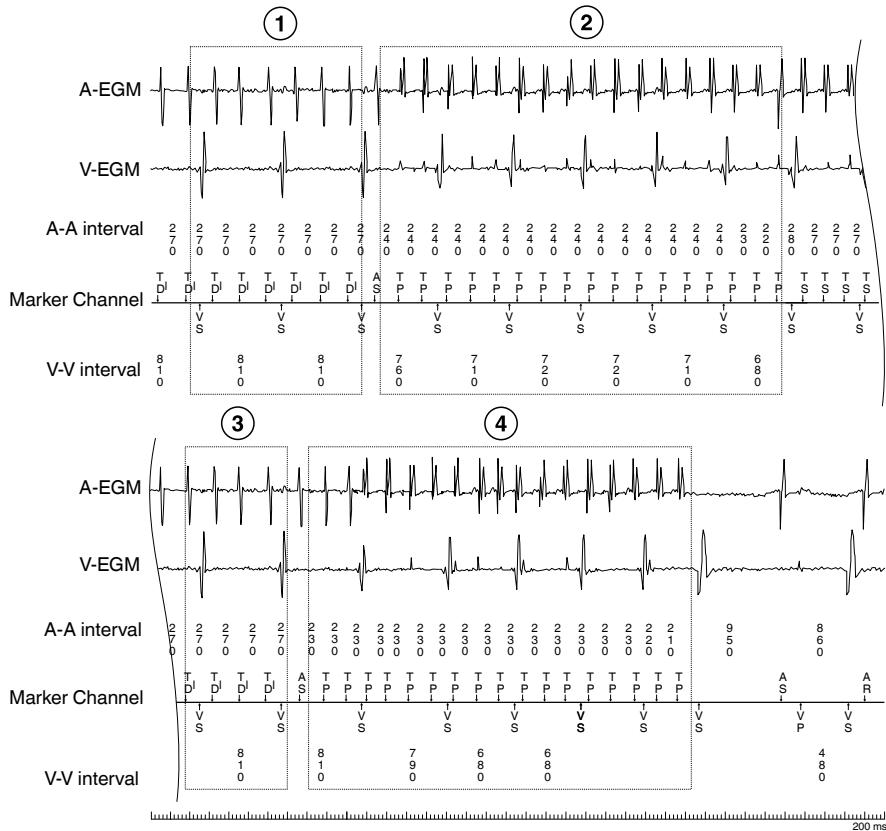
6.2.1.3 Operation of Burst+ pacing

The programmable parameter Initial #S1 Pulses sets the number of Initial #S1 Pulses in each Burst+ therapy sequence. A-S1 Interval (%AA), S1-S2 (%AA), and S2-S3 Decrement are programmable parameters that determine the pacing intervals in a Burst+ sequence.

Each Burst+ sequence consists of the programmed number of Initial #S1 Pulses, followed by up to 2 additional pulses, if the parameters for these pulses are programmed to On. The pacing intervals for the first Burst+ sequence and additional pulses are determined as percentages of the atrial tachycardia cycle length. In the first Burst+ sequence, all Initial #S1 Pulses are delivered at the same pacing interval, which is determined by the A-S1 Interval (%AA) percentage. The first additional pulse is delivered at an interval determined by the S1-S2 (%AA) percentage. The pacing interval for the subsequent pulse is calculated by subtracting the S2-S3 Decrement value from the previous interval. This pulse is delivered only if the S1-S2 (%AA) parameter is programmed to On.

If the atrial tachycardia is redetected after an unsuccessful sequence, the device delivers another Burst+ sequence with shorter pacing intervals. For this sequence, the device calculates the pacing intervals by subtracting the programmed Interval Decrement value from each pacing interval in the previous sequence.

VVI ventricular backup pacing is available during Burst+ pacing.

Figure 159. Example of Burst+ pacing operation

- 1 The device detects an AT/AF episode.
- 2 The first Burst+ sequence is delivered with 15 pulses at pacing intervals of 240 ms. The sequence continues with 2 additional pulses at intervals shorter than 240 ms. The interval is decremented by 10 ms for each additional pulse. This sequence fails to terminate the AT/AF episode.
- 3 The device redetects the AT/AF episode.
- 4 The second Burst+ sequence is delivered with 15 pulses at pacing intervals of 230 ms. The sequence continues with 2 additional pulses at intervals shorter than 230 ms. The interval is decremented by 10 ms for each additional pulse. This sequence terminates the AT/AF episode.

6.2.1.4 Operation of Ramp pacing

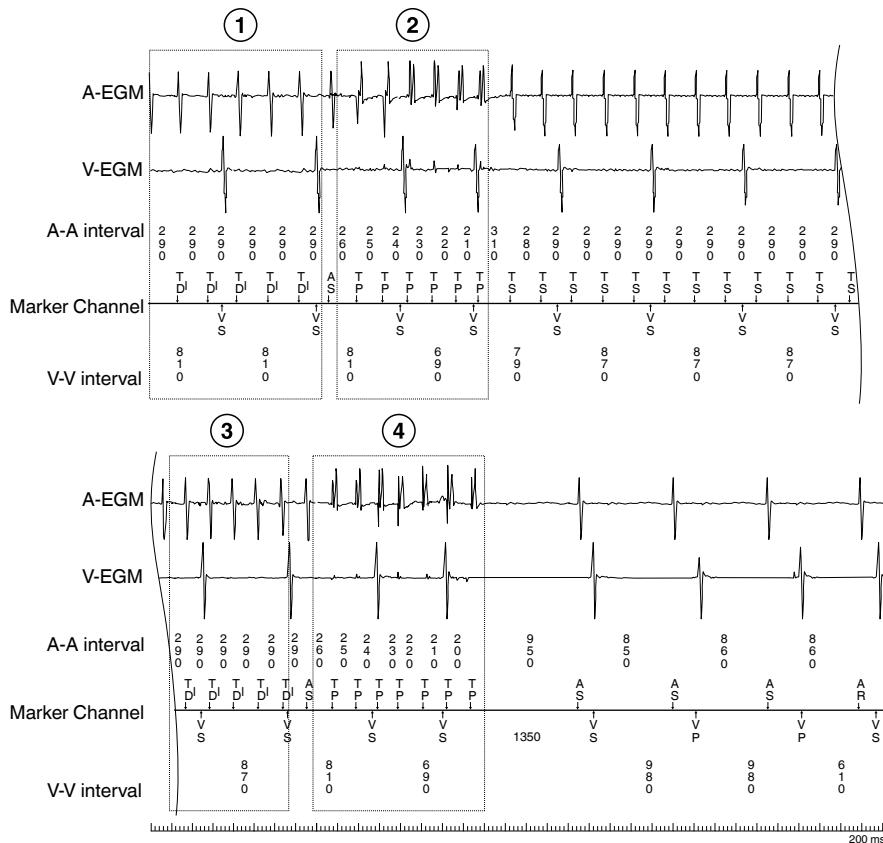
The Initial #S1 Pulses parameter sets the number of pulses in the first Ramp sequence. A-S1 Interval (%AA) and Interval Decrement are programmable parameters that determine the Ramp pacing intervals.

Each Ramp therapy sequence consists of the programmed number of pulses delivered at decreasing pacing intervals. In each sequence, the first pulse is delivered at a pacing interval determined by the A-S1 Interval (%AA) parameter as a percentage of the atrial tachycardia cycle length. The remaining pulses in the sequence are delivered at progressively shorter pacing intervals by subtracting the Interval Decrement value for each pulse.

If the atrial tachycardia is redetected after an unsuccessful sequence, the device applies the programmed A-S1 Interval (%AA) percentage to the new atrial tachycardia cycle length at redetection to determine the initial pacing interval for the next sequence. Each sequence contains one more pacing pulse than the previous sequence.

VVI ventricular backup pacing is available during Ramp pacing.

Figure 160. Example of Ramp pacing operation

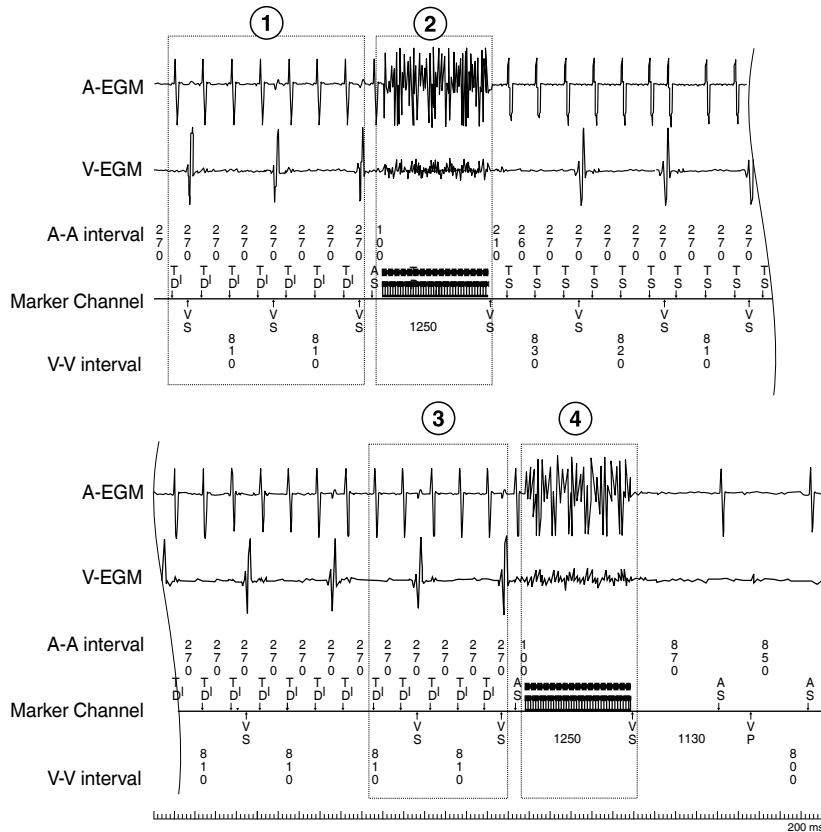


- 1 The device detects an AT/AF episode.
 - 2 The first Ramp sequence is delivered with 6 pulses. The first interval is 260 ms, and each interval that follows is decremented 10 ms, the Interval Decrement value. This sequence fails to terminate the AT/AF episode.
 - 3 The device redetects the AT/AF episode.
 - 4 The second Ramp sequence is delivered with 7 pulses. The first interval is 260 ms, and each interval that follows is decremented 10 ms, the Interval Decrement value. This sequence terminates the AT/AF episode.
-

6.2.1.5 Operation of 50 Hz Burst pacing

The device delivers a 50 Hz Burst therapy sequence with a burst of pulses at 20 ms pacing intervals for the programmed 50 Hz Burst Duration. Each time the atrial tachyarrhythmia is redetected, the device delivers another identical 50 Hz Burst sequence until delivering the last programmed sequence. Atrial therapy scheduling is delayed for 16 ventricular events after each 50 Hz Burst therapy sequence.

VOO ventricular backup pacing is available during 50 Hz Burst therapy.

Figure 161. Example of 50 Hz Burst pacing operation

- 1 The device detects an AT/AF episode.
- 2 The first 50 Hz Burst sequence is delivered for a programmed duration. This sequence fails to terminate the AT/AF episode.
- 3 The device redetects the AT/AF episode.
- 4 An identical 50 Hz Burst sequence is delivered. This sequence terminates the AT/AF episode.

6.2.1.6 Ventricular backup pacing during an atrial ATP therapy

Ventricular backup pacing in the VVI and VOO modes 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/VOO Backup Pacing:

- On (Always): backup pacing is delivered during every atrial ATP therapy.
- On (Auto Enable): backup pacing is delivered if 1 of the 4 ventricular events preceding the therapy is paced. When Auto Enable is selected, the device monitors for rapidly conducting ventricular sense events that may occur during an ATP therapy delivery.

Note: VVI Backup Pacing could be competitive with intrinsic ventricular activity during the atrial ATP sequence.

6.2.1.7 Automatically disabling atrial therapies

In some situations the device may automatically disable or suspend an ATP therapy.

VT/VF detection after an AT/AF therapy delivery – Atrial therapies are disabled if VT/VF is detected immediately after an AT/AF therapy is delivered. In this case, atrial therapies remain disabled until you reprogram them.

VT/VF detection unrelated to AT/AF therapy delivery – If the device detects VT/VF during an AT/AF episode and the detection is not related to therapy delivery, the device temporarily suspends atrial therapies. Atrial therapies automatically resume when the VT/VF episode ends.

For information about programmable options that disable therapies, see Section 6.1, “Atrial therapy scheduling”, page 275.

6.2.2 Programming atrial ATP therapies

Navigation to parameters for ATP therapies in the AT/AF zone is in Table 34. To navigate to parameters for ATP therapies in the Fast AT/AF zone, select Params > AT/AF Therapies...> 2 Zones > Fast AT/AF Rx Anti-Tachy Pacing (ATP)....

Table 34. How to navigate to parameters for atrial ATP therapies in the AT/AF zone

Parameters	Path
AT/AF Rx (Rx1, Rx2, Rx3) AT/AF Rx Status (On, Off)	Params > AT/AF Therapies... > AT/AF Rx Anti-Tachy Pacing (ATP)...
Therapy Type (Burst+) Burst+ therapy parameters	
Therapy Type (Ramp) Ramp therapy parameters	
Therapy Type (50 Hz Burst) 50 Hz Burst Therapy parameters	
Shared A. ATP therapy parameters	Params > AT/AF Therapies... > AT/AF Rx Anti-Tachy Pacing (ATP)...

Backup pacing for 50 Hz Burst therapy – VOO backup pacing is competitive with the intrinsic ventricular rate if there is an intrinsic rate.

VF therapy – You must program VF therapy to On before programming atrial ATP therapies to On.

AT/AF Detection – Make sure that AT/AF Detection is programmed to On before programming atrial ATP therapies. The device does not deliver Atrial ATP therapies if AT/AF Detection is not programmed to On.

6.2.3 Evaluation of atrial ATP therapies

6.2.3.1 The Quick Look II screen

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

Treated AT/AF episodes – This section includes a count of treated AT/AF episodes. You can select the Treated [>>] button to view the data for treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information about an observation is available, you can select the observation and then select the Observations [>>] button to view related information.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

6.2.3.2 AT/AF therapy counters

To access AT/AF therapy counter information, select Data > Clinical Diagnostics > Counters > AT/AF Rx.

The AT/AF therapy counters provide information that helps you to evaluate the efficacy of atrial ATP therapies delivered since the last session. These counters also include data about high-voltage atrial therapies.

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.

6.3 Atrial cardioversion

An AT/AF episode is detected when sustained atrial tachycardia occurs. Treatments for these episodes are intended to interrupt the atrial tachyarrhythmia and restore sinus rhythm. Atrial ATP therapies may terminate these episodes. High-voltage therapies may terminate these episodes if ATP therapies are ineffective.

The device can respond to an AT/AF episode by delivering atrial cardioversion therapy to the patient's heart. Cardioversion is intended to terminate the episode by simultaneously depolarizing the heart tissue and restoring the patient's normal sinus rhythm.

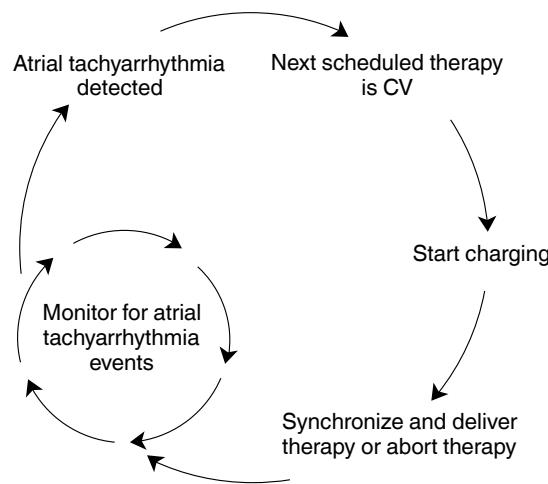
Atrial cardioversion is delivered automatically when it is scheduled by the device. Optionally, it can be delivered when the patient uses the patient assistant to request it.

For related information, see the following sections:

- Section 5.1, “AT/AF detection”, page 224
- Section 6.1, “Atrial therapy scheduling”, page 275
- Section 6.4, “Patient-activated atrial cardioversion”, page 298

6.3.1 Operation of atrial cardioversion

When an automatic atrial cardioversion (CV) is scheduled to be delivered during an AT/AF episode, the device charges the high-voltage capacitors to the programmed energy level and attempts to synchronize the shock to a sensed ventricular event outside the ventricular vulnerable period. If synchronization cannot occur, the device aborts the therapy.

Figure 162. Overview of automatic atrial cardioversion (CV)

6.3.1.1 Delivering high-voltage therapies

To deliver an atrial cardioversion therapy, the device must first charge its high-voltage capacitors to the programmed energy level. The length of time required to charge the capacitors depends on the programmed energy level and battery depletion. The delivered energy level is programmed independently for each cardioversion therapy. Cardioversion pulses use a biphasic waveform in which the current pathway for the high-voltage pulse is reversed midway through the pulse delivery.

See the device manual for the following information:

- typical full-energy capacitor charging periods
- comparison of delivered and stored energy levels

During the capacitor-charging period, the device continues to pace and sense in the programmed pacing mode. However, it freezes Rate Response operation and disables the atrial intervention pacing features.

6.3.1.2 Selecting the high-voltage electrodes and current pathway

The Active Can/SVC Coil parameter and the Pathway parameter specify the electrodes and direction of current flow for defibrillation and cardioversion pulses. The Active Can/SVC Coil parameter has the following settings:

- The Can+SVC On setting connects the Active Can and the SVC Coil. Current flows between these electrodes and the RV Coil.
- The Can Off setting disables the Active Can feature. In this case, an SVC lead must be implanted. Current flows between the SVC Coil and the RV Coil.
- The SVC Off setting ensures that the SVC lead, if implanted, is not used. Current flows between the Active Can and the RV Coil.

The settings for the Pathway parameter are AX>B and B>AX. AX refers to the Active Can and SVC Coil electrodes, which may be used individually or in combination. B refers to the RV Coil electrode. The Pathway setting defines direction of current flow during the initial segment of the biphasic waveform. If the parameter is set to AX>B, current flows from the Active Can and SVC Coil to the RV Coil. If the parameter is set to B>AX, this current flow is reversed.

6.3.1.3 Scheduling an automatic atrial cardioversion

The device schedules an automatic CV therapy if the following conditions are met:

- CV is enabled for the given rhythm classification (AT/AF or Fast AT/AF).
- An undelivered CV therapy is available for the given rhythm classification.
- An atrial episode is in progress at the time of the scheduled delivery.
- The episode duration occurs within a programmable delivery window.
- The maximum number of atrial shocks per day has not been reached.

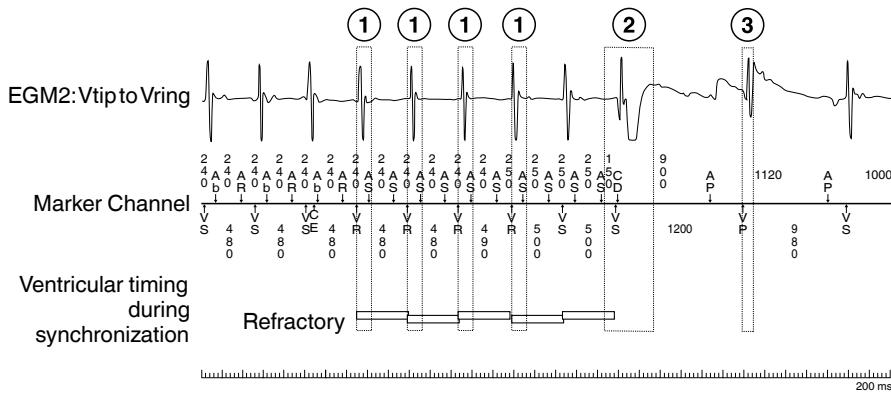
For more information, see Section 6.1, “Atrial therapy scheduling”, page 275. When the CV therapy is scheduled, the device starts charging the capacitors.

6.3.1.4 Synchronizing atrial cardioversion

After charging is complete, the device starts a synchronization interval on the next sensed or paced ventricular event. The synchronization interval is equal to the Lower Rate pacing interval. The device uses the synchronization interval to identify the R-wave to deliver the shock. The atrial cardioversion therapy is delivered on the second ventricular event that is outside the ventricular refractory period. The length of the ventricular refractory period is set by the shared programmable parameter called the Minimum R-R Interval. During synchronization, a ventricular event inside the ventricular refractory period restarts the synchronization interval. The timing of a typical synchronization for atrial cardioversion is shown in Figure 163.

The device attempts to synchronize atrial cardioversion with sensed ventricular events. In the absence of sensed ventricular activity, the device delivers the atrial shock when the synchronization interval expires. This allows treatment of atrial tachyarrhythmias in patients with complete heart block.

Figure 163. Atrial cardioversion synchronization



- 1 The device does not deliver CV therapy on any of these ventricular events because each one is inside the ventricular refractory period.
- 2 The device delivers the CV therapy on the second ventricular event that is outside the ventricular refractory period.
- 3 Programmed pacing resumes after the next ventricular event.

The atrial cardioversion therapy aborts if 12 refractory sensed ventricular events occur. Aborting the therapy in this situation prevents delivery during the vulnerable period preceding a ventricular depolarization. An atrial cardioversion therapy delivered during this vulnerable period might induce a ventricular tachyarrhythmia.

6.3.1.5 Device operation after an atrial cardioversion therapy

After an atrial cardioversion therapy is delivered, the device monitors for the end of the episode or redetection of the episode. Immediately after delivering a cardioversion therapy, the device starts a post-shock blanking period of 520 ms.

After the post-shock blanking period, the device resumes bradycardia pacing. If the programmed pacing mode is an MVP mode (AAIR<=>DDDR or AAI<=>DDD), the device operates in DDDR or DDD mode for 1 min after a cardioversion therapy. In other cases, the device operates in the programmed pacing mode. The pacing amplitude and pulse width settings are controlled by Post Shock Pacing parameters. For more information, see Section 4.20, "Post Shock Pacing", page 219.

The device monitors the episode for an outcome of either termination or redetection as a result of the therapy.

6.3.1.6 Device operation after an aborted atrial cardioversion therapy

After an atrial cardioversion therapy is aborted, the device reverts immediately to the programmed bradycardia pacing settings, not the Post Shock Pacing parameters.

The device resumes monitoring for atrial tachyarrhythmias after the next paced or sensed ventricular event. If the device redetects the AT/AF episode before the episode ends, it attempts to synchronize and deliver the programmed therapy that was aborted. However, if the episode ends, the device resumes normal detection.

Note: If the device aborts the cardioversion therapy leaving energy stored on the capacitors, the delivered energy of the next high-voltage therapy may be higher than the programmed value.

6.3.2 Programming atrial cardioversion

Navigation to parameters for atrial cardioversion (CV) in the AT/AF zone and the Fast AT/AF zone is provided in Table 35.

Table 35. How to navigate to parameters for atrial CV therapies in the AT/AF zone and Fast AT/AF zone

Parameters	Path
AT/AF Rx (Rx4, Rx5)	Params > AT/AF Therapies... > AT/AF Rx Automatic CV...
Automatic CV Status (On, Off)	
Energy	
Pathway	
Shared CV	Params > AT/AF Therapies... > AT/AF Rx Automatic CV...
Minimum R-R Interval	
Active Can/SVC Coil	
Fast AT/AF Rx (Rx4, Rx5)	Params > AT/AF Therapies... > Fast AT/AF Rx Automatic CV...
Automatic CV Status (On, Off)	
Energy	
Pathway	

Warning: After an ischemic or cerebrovascular accident, disable atrial cardioversion therapies until the patient has stabilized.

Caution: If the Active Can feature is not used, the device delivers defibrillation and cardioversion therapies between the RV Coil and SVC Coil electrodes only. To ensure that the device can deliver defibrillation and cardioversion therapies, make sure a supplementary SVC Coil electrode is implanted and connected to the device before programming the Active Can/SVC Coil parameter to Can Off.

Active Can/SVC Coil – The programmed setting for the Active Can/SVC Coil parameter applies to all features that deliver high-voltage shocks.

Sensing – To ensure appropriate delivery of atrial cardioversion therapy, program the device to prevent sensing of far-field R-waves.

Automatic CV Limits – You can program the device to deliver automatic atrial cardioversion therapies during selected hours of the day or night. You can also limit the number of automatic atrial cardioversion therapies that the device can deliver during a single 24-hour cycle.

VF therapy – You must program at least one VF therapy to On before enabling automatic atrial cardioversion.

6.3.3 Evaluation of atrial cardioversion

6.3.3.1 The Quick Look II screen

To access Quick Look II screen information about AT/AF therapies, select Data > Quick Look II.

Treated AT/AF episodes – This section includes a count of treated AT/AF episodes. You can select the Treated [>>] button to view data for the 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 select the Observations [>>] button to view related information.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

6.3.3.2 AT/AF therapy counters

The AT/AF therapy counters provide information that helps you to evaluate the efficacy of atrial cardioversion for therapies delivered since the last session. The counters also include data about atrial ATP therapies.

To access AT/AF therapy counters, select Data > Clinical Diagnostics > Counters > AT/AF Rx.

For high-voltage therapies, the following therapy counter data is available:

Automatic Shocks – Reports the number of automatic atrial shocks delivered and the number failed.

Patient Activated Shocks – Reports the number of patient-activated atrial shocks delivered and the number failed.

6.4 Patient-activated atrial cardioversion

Treatments for AT/AF episodes are intended to interrupt the atrial tachyarrhythmias and restore sinus rhythm. Although automatic atrial therapies (ATP and cardioversion) are available to terminate these episodes, it may also be desirable to allow the patient to request atrial cardioversion.

Patient-activated atrial cardioversion allows the patient to request therapy delivery according to instructions that you provide in advance. This is intended to give the patient more control over the setting and timing of the therapy. For a patient-activated therapy, the patient uses the Model 2696 InCheck Patient Assistant to request delivery of an atrial cardioversion therapy by the device. The device delivers atrial cardioversion therapy if certain conditions are met.

For related information, see the following sections:

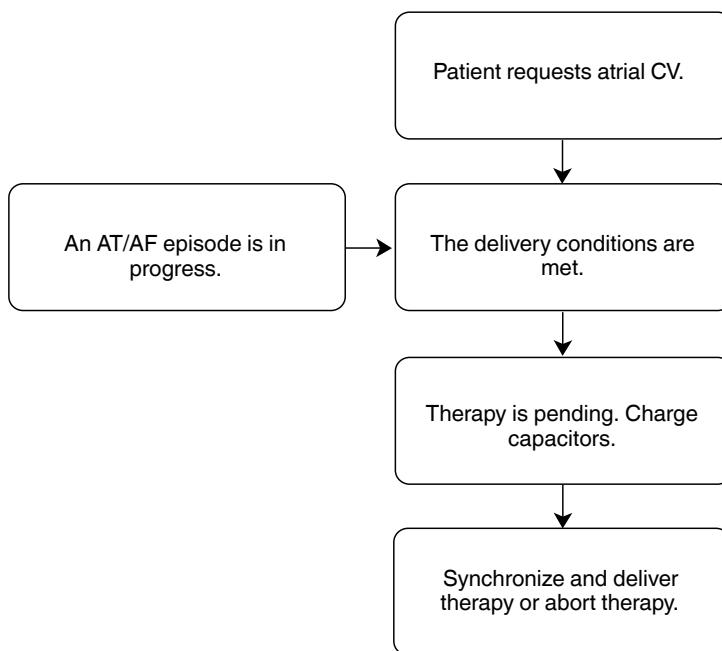
- Section 5.1, “AT/AF detection”, page 224
- Section 6.3, “Atrial cardioversion”, page 292

For additional information about the InCheck Patient Assistant, refer to the manual provided with it.

6.4.1 Operation of patient-activated atrial cardioversion

To request atrial cardioversion, the patient first uses the patient assistant to learn whether an AT/AF episode is in progress. If an episode is in progress, the patient can request cardioversion. A patient-activated atrial cardioversion becomes pending when the delivery conditions are met. When a patient-activated atrial cardioversion is pending, it takes priority over a scheduled automatic atrial therapy.

When a patient-activated atrial cardioversion is pending, the device charges the high-voltage capacitors to the programmed energy level and attempts to synchronize the shock to a sensed ventricular event outside the ventricular vulnerable period. If synchronization cannot occur, the device aborts the therapy.

Figure 164. Overview of patient-activated atrial cardioversion (CV)

Patient-activated atrial cardioversion uses the same methods for synchronization and therapy delivery as automatic atrial cardioversion. For more information, see Section 6.3, “Atrial cardioversion”, page 292.

6.4.1.1 Delivery conditions for patient-activated atrial cardioversion

For a patient-activated atrial cardioversion to become pending, the following conditions must be met:

- The device is programmed to allow patient-activated atrial cardioversion therapy.
- The request for cardioversion therapy is received during an AT/AF episode.
- A ventricular episode or VT Monitor episode is not in progress.
- The atrial episode length is shorter than the programmed Duration to Stop therapy parameter.
- The atrial therapies have not been disabled.

- Fewer than 15 automatic or patient-activated atrial shocks have been aborted in the current episode because of a failure to synchronize. This requirement protects the longevity of the device by limiting ineffective cardioversion charges.

A pending patient-activated atrial cardioversion is delivered if all of the following events occur:

- The device is able to synchronize to a sensed ventricular event.
- Of the 12 most recent ventricular intervals, fewer than 10 intervals are shorter than the programmed Minimum R-R Interval.
- The patient-activated atrial cardioversion has been pending for less than 60 s.

6.4.1.2 Device operation after a patient-activated atrial cardioversion therapy

After an atrial cardioversion therapy is delivered, the device monitors for the end of the episode or redetection of the episode. Immediately after delivering a cardioversion therapy, the device starts a post-shock blanking period of 520 ms.

After the post-shock blanking period, the device resumes bradycardia pacing. If the programmed pacing mode is an MVP mode (AAIR<=>DDDR or AAI<=>DDD), the device operates in DDDR or DDD mode for 1 min after a cardioversion therapy. In other cases, the device operates in the programmed pacing mode. The pacing amplitude and pulse width settings are controlled by Post Shock Pacing parameters. For more information, see Section 4.20, “Post Shock Pacing”, page 219.

The device monitors the episode for an outcome of either termination or redetection as a result of the therapy.

If the episode is redetected, the device can schedule an available automatic atrial therapy. For more information, see Section 6.1, “Atrial therapy scheduling”, page 275. Another patient-activated atrial cardioversion is delivered only if a new request is received.

6.4.1.3 Device operation after an aborted patient-activated atrial cardioversion therapy

After an atrial cardioversion therapy is aborted, the device reverts immediately to the programmed bradycardia pacing settings, not the Post Shock Pacing parameters.

The device resumes monitoring for atrial tachyarrhythmias after the next paced or sensed ventricular event. Unlike automatic atrial cardioversion, if the device redetects an AT/AF episode before the episode ends, it does not attempt to synchronize and deliver the patient-activated atrial cardioversion that was aborted. If the episode is redetected, the device can schedule an available automatic atrial therapy. If the episode ends, the device resumes normal detection.

6.4.2 Programming patient-activated atrial cardioversion

Table 36. How to navigate to parameters for patient-activated atrial CV

Parameters	Path
Patient Activated CV Status (On, Off) Energy Pathway	Params > AT/AF Therapies... > Patient Activated CV...
Shared CV Minimum R-R Interval Active Can/SVC Coil	Params > AT/AF Therapies... > Patient Activated CV...

The programming considerations for patient-activated atrial cardioversion also apply to automatic atrial cardioversion.

Warning: After an ischemic or cerebrovascular accident, disable atrial cardioversion therapies until the patient has stabilized.

Caution: If the Active Can feature is not used, the device delivers defibrillation and cardioversion therapies between the RV Coil and SVC Coil electrodes only. To ensure that the device can deliver defibrillation and cardioversion therapies, make sure a supplementary SVC Coil electrode is implanted and connected to the device before programming the Active Can/SVC Coil parameter to Can Off.

Active Can/SVC Coil – The programmed setting for the Active Can/SVC Coil parameter applies to all features that deliver high-voltage shocks.

Sensing – To ensure appropriate delivery of atrial cardioversion therapy, program the device to prevent sensing of far-field R-waves.

VF therapy – You must program at least one VF therapy to On before enabling atrial cardioversion.

6.4.3 Evaluation of patient-activated atrial cardioversion

The AT/AF therapy counters report the number of patient-activated atrial shocks that were delivered and the number that failed to terminate an AT/AF episode. For more information, see Section 3.8, “Arrhythmia Episodes data”, page 115.

6.5 VF therapies

Ventricular fibrillation (VF) is recognized by the presence of a grossly irregular ventricular rhythm. VF is life threatening if it is not treated promptly with defibrillation therapy.

The device can respond to ventricular tachyarrhythmia episodes detected in the VF zone (VF episodes) by delivering defibrillation therapy to the patient's heart. The defibrillation therapy is intended to terminate the episode by simultaneously depolarizing the heart tissue and restoring the patient's normal sinus rhythm.

The device can be programmed to deliver a sequence of ventricular antitachycardia pacing (ATP) therapy before or during charging for the first defibrillation therapy. This allows the device to attempt to terminate rapid but stable ventricular tachyarrhythmias that may not require defibrillation therapy for termination.

For more information, see Section 5.2, "VT/VF detection", page 230 and Section 6.6, "Ventricular ATP therapies", page 313.

6.5.1 Operation of VF therapies

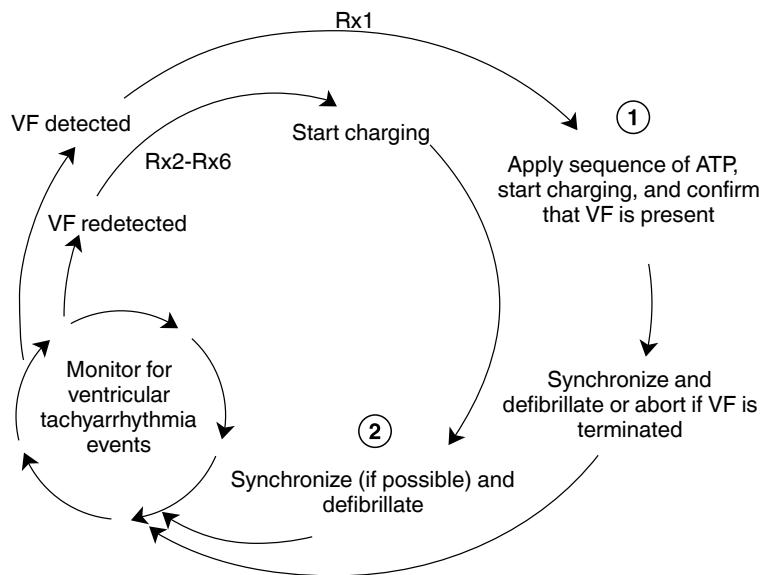
The device can be programmed to deliver a sequence of up to 6 therapies to treat VF episodes, each with specific energy and pathway settings. If the first therapy (labeled Rx1) is successful in terminating the episode, the device continues monitoring for subsequent VF episodes. If the device redetects the VF episode after the first therapy delivery, it delivers the second VF therapy (labeled Rx2). It continues this process until either the episode terminates or the last programmed therapy has been delivered. If therapy is successful, the device continues monitoring for subsequent VF episodes.

For the first VF therapy (Rx1), the device can be programmed to attempt to terminate the ventricular tachyarrhythmia with ventricular antitachycardia pacing (ATP) therapy before delivering a defibrillation shock. This may allow the device to terminate rapid but stable ventricular tachyarrhythmias that do not require defibrillation therapy. ATP therapy can be programmed to deliver before or during charging for the first defibrillation therapy.

During charging for Rx1, the device attempts to confirm the continued presence of VF before delivering the shock. If the VF has stopped spontaneously or if it has been terminated by ATP During Charging, the device cancels the therapy and resumes monitoring.

Note: If Confirmation+ is programmed Off and the VF has stopped spontaneously or has been terminated by ATP During Charging, the device cancels the therapy after charging ends. Then it resumes monitoring.

If the VF episode resumes, the device redetects. This process continues until the VF episode ends, whether spontaneously or through device intervention.

Figure 165. Overview of VF therapies

- 1 The use of ATP Before Charging, ATP During Charging, or no ATP determines when charging starts and when VF confirmation occurs. (Note that if ATP During Charging is applied and Confirmation+ is programmed Off, confirmation for VF does not occur.)
- 2 The device attempts to synchronize defibrillation to a ventricular event. If this is not possible, it delivers defibrillation asynchronously.

6.5.1.1 Delivering high-voltage therapies

To deliver a defibrillation therapy, the device must first charge its high-voltage capacitors to the programmed energy level. The length of time required to charge the capacitors depends on the programmed energy level and battery depletion. The delivered energy level is programmed independently for each defibrillation therapy. Defibrillation pulses use a biphasic waveform in which the current pathway for the high-voltage pulse is reversed midway through the pulse delivery.

For information about typical full-energy capacitor charging periods and a comparison of delivered and stored energy levels, see the device manual for the specific device.

6.5.1.2 Selecting the high-voltage electrodes and current pathway

The Active Can/SVC Coil parameter and the Pathway parameter specify the electrodes and direction of current flow for defibrillation and cardioversion pulses. The Active Can/SVC Coil parameter has the following settings:

- The Can+SVC On setting connects the Active Can and the SVC Coil. Current flows between these electrodes and the RV Coil.
- The Can Off setting disables the Active Can feature. In this case, an SVC lead must be implanted. Current flows between the SVC Coil and the RV Coil.
- The SVC Off setting ensures that the SVC lead, if implanted, is not used. Current flows between the Active Can and the RV Coil.

The settings for the Pathway parameter are AX>B and B>AX. AX refers to the Active Can and SVC Coil electrodes, which may be used individually or in combination. B refers to the RV Coil electrode. The Pathway setting defines direction of current flow during the initial segment of the biphasic waveform. If the parameter is set to AX>B, current flows from the Active Can and SVC Coil to the RV Coil. If the parameter is set to B>AX, this current flow is reversed.

6.5.1.3 Delivering ATP before the first defibrillation

You can program the device to deliver ATP therapy before delivering the first defibrillation therapy. This can prevent delivery of high-voltage shocks for rhythms that can be terminated by ATP (rapid monomorphic VT, for example).

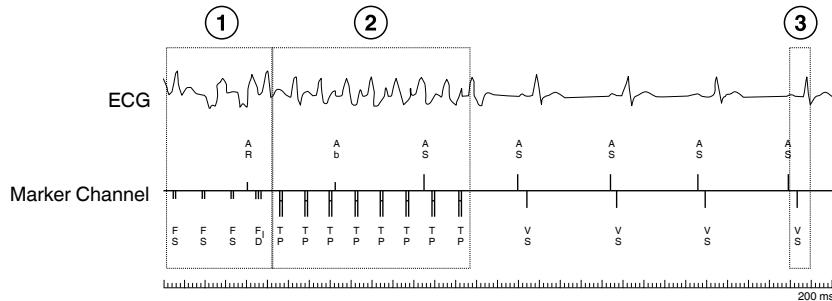
If the ATP parameter is set to During Charging, the device delivers a single sequence of ATP therapy when it starts charging for the defibrillation therapy. If charging completes before the ATP therapy sequence completes, synchronization of the defibrillation therapy is delayed until the ATP therapy is finished.

If the ATP parameter is set to Before Charging, the device delivers a sequence of ATP therapy as soon as VF is detected. If VF is redetected, the device begins charging and delivers a second ATP sequence.

The device does not deliver ATP therapies before or during charging unless the last 8 ventricular sensed intervals are all greater than or equal to the programmed value for the parameter called “Deliver ATP if last 8 R-R >=”.

Note: For 30 s after a T-Shock or ventricular 50 Hz Burst induction is delivered, the device prevents ATP therapies from being delivered during or before charging. This prevents the ATP therapies from interfering with defibrillation threshold (DFT) testing.

Figure 166. Successful termination of an episode detected as VF



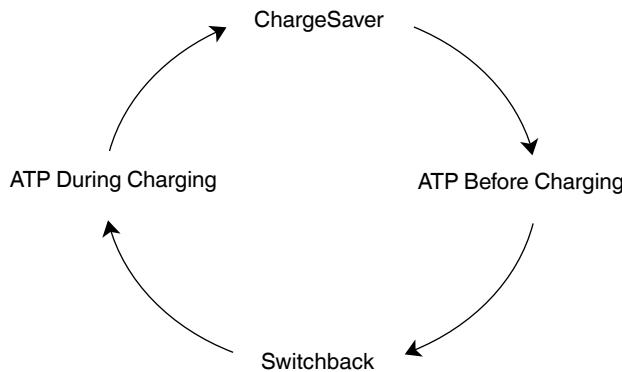
- 1 The device detects a fast ventricular rate as a VF episode and starts charging the capacitors for a defibrillation therapy.
- 2 While charging, the device delivers a sequence of Burst ATP therapy, which terminates the tachyarrhythmia.
- 3 Because VF is not Confirmed, the device aborts the defibrillation therapy and stops charging the capacitors.

Three features can automatically change the value of the ATP parameter: ChargeSaver, Switchback, and Smart Mode. The effect of ChargeSaver and Switchback on ATP programming is shown in Figure 167.

ChargeSaver feature – If the ChargeSaver option is programmed to On, the device can automatically switch from ATP During Charging operation to ATP Before Charging operation. This change occurs when ATP has successfully terminated the detected tachyarrhythmia on a programmable number of consecutive attempts during charging.

Note: If any ATP parameter is reprogrammed, the device resets the count of consecutive ATP successes used by the ChargeSaver feature.

Switchback feature – The Switchback feature allows the device to automatically switch from ATP Before Charging operation to ATP During Charging operation. This change occurs if ATP Before Charging fails to terminate the detected tachyarrhythmia on 2 consecutive attempts. The Switchback feature is available whenever ATP Before Charging is enabled.

Figure 167. Operation of ChargeSaver and Switchback

Smart Mode feature – If the Smart Mode feature is programmed to On, the device automatically sets the ATP parameter to Off if ATP therapies delivered before or during charging fail to terminate the tachyarrhythmia in 4 consecutive episodes.

6.5.1.4 Confirming VF for the first defibrillation

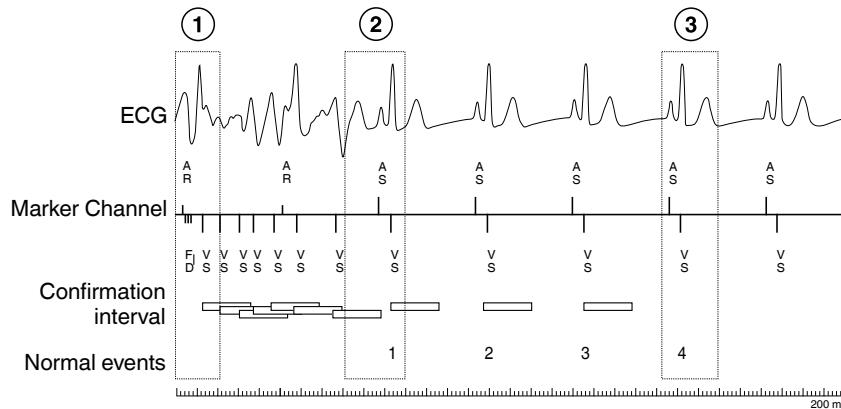
Before the device delivers the first defibrillation shock for a VF episode, it monitors cardiac rhythm to confirm the presence of VF. VF is confirmed using one of the following confirmation intervals:

- an interval calculated from the ventricular cycle length + 60 ms, if this interval is at least as long as the programmed VF detection interval. The interval is provided by the Confirmation+ option (nominally programmed to On) and is used when the ventricular rhythm is stable.
- the programmed VT Interval + 60 ms (or the programmed VF Interval if VT Detection is programmed to Off). This interval is used if Confirmation+ is turned off.

The device classifies any ventricular event that occurs within the confirmation interval as an “arrhythmic event” and any event that occurs outside the interval as a “normal event”.

With each ventricular event, the device reviews the previous 5 ventricular events. If the previous 5 ventricular events include 4 “normal events”, the device aborts the therapy.

Figure 168. Example of an aborted defibrillation therapy



- 1 The device detects VF, starts charging, and begins to confirm the tachyarrhythmia using the confirmation interval. In this example, ATP During Charging is disabled.
 - 2 The VF spontaneously terminates, and normal sinus rhythm resumes.
 - 3 When 4 of the last 5 events are “normal events”, the device aborts the therapy and stops charging its capacitors.

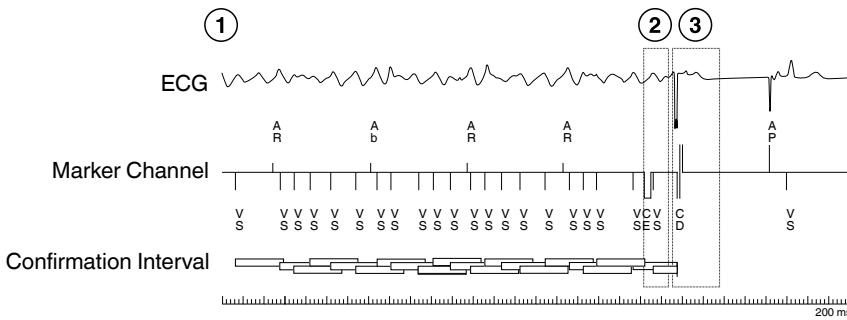
6.5.1.5 Synchronizing the initial defibrillation therapy

After charging and ATP During Charging are complete, the device continues to confirm the presence of VF. If VF persists, the device attempts to synchronize the defibrillation therapy to the second ventricular tachyarrhythmic event that occurs after charging ends, provided that it is outside the ventricular refractory period and the atrial vulnerable period. If this fails, the device then attempts to synchronize the defibrillation therapy to the next ventricular tachyarrhythmic event that occurs outside the ventricular refractory period.

The device continues to attempt to synchronize until it delivers the defibrillation therapy or it fails to confirm the presence of VF and aborts the therapy.

Note: The system defines the atrial vulnerable period as a window extending from 150 ms to 400 ms after a sensed atrial event. A defibrillation therapy is withheld during this period to avoid inducing an atrial tachyarrhythmia.

Figure 169. Synchronous delivery of defibrillation



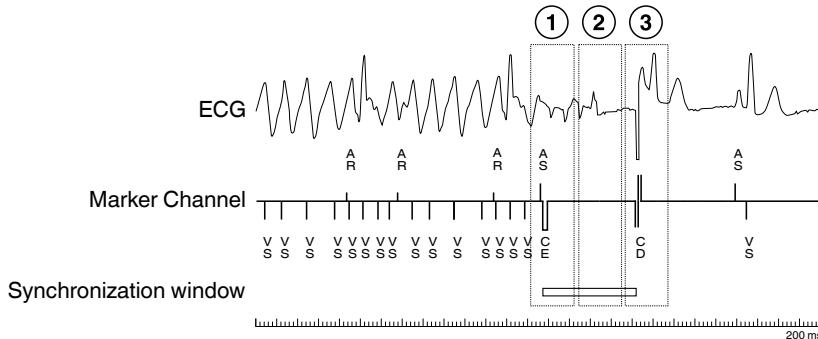
- 1 The device has detected VF. It charges its capacitors for defibrillation and confirms VF using the confirmation interval. In this example, ATP During Charging is disabled.
 - 2 The device completes charging and starts synchronization while continuing VF confirmation.
 - 3 On the second tachyarrhythmic event after charging, the device delivers the defibrillation therapy.

6.5.1.6 Synchronizing subsequent defibrillation therapies

If the first defibrillation therapy fails to terminate a VF episode, the device attempts to synchronize each subsequent defibrillation therapy to a sensed ventricular event. If synchronization is not possible, the device delivers the defibrillation therapy asynchronously.

Once the capacitors are charged to the programmed energy, the device starts a 900 ms synchronization window. If a qualified sensed ventricular event occurs during this window, the device delivers the defibrillation therapy synchronized to the event. Otherwise, the device delivers the therapy asynchronously after 900 ms (see Figure 170).

Any sensed ventricular event qualifies for therapy delivery unless it occurs in the refractory period or in the atrial vulnerable period. If an event occurs in the refractory period, the device continues to attempt to synchronize. If an event occurs in the atrial vulnerable period, the device changes the synchronization window to 500 ms and continues to attempt to synchronize. A subsequent sensed ventricular event that occurs outside the refractory period qualifies for therapy delivery even if it occurs in the atrial vulnerable period.

Figure 170. Asynchronous delivery of defibrillation

- 1 After redetecting VF, the device completes charging and starts a 900 ms synchronization window.
- 2 Several low-amplitude VF events go unsensed.
- 3 After 900 ms, the device delivers the defibrillation therapy asynchronously.

6.5.1.7 Device operation during and after a defibrillation therapy

On the first ventricular event after charging, the device changes the pacing mode to VVI until the charge is delivered or aborted. The pacing interval remains unchanged during this time.

After the defibrillation therapy is delivered, the device monitors for the end of the episode or redetection. The device suspends VT detection and Combined Count detection for 17 events following a defibrillation therapy that is delivered in response to a detected VF. Suspending VT detection helps avoid detecting transient VTs that can follow high-voltage therapies. For information about Combined Count detection, see Section 5.2, “VT/VF detection”, page 230.

Immediately after delivering the shock, the device starts a post-shock blanking period of 520 ms.

After the post-shock blanking period, the device resumes bradycardia pacing. If the programmed pacing mode is an MVP mode (AAIR<=>DDDR or AAI<=>DDD), the device operates in DDDR or DDD mode for 1 min after a defibrillation therapy. In other cases, the device operates in the programmed pacing mode. The Post Shock Pacing parameters are applied. For more information, see Section 4.20, “Post Shock Pacing”, page 219. If Post VT/VF Shock Pacing is programmed to On, the device paces at the programmed Overdrive Rate. For more information, see Section 4.21, “Post VT/VF Shock Overdrive Pacing”, page 220.

6.5.1.8 Device operation after an aborted defibrillation therapy

If the device aborts a defibrillation therapy, it reverts immediately to the programmed bradycardia pacing settings, not the Post Shock Pacing parameters.

The device resumes monitoring for ventricular tachyarrhythmias after the next paced or sensed ventricular event. If VF is redetected, the device proceeds as follows:

- If Confirmation+ is on (nominal) and the device redetects VF before the episode ends, the first programmed defibrillation therapy that was aborted (Rx1) is reconfirmed and synchronized prior to delivery. If the VF episode ends at any time, the device resumes monitoring.
- If Confirmation+ is off and the device redetects VF before the episode ends, Rx1 is not reconfirmed before it is delivered. If VF persists, Rx2 through Rx6 is delivered as needed without synchronization or confirmation. If the episode ends at any time, the device resumes monitoring.

Note: If the device aborts the defibrillation therapy leaving energy stored on the capacitors, the delivered energy of the next high-voltage therapy may be higher than the programmed value.

6.5.2 Programming VF therapies

Table 37. How to navigate to VF therapies parameters

Parameters	Path
VF therapies (Rx1 through Rx6)	Params > VF Therapies...
VF Therapy Status (On, Off)	
Energy	
Pathway	
ATP parameters (Rx1)	Params > VF Therapies... > ATP...
ChargeSaver parameters (ATP in Rx1)	Params > VF Therapies... > ATP... > During Charging > ChargeSaver...
Shared Settings (V. ATP and V. Therapies)	Params > VF Therapies... > Shared Settings...

Caution: If the Active Can feature is not used, the device delivers defibrillation and cardioversion therapies between the RV Coil (HVB) and SVC Coil (HVX) electrodes only. To ensure that the device can deliver defibrillation and cardioversion therapies, make sure a supplementary HVX electrode is implanted and connected to the device before programming the Active Can/SVC Coil parameter to Can Off.

Active Can/SVC Coil – The programmed setting for the Active Can/SVC Coil parameter applies to all features that deliver high-voltage shocks.

Energy – Programming VF therapies to the maximum energy level is recommended. However, programming the energy level for the first VF therapy to an optimized value (for example, the defibrillation threshold plus 10 J) can terminate the tachyarrhythmia with an appropriate safety margin and without wasting energy. A minimum of 20 J is recommended if ATP is programmed ON.

Energy level availability – Energy levels below 10 J are available for VF therapies Rx1 and Rx2. For VF therapies Rx3–Rx6, the energy level cannot be programmed below 10 J. Likewise, a VF therapy cannot be followed by another VF therapy that has a lower energy setting.

Energy and ATP During Charging – When you set the Energy parameter for a therapy to a value less than 20 J, the charge time for that therapy can be short. This may not allow time to determine that ATP During Charging has terminated an episode. Consider programming the Energy parameter for the first VF therapy to at least 20 J if ATP During Charging is enabled.

Progressive Episode Therapies – If Progressive Episode Therapies is programmed to On, the device may skip ATP Before Charging therapy or may deliver a high-voltage therapy at a higher energy level than the programmed level. This ensures that each therapy delivered during an ongoing episode is at least as aggressive as the previous therapy. For more information, see Section 6.8, “Progressive Episode Therapies”, page 331.

VT and FVT therapies – VT and FVT therapies cannot be programmed to On unless at least one VF therapy is also programmed to On.

6.5.3 Evaluation of VF therapies

6.5.3.1 The Quick Look II screen

To access Quick Look II screen information about VT/VF therapies, select Data > Quick Look II.

Treated VT/VF episodes – This section includes a count of treated VT/VF episodes. You can select the Treated [>>] button to view data for the treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information about an observation is available, you can select the observation and then select the Observations [>>] button to view the related information.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

6.5.3.2 VT/VF therapy counters

The VT/VF therapy counters provide information that helps you to evaluate the efficacy of defibrillation. The VT/VF therapy counters include the VT/VF Therapy Summary for the previous session, the last session, and the device lifetime. The VT/VF therapy counters also include the VT/VF Therapy Efficacy Since Last Session.

To access VT/VF therapy counter information, select Data > Clinical Diagnostics > Counters > [Open Data] > VT/VF Rx.

The following VT/VF therapy counter data is available:

VT/VF Therapy Summary – This section reports the number of pace-terminated ventricular tachyarrhythmias, shock-terminated ventricular tachyarrhythmias, total VT/VF shocks, and aborted charges for the prior session, the last session, and the device lifetime.

VT/VF Therapy Efficacy Since Last Session – For VF, FVT, and VT therapies, the counters report the number and types of therapies that were delivered and successful. The VT Therapy counter includes VT episodes that accelerated during the therapy or were redetected as an FVT or VF episode. The FVT therapy counter includes FVT episodes that were redetected as a VF episode.

6.6 Ventricular ATP therapies

The device detects sustained ventricular tachycardia as a ventricular tachycardia (VT) or fast ventricular tachycardia (FVT) episode. Treatments for these episodes are intended to interrupt the ventricular tachycardia and restore the patient's normal sinus rhythm. Pacing therapy can be a treatment option for terminating a VT or FVT episode that may not require high-voltage therapy.

The device can respond to a VT or FVT episode by delivering ventricular antitachycardia pacing (ATP) therapies to the patient's heart. Ventricular ATP therapies are designed to interrupt the VT or FVT reentrant activation pattern and restore the patient's normal sinus rhythm. ATP therapies deliver pacing pulses instead of high-voltage shocks delivered in cardioversion therapy.

For related information, see Section 5.2, “VT/VF detection”, page 230, and Section 6.7, “Ventricular cardioversion”, page 323.

6.6.1 Operation of ventricular ATP therapies

The device can deliver up to 6 therapies to treat a VT or FVT episode. You can program the device to deliver ATP therapies before delivering the first cardioversion therapy for each type of episode. This may allow the device to terminate a ventricular tachycardia episode using an ATP therapy, delivering cardioversion therapy only if the ATP therapy is unsuccessful.

ATP therapy options are Burst, Ramp, and Ramp+ pacing, each with a programmable number of sequences. When a VT or FVT episode is detected and the first programmed therapy is an ATP therapy, the device delivers the first sequence of the ATP therapy. After the first ATP sequence, it continues to monitor for the presence of the ventricular tachycardia episode. If the device redetects the ventricular tachycardia episode, it delivers the next sequence and repeats this cycle until the episode is terminated or all sequences in the therapy are exhausted.

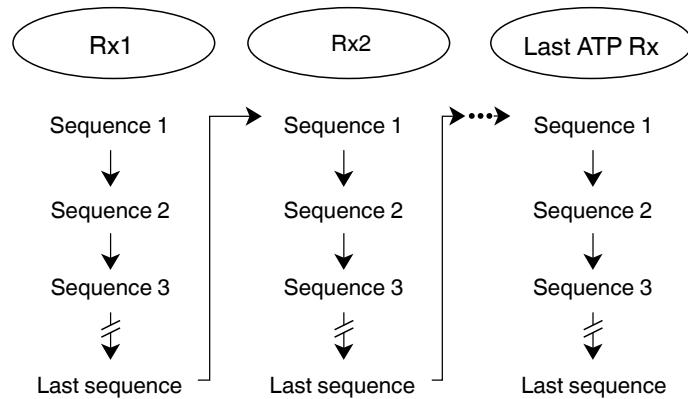
If all sequences in an ATP therapy are unsuccessful, the device starts delivering the next ATP or cardioversion therapy. If it detects that the current VT episode has accelerated (by at least 60 ms) or redetects the VT as FVT, the device skips the remaining sequences of an ATP therapy and starts the next programmed therapy for the episode.

If the device redetects the VT episode as VF, it delivers VF therapy. For more information, see Section 6.5, “VF therapies”, page 303.

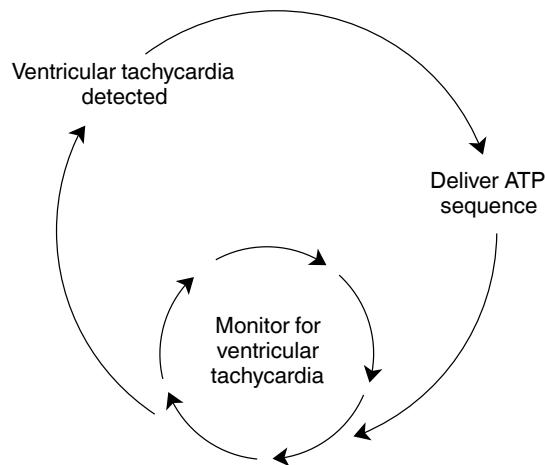
During an ongoing ventricular tachyarrhythmia episode, the ventricular rate may also decelerate, which can cause the device to redetect the episode as a different type of tachyarrhythmia. If deceleration occurs and all the following conditions exist, the device delivers the next available therapy programmed for the type of tachyarrhythmia that was redetected:

- This is the first deceleration that caused the device to redetect the episode as a different type of tachyarrhythmia.
- At least 4 defibrillation therapies remain.
- At least 2 FVT cardioversion therapies remain (when FVT through VF therapies are enabled).

If any of the above conditions do not exist, the device will not deliver less aggressive therapies and will deliver the remaining therapies according to progressive episode therapies. For more information about progressive episode therapies, see Section 6.8, “Progressive Episode Therapies”, page 331.

Figure 171. Overview of ventricular ATP therapy delivery

For an overview of ventricular ATP sequence delivery, see Figure 172.

Figure 172. Overview of ventricular ATP sequence delivery

The V. Amplitude, V. Pulse Width, and V. Pace Blanking parameters are the same for all ventricular ATP therapies. These parameters are programmable independently of the bradycardia pacing pulse width, amplitude, and pace blanking period.

6.6.1.1 Ventricular ATP therapy pacing rate

The ATP pacing interval is based on the ventricular tachycardia cycle length, which is calculated as the average of the last 4 ventricular intervals prior to VT or FVT detection (or redetection). The programmable parameter V-V Minimum ATP Interval limits the pacing interval at which the ATP pulses are delivered within a sequence. If the ATP pacing interval is shorter than the programmed V-V Minimum ATP Interval, the pulses are delivered at the programmed V-V Minimum ATP Interval.

If the intrinsic ventricular tachycardia interval is shorter than or equal to the programmed V-V Minimum ATP Interval, the device skips the rest of the ATP therapy and delivers the first programmed cardioversion therapy. If no cardioversion therapy is programmed, no therapy is delivered.

If the intrinsic ventricular tachycardia interval is longer than the programmed V-V Minimum ATP Interval but all the intervals of an ATP therapy sequence have been delivered at the V-V Minimum ATP Interval, the device skips the rest of the ATP therapy and delivers the next programmed ATP or cardioversion therapy. If the device detects an FVT episode, it delivers the next programmed cardioversion therapy.

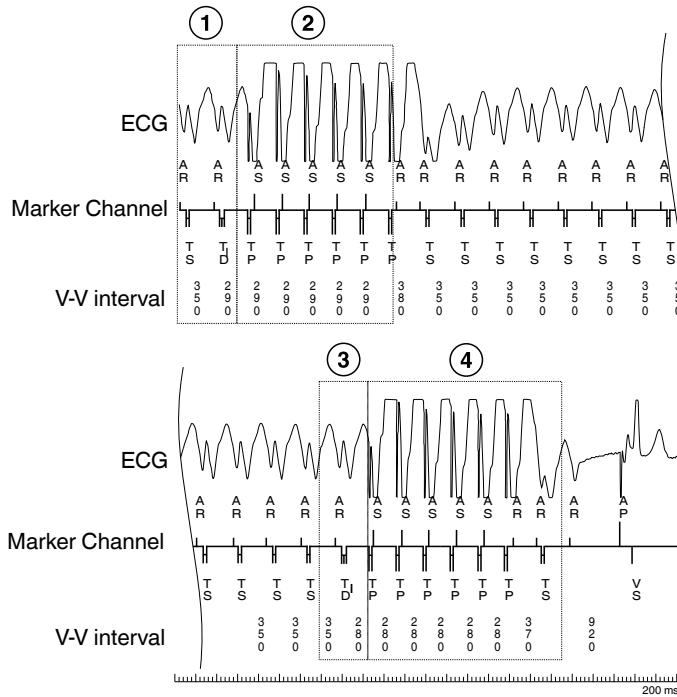
6.6.1.2 Burst pacing therapy

The programmable parameter Initial # Pulses sets the number of pulses in all sequences of a Burst therapy. R-S1 Interval=(%RR) and Interval Dec are programmable parameters that control Burst pacing intervals.

The first Burst sequence is delivered at a pacing interval determined by the R-S1 Interval=(%RR) parameter as a percentage of the ventricular tachycardia cycle length. Each pulse in the sequence is delivered at the same pacing interval. Each time the ventricular tachycardia is redetected after an unsuccessful sequence, the device applies the programmed Burst percentage to the new ventricular tachycardia cycle length. It then subtracts the Interval Dec value (once per sequence) to determine the pacing interval of the next Burst sequence.

Note: Burst pacing therapy is delivered in the VOO pacing mode.

In the example of Burst pacing operation in Figure 173, two Burst therapy sequences are delivered. The second therapy sequence terminates the VT episode.

Figure 173. Example of Burst pacing operation

- 1 The device detects a VT episode.
- 2 The first Burst sequence is delivered with a pacing interval of 290 ms, but this sequence fails to terminate the VT episode.
- 3 The device redetects the VT episode.
- 4 The second Burst sequence is delivered with a pacing interval of 280 ms (the interval decrement being 10 ms per sequence). This sequence terminates the VT episode.

6.6.1.3 Ramp pacing therapy

The programmable parameter Initial # Pulses sets the number of pulses in the first Ramp sequence. Ramp pacing intervals are controlled by the programmable parameters R-S1 Interval=(%RR) and Interval Dec.

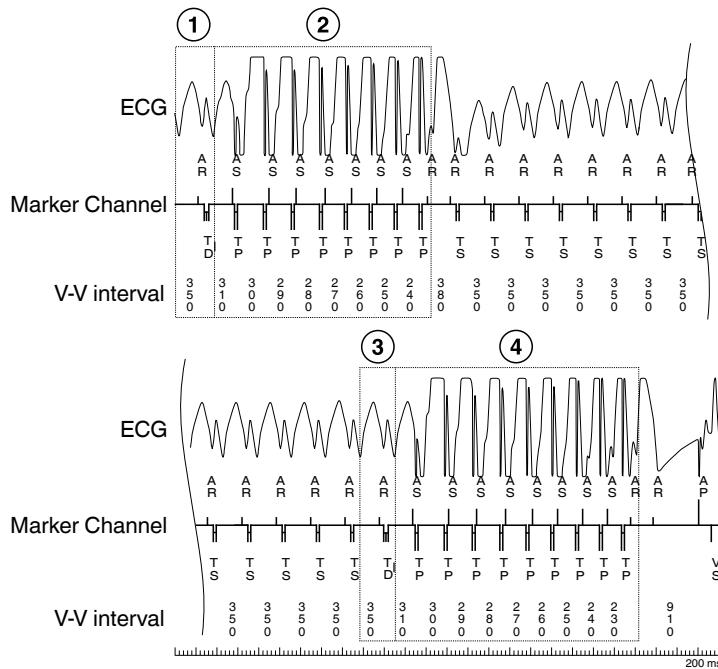
In each Ramp sequence, the first pulse is delivered at a pacing interval determined by the R-S1 Interval=(%RR) parameter as a percentage of the ventricular tachycardia cycle length. The remaining pulses in this sequence are delivered at progressively shorter pacing intervals by subtracting the Interval Dec value for each pulse.

Each time the ventricular tachycardia is redetected after an unsuccessful sequence, the device applies the programmed Ramp percentage to the new ventricular tachycardia cycle length to calculate the initial pacing interval for the next sequence. Each sequence adds one pacing pulse. Sensed ventricular events are counted as individual pulses of the Ramp sequence, even though they are not output pulses.

Note: Ramp pacing therapy is delivered in the VVI pacing mode.

In the example of Ramp pacing operation in Figure 174, 2 Ramp therapy sequences are delivered. The second therapy sequence terminates the VT episode.

Figure 174. Example of Ramp pacing operation



- 1 The device detects a VT episode.
- 2 The first Ramp sequence is delivered with an initial pacing interval of 310 ms. Each subsequent interval is decremented 10 ms per pulse. Eight pacing pulses are delivered, but the VT episode is not terminated.
- 3 The device redetects the VT episode.
- 4 The second Ramp sequence is delivered with an initial pacing interval of 310 ms. Each subsequent interval is decremented 10 ms per pulse. Nine pacing pulses are delivered, and the VT episode is terminated.

6.6.1.4 Ramp+ pacing therapy

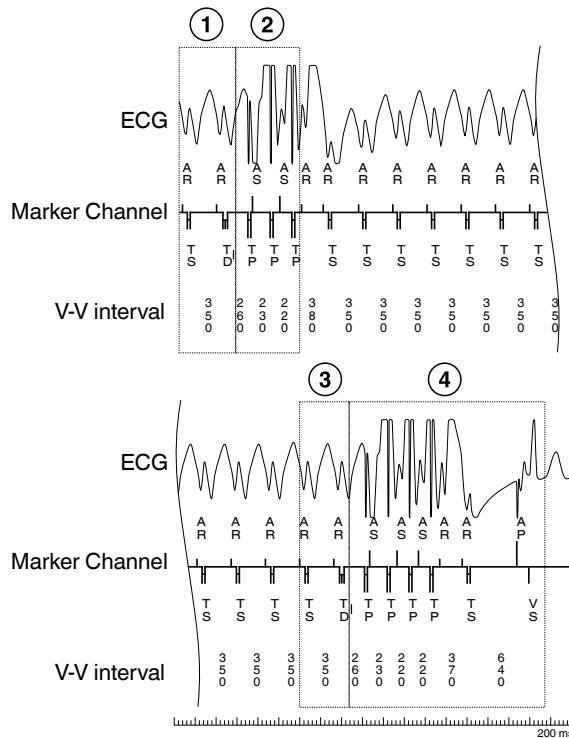
The programmable parameter Initial # Pulses sets the number of pulses in the first Ramp+ sequence. Ramp+ pacing intervals are controlled by the programmable parameters R-S1 Interval=(%RR), S1S2(Ramp+)=(%RR), and S2SN(Ramp+)=(%RR).

The pulses in the Ramp+ sequence are delivered at progressively shorter pacing intervals, each determined as a specific percentage of the ventricular tachycardia cycle length. The first pulse of each Ramp+ sequence is delivered at a pacing interval using the R-S1 Interval=(%RR) percentage. The pacing interval for the second pulse in the sequence is determined by the S1S2(Ramp+)=(%RR) percentage. Any remaining pulses in the sequence are delivered at a pacing interval using the S2SN(Ramp+)=(%RR) percentage.

If the ventricular tachycardia is redetected, the device applies the programmed percentages to the new ventricular tachycardia cycle length to determine the pacing intervals for the next Ramp+ sequence. Each sequence adds one pacing pulse.

Note: The Ramp+ pacing therapy is delivered in the VOO pacing mode.

In the example of Ramp+ pacing operation in Figure 175, 2 Ramp+ therapy sequences are delivered. The second therapy sequence terminates the VT episode.

Figure 175. Example of Ramp+ pacing operation

- 1 The device detects a VT episode.
- 2 The first Ramp+ sequence consists of 3 pacing pulses with intervals of 260, 230, and 220 ms. The VT episode is not terminated.
- 3 The device redetects the VT episode.
- 4 The second Ramp+ therapy repeats the first 3 intervals and adds another pulse with a 220 ms interval, which terminates the VT episode.

6.6.1.5 Optimizing ventricular ATP therapies with Smart Mode

Smart Mode is a programmable option for ventricular ATP therapies. You can program Smart Mode to On for all or selected ATP therapies for the first 4 VT or FVT therapies.

When Smart Mode is programmed to On for a ventricular ATP therapy, the device monitors the outcome of that therapy. If there are 4 consecutive episodes in which all sequences of the ATP therapy are delivered but are unsuccessful, Smart Mode cancels that ATP therapy. This action allows the device to treat subsequent episodes more quickly, using ATP therapies that may have been effective previously.

If Smart Mode cancels a ventricular ATP therapy, you can either select a different therapy or modify the current therapy settings to improve the therapy effectiveness. An ATP therapy cancelled by Smart Mode is indicated by the label “Off-SM” on the VT/VF therapy counters screen. For more information, see Section 6.6.3, “Evaluation of ventricular ATP therapies”, page 322.

6.6.2 Programming ventricular ATP therapies

Navigation to parameters for ventricular ATP therapies for VT episodes is shown in Table 38. To navigate to parameters for ventricular ATP therapies for FVT episodes, select Params > FVT Therapies....

Table 38. How to navigate to parameters for ventricular ATP therapies

Parameters	Path
VT therapies (Rx1 through Rx6) VT Therapy Status (On, Off)	Params > VT Therapies...
Therapy Type (Burst) Burst Therapy parameters	Params > VT Therapies... > Burst
Therapy Type (Ramp) Ramp Therapy parameters	Params > VT Therapies... > Ramp
Therapy Type (Ramp+) Ramp+ Therapy parameters	Params > VT Therapies... > Ramp+
Shared Settings (V. ATP and V. Therapies)	Params > VT Therapies... > Shared Settings...

VT and FVT therapies – You should not use ATP therapies exclusively to treat VT or FVT episodes. At least one VT therapy and one FVT therapy should be programmed to a maximum energy cardioversion.

Cardioversion therapies for FVT – You cannot program all FVT therapies as ATP therapies. If any FVT therapies are programmed on, at least one of the therapies must be programmed to cardioversion therapy. The final FVT therapy must always be programmed to cardioversion therapy.

Therapy aggressiveness – VT and FVT therapies must be programmed to be increasingly aggressive. For example, you cannot program one VT therapy as cardioversion and a subsequent VT therapy as a ventricular ATP therapy. Likewise, a VT cardioversion therapy cannot be followed by another VT cardioversion therapy with a lower energy setting.

VF therapies – You cannot program VT and FVT therapies to On unless at least one VF therapy is also programmed on.

Smart Mode – You can reset a ventricular ATP therapy cancelled by Smart Mode by programming the Therapy Status parameter for that therapy to On. Smart Mode is not available for the last two VT or FVT therapies.

6.6.3 Evaluation of ventricular ATP therapies

6.6.3.1 The Quick Look II screen

To access Quick Look II screen information about VT/VF therapies, select Data > Quick Look II.

Treated VT/VF episodes – This section includes a count of treated VT/VF episodes. You can select the Treated [>>] button to view the data for treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information about an observation is available, you can select the observation and then select the Observations [>>] button to view the related information.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

6.6.3.2 VT/VF therapy counters

The VT/VF therapy counters provide information that helps you to evaluate the efficacy of ventricular ATP therapies. The VT/VF therapy counters include the VT/VF Therapy Summary for the prior session, the last session, and the device lifetime. VT/VF therapy counters also include VT/VF Therapy Efficacy Since Last Session.

To access VT/VF therapy counter information, select Data > Clinical Diagnostics > Counters > [Open Data]> VT/VF Rx.

The following VT/VF therapy counter data is available:

VT/VF Therapy Summary – This counter reports the number of pace-terminated tachyarrhythmias, shock-terminated tachyarrhythmias, total VT/VF shocks, and aborted charges for the prior session, the last session, and the device lifetime.

VT/VF Therapy Efficacy Since Last Session – This counter reports the number and types of VF, FVT, and VT therapies that were delivered and successful. The VT Therapy counter includes VT episodes that accelerated during the therapy or were redetected as an FVT or VF episode. The FVT therapy counter includes FVT episodes that were redetected as a VF episode.

6.6.3.3 Smart Mode operation indicators

To access VT/VF therapy counter information about the operation of Smart Mode, select Data > Clinical Diagnostics > Counters > VT/VF Rx.

Information about Smart Mode operation is also available from the VT Therapies screen or the FVT Therapies screen.

Figure 176. VT Therapies screen

VT Therapies		Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
VT Therapy Status	(1)	Off-SM	On	On	On	On	On
Therapy Type		Ramp	CV	CV	CV	CV	CV
Energy			35 J	35 J	35 J	35 J	35 J
Pathway			B>AX	B>AX	AX>B	AX>B	AX>B
Initial # Pulses		8					
R-S1 Interval=(%RR)			91 %				
S1S2(Ramp+)=(%RR)							
S2SN(Ramp+)=(%RR)							
Interval Dec			10 ms				
# Sequences			1				
Smart Mode			On				
Shared Settings...				Auto Cap Formation...			
		Undo Pending				OK	

- 1 The label “Off-SM” for Rx1 indicates that Smart Mode cancelled an unsuccessful ATP therapy.

6.7 Ventricular cardioversion

A VT or FVT episode is detected when sustained ventricular tachycardia occurs. Treatments for these episodes are intended to interrupt the tachyarrhythmia and restore sinus rhythm. Ventricular ATP therapies may terminate these episodes. If the ATP therapies are ineffective, a high-voltage shock is required.

The device can respond to a VT or FVT episode by delivering ventricular cardioversion therapy to the patient’s heart. Cardioversion, like defibrillation, is intended to terminate the episode by simultaneously depolarizing the heart tissue and restoring the patient’s normal sinus rhythm. However, unlike defibrillation, cardioversion requires that the device synchronizes the therapy to a sensed ventricular event.

For more information, see Section 5.2, “VT/VF detection”, page 230.

6.7.1 Operation of ventricular cardioversion

When a VT or FVT episode is detected and the next programmed therapy is a cardioversion, the device begins charging its high-voltage capacitors and attempts to confirm the continued presence of the tachyarrhythmia. If the tachyarrhythmia terminates, the device cancels the therapy.

If the tachyarrhythmia is still present when the capacitors are charged to the programmed energy level, the device delivers the cardioversion pulse synchronized to a sensed ventricular event. If synchronization is not possible, the device cancels the therapy.

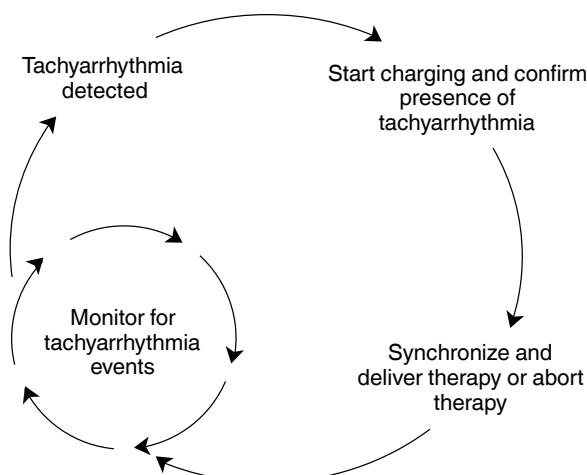
If the cardioversion therapy is unsuccessful, the device starts delivering the next cardioversion therapy. If the device redetects the VT episode as VF, it delivers therapy. See Section 6.5, "VF therapies", page 303.

During an ongoing ventricular tachyarrhythmia episode, the ventricular rate may accelerate or decelerate, which can cause the device to redetect the episode as a different type of tachyarrhythmia. If redetection occurs, the device delivers the next available therapy programmed for the type of tachyarrhythmia that was redetected, if all of the following conditions exist:

- This is the first deceleration that caused the device to redetect the episode as a different type of tachyarrhythmia.
- There are at least 4 defibrillation therapies remaining.
- There are at least 2 FVT cardioversion therapies remaining (when FVT through VF therapies are enabled).

If any of the above conditions do not exist, the device will not deliver less aggressive therapies and will deliver the remaining therapies. For more information, see Section 6.8, "Progressive Episode Therapies", page 331.

Figure 177. Overview of ventricular cardioversion



6.7.1.1 Delivering high-voltage therapies

To deliver a cardioversion therapy, the device must first charge its high-voltage capacitors to the programmed energy level. The length of time required to charge the capacitors depends on the programmed energy level and battery depletion. The delivered energy level is programmed independently for each cardioversion therapy. Cardioversion pulses use a biphasic waveform in which the current pathway for the high-voltage pulse is reversed midway through the pulse delivery.

See the device manual for the following information:

- typical full-energy capacitor charging periods
- comparison of delivered and stored energy levels

6.7.1.2 Selecting the high-voltage electrodes and current pathway

The Active Can/SVC Coil parameter and the Pathway parameter specify the electrodes and direction of current flow for defibrillation and cardioversion pulses. The Active Can/SVC Coil parameter has the following settings:

- The Can+SVC On setting connects the Active Can and the SVC Coil. Current flows between these electrodes and the RV Coil.
- The Can Off setting disables the Active Can feature. In this case, an SVC lead must be implanted. Current flows between the SVC Coil and the RV Coil.
- The SVC Off setting ensures that the SVC lead, if implanted, is not used. Current flows between the Active Can and the RV Coil.

The settings for the Pathway parameter are AX>B and B>AX. AX refers to the Active Can and SVC Coil electrodes, which may be used individually or in combination. B refers to the RV Coil electrode. The Pathway setting defines direction of current flow during the initial segment of the biphasic waveform. If the parameter is set to AX>B, current flows from the Active Can and SVC Coil to the RV Coil. If the parameter is set to B>AX, this current flow is reversed.

6.7.1.3 Confirming VT or FVT after detection

When the device begins charging its capacitors for a cardioversion therapy, it monitors the cardiac rhythm to ensure that the tachyarrhythmia remains present before delivering the therapy.

The device confirms the continued presence of the tachyarrhythmia using one of the following confirmation intervals:

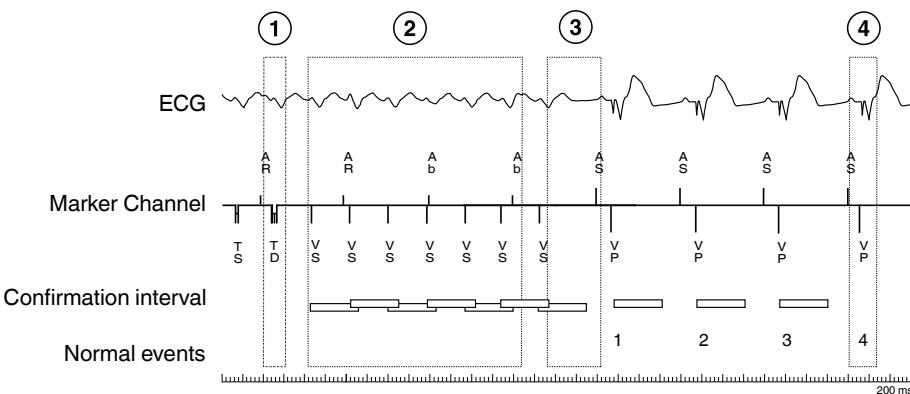
- the programmed VT interval + 60 ms. This is the default confirmation interval.
- an interval calculated from the ventricular cycle length + 60 ms. This interval is provided by the Confirmation+ option.

If Confirmation+ is on, the device uses the Confirmation+ interval if it is shorter than the default confirmation interval.

The device classifies any ventricular event that occurs within either confirmation interval as an “arrhythmic event” and any event that occurs outside the interval as a “normal event”.

On each ventricular event during charging, the device reviews the last 5 events since charging started. If the last 5 ventricular events included 4 “normal events”, the device stops charging and cancels the therapy.

Figure 178. Example of a cancelled cardioversion therapy



- 1 The device has detected VT and starts charging its capacitors for cardioversion.
- 2 The device confirms the tachyarrhythmia using the confirmation interval.
- 3 The VT spontaneously terminates, and normal sinus rhythm resumes.
- 4 When 4 of the last 5 events are “normal events”, the device stops charging its capacitors.

6.7.1.4 Synchronizing cardioversion after charging

After charging ends, the device continues to confirm the presence of the tachyarrhythmia. If the tachyarrhythmia persists, the device attempts to deliver the cardioversion therapy. If the tachyarrhythmia changes, the device aborts the therapy.

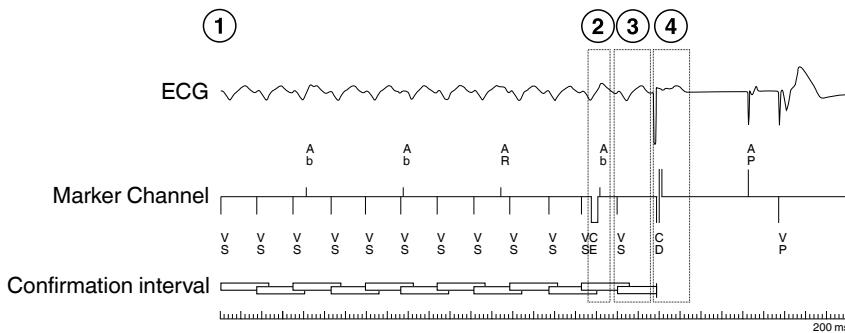
To deliver the cardioversion therapy, the device attempts to synchronize it to a nonrefractory ventricular event that meets one of the following conditions:

- The event is the second tachyarrhythmic ventricular event after charging, and it is outside the atrial vulnerable period.
- The event is the third tachyarrhythmic ventricular event.

Note: The system defines the atrial vulnerable period as a 250 ms window that extends from 150 ms to 400 ms after a sensed atrial event. A cardioversion therapy delivered during this period might induce an atrial tachyarrhythmia. If a cardioversion delivery is scheduled to be delivered during this period, it is postponed until the next qualifying event.

The device continues to attempt to synchronize until it delivers the cardioversion therapy or it fails to confirm the presence of the tachyarrhythmia and cancels the therapy.

Figure 179. Example of synchronous delivery of cardioversion

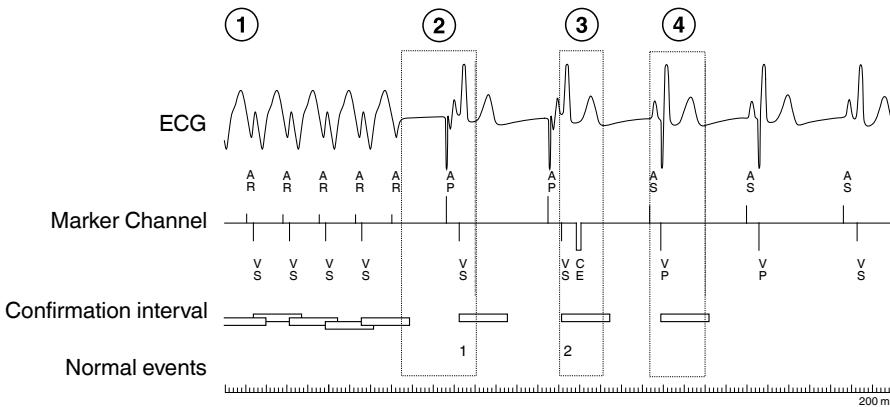


- 1 The device has detected VT. It charges its capacitors for cardioversion and confirms that the tachyarrhythmia is still present.
- 2 The device completes charging while continuing confirmation.
- 3 A tachyarrhythmic ventricular event occurs.
- 4 On the second tachyarrhythmic event after charging, the device delivers the cardioversion therapy.

The device confirms the presence of the detected tachyarrhythmia differently after charging than it does during charging. After charging, the device aborts the cardioversion therapy if one of the following events occurs:

- a “normal event” in the ventricle
- 3 consecutive ventricular sensed intervals less than 200 ms

The presence of short ventricular sensed intervals during synchronization indicates that the rhythm has either accelerated since initial detection or that significant oversensing is present. In either case, cardioversion may no longer be an appropriate therapy.

Figure 180. Example of an aborted cardioversion therapy

- 1 The device has detected VT. It charges its capacitors for cardioversion and confirms that the tachyarrhythmia is still present.
- 2 The VT spontaneously terminates, and normal sinus rhythm resumes.
- 3 The charging period ends, and synchronization starts. At this point, the device stops the confirmation process.
- 4 The cardioversion therapy aborts when a “normal event” occurs during synchronization.

6.7.1.5 Bradycardia pacing during and after a cardioversion therapy

On the first ventricular event after charging, the device changes the pacing mode to VVI until the charge is delivered or aborted. The pacing interval remains unchanged during this time.

After the cardioversion therapy is delivered, the device monitors for the end of the episode or redetection. Immediately after delivering the shock, the device starts a post-shock blanking period of 520 ms and resumes bradycardia pacing. If the programmed pacing mode is an MVP mode (AAIR<=>DDDR or AAI<=>DDD), the device operates in DDDR or DDD mode for 1 min after a cardioversion therapy. In other cases, the device operates in the programmed pacing mode.

The Post Shock Pacing parameters are applied. For more information, see Section 4.20, “Post Shock Pacing”, page 219. If Post VT/VF Shock Pacing is programmed to On, the device paces at the programmed Overdrive Rate. For more information, see Section 4.21, “Post VT/VF Shock Overdrive Pacing”, page 220.

6.7.1.6 Sequence after a cancelled cardioversion therapy

If the device cancels a cardioversion therapy, it reverts immediately to the programmed bradycardia pacing settings, not the Post Shock Pacing parameters.

The device resumes monitoring for arrhythmias after the next paced or sensed ventricular event. If the device redetects VT (or FVT) before the episode ends, it attempts to synchronize and deliver the programmed therapy that was aborted. However, if the episode ends, the device resumes normal detection.

Note: If the device cancels the cardioversion therapy, leaving energy stored on the capacitors, the delivered energy of the next high-voltage therapy may be higher than the programmed value.

6.7.2 Programming ventricular cardioversion

Navigation to parameters for ventricular cardioversion (CV) therapies for VT episodes is shown in Table 39. To navigate to parameters for ventricular cardioversion therapies for FVT episodes, select Params > FVT Therapies....

Table 39. How to navigate to ventricular cardioversion therapies parameters

Parameters	Path
VT therapies	Params > VT Therapies...
VT Therapy Status (On, Off)	
Therapy Type (CV)	
Energy	
Pathway	
Shared Settings (for V. ATP and V. Therapies)	Params > VT Therapies... > Shared Settings...

Caution: If the Active Can feature is not used, the device delivers defibrillation and cardioversion therapies between the RV Coil and SVC Coil electrodes only. To ensure that the device can deliver defibrillation and cardioversion therapies, make sure a supplementary SVC Coil electrode is implanted and connected to the device before programming the Active Can/SVC Coil parameter to Can Off.

Active Can/SVC Coil – The programmed setting for the Active Can/SVC Coil parameter applies to all features that deliver high-voltage shocks.

Energy – Programming the cardioversion therapy energy level to an optimized value can terminate the tachyarrhythmia with an appropriate safety margin and without wasting energy. At least 1 VT therapy and 1 FVT therapy should be programmed to a maximum energy cardioversion.

Cardioversion therapies for FVT – If FVT therapies are programmed to On, at least 1 FVT therapy must be programmed to cardioversion (at any energy level). The final FVT therapy must always be programmed to cardioversion.

Therapy aggressiveness – VT and FVT therapies must be programmed to be increasingly aggressive. For example, you cannot program 1 VT therapy to cardioversion and a

subsequent VT therapy to an ATP therapy. Likewise, a VT cardioversion therapy cannot be followed by another VT cardioversion therapy with a lower energy setting.

VF therapies – VT and FVT therapies cannot be programmed to On unless at least 1 VF therapy is also programmed to On.

6.7.3 Evaluation of ventricular cardioversion

6.7.3.1 The Quick Look II screen

To access Quick Look II screen information about VT/VF therapies, select Data > Quick Look II.

Treated VT/VF episodes – This section includes a count of treated VT/VF episodes. You can select the Treated [>>] button to view data for the treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information about an observation is available, you can select the observation and then select the Observations [>>] button to view the related information.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, “Quick Look II summary data”, page 69.

6.7.3.2 VT/VF therapy counters

The VT/VF therapy counters provide information that helps you to evaluate the efficacy of ventricular cardioversion. The VT/VF therapy counters include the VT/VF Therapy Summary for the prior session, the last session, and the device lifetime. The VT/VF therapy counters also include the VT/VF Therapy Efficacy Since Last Session.

To access VT/VF therapy counter information, select Data > Clinical Diagnostics > Counters > [Open Data] > VT/VF Rx.

VT/VF Therapy Summary – This section reports the number of pace-terminated arrhythmias, shock-terminated arrhythmias, total VT/VF shocks, and aborted charges for the prior session, the last session, and the device lifetime.

VT/VF Therapy Efficacy Since Last Session – For VF, FVT, and VT therapies, the counters report the number and types of therapies that were delivered and successful. The VT Therapy counter includes VT episodes that accelerated during the therapy or were redetected as an FVT or VF episode. The FVT therapy counter includes FVT episodes that were redetected as a VF episode.

6.8 Progressive Episode Therapies

During an ongoing ventricular tachyarrhythmia episode, the ventricular rate may accelerate or decelerate, which can cause the device to redetect the episode as a different type of tachyarrhythmia. If this occurs, the device delivers the next available therapy programmed for the type of tachyarrhythmia that was redetected. In some cases, deceleration can cause the therapies delivered later in an episode to be less aggressive than those delivered earlier in the same episode. For example, the device could detect an episode as VF, deliver a defibrillation therapy, redetect the episode as FVT, and then deliver an ATP therapy. The device will not deliver less aggressive therapies if there are less than 4 defibrillation therapies remaining or less than 2 FVT cardioversion therapies remaining (when FVT therapies are enabled) in the episode or there has been a second deceleration in the episode.

When the Progressive Episode Therapies feature is programmed On, the device skips therapies or modifies high-voltage energy levels to ensure that each therapy delivered during a ventricular tachyarrhythmia episode is at least as aggressive as the previous therapy.

6.8.1 Operation of Progressive Episode Therapies

Each time the device delivers a therapy during a ventricular tachyarrhythmia episode, Progressive Episode Therapies adjusts the therapies that are available if the episode is redetected. It makes 3 different kinds of adjustments.

First, the device does not deliver therapies programmed for slower tachyarrhythmia types for the remainder of the episode. Instead, it delivers the next therapy programmed for the fastest tachyarrhythmia type detected during the episode. For example, if the device detects VF and delivers a defibrillation therapy, it delivers only VF defibrillation therapies for the rest of the episode.

Second, if the device delivers a ventricular cardioversion therapy, it skips all ATP therapies for the remainder of the episode. For example, if the device detects a VT, delivers a cardioversion therapy, and redetects the episode as FVT, it skips any ATP therapies programmed for FVT. Instead, the device delivers the next cardioversion therapy programmed for FVT.

Finally, if the device delivers a ventricular cardioversion therapy, it adjusts the energy value for the next cardioversion or defibrillation therapy to be equal to or greater than the energy value of the last delivered therapy. For example, if the device detects a VT, delivers a 35 J cardioversion, and redetects the episode as FVT, the next cardioversion therapy will also deliver 35 J, even if the programmed value is 20 J.

Note: Progressive Episode Therapies operation does not cause the device to skip ATP During Charging. However, if ATP Before Charging is enabled and if Progressive Episode Therapies criteria have been met, the device skips the ATP sequence before charging and only delivers an ATP sequence during charging.

6.8.2 Programming Progressive Episode Therapies

To access Progressive Episode Therapies, select Params > VF Therapies...> Shared Settings....

6.8.3 Evaluation of Progressive Episode Therapies

6.8.3.1 Treated VT/VF episode text

To access the episode text for a treated ventricular tachyarrhythmia episode, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] > Text. The episode text lists all the therapies the device delivered during the episode. If Progressive Episode Therapies is enabled, this fact is noted before the list of therapies.

6.8.3.2 Treated VT/VF episode plot

To access the interval or rate plot for a ventricular tachyarrhythmia episode, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] > Plot. The interval or rate plot shows how the ventricular rate varied during an episode and how the rate compared to the programmed VF Interval (Rate), FVT Interval (Rate) and VT Interval (Rate) values. This plot is also annotated with each therapy delivered during the episode, allowing you to compare the delivered therapies to the detected rhythm.

7 System test and EP Study features

7.1 Underlying Rhythm Test

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.

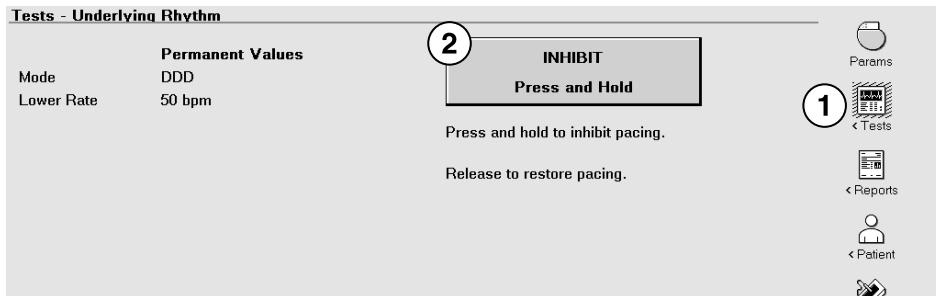
7.1.1 Considerations for evaluating the underlying rhythm

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.

7.1.2 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, use the real-time strip recorder or Electronic Strip Chart (eStrip) recorder, whichever is available. The ECG trace should not show any pacing.

7.2 Pacing Threshold Test

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 device longevity.

7.2.1 Considerations for measuring pacing thresholds

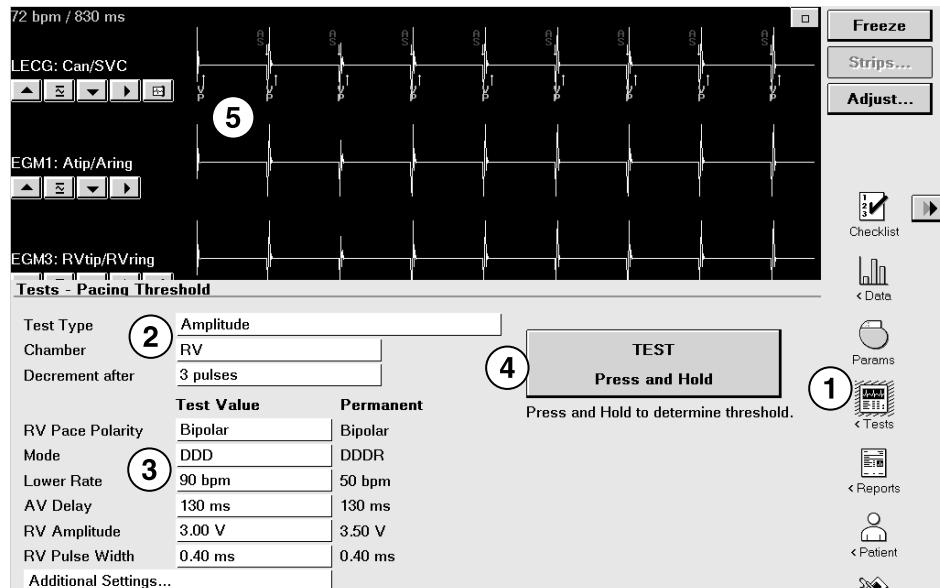
Selectable and default values – The selectable and default values provided by the Pacing Threshold Test depend on the programmed values for pacing therapy.

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.

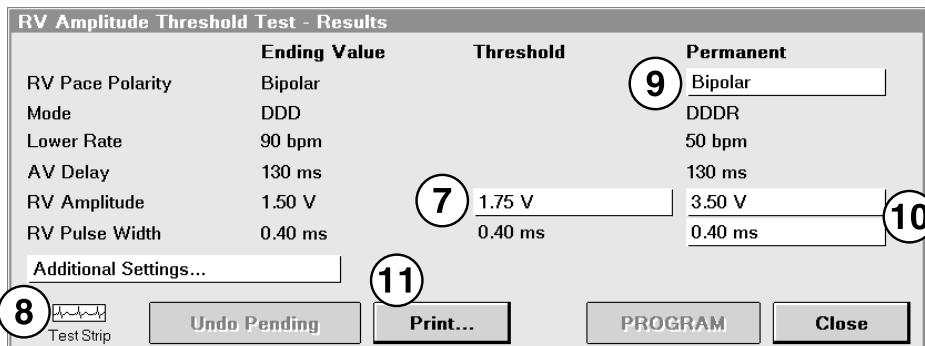
Measuring pacing thresholds in the two-lead system – The device provides independently selected outputs for Atrial and RV pacing. The Atrial and RV thresholds may be measured separately and individual safety margins applied to each threshold.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during a Pacing Threshold Test.

7.2.2 How to measure pacing thresholds



1. Select Tests > Pacing Threshold.
2. Select Atrium or RV for Chamber and values for Test Type and Decrement after, or accept the displayed values.
3. Select the starting Test Value for Pace Polarity, Mode, Lower Rate, AV Delay, Amplitude, and Pulse Width, or accept the displayed values.
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 for the selected Test Type.
7. To change the detected pacing threshold, select the threshold field (Amplitude or Pulse Width) displayed in the Threshold column of the Test - Results window.



8. To view a test strip from the Pacing Threshold Test, select the Test Strip icon in the lower-left corner of the Test - Results window. For more information, see Section 2.7, "Monitoring cardiac activity with the Live Rhythm Monitor", page 28.
9. If you are testing the RV pacing threshold, you can program a new RV Pace Polarity value by selecting the Pace Polarity field in the Permanent column of the Test - Results window. When the Pace Polarity window opens, select the desired value and then select [PROGRAM] in the Test - Results window.
10. To program new amplitude or pulse width values, select the Amplitude or Pulse Width field in the Permanent column of the Test - Results window. When the Capture window opens, select the desired values and select [OK]. Then, select [PROGRAM] in the Test - Results window.
11. To print a Pacing Threshold Test Report, select [Print...].
12. To return to the Pacing Threshold test screen, select [Close].

7.3 Wavelet Test

The Wavelet feature is designed to discriminate between rapid SVT and VT/VF episodes by comparing a patient's QRS waveforms to a stored template collected during normal sinus rhythm. The Wavelet test allows you to evaluate the current template and collect a new template, if necessary.

For a full description of the Wavelet feature, including automatic template collection, see Section 5.4, "Wavelet", page 248.

7.3.1 Evaluating the current template

You can use the Wavelet test to evaluate the accuracy of the current Wavelet template. As the test is conducted, intrinsic QRS waveforms are assigned match scores (percentages) in the Live Rhythm Monitor area. The higher the percentage, the closer the template event matches the patient's intrinsic event. Waveforms that fall below the programmable Match Threshold value are determined to be non-match events.

Note that changes to the Match Threshold value may adversely affect Wavelet operation. For information about Wavelet and the impact of increasing or decreasing the Match Threshold value, see Section 5.4, "Wavelet", page 248.

7.3.1.1 Considerations for evaluating a template

Select temporary pacing settings – To increase the likelihood that sensed events will occur during the test, you can select temporary pacing settings that evoke the patient's intrinsic rhythm.

Patient comfort – Reduce the pacing rate gradually to minimize symptoms associated with abrupt changes in heart rate.

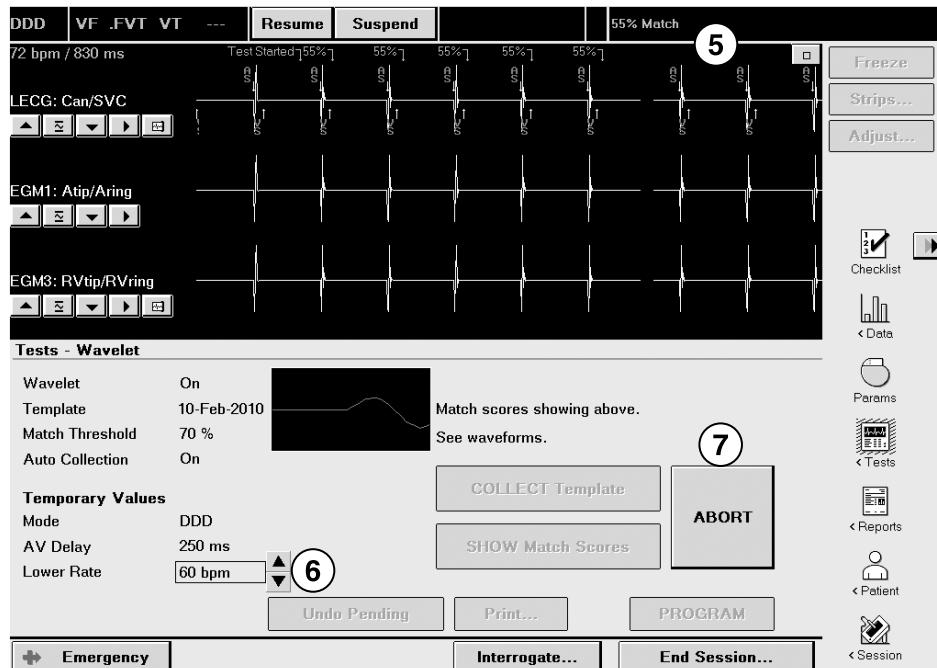
DOO, VOO, and AOO pacing modes – The Wavelet test cannot be performed if the programmed pacing mode is AOO, VOO, or DOO because sensing is turned off in these modes.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended when you select [Show Match Scores] to evaluate a Wavelet template.

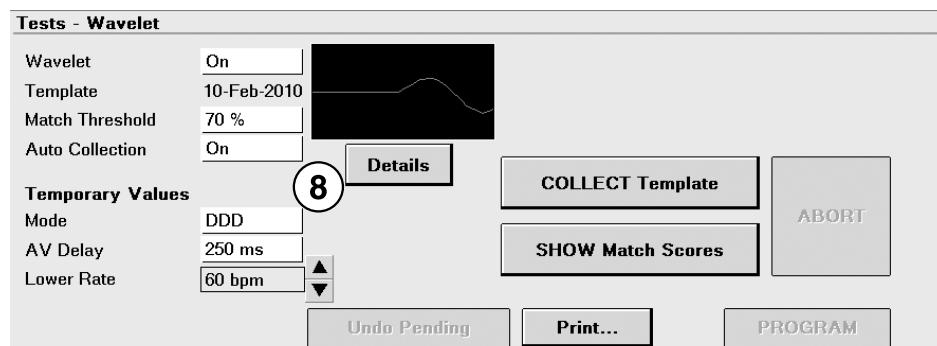
7.3.1.2 How to evaluate the current template

1. Interrogate the device.
2. Select Tests > Wavelet.
3. Set the Mode, AV Delay, and Lower Rate for the test, or accept the displayed values.
4. Select [SHOW Match Scores].

5. Observe the Live Rhythm Monitor for the intrinsic rhythm and the match scores for each compared event. The higher the percentage shown for the match scores, the more likely the template reflects the patient's intrinsic morphology.



6. If consistent pacing is still occurring, gradually decrease the Lower Rate to evoke the intrinsic rhythm.



7. If necessary, you can abort the test by selecting [ABORT]. Pacing settings will return to the programmed values.
8. After the test completes, you may select [Details] to view details about the stored template.

7.3.2 Collecting a template

You can use the Wavelet test to collect a template manually if one does not exist or if the existing template no longer matches the patient's intrinsic QRS morphology. Certain factors, such as a change in the patient's medication or disease progression, may have affected the appropriateness of the currently stored template. See Section 7.3.1.

After you successfully collect a template, the template goes into effect immediately and does not go through a confirmation process.

7.3.2.1 Considerations for collecting a new template

Intrinsic events – There must be a sufficient number of intrinsic events that occur during the template collection process in order to collect a template. You may need to adjust the Lower Rate or the Mode to promote intrinsic events. The test ends automatically after several seconds and restores the programmed settings if no intrinsic events occur and you make no changes to the Lower Rate.

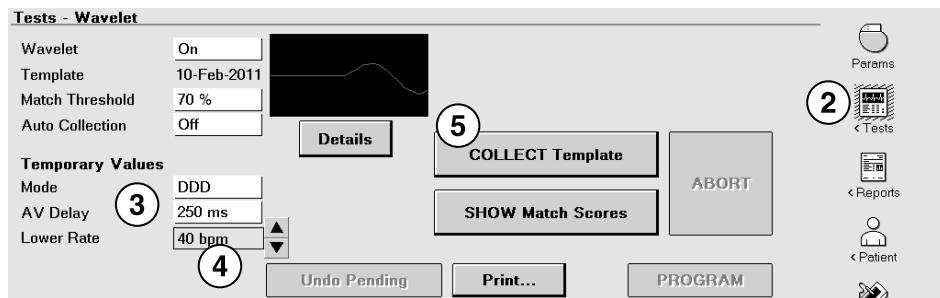
High or low EGM amplitude – Ensure that the EGM2 Range closely matches the amplitude of the patient's EGM signals so that a template can be collected. If the EGM signal exceeds the EGM2 programmed range, you may need to increase the EGM2 Range to prevent clipping of the signal. If the EGM signal occupies only a small fraction of the EGM amplitude range, decrease the EGM2 Range so that the signal uses a larger portion of the range. You can access the EGM2 Range by selecting the Params icon and choosing the Data Collection Setup... field. After adjusting the EGM2 Range, you will need to collect a new template. For more information about adjusting the EGM2 Range, see Section 5.4, "Wavelet", page 248.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended when you select [Collect Template] to manually collect a new Wavelet template.

7.3.2.2 How to collect a new template

1. Interrogate the device.
2. Select Tests > Wavelet.
3. Set the Mode, AV Delay, and Lower Rate for the test, or accept the displayed values.
4. If consistent pacing is still occurring, gradually decrease the Lower Rate until pacing does not occur.

5. Select [COLLECT Template].



Note: If pacing prevents you from collecting a valid sample, readjust the values for Mode, AV Delay, and Lower Rate and re-select [COLLECT Template].

6. After a template is collected, observe the Live Rhythm Monitor for the patient's intrinsic rhythm and the match scores for each compared event. If necessary, you can abort the test by selecting [ABORT]. Pacing settings return to the programmed values.

If the Wavelet test cannot collect enough matching EGM signals, the programmer automatically displays the Template Collection Problem window, which is then used to manually collect a template.

- Select [Close], and try to collect the template again. If you cannot collect a template automatically, then use the Template Collection Problem window to manually select a set of waveforms for the template.
- Refine the template by clearing the check box next to the color bar for each waveform sample that you do not want to include in the new template.
- Select [Calculate Template].
- Select [SHOW Match Scores] to evaluate the newly collected template.

7.4 Lead Impedance Test

The Lead Impedance Test allows you to test the integrity of the implanted lead system by measuring the impedance of the pacing and high-voltage electrodes. Impedance measurements are made without delivering a high-voltage shock or pacing pulses that capture the heart. The device makes these measurements by using low-voltage subthreshold pulses.

7.4.1 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 one or more of the EGM channels or the LECG channel. Pulses delivered during a Lead Impedance Test do not capture the heart or affect tachyarrhythmia detection.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during the Lead Impedance Test.

7.4.2 How to measure lead impedance

1. Select Tests > Lead Impedance.
2. Select [START Measurement]. Wait for confirmation of programming and a Measurement 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 programmed polarities are displayed. You may also view the measurements for all available lead polarities by selecting the All Measured Polarities [>>] button.

To determine if lead impedance has changed, compare measured values to the values reported on the Lead Impedance Trends screen and to the values measured during previous follow-up appointments (look in the patient's chart).

7.5 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.

7.5.1 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.

RV Sense Polarity – The ventricular sensing electrodes included in Sensing Test measurements depend on the programmed RV Sense Polarity value.

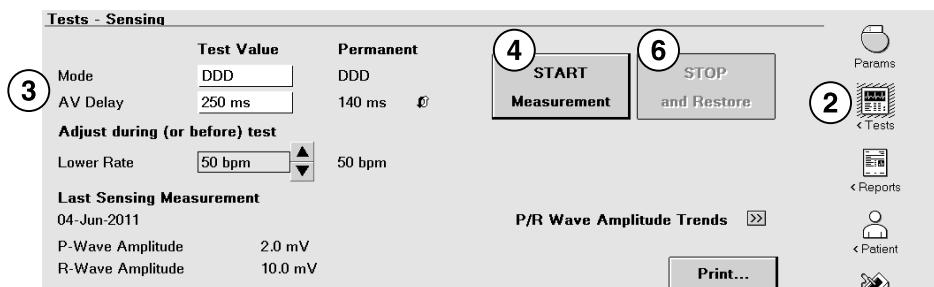
Maximum measured value – The maximum amplitude value that the Sensing Test can measure is 20 mV. If the amplitude is over 20 mV, the results are displayed as >20 mV.

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 4.1, “Sensing”, page 140.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during the Sensing Test.

7.5.2 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.
2. Select Tests > Sensing.

3. Program the Test Value parameters for Mode and AV Delay or accept the displayed values.
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 saved and 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.

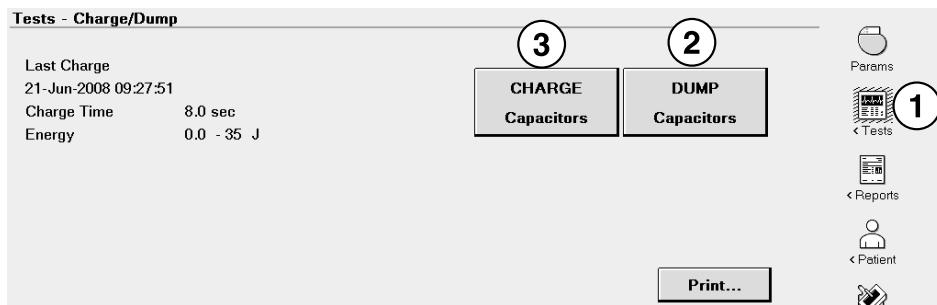
Select the [Print] button to print the test results.

7.6 Charge/Dump Test

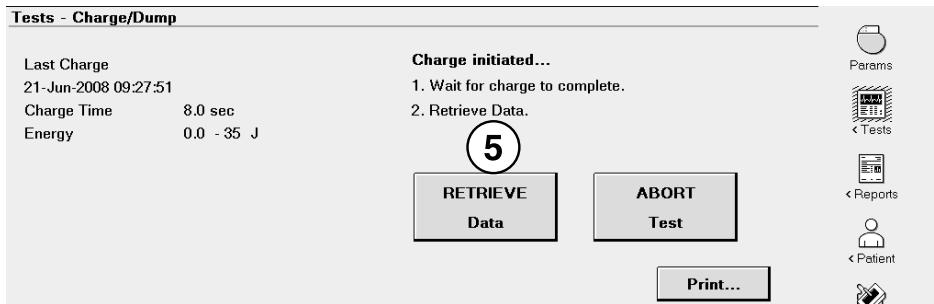
The Charge/Dump Test allows you to test the charge time of the capacitors and dump any charge remaining on the capacitors. After the capacitors are charged, the charge remains on the capacitors until the charge is dumped, delivered by a cardioversion or defibrillation therapy, or allowed to dissipate. The Charge/Dump Test screen displays the date, time, charge time, and energy values for the last time the device capacitors were charged (from any starting energy to any final energy).

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during the Charge portion of the Charge/Dump Test.

7.6.1 How to perform a Charge/Dump Test



1. Select Tests > Charge/Dump.
2. To remove any charge from the capacitors, select [DUMP Capacitors] and wait approximately 20 s.
3. To charge the capacitors, select [CHARGE Capacitors]. The message “Manual operation charging” appears on the Device Status Line. If necessary, select [ABORT Test] to abort the test charge.
Note: Charging the capacitors reduces device longevity by approximately 1 month.
4. When charging is complete, the Charge End (CE) symbol appears on the Marker Channel display and the message “Manual operation charging” no longer appears on the Device Status Line.
5. To retrieve the charge time data from the device, select [RETRIEVE Data].



7.7 Arrhythmia inductions with EP Studies

The device provides several electrophysiology study (EP study) functions, including cardiac stimulation protocols that induce tachyarrhythmias. The available induction methods are T-Shock, 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.

7.7.1 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.

When using wireless telemetry, verify that at least 3 of the green lights on the wireless telemetry icon are illuminated. For more information, see Section 2.1, "Establishing telemetry between the device and the programmer", page 11.

Resuming detection – Tachyarrhythmia detection is automatically suspended during all EP study functions. Following a manual therapy, detection must be resumed manually. Following an induction, detection is resumed either automatically or manually.

- Following EP study manual therapies, detection remains suspended until [Resume] is selected or until the programming head is removed from the implanted device.
- Following EP study inductions, detection is resumed automatically, with one exception: If [Suspend] was selected and the Resume at BURST or Resume at DELIVER check box was NOT selected before performing the induction, detection remains suspended until [Resume] is selected or until the programming head is removed from the implanted device.

Note: The SUSPENDED annotation is only displayed on the programmer status bar during EP study inductions if [Suspend] was selected before performing the induction.

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.

Last Induction (mm:ss) – A timer is available, for the T-Shock and ventricular 50 Hz Burst protocols, to track the length of time since the last induction. The timer is located in the lower left corner of the programmer screen.

7.7.2 Inducing VF with T-Shock

You can use the T-Shock induction to induce VF. To induce VF, the device delivers a series of VOO pacing pulses to make the T-wave timing more predictable. The device then simultaneously delivers a shock with a T-wave, the refractory period of the cardiac cycle. The device allows you to specify the characteristics of the pacing pulses and high-voltage shock and to implement a delay between the final pacing pulse and the shock.

The T-Shock induction interface includes features to help simplify DFT testing.

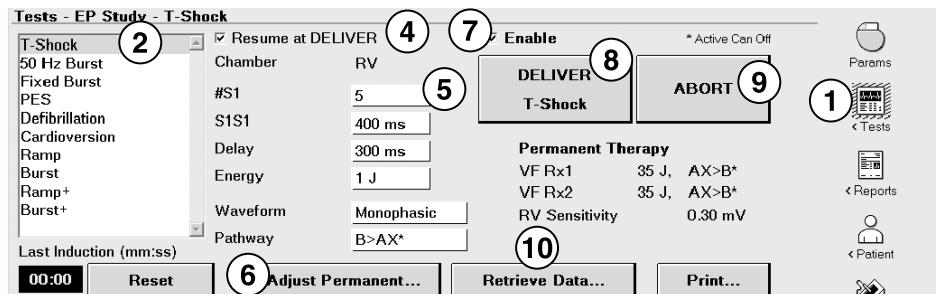
7.7.2.1 Considerations for inducing VF with T-Shock

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.

ATP Before Charging and ATP During Charging – ATP Before Charging and ATP During Charging are automatically disabled for 30 s after delivery of a T-Shock induction. This prevents ATP therapies from interfering with defibrillation threshold testing.

The Enable check box – As a safety measure, you cannot select [DELIVER T-Shock] until you have selected the Enable check box. After delivering a shock or exiting the T-Shock screen, you must select the Enable check box before delivering another T-Shock induction.

7.7.2.2 How to induce VF with T-Shock



1. Select Tests > EP Study.
2. Select T-Shock 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 at the top of the screen and is not shown in the illustration.

4. Select the Resume at DELIVER check box for automatic detection and therapy, or clear the check box for manual therapy.

Note: During a wireless telemetry session, you cannot deliver a T-Shock induction when there is a magnet or programming head over the device and the Resume at DELIVER check box is selected. If an error message appears, remove the magnet or programming head or clear the Resume at DELIVER check box.

5. Accept the displayed test values, or select new test values.
6. To view and adjust VF detection and therapy parameters, select [Adjust Permanent...].
7. Select the Enable check box.
8. Select [DELIVER T-Shock].

Note: If the energy on the capacitors is higher than the energy level you selected, the programmer displays a warning when you select [DELIVER T-Shock]. To clear this warning select either [DUMP] or [CANCEL].

9. If necessary, select [ABORT] to abort the induction or any therapy in progress.
10. Select [Retrieve Data...] and [Print...] to review and print patient data.

7.7.3 Inducing VF with 50 Hz Burst

You can use ventricular 50 Hz Burst to induce VF. To induce VF, the 50 Hz Burst induction delivers a rapid burst of VOO pacing pulses to the ventricle. 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).

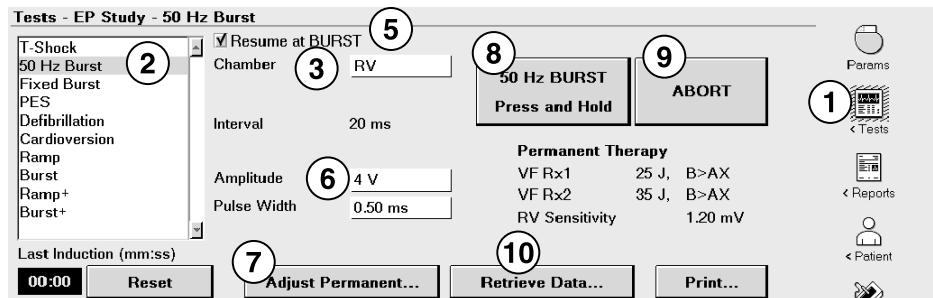
The ventricular 50 Hz Burst interface includes features to help simplify DFT testing.

7.7.3.1 Considerations for inducing VF with 50 Hz 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.

ATP Before Charging and ATP During Charging – ATP Before Charging and ATP During Charging are automatically disabled for 30 s after delivery of a 50 Hz Burst induction. This prevents ATP therapies from interfering with defibrillation threshold testing.

7.7.3.2 How to deliver a ventricular 50 Hz Burst induction



1. Select Tests > EP Study.
2. Select 50 Hz Burst from the list of inductions and therapies.
3. If the Select Chamber dialog box appears, select [RV]. Otherwise, make sure that the Chamber parameter is set to 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 at the top of the screen and is not shown in the illustration.
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. To view and adjust VF detection and therapy parameters, select [Adjust Permanent...].
8. Press and hold [50 Hz BURST Press and Hold]. Release the button to end the induction.
9. If necessary, select [ABORT] to abort a therapy in progress.
10. Select [Retrieve Data...] and [Print...] to review and print patient data.

7.7.4 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.

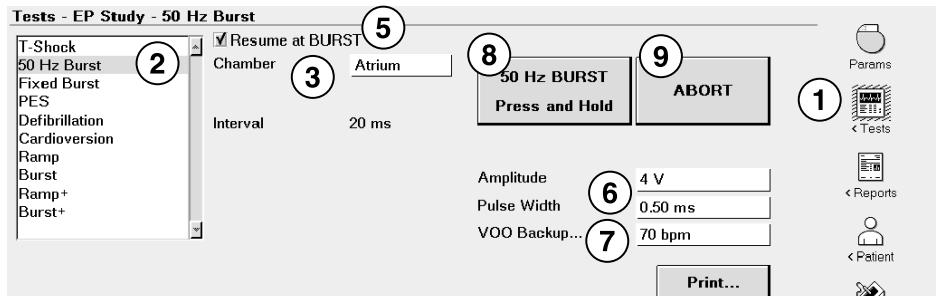
As long as you press and hold the [50 Hz BURST Press and Hold] button on the programmer screen, the device continues delivering the induction (up to a maximum of 10 s).

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.

7.7.4.1 How to deliver an atrial 50 Hz Burst



1. Select Tests > EP Study.
2. Select 50 Hz Burst from the list of inductions and therapies.
3. If the Select Chamber dialog box appears, select [Atrium]. Otherwise, make sure that the Chamber parameter is set to Atrium.
4. If you want to treat the induced episode with a manual therapy, select [Suspend] to prevent automatic detection.
- Note:** The [Suspend] button is at the top of the screen and is not shown in the illustration.
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 VOO Backup pacing during the pacing burst, select values for VOO Backup.
8. Press and hold [50 Hz BURST Press and Hold]. Release the button to end the induction.
9. If necessary, select [ABORT] to abort a therapy in progress.

7.7.5 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.

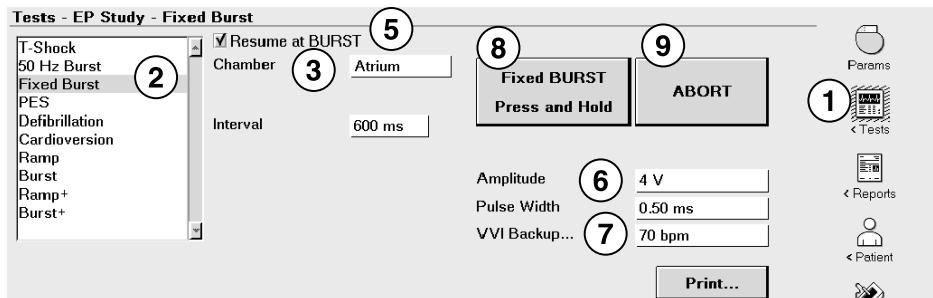
If you perform an atrial Fixed Burst induction, you may choose to have the device deliver VVI Backup pacing.

7.7.5.1 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.

7.7.5.2 How to deliver a Fixed Burst induction



1. Select Tests > EP Study.
2. Select Fixed Burst from the list of inductions and therapies.
3. If the Select Chamber 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 at the top of the screen and is not shown in the illustration.
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.

7.7.6 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.

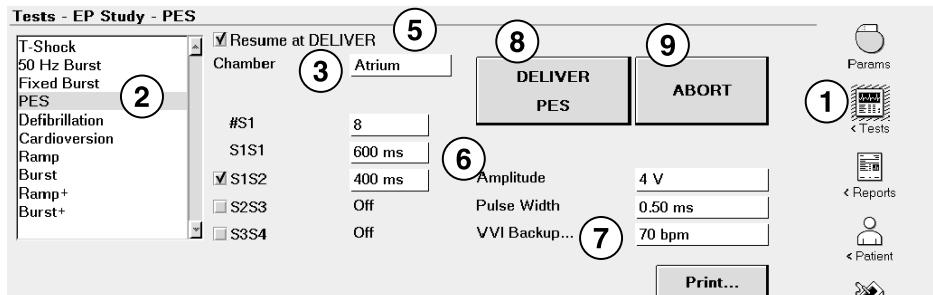
If you perform an atrial PES induction, you may choose to have the device deliver VVI Backup pacing.

7.7.6.1 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.

7.7.6.2 How to deliver a PES induction



1. Select Tests > EP Study.
2. Select PES from the list of inductions and therapies.

3. If the Select Chamber 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 at the top of the screen and is not shown in the illustration.
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].
9. If necessary, select [ABORT] to abort a therapy in progress.

7.8 Manual therapies with EP Studies

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 Defibrillation, Cardioversion, Ramp, Burst, Ramp+, and Burst+.

7.8.1 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.

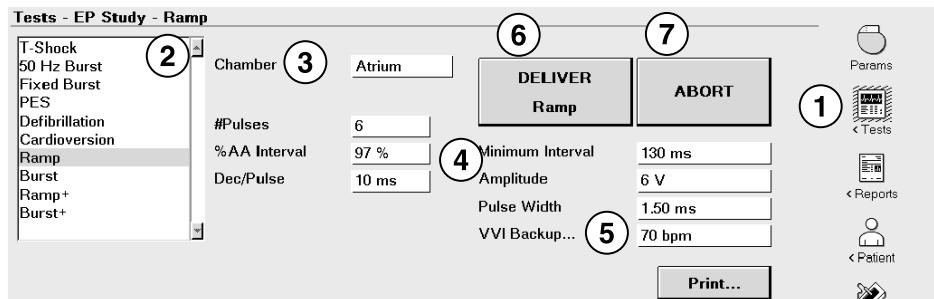
Telemetry – Ensure that a telemetry link is established between the device and the programmer before you perform a manual therapy. Successful interrogation or programming confirms proper communication between the device and the programmer.

When using wireless telemetry, verify that at least 3 of the green lights on the wireless telemetry icon are illuminated. For more information, see Section 2.1, “Establishing telemetry between the device and the programmer”, page 11.

Note: The telemetry link may be lost during the charging period for a high-voltage therapy due to electrical noise. Telemetry resumes after charging completes.

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.

7.8.2 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.

7.8.3 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 ATP therapies deliver one sequence of the selected therapy. For information about the operation of atrial Ramp and Burst+ therapies, see Section 6.2, “Atrial ATP therapies”, page 282. For information about the operation of ventricular Ramp, Burst, and Ramp+ therapies, see Section 6.6, “Ventricular ATP therapies”, page 313.

Defibrillation – Manual defibrillation therapy charges the device capacitors and delivers a biphasic shock, which is synchronized to a sensed R-wave if possible. The device does not confirm the presence of VF before delivering the shock. For more information about defibrillation, see Section 6.5, “VF therapies”, page 303.

Ventricular cardioversion – Manual ventricular cardioversion therapy charges the capacitors and attempts to synchronize the shock to a ventricular sensed event that is outside the refractory period. If the device cannot synchronize the therapy, the device aborts the therapy. For more information, see Section 6.7, “Ventricular cardioversion”, page 323.

Atrial cardioversion – Manual atrial cardioversion therapy charges the capacitors and attempts to synchronize the shock to a ventricular sensed event that is outside of the refractory period. If the ventricular interval is shorter than the selected R-R Interval, the device aborts the therapy. For more information, see Section 6.3, “Atrial cardioversion”, page 292.

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.

50 Hz Burst – induction protocol that delivers a train of pacing pulses into the selected chamber (atrium or ventricle) at 20 ms intervals. It is also provided as an AT/AF therapy.

Active Can – option to select the device case as an active electrode for delivering defibrillation and cardioversion therapies.

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.

AF/AfI feature – PR Logic feature designed to discriminate between rapidly conducted atrial fibrillation or atrial flutter and ventricular tachyarrhythmia.

antitachycardia pacing (ATP) – therapies that deliver rapid sequences of pacing pulses to terminate tachyarrhythmias.

Arrhythmia episode data – system that compiles an arrhythmia episode log that the clinician can use to view summary and detailed diagnostic data quickly, including stored EGM, for the selected arrhythmia episode.

AT/AF detection – feature that analyzes the atrial rate and its effect on the ventricular rhythm to determine whether the patient is currently experiencing an atrial tachyarrhythmia. Depending on programming, the device delivers a programmed sequence of atrial therapies or continues monitoring without delivering therapy.

AT/AF Interval – programmable interval used to define the AT/AF detection zone. The median atrial interval must be shorter than this value to detect an AT/AF episode.

ATP During Charging – device delivers a ventricular antitachycardia therapy sequence while the device charges its capacitors for the first defibrillation therapy during a VF episode.

Atrial antitachycardia pacing (ATP) – therapies that respond to an AT/AF episode or a Fast AT/AF episode with rapid sequences of pacing pulses to terminate detected atrial tachyarrhythmias.

Atrial cardioversion – therapy that delivers a high-voltage shock to treat an AT/AF episode or a Fast AT/AF episode. Atrial cardioversion delivery is synchronized to a sensed ventricular event and cannot exceed a programmable daily limit within programmable times.

Atrial Preference Pacing (APP) – atrial rhythm management feature that adapts the pacing rate to slightly higher than the intrinsic sinus rate.

Atrial Rate Stabilization (ARS) – atrial rhythm management feature that eliminates a prolonged pause following a premature atrial contraction (PAC).

Atrial Refractory Period (ARP) – interval that follows an atrial paced or sensed event during which the device senses events but responds to them in a limited way. This interval is applied when the device is operating in a single chamber, atrial pacing mode.

Atrial therapy scheduling – feature that enables the clinician to program the delivery of automatic atrial therapies. Each time that an AT/AF therapy is needed, the device schedules one of the available therapies based on clinician programming.

atrial tracking – dual chamber pacing operation that paces the ventricle in response to atrial events.

Auto PVARP – Adjusts PVARP (Post-Ventricular Atrial Refractory Period) in response to changes in the patient's heart rate or pacing rate. PVARP is longer at lower tracking rates to prevent pacemaker-mediated tachycardia (PMT) and shorter at higher rates to maintain 1:1 tracking.

AV synchrony – coordinated contraction of the atria and ventricles for most effective cardiac output.

blanking period – time interval during which sensing in a chamber is disabled to avoid oversensing.

Burst pacing – antitachycardia pacing (ATP) therapy that delivers sequences of ventricular pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length. With each sequence of Burst pacing delivered, the device shortens the pacing interval by a programmable interval.

Burst+ pacing – antitachycardia pacing (ATP) therapy that delivers sequences of atrial pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length, followed by up to 2 premature stimuli delivered at programmable intervals. With each sequence of Burst+ pacing delivered, the device shortens the pacing interval by a programmable interval.

capacitor – component in the device that stores electrical energy so that high-voltage therapies can be delivered from a relatively small battery.

Capture Management – feature that monitors pacing thresholds with daily pacing threshold searches and, if programmed to do so, adjusts the pacing amplitudes toward a target amplitude.

Cardiac Compass Trends – overview of the patient’s condition over the last 14 months with graphs that display long-term clinical trends in heart rhythm and device status, such as frequency of arrhythmias, heart rates, and device therapies.

Charge/Dump Test – feature that tests the charge time of the capacitors and dumps any charge remaining on the capacitors.

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.

Combined Count detection – feature designed to prevent a delay in VF detection when ventricular tachyarrhythmia fluctuates between the VF and VT zones.

Conducted AF Response – feature that adjusts the pacing rate to help promote a regular ventricular rate during AT/AF episodes.

Conexus wireless telemetry – feature that uses radio frequency (RF) telemetry for communication between the implanted device and programmer in the hospital or clinic and between the implanted device and home monitor in the patient’s home.

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 and an automatic Medtronic CareAlert tone.

electromagnetic interference (EMI) – energy transmitted from external sources by radiation, conduction, or induction that may interfere with device operations, such as sensing, or may potentially damage device circuitry.

Emergency therapies – Therapies such as defibrillation, cardioversion, fixed burst pacing, and emergency VVI that can be initiated manually to treat ventricular tachyarrhythmia episodes quickly.

EOS (End of Service) – battery status indicator displayed by the programmer to indicate that the device should be replaced immediately and that it may not operate per specifications.

EP Studies – set of protocols that allows clinicians to induce arrhythmias during electrophysiology studies. Manual therapies are also available.

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.

far-field EGM – the EGM signal sensed between distant electrodes. For example, the EGM sensed between the device can and the ventricular lead ring.

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.

Heart Failure Management Report – printed report that summarizes the patient's clinical status and observations since the last follow-up appointment and provides graphs that show trends in heart rates, arrhythmias, and fluid accumulation indicators over the last 14 months.

High Rate Timeout – feature that allows the device to delivery therapy for any ventricular tachyarrhythmia that continues beyond the programmed length of time.

Holter telemetry – telemetry feature that transmits EGM and Marker Channel data continuously for a programmable number of hours, regardless of whether telemetry actually exists between the device and programmer.

hysteresis – a pacing operation and programmable parameter that allows a longer escape interval after a sensed event, giving the heart a greater opportunity to beat on its own.

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.

Lead Impedance Test – feature that tests the integrity of the implanted lead system by measuring the impedance of the pacing and high-voltage electrodes. The test uses low-voltage, subthreshold pulses to make these measurements.

Leadless ECG – device feature that enables physicians to perform tests and record a signal equivalent to an ECG without attaching surface ECG leads.

Live Rhythm Monitor – configurable programmer window that displays ECG, Leadless ECG, Marker Channel with marker annotations, and telemetered EGM waveform traces. It also displays the patient heart rate and interval in the upper left corner of the window.

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.

median ventricular interval – the seventh in a numerically ordered list of the 12 most recent V-V intervals.

Medtronic CareAlert Monitoring – the continuous monitoring for, and silent, wireless transmission of, alert data between an implanted device and the Medtronic monitor.

Medtronic CareAlert Notifications – alert information sent via the Medtronic CareLink Network that notifies clinics and clinicians of events that impact patients or their implanted devices.

Medtronic CareLink Network – Internet-based service that allows a patient to transmit full cardiac device information from home or other locations to the physician over a secure server. The CareLink Network may be unavailable in some geographic locations.

Medtronic patient monitor – instrument used in the patient's home that receives data from an implanted device via telemetry and transmits that data to the Medtronic CareLink Network.

Mode Switch – feature that switches the device pacing mode from a dual chamber atrial tracking mode to a nontracking mode during an atrial tachyarrhythmia. This feature prevents rapid ventricular pacing that may result from tracking a high atrial rate and restores the programmed pacing mode when the atrial tachyarrhythmia ends.

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. MVP 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.

non-sustained VT (VT-NS) – ventricular rhythm that is fast enough to fall within the programmed VT and VF zones for at least 5 beats but does not meet any episode detection criteria.

Onset – feature that helps prevent detection of sinus tachycardia as VT by evaluating the acceleration of the ventricular rate.

OptiVol 2.0 fluid status monitoring – feature that identifies a potential increase in thoracic fluid, which may indicate lung congestion, by monitoring changes in thoracic impedance.

OptiVol event – an occurrence of the OptiVol 2.0 Fluid Index exceeding the programmed OptiVol Threshold, which may indicate fluid accumulation in the patient's thoracic cavity.

OptiVol Threshold – a programmable value of the OptiVol 2.0 Fluid Index. Values above this threshold may indicate fluid accumulation in the patient’s thoracic cavity and define the occurrence of an OptiVol event.

Other 1:1 SVTs feature – PR Logic feature designed to withhold ventricular detection for supraventricular tachycardias that exhibit nearly simultaneous atrial and ventricular activation.

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 dual chamber 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.

Pacing Threshold Test – test that allows the clinician to determine the patient’s pacing thresholds.

patient-activated atrial cardioversion – therapy that delivers a synchronized atrial cardioversion that the patient requests using an external Patient Assistant. The therapy is delivered only if an AT/AF episode is detected at the time of the request.

patient alert – a tone emitted from an implanted device to notify the patient of an alert condition.

Patient Information – feature that allows clinicians to store patient-related information on the programmer that they can view and print during a patient session.

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.

Post Shock Pacing – feature that provides temporary pacing support after a high-voltage therapy by increasing the pacing amplitude and pulse width to prevent loss of capture.

Post VT/VF Shock Pacing – feature that provides temporary overdrive pacing that may improve cardiac output after a high-voltage therapy.

Pre-arrhythmia EGM storage – (also called EGM pre-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.

PR Logic – set of features that uses pattern and rate analysis to discriminate between supraventricular tachycardias (SVTs) and true ventricular tachyarrhythmias.

Programmed Electrical Stimulation (PES) – Tachyarrhythmia induction protocol that delivers pacing pulses at specific, programmable intervals.

Progressive Episode Therapies – feature that causes the device to skip therapies or modify high-voltage energy levels to ensure that each therapy delivered during an episode is at least as aggressive as the previous therapy.

PVAB (Post-Ventricular Atrial Blanking) – interval after ventricular events during which atrial events are ignored by bradycardia pacing features or are not sensed by the device, depending on the programmed PVAB method.

PVARP (Post Ventricular Atrial Refractory Period) – atrial refractory period following a ventricular event used to prevent inhibition or pacemaker-mediated tachycardias (PMTs) in dual chamber pacing modes.

PVC (premature ventricular contraction) – a sensed ventricular event that directly follows any other ventricular event with no atrial event between them.

PVC Response – feature that extends PVARP following a premature ventricular contraction (PVC) to avoid tracking a retrograde P-wave and to prevent retrograde conduction from inhibiting an atrial pace.

Quick Look II – programmer screen that presents overview data about device operation and patient rhythms collected since the last patient session. It includes links to more detailed status and diagnostic information stored in the device, such as arrhythmia episodes and therapies provided.

Ramp pacing – antitachycardia pacing (ATP) therapy that delivers pacing pulses with progressively shorter pacing intervals per pulse. Each sequence of Ramp pacing that is delivered during a therapy includes an additional pacing pulse.

Rate Adaptive AV (RAAV) – dual chamber pacing feature that varies the Paced AV (PAV) and Sensed AV (SAV) intervals as the heart rate increases or decreases to maintain 1:1 tracking and AV synchrony.

Rate Drop Response – feature that monitors the heart for a significant drop in rate and responds by pacing the heart at an elevated rate for a programmed duration.

Rate Drop Response episodes data – feature that displays beat-to-beat data that is useful in analyzing Rate Drop Response episodes and the events leading up to those episodes.

Rate Histograms – diagnostic feature that shows range distributions for a patient's heart rate.

rate profile – rate histogram of the sensor rates used by Rate Profile optimization to automatically adjust Rate Response settings.

Rate Profile Optimization – feature that monitors the patient's daily and monthly sensor rate profiles and adjusts the rate response curves over time to achieve a prescribed target rate profile.

Rate Response – feature that adjusts the cardiac pacing rate in response to changes in sensed patient activity.

Reactive ATP – feature that allows the device to repeat programmed atrial antitachycardia pacing (ATP) therapies during long AT/AF episodes. Therapies are repeated after a programmed time interval or when the atrial rhythm changes in regularity or cycle length.

reference impedance – a baseline against which daily thoracic impedance is compared to determine if thoracic fluid is increasing.

refractory period – time interval during which the device senses events normally but classifies them as refractory and responds to them in a limited way.

Remaining Longevity estimate – an estimate of remaining device longevity that is displayed on the Quick Look II and Battery and Lead Measurements screens. On both screens, this information includes a graphical display for easy reference and the estimated number of years or months of remaining longevity. On the Battery and Lead Measurements screen, the Minimum and Maximum number of years or months of remaining device longevity are also provided.

Resume – programming command that reinstates automatic tachyarrhythmia detection.

retrograde conduction – electrical conduction from the ventricles to the atria.

RRT (Recommended Replacement Time) – battery status indicator displayed by the programmer to indicate when replacement of the device is recommended.

RV Lead Integrity Alert – feature that sounds an alert tone to warn the patient that a potential RV lead problem is suspected, which could indicate a lead fracture.

RV Lead Noise Alert – feature that sounds an alert tone when RV Lead Noise Discrimination withholds VT/VF detection because of the presence of noise on the RV lead. Noise could indicate lead fracture, breached lead insulation, lead dislodgment, or improper lead connection.

RV Lead Noise Discrimination – feature that compares a far-field EGM signal to the near-field sensing signal to differentiate RV lead noise from VT/VF. If lead noise is identified when these signals are compared, the device withholds VT/VF detection and therapy and triggers an RV Lead Noise Alert.

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.

Sensing Test – feature that measures P-wave and R-wave amplitudes to help assess lead integrity and sensing performance.

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.

sequence, ATP – one programmable set of antitachycardia pacing (ATP) therapy pulses.

Sinus Tach feature – PR Logic feature designed to discriminate between high rate sinus tachycardia and ventricular tachyarrhythmia.

Sleep – feature that causes the device to pace at a slower rate during a programmed sleep period.

Smart Mode – feature that disables an ATP therapy that has been unsuccessful in 4 consecutive episodes so the device can treat subsequent episodes more quickly with therapies that have been effective.

Stability – feature that helps prevent detection of atrial fibrillation as ventricular tachyarrhythmia by evaluating the stability of the ventricular rate. If the device determines that the ventricular rate is not stable, it withholds VT detection.

Suspend – programming command that temporarily deactivates the tachyarrhythmia detection functions.

SVT V. Limit – feature that allows you to program a highest rate for which PR Logic and Wavelet can withhold detection and therapy.

synchronization – period during defibrillation and cardioversion therapies when the device attempts to deliver the therapy shock simultaneously with a sensed ventricular event.

telemetry – transmission of data between the device and the programmer by radio waves.

TherapyGuide – feature that suggests a set of parameters based on the programmed information about the patient's clinical conditions. The physician can accept, reject, or modify any of the suggested parameter values.

thoracic impedance – impedance across the thorax as measured from 2 points within the thorax.

T-Shock induction – VF induction protocol that delivers a programmable shock synchronized with the ventricular repolarization or T-wave.

TWave Discrimination – feature that withholds VT/VF detection when a fast ventricular rate is detected because of oversensed T-waves.

Underlying Rhythm Test – feature that temporarily inhibits the pacing output of the device to enable evaluation of the patient's intrinsic heart rhythm.

undersensing – failure of the device to sense intrinsic cardiac activity.

ventricular antitachycardia pacing (ATP) – therapies that respond to a VT episode or an FVT episode with rapid sequences of pacing pulses to terminate detected ventricular tachyarrhythmias.

ventricular cardioversion – therapy that delivers a high-voltage shock to treat a VT or an FVT episode. Therapy is synchronized to a sensed ventricular event.

ventricular fibrillation (VF) therapies – therapies that deliver automatic defibrillation shocks to treat VF episodes. The first defibrillation therapy requires VF confirmation before delivery. After the first shock has been delivered, shocks are delivered asynchronously if synchronization fails.

Ventricular Rate Stabilization (VRS) – ventricular rhythm management feature that adjusts the pacing rate dynamically to eliminate the long pause that typically follows a premature ventricular contraction (PVC).

Ventricular Safety Pacing (VSP) – pacing therapy feature that prevents inappropriate inhibition of ventricular pacing caused by crosstalk or ventricular oversensing.

VF confirmation – device operation that confirms the presence of VF after initial detection but before a defibrillation therapy is delivered. This feature applies only to the first programmed VF therapy.

VT monitoring – programmable option that allows the device to detect fast rhythms as VT and record episode data without delivering VT therapy.

VT/VF detection – feature that uses programmable detection zones to classify ventricular events. Depending on programming, the device delivers a scheduled therapy, re-evaluates the patient's heart rhythm, and terminates or redetects the episode.

waveform – graphic plot of electrical activity, for example, intracardiac EGM or surface ECG trace.

Wavelet – feature designed to prevent detection of rapidly conducted SVTs as ventricular tachyarrhythmias by comparing the shape of each QRS complex during a fast ventricular rate to a template.

Wavelet Test – test that evaluates the accuracy of the current Wavelet template and allows the clinician to collect a new template, if necessary.

wireless telemetry – transmission of data between the device and the programmer by radio waves.

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