Boston Scientific

REFERENCE GUIDE

ADVANTIO™

PACEMAKER

REF K082, K083, K084

ABOUT THIS MANUAL

This family of implantable pacemakers contains both single- and dual-chamber pulse generators that provide atrial and/or ventricular pacing and sensing and a variety of diagnostic tools.

The organization of the manuals provided for Boston Scientific pulse generators has changed. System Guides have been replaced by Reference Guides, and the Physician's Technical Manual has been expanded.

Information for Use, Implant Information, and Post Implant Information, topics formerly covered in the System Guide, can now be found in the Physician's Technical Manual.

For copies of any of these documents, contact Boston Scientific using the information on the back cover.

NEW OR ENHANCED FEATURES

These pulse generator systems include additional or enhanced features as compared to previous Boston Scientific pacemakers.

The list below is intended to highlight some of these features, it is not a comprehensive list. Please refer to the feature-specific content elsewhere in this manual for detailed descriptions of these features.

User Experience

- Hardware: the number of setscrews has been reduced to one setscrew per port
- ZIP Telemetry: provides wandless, two-way RF communication with the pulse generator
- ZOOMVIEW Programmer Software: the new user interface is consistent across Boston Scientific brady, tachy, and heart failure devices.
- Single Chamber Devices: incorporates programmability to select atrial or ventricular specific modes
- USB storage devices are supported: pulse generator data can be saved and transferred to a USB pen drive

Tachy Detection

- Ventricular Tachy EGM Storage utilizes the strengths of an ICD-based tachycardia detection strategy including a V > A detection enhancement

Brady Therapy

- New brady modes available include VDDR and Off
- AV Search+: designed to reduce unnecessary RV pacing for patients with intact or intermittent AV conduction by allowing intrinsic AV conduction beyond the programmed AV delay during episodes of normal AV nodal function
- RightRate Pacing: utilizes minute ventilation to provide rate adaptive pacing based on physiologic changes along with automatic calibration, a simplified user interface, and filtering designed to mitigate MV interactions
- Safety Core: safety architecture is utilized to provide basic pacing if non-recoverable or repeated fault conditions occur

- Electrocautery Protection: provides asynchronous pacing operation at the LRL

Sensing

- Automatic gain control (AGC): dynamically adjusts sensitivity in both the atrium and ventricle
- Smart Blanking: used in conjunction with AGC sensing to promote appropriate cross-chamber sensing capabilities

Patient Diagnostics

- Trends: expanded set of trends is provided including:
  - Heart Rate
  - Atrial burden (including total number of episodes)
  - Events
- Average V Rate in ATR: provides the average ventricular rate during ATR episodes
- Arrhythmia Logbook: memory is allocated between numerous episode types with increased data storage available
- Lead Safety Switch: diagnostic information is provided to show the date and impedance value which caused the LSS

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient material. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

The text conventions discussed below are used throughout this manual.

PRM KEYS	The names of Programmer/Recorder/Monitor (PRM) keys appear in capital letters (e.g., PROGRAM, INTERROGATE).
1., 2., 3.	Numbered lists are used for instructions that should be followed in the order given.
•	Bulleted lists are used when the information is not sequential.

This product family includes single- and dual-chamber models, with feature variations. This manual describes the full-featured model (e.g., a dual-chamber model with ZIP telemetry). Some models will contain fewer features; for those devices, disregard descriptions of the unavailable features.

The screen illustrations used in this manual are intended to familiarize you with the general screen layout. The actual screens you see when interrogating or programming the pulse generator will vary based on the model and programmed parameters.

A complete list of programmable options is provided in the appendix ("Programmable Options" on page A-1). The actual values you see when interrogating or programming the pulse generator will vary based on the model and programmed parameters.

The following acronyms may be used in this Reference Guide:

A	Atrial
AF	Atrial Fibrillation
AGC	Automatic Gain Control
AT	Atrial Tachycardia
ATP	Antitachycardia Pacing
ATR	Atrial Tachy Response

AV	Atrioventricular
BPEG	British Pacing and Electrophysiology Group
CPR	Cardiopulmonary Resuscitation
EAS	Electronic Article Surveillance
ECG	Electrocardiogram
EF	Ejection Fraction
EGM	Electrogram
EMI	Electromagnetic Interference
EP	Electrophysiology; Electrophysiologic
ICD	Implantable Cardioverter Defibrillator
LRL	Lower Rate Limit
MI	Myocardial Infarction
MPR	Maximum Pacing Rate
MRI	Magnetic Resonance Imaging
MSR	Maximum Sensor Rate
MTR	Maximum Tracking Rate
MV	Minute Ventilation
NASPE	North American Society of Pacing and Electrophysiology
NSR	Normal Sinus Rhythm
NSVT	Nonsustained Ventricular Tachycardia
PAC	Premature Atrial Contraction
PAT	Paroxysmal Atrial Tachycardia
PES	Programmed Electrical Stimulation
PMT	Pacemaker-Mediated Tachycardia
PRM	Programmer/Recorder/Monitor
PSA	Pacing System Analyzer
PTM	Patient Triggered Monitor
PVARP	Post-Ventricular Atrial Refractory Period
PVC	Premature Ventricular Contraction
RADAR	Radio Detection and Ranging
RF	Radio Frequency
RTTE	Radio and Telecommunications Terminal Equipment
RV	Right Ventricular
RVAC	Right Ventricular Automatic Capture
RVRP	Right Ventricular Refractory Period
SCD	Sudden Cardiac Death
SVT	Supraventricular Tachycardia
TARP	Total Atrial Refractory Period
TENS	Transcutaneous Electrical Nerve Stimulation
V	Ventricular
VF	Ventricular Fibrillation
VRP	Ventricular Refractory Period
VT	Ventricular Tachycardia

TABLE OF CONTENTS

USING THE PROGRAMMER/RECORDER/MONITOR

CHAPTER 1

This chapter contains the following topics:

ZOOM LATITUDE PROGRAMMING SYSTEM

The ZOOM LATITUDE Programming System is the external portion of the pulse generator system and includes:

- Model 3120 Programmer/Recorder/Monitor (PRM)
- Model 2869 ZOOMVIEW Software Application
- Model 6577 Accessory Telemetry Wand

The ZOOMVIEW software provides advanced device programming and patient monitoring technology. It was designed with the intent to:

- Enhance device programming capability
- Improve patient and device monitoring performance
- Simplify and expedite programming and monitoring tasks

You can use the PRM system to do the following:

- Interrogate the pulse generator
- Program the pulse generator to provide a variety of therapy options
- Access the pulse generator’s diagnostic features
- Perform noninvasive diagnostic testing
- Access therapy history data
- Access an interactive Demonstration Mode or Patient Data Mode without the presence of a pulse generator
- Print patient data including pulse generator therapy options and therapy history data
- Save patient data

For more detailed information about using the PRM, refer to the PRM Operator’s Manual.

SOFTWARE TERMINOLOGY AND NAVIGATION

This section provides an overview of the PRM system.

Main Screen

The main PRM screen is shown below, followed by a description of the components (Figure 1-1 on page 1-3).

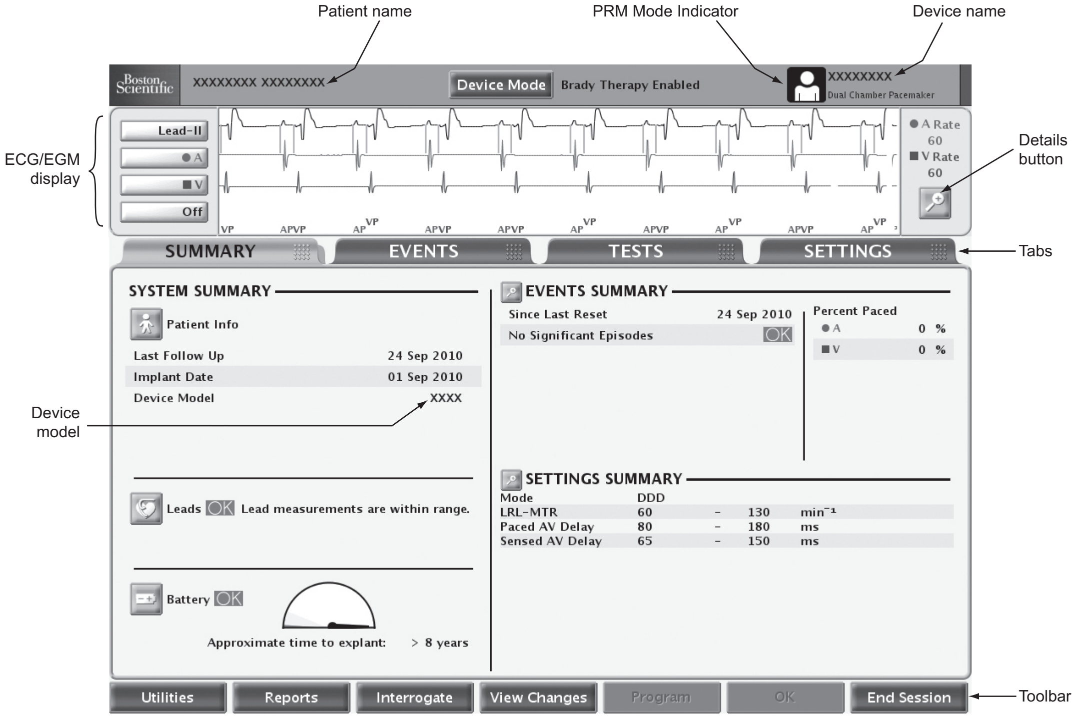


Figure 1-1. Main Screen

PRM Mode Indicator

The PRM Mode Indicator displays at the top of the screen to identify the current PRM operational mode.

Patient—indicates that the PRM is displaying data obtained by communicating with a device.

Patient Data—indicates that the PRM is displaying stored patient data.

Demo Mode—indicates that the PRM is displaying sample data and operating in demonstration mode.

ECG/EGM Display

The ECG area of the screen shows real-time status information about the patient and the pulse generator that can be useful in evaluating system performance. The following types of traces can be selected:

- Surface ECGs are transmitted from body surface lead electrodes that are connected to the PRM, and can be displayed without interrogating the pulse generator.

- Real-time EGMs are transmitted from the pace/sense electrodes, and are often used to evaluate lead system integrity and help identify faults such as lead fractures, insulation breaks, or dislodgments.

  Real-time EGMs can only be displayed upon interrogation of the pulse generator. Because they rely on ZIP or wanded telemetry, they are susceptible to radio frequency interference. Significant interference may cause a break or drop-out of real-time EGMs ("ZIP Telemetry Security" on page 1-9).

  NOTE: *If the PRM is left idle for 15 minutes (or 28 minutes if the pulse generator was in Storage Mode at interrogation) real-time EGMs are shut off. The PRM provides a dialog box allowing real-time EGMs to be restored.*

NOTE: *In the presence of telemetry interference, the real-time intracardiac EGM traces and markers may become misaligned from the real-time surface ECG traces. When the telemetry link has improved, re-select any of the intracardiac EGM traces to cause re-initialization.*

You can select the Details button to enlarge the ECG/EGM screen. The following options are available:

- Show Device Markers—displays annotated event markers, which identify certain intrinsic cardiac and device-related events, and provide information such as sensed/paced events
- Enable Surface Filter—minimizes noise on the surface ECG
- Display Pacing Spikes—shows detected pacing spikes, annotated by a marker on the surface ECG waveform

You can print real-time EGMs, which include annotated event markers, by performing the following steps:

1. Press one of the print speed keys on the PRM (e.g., speed key 25) to begin printing.
2. Press the 0 (zero) speed key to stop printing.
3. Press the paper-feed key to fully eject the last printed sheet.

You can print definitions of the annotated markers by pressing the calibration key while the EGM is printing. Alternatively you can print a full report containing the definitions of all of the annotated markers by performing the following steps:

1. From the toolbar, click the Reports button. The Reports window displays.
2. Select the Marker Legend checkbox.
3. Click the Print button. The Marker Legend Report is sent to the printer.

Toolbar

The toolbar allows you to perform the following tasks:

- Select system utilities
- Generate reports
- Interrogate and program the pulse generator
- View pending or programmed changes
- View attentions and warnings
- End your PRM session

Tabs

Tabs allow you to select PRM tasks, such as viewing summary data or programming device settings. Selecting a tab displays the associated screen. Many screens contain additional tabs, which allow you to access more detailed settings and information.

Buttons

Buttons are located on screens and dialogs throughout the application. Buttons allow you to perform various tasks, including:

- Obtain detailed information
- View setting details
- Set programmable values
- Load initial values

When a button selection opens a window in front of the Main Screen, a Close button displays in the upper-right corner of the window to allow you to close the window and return to the Main Screen.

Icons

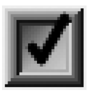
Icons are graphic elements that, when selected, may initiate an activity, display lists or options, or change the information displayed.

Details—opens a window containing detailed information.

Patient—opens a window with patient information details.

Leads—opens a window with details on leads.

Battery—opens a window with details on the pulse generator battery.



Check—indicates that an option is selected.

Event—indicates that an event has occurred. When you view the Trends timeline on the Events tab, event icons display wherever events have occurred. Selecting an events icon displays details about the event.

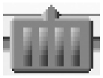
Action Icons

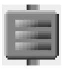
Run—causes the programmer to perform an action.


Hold—causes the programmer to pause an action.


Continue—causes the programmer to continue an action.

Slider Icons


Horizontal Slider—indicates that a slider object can be clicked and dragged left or right.


Vertical Slider—indicates that a slider object can be clicked and dragged up or down.

Sort Icons


Sort Ascending—indicates that Ascending sort is currently selected on a table column sort button. (e.g., 1, 2, 3, 4, 5)


Sort Descending—indicates that Descending sort is currently selected on a table column sort button. (e.g., 5, 4, 3, 2, 1)

Increment and Decrement Icons


Increment—indicates that an associated value can be incremented.


Decrement—indicates that an associated value can be decremented.

Scroll Icons


Scroll Left—indicates that an associated item can be scrolled left.


Scroll Right—indicates that an associated item can be scrolled right.


Scroll Up—indicates that an associated item can be scrolled up.


Scroll Down—indicates that an associated item can be scrolled down.

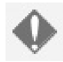
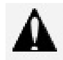
Common Objects

Common objects such as status bars, scroll bars, menus, and dialogs are used throughout the application. These operate similarly to the objects found in web browsers and other computer applications.

Use of Color

Colors and symbols are used to highlight buttons, icons, and other objects, as well as certain types of information. The use of specific color conventions and symbols is intended to provide a more consistent user experience and simplify programming. Refer to the table below to understand how colors and symbols are used on the PRM screens (Table 1-1 on page 1-7).

Table 1-1. PRM color conventions

Color	Meaning	Examples	Symbol
Red	Indicates warning conditions	The selected parameter value is not allowed; click the red warning button to open the Parameter Interactions screen, which provides information about corrective action.	
		Device and patient diagnostic information that requires serious consideration.	
Yellow	Indicates conditions requiring your attention	The selected parameter value is allowed, but not recommended; click the yellow attention button to open the Parameter Interactions screen, which provides information about corrective action.	
		Device and patient diagnostic information that should be addressed.	
Green	Indicates acceptable changes or conditions	The selected parameter value is allowed, but is still pending.	
		There is no device or patient diagnostic information requiring your specific attention.	
White	Indicates the value that is currently programmed		

DEMONSTRATION MODE

The PRM includes a Demonstration Mode feature, which enables the PRM to be used as a self-teaching tool. When selected, this mode allows you to practice PRM screen navigation without interrogating a pulse generator. You can use Demonstration Mode to familiarize yourself with many of the specific screen sequences that will display when interrogating or programming a specific pulse generator. You can also use Demonstration Mode to examine available features, parameters, and information.

To access Demonstration Mode, select the appropriate PG from the Select PG screen, and then select Demo from the Select PG Mode dialog. When the PRM is operating in Demonstration Mode, the PRM Mode Indicator displays the Demo Mode icon. The pulse generator cannot be programmed when the PRM is operating in Demonstration Mode. Exit the Demonstration Mode before attempting to interrogate or program the pulse generator.

COMMUNICATING WITH THE PULSE GENERATOR

The PRM communicates with the pulse generator using a telemetry wand.

After initiating communication with the wand, some pulse generator models can use wandless ZIP telemetry (two-way RF communication) to interface with the PRM.

Telemetry is required to:

- Direct commands from the PRM system, such as:
  - INTERROGATE
  - PROGRAM
  - STAT PACE
  - DIVERT THERAPY

- Modify device parameter settings
- Conduct EP testing
- Conduct diagnostic tests including the following:
  - Pacing impedance tests
  - Pacing threshold tests
  - Intrinsic amplitude tests

ZIP Telemetry

ZIP telemetry is a wandless, two-way RF communication option that allows the PRM system to communicate with some pulse generator models. When a wanded telemetry session is initiated, the PRM checks the pulse generator's telemetry capability. If the PRM detects a pulse generator with ZIP telemetry capability, a message will display indicating that ZIP telemetry is available and the wand can be removed. Otherwise, the session will continue with wanded telemetry.

ZIP telemetry offers the following advantages over traditional wanded telemetry:

- The faster data transmission speed means less time is required for device interrogation
- Data transmission over a longer distance (within 3 m [10 ft]) minimizes the need to keep the wand in the sterile field during implant, which may reduce the risk of infection
- Continuous telemetry is possible during the entire implant procedure, allowing monitoring of pulse generator performance and lead integrity during implant

Regardless of whether ZIP telemetry is being used, wanded communication is still available.

Starting a Wanded Telemetry Session

Follow this procedure to begin a wanded telemetry communication session:

1. Make sure the telemetry wand is connected to the PRM system and is available throughout the session.
2. Position the wand over the pulse generator at a distance not greater than 6 cm (2.4 inches).
3. Use the PRM to Interrogate the pulse generator.
4. Retain the wand position whenever communication is required.

Starting a ZIP Telemetry Session

Follow this procedure to begin a ZIP telemetry communication session:

1. Start a wanded telemetry session. Verify that the wand cord is within reach of the pulse generator to enable the use of wanded telemetry should it become necessary.
2. Keep the telemetry wand in position until either a message appears, indicating that the telemetry wand may be removed from proximity of the pulse generator, or the ZIP telemetry light illuminates on the PRM system.

Ending a Telemetry Session

Select the End Session button to quit a telemetry session and return to the startup screen. You can choose to end the session or return to the current session. Upon ending a session, the PRM system terminates all communication with the pulse generator.

ZIP Telemetry Security

The pulse generator is a compliant low-power transceiver. The pulse generator can only be interrogated or programmed by RF signals that employ the proprietary ZIP telemetry protocol. The pulse generator verifies that it is communicating with a ZOOMVIEW system before responding to any RF signals. The pulse generator stores, transmits, and receives individually identifiable health information in an encrypted format.

ZIP telemetry is possible when all of the following conditions are met:

- ZIP telemetry setting for the PRM is programmed On
- The pulse generator has RF communication capabilities
- The ZIP telemetry channel is available for use
- The pulse generator is within range of the PRM system
- The pulse generator has not reached Explant; note that a total of 1.5 hours of ZIP telemetry will be available after the pulse generator reaches Explant
- The pulse generator battery capacity is not depleted

In order to meet local communications rules and regulations, ZIP telemetry should not be used when the pulse generator is outside its normal operating temperature of 20°C–43°C (68°F–109°F).

Communication is supported between two PRMs and two pulse generators at a time, as two independent sessions. If there are two PRM–pulse generator communication sessions already occurring in the vicinity, a third session will not be allowed to start; wanded communication will be necessary in this case.

The PRM notifies you if ZIP telemetry is unavailable because of other sessions already in progress.

RF signals in the same frequency band used by the system may interfere with ZIP telemetry communication. These interfering signals include:

- Signals from other pulse generator/PRM system RF communication sessions after the maximum number of independent sessions has been reached. Other nearby pulse generators and PRMs using ZIP telemetry may prevent ZIP telemetry communication.

- Interference from other RF sources.

CAUTION: RF signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator. Examples of devices that may cause interference include:

- Cordless phone handsets or base stations
- Certain patient monitoring systems

Radio frequency interference may temporarily disrupt ZIP telemetry communication. The PRM will normally reestablish ZIP communication when the RF interference ends or subsides. Because continued RF interference may prevent ZIP telemetry communication, the system is designed to use wanded telemetry when ZIP telemetry is not available.

If ZIP telemetry is not available, wanded telemetry communication with the PRM can be established. The system provides the following feedback to indicate that ZIP telemetry is not available:

- The ZIP telemetry indicator light on the PRM turns off

- If event markers and/or EGMs are activated, transmission of the event markers and/or EGMs is interrupted

- If a command or other action has been requested, the PRM displays a notification indicating the wand should be placed in range of the pulse generator

ZIP telemetry operates consistently with wanded telemetry—no programming step can be completed unless the entire programming command has been received and confirmed by the pulse generator.

The pulse generator cannot be misprogrammed as a result of interrupted ZIP telemetry. Interruptions of ZIP telemetry may be caused by RF signals that operate at frequencies near that of the pulse generator and are strong enough to compete with the ZIP telemetry link between the pulse generator and the PRM. Significant interference may result in a break or drop-outs of real-time EGMs. If commands are interrupted, the PRM displays a message to place the wand on the pulse generator. Repeated displays of this message may indicate the presence of intermittent interference. These situations can be resolved by repositioning the PRM or using standard wanded telemetry. There will be no interruption of device functionality or therapy during this period.

NOTE: *When both ZIP and wanded telemetry are being used (for example, switching from ZIP to wanded because of the presence of interference), the pulse generator will communicate with the programmer by ZIP telemetry when possible. If wanded telemetry only is desired, ZIP must be programmed Off.*

NOTE: *To conserve battery longevity, a ZIP telemetry session will be terminated if the pulse generator completely loses communication with the PRM for a continuous period of one hour. Wanded telemetry must be used to re-establish communication with the pulse generator after this one hour period has elapsed.*

NOTE: *The PRM operates on a country–specific frequency range. The PRM determines the ZIP frequency range that the pulse generator uses based on the specific device model. If the PRM and pulse generator ZIP frequency ranges do not match, it indicates that the patient has traveled outside the country in which the pulse generator was implanted. The PRM will display a message indicating that ZIP telemetry cannot be used; however, the patient's pulse generator can be interrogated by using the wand. If out-of-country interrogation is needed, contact Boston Scientific using the information on the back cover of this manual.*

Considerations for Reducing Interference

Increasing the distance from the source of interfering signals may enable the use of the ZIP telemetry channel. A minimum distance of 14 m (45 ft) is recommended between the source of interference (having an average output of 50 mW or less) and both the pulse generator and PRM.

Repositioning the PRM antenna or repositioning the PRM may improve ZIP telemetry performance. If ZIP telemetry performance is not satisfactory, the option of using wanded telemetry is available.

Positioning the PRM at least 1 m (3 ft) away from walls or metal objects and ensuring the pulse generator (prior to implant) is not in direct contact with any metal objects may reduce signal reflection and/or signal blocking.

Ensuring there are no obstructions (e.g., equipment, metal furniture, people, or walls) between the PRM and pulse generator may improve signal quality. Personnel or objects that momentarily move between the PRM and pulse generator during ZIP telemetry may temporarily interrupt communication, but will not affect device functionality or therapy.

Checking the time required to complete an interrogation after ZIP telemetry is established can provide an indication of whether interference is present. If an interrogation using ZIP telemetry takes less than 20 seconds, the current environment is likely free of interference. Interrogation times longer than 20 seconds (or short intervals of EGM drop-outs) indicate that interference may be present.

MANUAL PROGRAMMING

Manual programming controls such as sliders and menus are available to allow you to individually adjust pulse generator program settings.

Manual programming controls are located on the Settings Summary tab, which can be accessed from the Settings tab or by selecting the Settings Summary button on the Summary tab. Refer to other feature descriptions in this manual for specific manual programming information and instructions. Refer to "Programmable Options" on page A-1 for detailed listings of available settings.

DIVERT THERAPY

The DIVERT THERAPY key can be used to terminate any diagnostic test in progress, as well as Electrocautery Protection Mode (maintain the telemetry wand position until the divert function is complete to avoid interruption to the divert command).

STAT PACE

Emergency bradycardia pacing using the STAT PACE command sets the bradycardia operation to parameters intended to ensure capture.

1. If you are not already in a session, position the telemetry wand within range of the pulse generator.

2. Press the STAT PACE key. A message window displays the STAT PACE values.

3. Press the STAT PACE key a second time. A message indicates that STAT PACE is being performed, followed by the STAT PACE values.

4. Select the Close button on the message window.

5. To stop STAT PACE, reprogram the pulse generator.

NOTE: *STAT PACE will terminate Electrocautery Protection Mode.*

CAUTION: When a pulse generator is programmed to STAT PACE settings, it will continue to pace at the high-energy STAT PACE values if it is not reprogrammed. The use of STAT PACE parameters will likely decrease device longevity.

The STAT PACE parameter values are listed below (Table 1-2 on page 1-11).

Table 1-2. STAT PACE Parameter Values

Parameter	Values
Mode	VVI
Lower Rate Limit	60 min^{-1}
Interval	1000 ms
Amplitude	7.5 V
Pulse Width	1.0 ms
Paced Refractory	250 ms
Lead Configuration (Pace/Sense)	Unipolar

NOTE: *STAT PACE pacing mode is AAI for single-chamber devices programmed to AAI(R) or AOO.*

DATA MANAGEMENT

The PRM system allows you to view, print, store, or retrieve patient and pulse generator data. This section describes the PRM data management capabilities.

Patient Information

Information about the patient can be stored in pulse generator memory. The information is accessible from the Summary screen by selecting the Patient icon. This information includes, but is not limited to, the following:

- Patient and physician data
- Pulse generator serial number
- Implant date
- Lead configurations
- Implant test measurements

The information can be retrieved at any time by interrogating the pulse generator and viewing it on the PRM screen or printing it as a report.

NOTE: *If the data for patient date of birth, gender, or fitness level are changed within Patient Information, the corresponding value in Minute Ventilation will automatically change. Likewise, if the data for fitness level is changed within Minute Ventilation, the corresponding value in Patient Information will automatically change.*

Data Storage

The PRM system allows you to save pulse generator data to the PRM hard drive or a removable floppy data disk. Data saved to the PRM can also be transferred to a removable USB pen drive.

Saved pulse generator data includes, but is not limited to, the following:

- Therapy history
- Programmed parameter values
- Trending values
- Histogram paced/sensed counters

Select the Utilities button, and then select the Data Storage tab to access the following options:

- Read Disk—allows you to retrieve saved pulse generator data from a floppy disk.

- Save All—allows you to save pulse generator data to either a floppy disk (disk must be inserted) or the PRM hard drive (if no floppy disk is detected). Data saved to a floppy disk can be retrieved using the Read Disk option described above. Data saved to the PRM can be read, deleted, or exported to a USB pen drive from the PRM startup screen. Refer to the PRM Operator's Manual for more information.

  NOTE: *While the data is being saved, a message on the right-hand side of the System Status screen indicates where the data is being saved.*

Consider the following when storing and retrieving pulse generator data:

- No more than 400 unique patient records may be saved to the PRM. When a pulse generator is interrogated, the PRM evaluates if there is already a record on file for this pulse generator, or if a new record will need to be created. If a new record is needed, and the PRM is at the 400 record capacity, the oldest record on file will be deleted to create space for the new patient record.

- When performing multiple patient checkups, be sure to start a new session for each patient.

- Be sure to save all pulse generator data to either a floppy disk or USB pen drive before returning a PRM to Boston Scientific, as all patient and pulse generator data will be erased from the PRM when it is returned.

- To protect patient privacy, pulse generator data is encrypted before it is transferred to removable media.

Device Memory

The Device Memory utility allows you to retrieve, save, and print pulse generator memory data, which is intended for use by a Boston Scientific representative for clinical and troubleshooting purposes. This utility should only be used when directed by a Boston Scientific representative. Digital media with device memory data contains protected health information and therefore should be handled in accordance with applicable privacy and security policies and regulations.

NOTE: *Use the Data Storage tab to access pulse generator data for clinician use ("Data Storage" on page 1-12).*

Print

You can print PRM reports by using the internal printer, or by connecting to an external printer. To print a report, select the Reports button. Then select the report you wish to print from the following categories:

- Follow-up reports
- Episode reports
- Other reports (includes device settings, patient data, and other information)

SAFETY MODE

The pulse generator is equipped with dedicated Safety Core hardware that is intended to provide life-sustaining therapy if certain nonrecoverable or repeat fault conditions occur and cause a system reset. These types of faults indicate a loss of component integrity in the pulse generator’s central processing unit (CPU), including the microprocessor, program code, and system memory. Using minimal hardware (i.e., unipolar lead configuration), Safety Core operates independently and acts as a backup to these components.

Safety Core also monitors the device during normal pacing; if normal pacing does not occur, Safety Core delivers an escape pace, and a system reset is initiated.

If the pulse generator experiences three resets within approximately 48 hours, the device reverts to Safety Mode and device replacement should be considered. The following will also occur:

- ZIP telemetry is unavailable when Safety Mode is active; wanded telemetry must be used instead.

- Upon interrogation, a warning screen is displayed indicating that the pulse generator is in Safety Mode, and directing you to contact Boston Scientific.

Backup Pacemaker

Safety Mode provides ventricular pacing, with the following parameters:

NOTE: *For single-chamber pacemakers, Safety Mode does not distinguish between lead positions. Pacing therapy is provided with the parameters listed below regardless of whether the lead is placed in the atrium or ventricle. Additionally, if the lead is placed in the right atrium, the Safety Mode screen will still indicate that ventricular therapy is being provided. For dual-chamber pacemakers, Safety Mode pacing is provided in the ventricle only.*

- Brady Mode—VVI
- LRL—72.5 min^{-1}
- Pulse Amplitude—5.0 V
- Pulse Width—1.0 ms
- RV Refractory Period (RVRP)—250 ms
- RV Sensitivity—AGC 0.25 mV
- RV lead configuration—Unipolar
- Noise Response—VOO

NOTE: *Safety Mode also disables Magnet Response.*

PACING THERAPIES

CHAPTER 2

This chapter contains the following topics:

PACING THERAPIES

The bradycardia pacing function is independent of the tachycardia detection function of the device, with the exception of interval-to-interval sensing.

Single and dual-chamber pacemakers provide atrial and/or ventricular sensing and pacing, including adaptive-rate modes.

The pulse generator provides the following types of therapies:

Normal Bradycardia Pacing

- If the intrinsic heart rate falls below the programmed pacing rate (i.e., LRL), the device delivers pacing pulses at the programmed settings.
- Adaptive-rate pacing allows the pulse generator to adapt the pacing rate to the patient's changing physiologic needs.

Additional Options

- Temporary Bradycardia Pacing—allows the clinician to examine alternate therapies while maintaining the previously programmed normal pacing settings in the pulse generator memory ("Temporary Brady Pacing" on page 2-18).
- STAT PACE—initiates emergency ventricular pacing at high output settings when commanded via the PRM using telemetry communication ("STAT PACE" on page 1-11).
- Electrocautery Protection—provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer ("Electrocautery Protection Mode" on page 2-2).

DEVICE MODES

Once the pulse generator has been programmed out of Storage Mode, the following device modes are available:

- Brady Therapy Enabled—indicates that the pulse generator is providing normal pacing therapy. This mode is not selectable; it is set automatically so long as Brady Mode is programmed to anything except Off.
- Brady Therapy Off—indicates that the pulse generator is not providing any therapy. This mode is not selectable; it is set automatically when the Brady Mode is programmed to Off.
- Electrocautery Protection Mode—provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer. This mode is enabled via the Device Mode button.
- Safety Mode—automatically activated by the pulse generator when it experiences a nonrecoverable fault. This mode is not selectable ("Safety Mode" on page 1-13).

Electrocautery Protection Mode

Electrocautery Protection Mode provides asynchronous pacing at the programmed outputs and LRL. Tachyarrhythmia detection is deactivated.

When Electrocautery Protection is enabled, the Brady Mode switches to an XOO mode (where X is determined by the programmed Brady Mode). Other pacing parameters remain at the programmed settings (including pacing output). If Brady Mode is Off prior to enabling

Electrocautery Protection, it will remain Off during Electrocautery Protection. Once enabled, Electrocautery Protection does not require constant telemetry to remain active.

After cancelling Electrocautery Protection, the Brady Mode will revert to the previously programmed setting.

After attempting to enable Electrocautery Protection Mode, refer to the message on the PRM screen confirming that Electrocautery Protection is active.

Except for STAT PACE, no commanded therapies, diagnostic tests, or printing of reports will be allowed while Electrocautery Protection is enabled.

Application of a magnet while the device is in Electrocautery Protection has no effect on pacing rate.

To enable and disable Electrocautery Protection Mode, perform the following steps:

1. Select the Device Mode button from the top of the PRM screen.

2. Select the check box to Enable Electrocautery Protection.

3. Select the Apply Changes button to enable Electrocautery Protection Mode. A dialog window will appear, indicating that Electrocautery Protection is active.

4. Select the Cancel Electrocautery Protection button on the dialog window to return the device to the previously programmed mode. Electrocautery Protection can also be cancelled by pressing the STAT PACE or Divert Therapy key on the PRM.

BASIC PARAMETERS

Normal Settings include the following:

- Pacing parameters, which are independently programmable from temporary pacing parameters
- Pacing and Sensing
- Leads
- Rate Adaptive Pacing and Sensor Trending

Interactive Limits

Because many features with programmable parameters interact, programmed values must be compatible across such features. When values requested by the user are incompatible with existing parameters, the programmer screen displays an alert describing the incompatibility and either prohibits the selection or instructs the user to proceed with caution ("Use of Color" on page 1-6).

Brady Mode

Brady modes provide programmable options to help individualize patient therapy.

DDD and DDDR

In the absence of sensed P- and R-waves, pacing pulses will be delivered to the atrium and the ventricle at the LRL (DDD) or the sensor-indicated rate (DDDR), separated by the AV Delay. A sensed P-wave will inhibit an atrial pace and start the AV Delay. At the end of the AV Delay, a ventricular pace will be delivered unless inhibited by a sensed R-wave.

DDI and DDIR

In the absence of sensed P- and R-waves, pacing pulses will be delivered to the atrium and the ventricle at the LRL (DDI) or the sensor-indicated rate (DDIR), separated by the AV Delay. A sensed P-wave will inhibit an atrial pace but will not start the AV Delay.

VDD and VDDR

In the absence of sensed P- and R-waves, pacing pulses will be delivered to the ventricle at the LRL (VDD) or the sensor-indicated rate (VDDR). A sensed P-wave will start the AV Delay. At the end of the AV Delay, a ventricular pace will be delivered unless inhibited by a sensed R-wave. A sensed R-wave or a paced ventricular event will determine the timing of the next ventricular pace.

VVI and VVIR

In VVI(R) mode, sensing and pacing occur only in the ventricle. In the absence of sensed events, pacing pulses will be delivered to the ventricle at the LRL (VVI) or the sensor-indicated rate (VVIR). A sensed R-wave or a paced ventricular event will determine the timing of the next ventricular pace.

AAI and AAIR

In AAI(R) mode, sensing and pacing occur only in the atrium. In the absence of sensed events, pacing pulses will be delivered to the atrium at the LRL (AAI) or the sensor-indicated rate (AAIR). A sensed P-wave or a paced atrial event will determine the timing of the next atrial pace.

DOO

Pacing pulses will be delivered asynchronously to the atrium and the ventricle at the LRL, separated by the AV Delay. Intrinsic events will neither inhibit nor trigger pacing in either chamber.

NOTE: *DOO mode is the magnet mode of DDD(R) and DDI(R) modes.*

- May be used intraoperatively to reduce the likelihood of inhibition when sources of conducted electrical current are present

NOTE: *Electrocautery Protection Mode is the preferred option if available.*

VOO

Pacing pulses will be delivered asynchronously to the ventricle at the LRL. Intrinsic events will neither inhibit nor trigger pacing in the ventricle.

NOTE: *VOO mode is the magnet mode of VVI(R) and VDD(R) modes.*

- May be used intraoperatively to reduce the likelihood of inhibition when sources of conducted electrical current are present

NOTE: *Electrocautery Protection Mode is the preferred option if available.*

AOO

Pacing pulses will be delivered asynchronously to the atrium at the LRL. Intrinsic events will neither inhibit nor trigger pacing in the atrium.

NOTE: *AOO mode is the magnet mode of AAI(R) mode.*

- May be used intraoperatively to reduce the likelihood of inhibition when sources of conducted electrical current are present

NOTE: *Electrocautery Protection Mode is the preferred option if available.*

Single-Chamber Modes

Single-chamber pulse generators may be programmed to VVI(R), AAI(R), VOO or AOO mode to specify the lead position.

NOTE: *If a lead position is specified on the Patient Information screen, the Brady Mode must comply with that lead position.*

Some features may behave differently or become unavailable under the following circumstances:

- In a dual-chamber device programmed to a single-chamber mode
- In a single-chamber device programmed to AAI(R)

Dual-Chamber Modes

Do not use DDD(R) and VDD(R) modes in the following situations:

- In patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which may trigger ventricular pacing
- In the presence of slow retrograde conduction that induces PMT, which cannot be controlled by reprogramming selective parameter values

Atrial Pacing Modes

In DDD(R), DDI(R), AAI(R), DOO, and AOO modes, atrial pacing may be ineffective in the presence of chronic atrial fibrillation or flutter or in an atrium that does not respond to electrical stimulation. In addition, the presence of clinically significant conduction disturbances may contraindicate the use of atrial pacing.

The following graphic may be used to assist in determining the most appropriate mode for a specific patient.

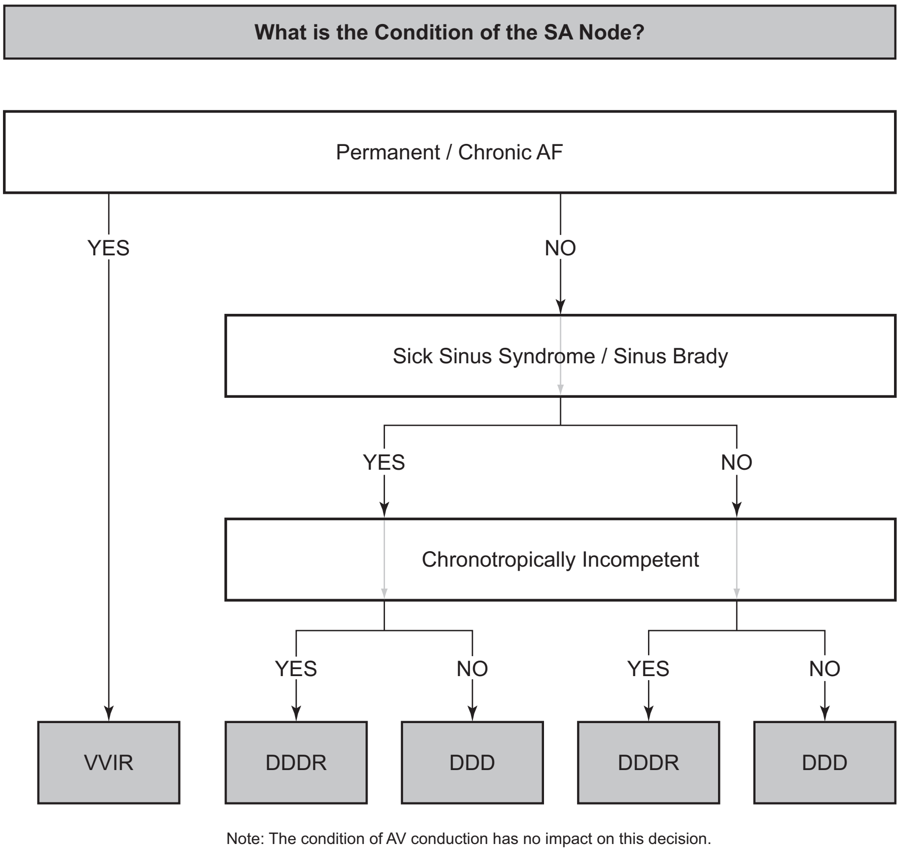


Figure 2-1. Optimal pacing mode decision tree

WARNING: Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.

CAUTION: If a dual-chamber device is programmed to AAI(R), ensure that a functional RV lead is present. In the absence of a functional RV lead, programming to AAI(R) may result in undersensing or oversensing.

If you have any questions regarding the individualization of patient therapy, contact Boston Scientific using the information on the back cover.

Lower Rate Limit (LRL)

LRL is the number of pulses per minute at which the pulse generator paces in the absence of sensed intrinsic activity.

As long as the ventricle is being paced (or if a PVC occurs), the interval is timed from one ventricular event to the next. Whenever an event is sensed in the ventricle (e.g., intrinsic AV conduction occurs before the AV Delay elapses), the timing base switches from ventricular-based timing to modified atrial-based timing (Figure 2-2 on page 2-7). This switching of timing base ensures accurate pacing rates since the difference between the intrinsic AV conduction and programmed AV Delay is applied to the next V–A interval.

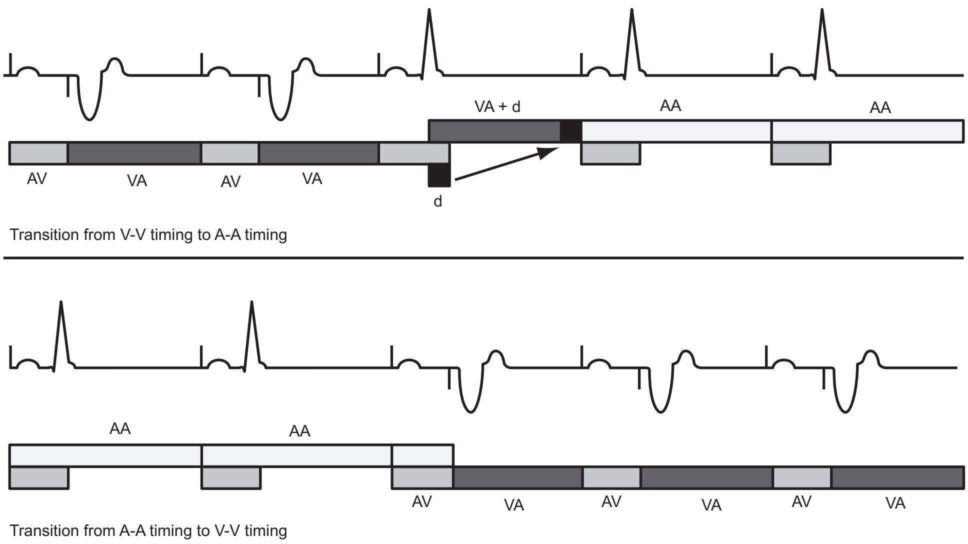


Illustration of timing transitions (d = the difference between AV Delay and the AV interval in the first cycle during which intrinsic conduction occurs. The value of d is applied to the next V–A interval to provide a smooth transition without affecting A–A intervals).

Figure 2-2. LRL timing transitions

Maximum Tracking Rate (MTR)

The MTR is the maximum rate at which the paced ventricular rate tracks 1:1 with nonrefractory sensed atrial events in the absence of a sensed ventricular event within the programmed AV Delay. MTR applies to atrial synchronous pacing modes, namely DDD(R) and VDD(R).

Consider the following when programming MTR:

- The patient’s condition, age, and general health
- The patient’s sinus node function
- A high MTR may be inappropriate for patients who experience angina or other symptoms of myocardial ischemia at higher rates

NOTE: *If the pulse generator is operating in DDDR or VDDR mode, the MSR and MTR may be programmed independently to different values.*

Upper Rate Behavior

When the sensed atrial rate is between the programmed LRL and MTR, 1:1 ventricular pacing will occur in the absence of a sensed ventricular event within the programmed AV Delay. If the sensed atrial rate exceeds the MTR, the pulse generator begins a Wenckebach-like behavior to prevent the paced ventricular rate from exceeding the MTR. This Wenckebach-like behavior is characterized by a progressive lengthening of the AV delay until an occasional P-wave is not tracked because it falls into the PVARP. This results in an occasional loss of 1:1 tracking as the pulse generator synchronizes its paced ventricular rate to the next sensed P-wave. Should the sensed atrial rate continue to increase further above the MTR, the ratio of sensed atrial events to sequentially paced ventricular events becomes lower until, eventually, 2:1 block results (e.g., 5:4, 4:3, 3:2, and finally 2:1).

The sensing window should be maximized by programming the appropriate AV Delay and PVARP. At rates close to the MTR, the sensing window can be maximized by programming Dynamic AV Delay and Wenckebach behavior will be minimized.

High rate atrial tracking is limited by the programmed MTR and the total atrial refractory period (TARP) (AV Delay + PVARP = TARP). In order to avoid complete closure of the sensing window at MTR, the PRM will not allow a TARP interval that is longer (lower pacing rate) than the programmed MTR interval.

If the TARP interval is shorter (higher pacing rate) than the interval of the programmed MTR, then the pulse generator’s Wenckebach-like behavior limits the ventricular pacing rate to the MTR. If the TARP interval is equal to the interval of the programmed MTR, 2:1 block may occur with atrial rates above the MTR.

The PRM does not consider the AV Delay associated with AV Search+ when calculating the TARP interval ("AV Search+" on page 2-45).

Rapid changes in the paced ventricular rate (e.g., Wenckebach-like, 2:1 block) caused by sensed atrial rates above the MTR may be dampened or eliminated by the implementation of any of the following:

- ATR
- Rate Smoothing parameters and sensor input

NOTE:

For the purpose of atrial tachycardia detection and histogram updates, atrial events are detected throughout the cardiac cycle (except during atrial blanking), including AV Delay and PVARP.

Examples

If the atrial rate exceeds the MTR, the AV Delay will be progressively lengthened (AV’) until an occasional P-wave is not tracked because it falls into the atrial refractory period (Figure 2-3 on page 2-8). This results in occasional loss of 1:1 tracking as the pulse generator synchronizes its paced ventricular rate to the next tracked P-wave (pacemaker Wenckebach).

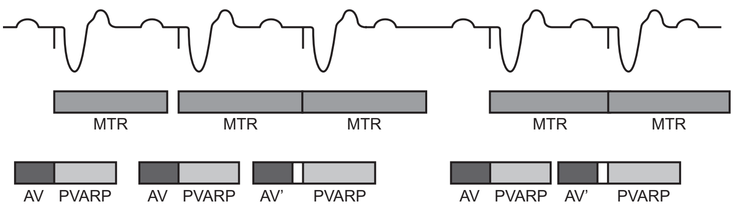


Figure 2-3. Wenckebach behavior at MTR

Another type of pulse generator upper rate behavior (2:1 block) can occur when tracking high atrial rates. In this type of behavior, every other intrinsic atrial event occurs during PVARP and, thus, is not tracked (Figure 2-4 on page 2-8). This results in a 2:1 ratio of atrial-to-ventricular events or a sudden drop in the ventricular paced rate to half of the atrial rate. At faster atrial rates, several atrial events can fall in the TARP period, resulting in the pulse generator tracking only every third or fourth P-wave. The block then occurs at rates such as 3:1 or 4:1.

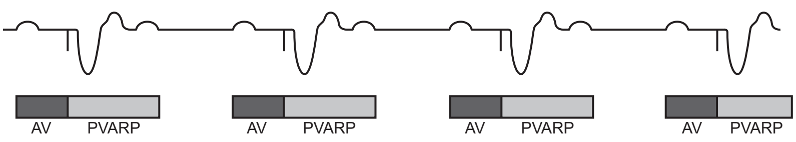


Illustration of pacemaker 2:1 block, in which every other P-wave falls inside the PVARP interval.

Figure 2-4. Pacemaker 2:1 block

Maximum Sensor Rate (MSR)

MSR is the maximum pacing rate allowed as a result of rate-adaptive sensor control from accelerometer, MV, or a blend of both.

Consider the following when programming MSR:

- Patient's condition, age, and general health:
  - Adaptive-rate pacing at higher rates may be inappropriate for patients who experience angina or other symptoms of myocardial ischemia at these higher rates
  - An appropriate MSR should be selected based on an assessment of the highest pacing rate that the patient can tolerate well

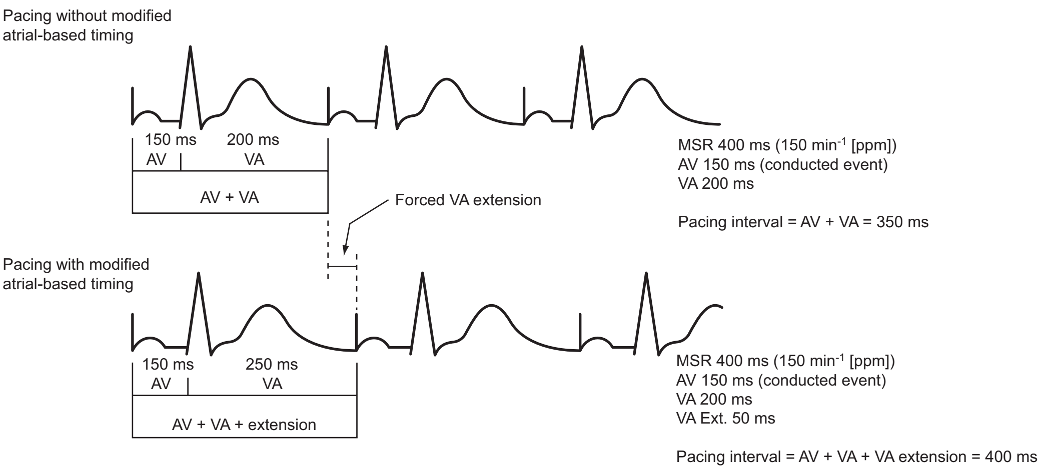
NOTE: *If the pulse generator is operating in DDDR or VDDR mode, the MSR and MTR may be programmed independently to different values.*

MSR is independently programmable at, above, or below the MTR. If the MSR setting is higher than the MTR, pacing above the MTR may occur if the sensor rate exceeds the MTR.

Pacing above the MSR (when programmed lower than the MTR) can only occur in response to sensed intrinsic atrial activity.

CAUTION: Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods because the combination can cause a very small sensing window or none at all.

With intrinsic conduction, the pulse generator maintains the A–A pacing rate by extending the V–A interval. This extension is determined by the degree of difference between the AV Delay and the intrinsic ventricular conduction—often referred to as modified atrial-based timing (Figure 2-5 on page 2-9).



The pulse generator's timing algorithm provides effective pacing at the MSR with intrinsic ventricular conduction. Extending the VA interval prevents the A pace from exceeding the MSR at high rates.

Figure 2-5. VA interval extension and MSR

Runaway Protection

Runaway protection is designed to prevent pacing rate accelerations above the MTR/MSR for most single-component failures. This feature is not programmable and operates independently from the pulse generator's main pacing circuitry.

Runaway protection prevents the pacing rate from increasing above 205 min^{-1}.

NOTE: *Runaway protection is not an absolute assurance that runaways will not occur.*

During PES and Manual Burst pacing, runaway protection is temporarily suspended to allow for high-rate pacing.

Pulse Width

Pulse Width, also referred to as pulse duration, determines how long the output pulse will be applied between the pacing electrodes.

Consider the following when programming Pulse Width:

- Pulse Widths are independently programmable for each chamber.
- If a pulse width threshold test is performed, a minimum 3X pulse width safety margin is recommended.
- The energy delivered to the heart is directly proportional to the pulse width; doubling the Pulse Width doubles the energy delivered. Therefore, programming a shorter pulse width while maintaining an adequate safety margin may increase battery longevity. To prevent loss of capture, exercise caution when you are programming permanent pulse width values of less than 0.3 ms (Figure 2-6 on page 2-10).

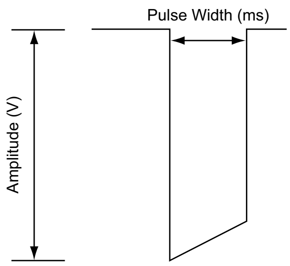


Figure 2-6. Pulse waveform

Amplitude

The pulse Amplitude, or voltage of the output pulse, is measured at the leading edge of the output pulse (Figure 2-6 on page 2-10).

Consider the following when programming Amplitude:

- Amplitudes are independently programmable in each chamber.
- Brady Mode may be programmed to Off via permanent or temporary programming. In effect, this turns Amplitude off to monitor the patient's underlying rhythm.
- A minimum 2X voltage safety margin is recommended for each chamber based on the capture thresholds. If PaceSafe is programmed On, it will automatically provide an adequate safety margin and help preserve battery longevity.

- The energy delivered to the heart is directly proportional to the square of the amplitude: doubling the amplitude quadruples the energy delivered. Therefore, programming to a lower Amplitude while maintaining an adequate safety margin may increase battery longevity.

PaceSafe

PaceSafe Right Ventricular Automatic Capture (RVAC)

PaceSafe RVAC is designed to dynamically adjust the right ventricular pacing output to ensure capture of the ventricle by optimizing the output voltage to 0.5 V above the capture threshold. RVAC maintains this output while confirming capture on a beat-to-beat basis. An acceptable pacing threshold is between 0.2 V and 3.0 V at 0.4 ms, and the output will be a minimum of 0.7 V and a maximum of 3.5 V with a fixed pulse width of 0.4 ms.

NOTE: *RVAC is intended for ventricular use only. It is not intended to be used with Amplitude programmed to Auto for single-chamber devices implanted in the atrium.*

NOTE: *RVAC is available in DDD(R), DDI(R), VDD(R), and VVI(R) modes, as well as during VDI(R) and DDI(R) Fallback Modes.*

RVAC can be programmed by selecting Auto from the Ventricular Amplitude parameter options. If starting from a fixed amplitude greater than 3.5 V, program a fixed amplitude of 3.5 V prior to selecting Auto. Programming the ventricular output to Auto will automatically adjust the Pulse Width to 0.4 ms and set the ventricular voltage output to an initial value of 5.0 V unless there is a successful test result within the last 24 hours.

RVAC must first successfully measure the ventricular threshold before it will enter its beat-to-beat capture verification mode. This measurement can be made through a commanded test, or it will be performed automatically within one hour after the programming session is completed. Both methods are described below.

NOTE: *Prior to programming RVAC on, consider performing a Commanded Ventricular Automatic Capture Measurement to verify that the feature functions as expected.*

RVAC is designed to work with typical lead implant criteria and a ventricular threshold between 0.2 V and 3.0 V at 0.4 ms.

The RVAC algorithm then measures the ventricular pacing threshold each day and adjusts the voltage output. During testing and on a beat-to-beat basis, RVAC uses an evoked response signal to confirm that each ventricular pacing output captures the ventricle.

If any loss of capture occurs during beat-to-beat operation, then the pulse generator will deliver a backup pacing output within approximately 70 ms of the primary pulse. The backup safety pulse amplitude will be a minimum of 3.5 V and a maximum of 5.0 V. If there is a Confirmed Loss of Capture (C-LOC; 2 out of 4 cardiac cycles do not capture the ventricle), RVAC will enter Suspension and a test re-attempt will occur at the next hourly interval.

When Daily Trend is selected along with a fixed Amplitude, ambulatory ventricular automatic capture measurements will occur every 21 hours with no change to programmed output.

The RVAC feature is designed to operate with a large range of pacing leads (high impedance, low impedance, tined fixation, or positive fixation). Also, RVAC is independent of pacing and sensing lead polarity; the Ventricular Pace and Sense Lead Configurations can be programmed to Unipolar or Bipolar.

Ambulatory Ventricular Automatic Capture Measurement

When RVAC is set to Auto or Daily Trend, ambulatory ventricular automatic capture measurements are conducted every 21 hours, or when loss of capture is detected while in beat-to-beat mode, up to hourly until the next daily measurement.

In atrial tracking modes, the automatic capture measurement adjusts the following parameters to help ensure a valid measurement is obtained:

- Paced AV Delay is fixed at 60 ms.
- Sensed AV Delay is fixed at 30 ms.
- Starting ventricular pacing output amplitude is 3.5 V.
- A backup pulse between 3.5 V to 5.0 V is delivered approximately 70 ms after every primary pacing pulse.

In nontracking modes, the automatic capture measurement adjusts the following parameters to help ensure a valid measurement is obtained:

- Paced AV Delay is fixed at 60 ms.
- Starting ventricular pacing output amplitude is 3.5 V.
- A backup pulse between 3.5 V to 5.0 V is delivered approximately 70 ms after every primary pacing pulse.
- The ventricular pacing rate will be increased by 10 min^{-1} above the current rate (paced or intrinsic) and is capped at the lowest of the MPR, MSR, 110 min^{-1}, or 5 min^{-1} below the VT Detection Rate.

NOTE: *If noise (which could potentially be a fusion beat) is detected, the AV interval and/or V–V interval may be extended on the next cardiac cycle in an attempt to distinguish the fusion beat from ventricular capture.*

Following initialization paces, the pulse generator will decrement the ventricular output every 3 paces until a threshold is determined. Additional pacing pulses will be issued if there is fusion or intermittent loss of capture. Threshold is declared as the previous output level that demonstrated consistent capture.

If daily testing is unsuccessful, RVAC will enter Suspension and perform up to 3 re-attempts at hourly intervals. If a successful test does not occur for 4 days, a Lead Alert will be triggered and RVAC will remain in Suspension.

Right Ventricular Automatic Capture Suspension

RVAC will enter Suspension mode when any of the following occur:

- Confirmed Loss of Capture occurs in beat-to-beat capture verification mode
- Unsuccessful Ambulatory or Commanded Tests
- Battery Capacity Depleted is reached

The pacing output will operate at 2X the last measured threshold between 3.5 V and 5.0 V at 0.4 ms (Table 2-1 on page 2-13). Ambulatory testing will occur each day with up to 3 re-attempts at hourly intervals to measure the ventricular threshold. If successful, RVAC will return to the beat-to-beat mode. If a successful test does not occur for 4 days, RVAC will remain in

Suspension but testing will continue each day to evaluate thresholds and the pulse generator will adjust to a lower output setting when indicated by a successful test.

Table 2-1. Pacing output during Automatic Capture Suspension

Last Measured Threshold (V)	Output During Suspension (V)
0.5	3.5
1.0	3.5
2.0	4.0
3.0	5.0

Although RVAC is designed to work with a wide range of pacemaker leads, in some patients the lead signals may hinder successful determination of the ventricular threshold. In these instances, RVAC will continually operate in the Suspension mode with a minimum ventricular output of 3.5 V and a maximum of 5.0 V. In situations where Suspension mode persists for an extended period of time, it is recommended to turn RVAC off by programming a fixed ventricular output.

Commanded Right Ventricular Automatic Capture Measurement

An automatic capture measurement can be commanded via the Threshold Tests Screen by selecting Auto Amplitude as the Test Type. If testing completes successfully and RVAC is programmed on, it will enter its beat-to-beat capture verification mode with the output set to 0.5 V above threshold (if the test is performed in the currently programmed pacing lead configuration). This can be confirmed by observing the output voltage on the Brady Settings screen, which will show the actual operating voltage of the RVAC algorithm (the ventricular threshold + 0.5 V).

Backup pacing between 3.5 V to 5.0 V is delivered approximately 70 ms after the primary pace for every loss of capture beat during commanded testing.

If testing is unsuccessful, the Threshold Tests screen will display the reason the test was not successful and RVAC will enter Suspension (Table 2-2 on page 2-14).

NOTE: *For the initial Ventricular Threshold test after the pulse generator is implanted, the Test Type field is seeded to Auto. Choose the desired test type from the Test Type field options, and adjust any other programmable values as appropriate.*

Test Results and Lead Alerts

A stored EGM for the most recent successful ambulatory test will be stored in the Arrhythmia Logbook ("Arrhythmia Logbook" on page 4-2). Refer to the Daily Measurements screen for the resulting threshold value. If desired, the stored EGM can be reviewed to determine where loss of capture occurred.

Up to 12 months of Ambulatory Threshold Test results, as well as test failure codes and lead alerts, can be found within the Daily Measurement and Trends screens. To provide further information on the reason for test failure, a failure code is provided for each day in which testing fails. Additionally, failure codes are provided on the Threshold Test screen if a commanded automatic capture test does not complete successfully. Threshold Test Failure Codes are listed below (Table 2-2 on page 2-14).

The following scenarios will trigger the Check RV Lead alert:

- Threshold > Programmed Amplitude will be displayed if RVAC is in Daily Trend mode and the ambulatory test results of the last 4 consecutive days exceed the manually programmed fixed output.

- Automatic Capture Suspension will be displayed if no successful tests are performed for 4 consecutive days in Auto or Daily Trend mode.

Table 2-2. Threshold Test Failure Codes

Code	Reason
N/R: Device Telem	Telemetry started during an ambulatory test
N/R: Comm Lost	Telemetry was lost during a commanded test
> 3.0 V	Threshold was measured between 3.5 V and 3.1 V for commanded or ambulatory tests
N/R: No Capture	Capture was not obtained at the starting amplitude for commanded or ambulatory tests
N/R: Mode Switch	ATR either started or stopped (testing will not fail if ATR is already active and stays active during testing)
No Data Collected	Minimum pacing amplitude was reached without losing capture for an ambulatory test, or neither Auto nor Daily Trend is turned on to obtain an ambulatory test result
N/R: Battery Low	Test was skipped due to Battery Capacity Depleted
N/R: Noise	Too many consecutive sense channel noise or Evoked Response noise cycles occurred
N/R: Incompat Mode	Test failed due to being in an incompatible Brady mode (magnet mode)
N/R: Rate Too High	Rate was too high at the start of the test, or during testing
N/R: User Cancelled	Commanded test was stopped by the user
N/R: Intrinsic Beats	Too many cardiac cycles occurred during the test
N/R: Test Delayed	Test was delayed due to telemetry being active, VT episode already in progress, Electrocautery mode, or RVAC was turned on while the device remained in Storage mode
N/R: Vent Episode	A Ventricular Episode started during testing
N/R: Respiration	Respiratory artifact was too high
N/R: Low ER	The Evoked Response signal could not be assessed adequately
Auto N/R	Minimum pacing amplitude was reached without losing capture for a commanded test or telemetry is manually cancelled during a commanded test
Invalid Failure Code	Unexpected Failure

Sensitivity

The Sensitivity feature can be programmed to either AGC or Fixed Sensing. The Sensitivity feature allows the pulse generator to detect intrinsic cardiac signals that exceed the programmed Fixed Sensitivity value or the dynamically increasing sensitivity of AGC. Adjusting the Sensitivity value shifts the atrial and/or ventricular sensing range to higher or lower sensitivity. Detection and timing decisions are based on the sensed cardiac signals. Although the atrial and ventricular Sensitivity values are independently programmable, the type of sensing method used (AGC or Fixed) must be the same for all chambers.

- High Sensitivity (low programmed value)—when Sensitivity is programmed to a very sensitive setting, the pulse generator may detect signals unrelated to cardiac depolarization (oversensing, such as sensing of myopotentials)

- Low Sensitivity (high programmed value)—when Sensitivity is programmed to a less sensitive setting, the pulse generator may not detect the cardiac depolarization signal (undersensing)

NOTE: *When a single pass VDD lead is used with a dual-chamber device, the atrial electrodes may not be in contact with the atrial wall. In this case, the measured depolarization signal has a relatively low Amplitude and could require a more sensitive setting.*

Should it become necessary to adjust the Sensitivity parameter in a chamber, always choose the setting that provides appropriate sensing of intrinsic activity and best resolves oversensing/undersensing.

If proper sensing cannot be restored with an adjustment or if any undersensing or oversensing is observed after making a change, consider any of the following (taking into account individual patient characteristics):

- Reprogram the Sensing Method from Fixed to AGC or from AGC to Fixed

NOTE: *The Sensing Method selected applies to all chambers. When changing the Sensing Method, verify appropriate sensing in all chambers.*

- Reprogram the AGC or Fixed sensitivity value
- Evaluate the sensing lead configuration (Unipolar versus Bipolar or Bipolar versus Unipolar)
- Reprogram the refractory or cross-chamber blanking period appropriately to address the observed undersensing or oversensing
- Reposition the lead
- Implant a new sensing lead

After any change to Sensitivity, evaluate the pulse generator for appropriate sensing and pacing.

CAUTION: Following any Sensitivity parameter adjustment or any modification of the sensing lead, always verify appropriate sensing. Programming Sensitivity to the highest value (lowest sensitivity) may result in undersensing of cardiac activity. Likewise, programming to the lowest value (highest sensitivity) may result in oversensing of non-cardiac signals.

Unipolar Sensing

When the unipolar sensing configuration is programmed, the cardiac signals are detected between the lead tip and the pulse generator case. In the unipolar sensing configuration, the pacemaker can generally discern smaller intrinsic cardiac signals than in the bipolar configuration. However, the unipolar configuration is also more sensitive to myopotentials. In bipolar configurations, due to the relatively short distance between the tip and ring electrodes, sensitivity is highest for signals originating in the proximity of the lead tip and ring. As a result, the pulse generator is less likely to sense myopotentials and other signals unrelated to cardiac depolarization.

NOTE: *For pacemaker-dependent patients with unipolar pacing leads, consider using Fixed Sensing instead of AGC.*

NOTE: *Blanking Period behavior will vary depending on which Lead Configuration is selected. Refer to cross-chamber blanking for more details ("Cross-Chamber Blanking" on page 2-49).*

CAUTION: The amplitude and prevalence of myopotential noise is increased in unipolar lead configurations, as compared to bipolar lead configurations. For patients with a unipolar lead configuration and myopotential oversensing during activity involving the pectoral muscles, the programming of Fixed Sensitivity is recommended.

Automatic Gain Control

The pulse generator has the option to use digital Automatic Gain Control (AGC) to dynamically adjust the sensitivity in both the atrium and the ventricle. The pulse generator has independent AGC circuits for each chamber. Selection of the AGC Sensing Method applies that method to all chambers.

Cardiac signals can vary widely in size and rate; therefore the pulse generator needs the ability to:

- Sense an intrinsic beat, regardless of rate or size
- Adjust to sense varying amplitude signals, but not overreact to aberrant beats
- Sense any intrinsic activity after a paced beat
- Ignore T-waves
- Ignore noise

The programmable AGC value is the minimum sensitivity value (floor) that could be reached between one beat and the next beat. This programmable value is not a fixed value present throughout the cardiac cycle; rather, the sensitivity level begins at a higher value (based on the peak of a sensed event or a fixed value for a paced event) and decrements towards the programmed floor (Figure 2-7 on page 2-17).

With Fixed Sensing, signal amplitudes below the Fixed Sensitivity setting will not be sensed, whether during pacing or sensing. In contrast, AGC will typically reach the programmable floor during pacing (or with low amplitude signals). But when moderate or high amplitude signals are sensed, AGC will typically be less sensitive and not reach the programmable floor.

In single-chamber pulse generators, the AGC (and the associated Refractory Period) is automatically adjusted so that the appropriate chamber-specific AGC profile is utilized based on the mode selected [e.g., ventricular AGC is utilized in VVI(R); atrial AGC is utilized in AAI(R)]. This ensures that AGC will function the same for the atrium or ventricle in both dual- and single-chamber pulse generators ("Refractory" on page 2-46).

The AGC circuit in each respective chamber processes an electrogram signal via a two step process to optimize sensing of potentially rapidly changing cardiac signals. The process is illustrated in the figure below (Figure 2-7 on page 2-17):

- First step

  1. AGC uses a rolling average of previous signal peaks to calculate a search area where the next peak will likely occur.

     – If the previous beat is sensed, it is incorporated into the rolling peak average.

     – If the previous beat is paced, the peak average is calculated using the rolling average and a paced peak value. The paced peak value depends on the settings:

       – For nominal or more sensitive settings, it is a fixed value (initial value 4.8 mV in the RV; initial value 2.4 mV in the RA).

       – For less sensitive settings, it is a higher value calculated using the programmed AGC floor value (for example, if RV sensitivity is programmed to the least sensitive setting or the highest value of 1.5 mV, the paced peak value = 12 mV).

     The peak average is then used to bound an area with MAX (maximum) and MIN (minimum) limits.

- Second step

  2. AGC senses the peak of the intrinsic beat (or uses the calculated peak for a paced beat as described above).
  3. It holds the sensitivity level at the peak (or MAX) through the absolute refractory period + 15 ms.
  4. It drops to 75% of the sensed peak or calculated peak average for paced events (ventricular paced events only).
  5. AGC becomes more sensitive by 7/8 of the previous step.
  6. Sensed beat steps are 35 ms for the RV and 25 ms for the atrium. Paced beat steps are adjusted based on the pacing interval to ensure an approximately 50 ms sensing window at the MIN level.
  7. It reaches the MIN (or programmed AGC floor).
     – The programmed AGC floor will not be reached if the MIN value is higher.
  8. The AGC remains at the MIN (or programmed AGC floor) until a new beat is sensed, or the pacing interval times out and a pace is delivered.

NOTE: *If a new beat is sensed as the sensitivity level steps down, AGC starts over at Step 1.*

NOTE: *If the amplitude of a signal is below the sensitivity threshold in effect at the time the signal occurs, it will not be sensed.*

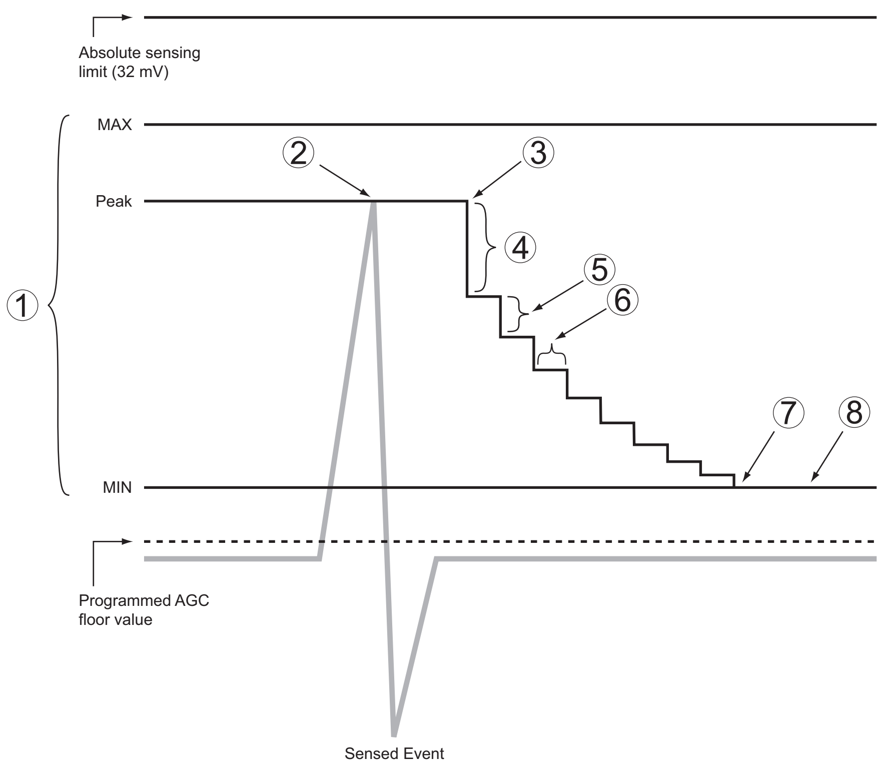


Figure 2-7. AGC sensing

A nonprogrammable Dynamic Noise Algorithm is active in rate channels where AGC sensing is used. The Dynamic Noise Algorithm is intended to help filter out persistent noise. The Dynamic Noise Algorithm is a separate noise channel for each chamber that continuously measures the baseline signal that is present and is designed to adjust the sensitivity floor to minimize the effects of noise.

The algorithm uses the characteristics of a signal (frequency and energy) to classify it as noise. When persistent noise is present, the algorithm is designed to minimize its impact, which may help to prevent oversensing myopotentials and the associated inhibition of pacing. Noise that affects the sensing floor may be visible on the intracardiac EGMs, but would not be marked as sensed beats. However, if the noise is significant, the floor may rise to a level above the intrinsic electrogram and the programmed Noise Response behavior (asynchronous pacing or Inhibit Pacing) will occur ("Noise Response" on page 2-52).

NOTE: *The Dynamic Noise Algorithm does not ensure that AGC will always accurately distinguish intrinsic activity from noise.*

Fixed Sensing

With Fixed Sensing, the Sensitivity value will not dynamically adjust as in AGC, and the Dynamic Noise Algorithm is not utilized. Presence of persistent noise will result in the programmed Noise Response behavior: asynchronous pacing or Inhibit Pacing ("Noise Response" on page 2-52). For manual programming, Sensitivity must be programmed to a value that prevents sensing of extraneous signals, but ensures accurate sensing of intrinsic cardiac signals. Signals with an amplitude below the Fixed Sensitivity setting will not be sensed.

WARNING: If programmed to a fixed atrial sensitivity value of 0.15 mV, the pulse generator may be more susceptible to electromagnetic interference. This increased susceptibility should be taken into consideration when determining the follow-up schedule for patients requiring such a setting.

TEMPORARY BRADY PACING

The pulse generator can be programmed with temporary pacing parameter values that differ from the programmed Normal Settings. This allows you to examine alternate pacing therapies while maintaining the previously programmed Normal Settings in the pulse generator memory. During the Temporary function, all other bradycardia features not listed on the screen are disabled.

To use this function, follow these steps:

1. From the Tests tab, select the Temp Brady tab to display the temporary parameters. When the parameters are initially displayed, they are set to the Normal Settings values.

2. Select the desired values; these values are independent from other pacing functions.

   NOTE: *Any interactive limits must be corrected before Temporary programming can occur.*

   NOTE: *If Off is selected as the Temporary Brady Mode, the pulse generator will not sense or pace while Temporary pacing mode is in effect.*

3. Establish telemetry communication, then select the Start button. Pacing begins at the temporary values. A dialog box indicates that temporary parameters are being used, and a Stop button is provided.

NOTE: *Temporary pacing cannot be started while a tachyarrhythmia episode is in progress.*

NOTE: *Emergency therapy is the only function that can be initiated until the Temporary function is stopped.*

4. To stop the Temporary pacing mode, select the Stop button. The Temporary pacing mode also stops when you command emergency therapy from the PRM, when you press the DIVERT THERAPY key, or if telemetry is lost.

Once Temporary pacing mode is stopped, pacing reverts to the previously programmed Normal settings.

RATE ADAPTIVE PACING AND SENSOR TRENDING

Rate Adaptive Pacing

In rate adaptive pacing modes (i.e., any mode ending with R), sensors are used to detect changes in the patient's physiologic demand and increase the pacing rate accordingly. Rate adaptive pacing is intended for patients who exhibit chronotropic incompetence and who would benefit from increased pacing rates that are concurrent with increased physiologic need.

The device can be programmed to use the Accelerometer, Minute Ventilation, or a blend of both. The clinical benefit of rate adaptive pacing using either of these sensors has been shown in previous clinical studies.

CAUTION: Rate adaptive pacing should be used with care in patients who are unable to tolerate increased pacing rates.

When rate adaptive parameters are programmed, the pacing rate increases in response to increased physiologic need, then decreases as appropriate.

NOTE: *Activity involving minimal upper body motion, such as bicycling, may result in only a moderate pacing response from the accelerometer.*

Accelerometer

Motion-Based Pacing uses an accelerometer to detect motion that is associated with a patient's physical activity and generates an electronic signal that is proportional to the amount of body motion. Based on accelerometer input, the pulse generator estimates the patient's energy expenditure as a result of exercise, then translates it into a rate increase.

The pulse generator senses body motion by means of an integrated circuit accelerometer. The accelerometer sensor responds to activity in the frequency range of typical physiologic activity (1–10 Hz). The accelerometer evaluates both the frequency and the amplitude of the sensor signal.

- Frequency reflects how often an activity occurs (e.g., the number of steps taken per minute during a brisk walk)

- Amplitude reflects the force of motion (e.g., the more deliberate steps taken while walking)

Once detected, an algorithm translates the measured acceleration into a rate increase above the LRL.

Because the accelerometer is not in contact with the pulse generator case, it does not respond to simple static pressure on the device case.

There are three Accelerometer settings: On, Passive, and ATR Only. If the pulse generator is permanently programmed to a non–rate adaptive mode, it is possible to program the ATR Fallback mode to an adaptive-rate mode using the accelerometer sensor. In this case, the Accelerometer field will display ATR Only. If Passive is selected, the Accelerometer will not provide rate response but will continue to collect data for Sensor Trending.

The following programmable parameters control the pulse generator's response to the sensor values generated by the Accelerometer:

- Response Factor
- Activity Threshold
- Reaction Time
- Recovery Time

Response Factor (Accelerometer)

Response Factor (accelerometer) determines the pacing rate increase that will occur above the LRL at various levels of patient activity (Figure 2-8 on page 2-20).

- High Response Factor—results in less activity required for the pacing rate to reach the MSR
- Low Response Factor—results in more activity required for the pacing rate to reach the MSR

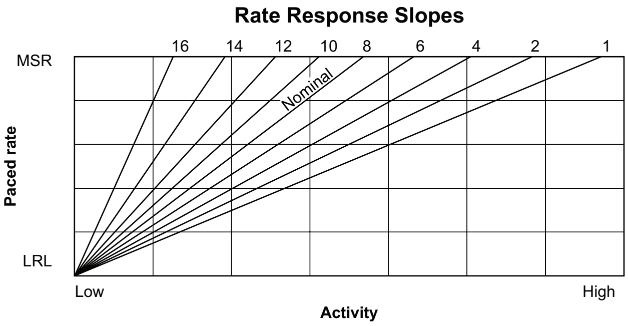
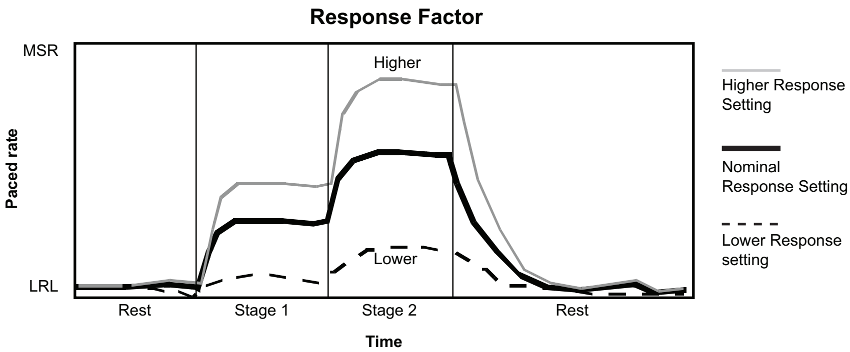


Figure 2-8. Response Factor and paced rate

The pacing rate achieved can be limited either by the detected activity level or the programmed MSR. If the detected activity level results in a steady-state rate below the MSR, the pacing rate can still increase when the detected activity levels increase (Figure 2-9 on page 2-20). The steady-state response is independent of the programmed reaction and recovery times.



This figure shows the effect of higher and lower settings during a theoretical two-stage exercise test.

Figure 2-9. Response Factor in exercise test

Programming the LRL up or down moves the entire response up or down without changing its shape.

Activity Threshold

Activity Threshold prevents rate increases due to low-intensity, extraneous motion (e.g., motion caused by respiration, heart beat, or in some cases tremor associated with Parkinson’s disease).

Activity Threshold represents the activity level that must be exceeded before the sensor-driven pacing rate will increase. The pulse generator will not increase the paced rate above the LRL until the activity signal increases above the Activity Threshold. An Activity Threshold setting should allow a rate increase with minor activity, such as walking, but be high enough so the pacing rate will not increase inappropriately when the patient is inactive (Figure 2-10 on page 2-21 and Figure 2-11 on page 2-21).

- Lower setting—less motion is required to increase the pacing rate
- Higher setting—more motion is required to increase the pacing rate

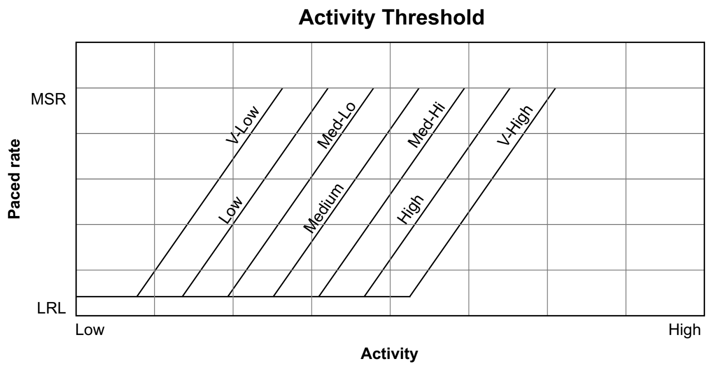
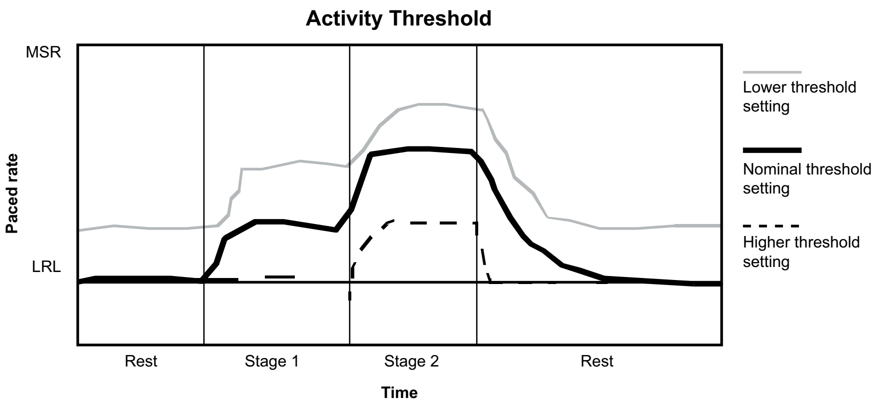


Figure 2-10. Activity Threshold and rate response



This figure demonstrates the effect of increased or decreased Activity Threshold settings in response to a theoretical two-stage exercise test.

Figure 2-11. Activity Threshold in exercise test

Reaction Time

Reaction Time determines how quickly the pacing rate will rise to a new level once an increase in activity level is detected.

Reaction Time affects only the time required for a rate increase to occur. The value selected determines the time required for the paced rate to move from the LRL to the MSR for a maximum level of activity (Figure 2-12 on page 2-22 and Figure 2-13 on page 2-22).

- Short Reaction Time: results in a rapid increase in the pacing rate
- Long Reaction Time: results in a slower increase in the pacing rate

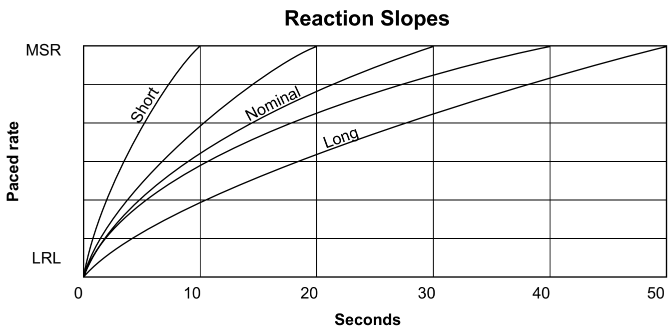


Figure 2-12. Reaction Time and paced rate

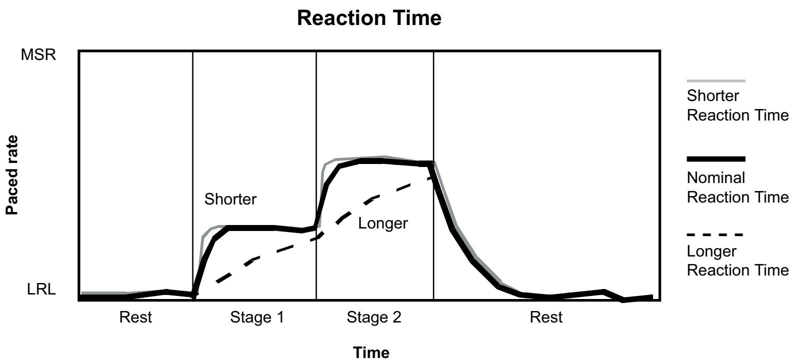
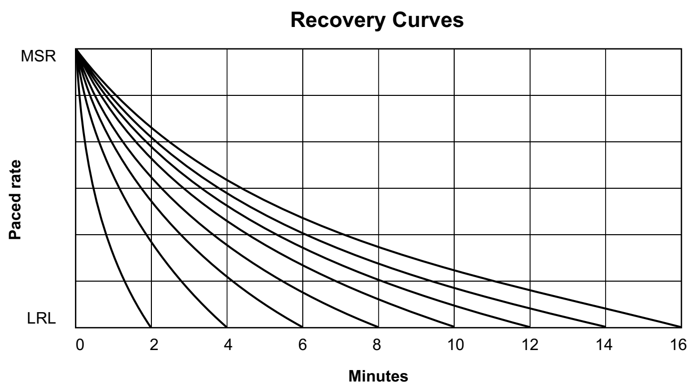


Figure 2-13. Reaction Time in exercise test

Recovery Time

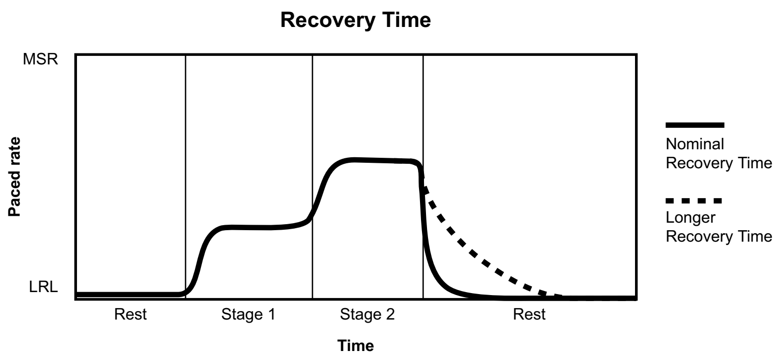
Recovery Time determines the time required for the paced rate to decrease from the MSR to the LRL in the absence of activity. When patient activity concludes, Recovery Time is used to prevent an abrupt decrease in pacing rate (Figure 2-14 on page 2-23 and Figure 2-15 on page 2-23).

- Short Recovery Time—results in a faster decrease in pacing rate after patient activity lowers or stops
- Long Recovery Time—results in a slower decrease in pacing rate after patient activity lowers or stops



There are 15 settings available; only the even-numbered settings are shown.

Figure 2-14. Recovery Time and paced rate



The figure shows the effect of higher and lower settings during a theoretical two-stage exercise test.

Figure 2-15. Recovery Time in exercise test

Minute Ventilation (MV)

The pulse generator uses transthoracic impedance to measure minute ventilation (MV), which is the product of respiration rate and tidal volume. Based on the MV measurement, the pulse generator calculates the sensor-indicated rate.

CAUTION: Do not program the MV sensor to On until after the pulse generator has been implanted and system integrity has been tested and verified.

Approximately every 50 ms (20 Hz), the device will deliver a current excitation waveform between the RA Ring electrode and Can (primary vector) or the RV Ring electrode and Can (secondary vector). Since either lead may be used to measure MV, at least one of the implanted leads must have normal bipolar lead impedances.

NOTE: *Only one vector is available in a single chamber device.*

NOTE: *Leads may be programmed Unipolar or Bipolar, but either Lead Configuration or Patient Information must indicate that a bipolar lead is present.*

Inductive (wanded) telemetry may temporarily interfere with the pulse generator's MV sensor function. MV driven rates may hold at the current rate for approximately one minute immediately following any interrogation or programming command. This period will be indicated by a Sensor Status of Rate Hold: Telemetry (Table 2-3 on page 2-26). If a significant amount of data (for example, Arrhythmia Logbook episodes) is being retrieved from the device, the MV driven rate may then decrease to the LRL and further rate changes may not occur for several additional minutes. This time period will be indicated by a Sensor Status of Suspended: Telemetry (Table 2-3 on page 2-26).

If MV driven rate changes are desired prior to the rate hold or suspension periods, allow the MV driven rate to reach the desired rate prior to using inductive telemetry, or use RF telemetry to communicate with the device.

CAUTION: Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.

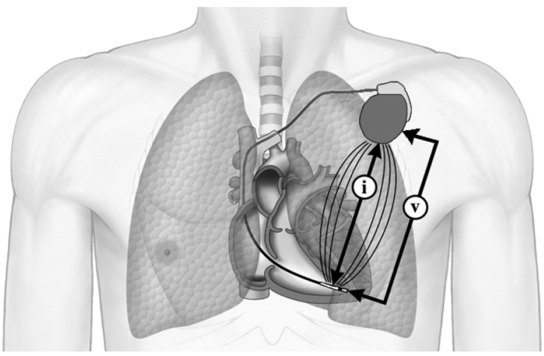
- External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may cause interference with the pulse generator that could result in accelerated pacing, possibly up to the maximum sensor-driven rate, when MV is programmed to On. To resolve suspected interactions, deactivate the MV sensor either by programming it to Off (no MV rate driving or MV sensor-based trending will occur), or Passive (no MV rate driving will occur). Alternatively, program the Brady Mode to a non-rate responsive mode (no MV rate driving will occur). If a PRM is not available and the pulse generator is pacing at the sensor-driven rate, apply a magnet to the pulse generator to initiate temporary asynchronous, non-rate responsive pacing.

During MV function, the active vector may be the primary vector (RA Ring electrode to Can) or secondary vector (RV Ring electrode to Can). Lead impedances for the active vector are evaluated each hour to assess lead integrity. If the active vector values are out of range, impedances for the alternate vector are evaluated to determine if that vector can be utilized for MV. If both the primary and secondary vectors are out of range, the sensor is suspended for the next one hour. Lead integrity will continue to be tested every hour to evaluate if the MV signal will use the primary vector, the secondary vector, or remain suspended. Acceptable lead impedance values are 200–2000 Ω for the tip to can vector and 100–1500 Ω for the ring to can vector.

If a vector switch occurs, an automatic 6-hour calibration will occur (no MV-driven rate response occurs during the 6-hour calibration period).

NOTE: *The waveform in a single chamber device will originate from and be measured in the chamber where the lead is located.*

The application of current between the ring electrode and the can will create an electrical field across the thorax, modulated by respiration. During inspiration the transthoracic impedance is high, and during expiration it is low. The device will measure the resulting voltage modulations between the lead tip electrode and the can.

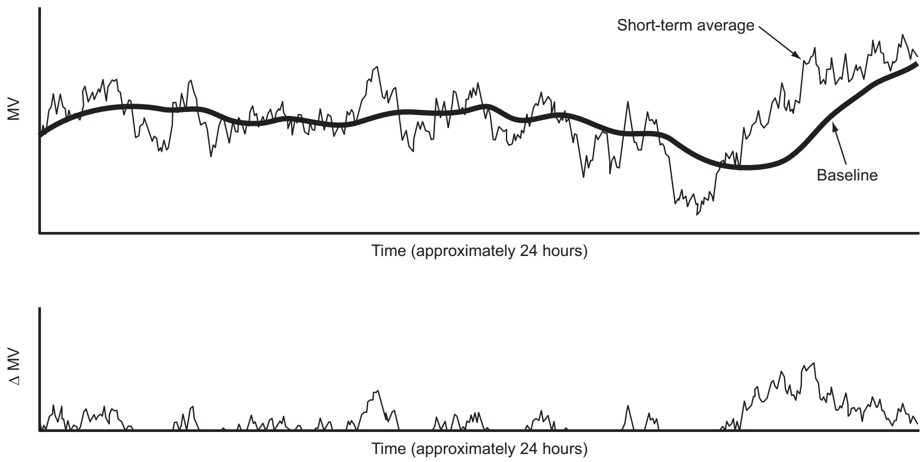


i = current, V = volts

Figure 2-16. Measurement of the MV signal from the RV lead

Due to advanced filtering, the algorithm supports breathing rates up to 72 breaths per minute. The filtered waveform is then processed to obtain the total volume measurement. The average excitation current that is delivered to the tissue is 320 µA. If the noise becomes excessive, the MV sensor will be suspended until the noise level decreases. The excitation waveform is a balanced low amplitude signal that will not distort surface ECG recordings. On some ECG monitoring equipment, the waveforms may be detected and displayed. These waveforms are present only when the MV sensor is used.

The pulse generator keeps a long-term moving average (baseline) of these measurements (updated every 4 minutes) as well as a short-term (approximately 30-second) moving average, which is updated every 7.5 seconds. The magnitude of the difference between the short-term average and long-term baseline determines the magnitude of the rate increase over the LRL, or decrease down to the LRL. The increase or decrease in the sensor-indicated rate occurs at a maximum of 2 min^{-1} per cycle (Figure 2-17 on page 2-25).



Top: The baseline (long-term average) follows the drift of the short-term average. Bottom: The difference between the short- and long-term average is used for increasing the sensor-driven rate upon exertion.

Figure 2-17. Difference between MV short-term average and MV baseline

NOTE: *Whenever a magnet is applied and the Magnet Response has been programmed to Pace Async, the pacemaker will pace asynchronously at the magnet rate and will not respond to MV data.*

CAUTION:

Program the MV Sensor to Off during mechanical ventilation. Otherwise, the following may occur:

- Inappropriate MV sensor-driven rate

For optimal rate response, a variety of Minute Ventilation parameters can be programmed via the RightRate Pacing area on the Rate Adaptive Pacing Settings screen.

To activate the MV sensor, the system needs a measure of the baseline or resting MV. Methods for calibration include:

- **Automatic Calibration.** An automatic, 6-hour calibration will occur whenever MV is programmed to On or Passive. No MV-driven rate response or hourly lead integrity checks will occur during the 6-hour calibration time. If MV is programmed to On at implant, there is a 2-hour wait period after lead attachment, followed by the 6-hour calibration. This 2-hour period will be indicated by a sensor status of Suspended and is intended to allow the implantation procedure to be completed.

- **Manual Calibration.** Whenever MV is programmed On, (including during the 2-hour period following lead attachment) the sensor can be calibrated manually. From the RightRate Pacing Details screen, select the Start Sensor Calibration button to initiate the manual calibration process. If the calibration is successful, MV-driven rate response takes effect within one minute. Manual calibration may take as little as 2 minutes or as much as 5 minutes to complete, depending on whether noise is encountered during data collection. The patient should be resting quietly and breathing normally for a few minutes prior to and during the manual calibration. If the manual calibration fails due to noise, it will be indicated by a Suspended: Noise Detected sensor status and the 6-hour automatic calibration will automatically begin. If the manual calibration fails due to no valid MV lead vector (indicated by a sensor status of Suspended), the pulse generator will continue to check for a valid vector every hour and will start the 6-hour calibration once a valid vector is detected.

NOTE: *The Manual Calibration method will not be available upon initial interrogation while information such as Arrhythmia Logbook episodes are retrieved from the device. This will be indicated by a dimmed Start Sensor Calibration icon and may occur for seconds to minutes depending on the amount of data being retrieved.*

There is no clinical difference between the Automatic and the Manual calibration methods. A successful Manual calibration simply allows a baseline to be obtained and MV-driven rate response to begin immediately. Neither calibration method requires that telemetry communication be maintained for the duration of the calibration.

CAUTION: To obtain an accurate MV baseline, the MV sensor will be calibrated automatically or can be calibrated manually. A new, manual calibration should be performed if the pulse generator is removed from the pocket following implant, such as during a lead repositioning procedure, or in cases where the MV baseline may have been affected by factors such as lead maturation, air entrapment in the pocket, pulse generator motion due to inadequate suturing, external defibrillation or cardioversion, or other patient complications (e.g., pneumothorax).

The PRM will display one of the messages below to indicate the current MV sensor status on the RightRate Pacing Details screen (Figure 2-20 on page 2-28). The messages of Suspended: Noise Detected, Suspended: Telemetry and Rate Hold: Telemetry are updated real-time while the remainder are updated upon interrogation.

Table 2-3. MV Sensor Status Messages

Sensor Status	MV Sensor Driven Pacing	MV Sensor Data Collection[a]
Off	No	No
Manual Calibration in Progress	No	Yes
Auto Calibration in Progress	No	Yes
Calibrated	Yes[b]	Yes
Suspended	No	No
Suspended: Noise Detected	No	Yes
Suspended: Telemetry	No	Yes
Rate Hold: Telemetry	No[c]	Yes

a. Individual Trends determine if data collected during Suspension is valid and incorporated into Trend results.
b. If the MV Sensor is programmed to Passive, MV sensor driven pacing will not occur
c. Rate will hold at the current MV indicated value for up to one minute; further MV based rate changes will not occur with this sensor status

There are four Minute Ventilation settings: On, Off, Passive, and ATR Only. If the pulse generator is permanently programmed to a non-rate adaptive mode, but a rate adaptive ATR Fallback mode is selected, the MV field will display ATR Only. If programmed to a non-rate adaptive mode, the ’On’ setting is not available. If Passive is selected, the MV sensor will not provide rate response but will continue to collect data for use by other features (e.g., Sensor Trending).

Response Factor (Minute Ventilation)

An increase in MV over baseline due to an increase in metabolic demand will be detected by the pulse generator and converted by its algorithm into an increased pacing rate. The relationship between the detected increase in MV and the resulting increase in the sensor-indicated rate is established by the MV Response Factor.

The Response Factor parameter determines the pacing rate that will occur above the LRL at various elevated levels of MV. Larger response factor values will result in higher sensor rates for a given MV level (Figure 2-18 on page 2-27). The effects of higher and lower Response Factor settings on sensor-driven pacing rate during a theoretical two-stage exercise test are illustrated below (Figure 2-19 on page 2-27).

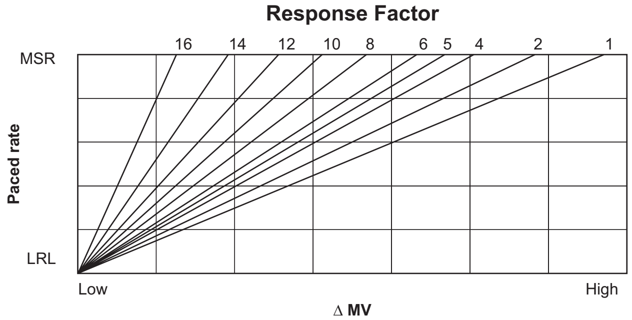


Figure 2-18. Relationship between the programmed Response Factor setting and rate response

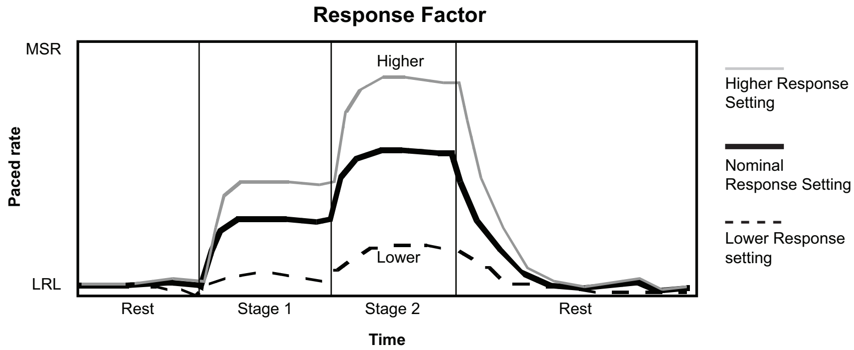


Figure 2-19. Effects of Response Factor settings in a two-stage exercise test

Ventilatory Threshold and Ventilatory Threshold Response

The Ventilatory Threshold and Ventilatory Threshold Response can be either manually programmed or automatically derived from patient information. The clinician can select Derive from Patient Attributes from the RightRate Pacing Details screen to obtain settings based on the patient’s age and gender (and Fitness Level, see below). As parameters are changed, the graph will likewise adjust to demonstrate the effect of the new programming on overall rate response (Figure 2-20 on page 2-28). If the Date of Birth or Gender is adjusted on the Patient Information screen, the new values will also be reflected on the RightRate Pacing Details screen.

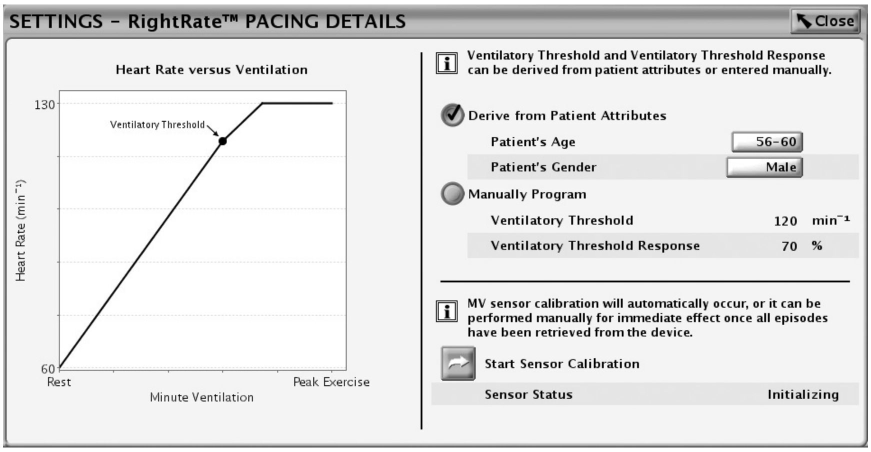


Figure 2-20. Ventilatory Threshold and Ventilatory Threshold Response

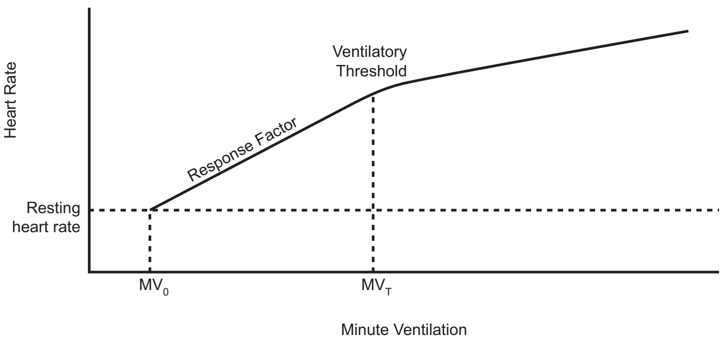
Ventilatory Threshold

Ventilatory Threshold is a physiologic term describing the point during exercise when the breathing rate increases faster than the heart rate (sometimes referred to as Anaerobic or Lactate Threshold).

The Response Factor controls the MV rate response for sensor rates between the LRL and the Ventilatory Threshold. The Ventilatory Threshold Response controls the MV rate response when the sensor rate is above the Ventilatory Threshold.

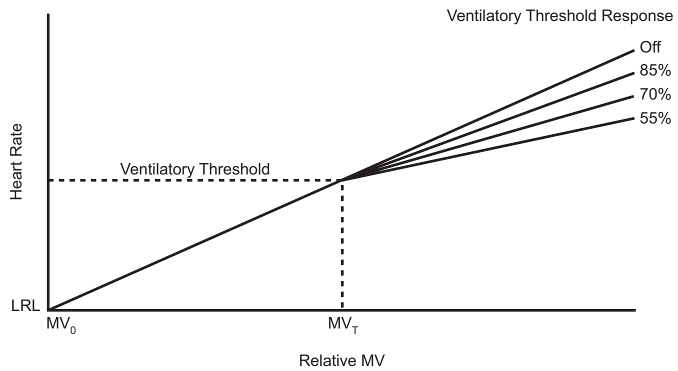
Ventilatory Threshold Response

The physiologic relationship between MV and rate is approximately bilinear as shown (Figure 2-21 on page 2-28). During exercise levels up to the Ventilatory Threshold, this relationship can be approximated by a linear relationship. At exertion levels above the Ventilatory Threshold, the relationship is still approximately linear, but at a reduced slope. The relationship between the two slopes varies from person to person and depends on several factors such as gender, age, and exercise frequency and intensity. The pulse generators allow programming of a slope above the Ventilatory Threshold that is less steep and thus designed to mimic the physiologic relationship between respiration rate and heart rate. The Ventilatory Threshold Response is programmed as a percentage of the Response Factor. Ventilatory Threshold Response is in effect at rates above the Ventilatory Threshold and will result in a less aggressive response to MV at higher rates (Figure 2-22 on page 2-29).



MV_0 = resting MV; MV_T = MV at the ventilatory threshold

Figure 2-21. Typical physiologic relationship between MV and heart rate



The Response Factor is linear from the resting state up to the Ventilatory Threshold (MV_0 = resting MV; MV_T = MV at the Ventilatory Threshold).

Figure 2-22. Ventilatory Threshold Response

Fitness Level

The selected Fitness Level will automatically determine an appropriate Ventilatory Threshold and Ventilatory Threshold Response factor. As the Fitness Level is increased, the Ventilatory Threshold increases and the Ventilatory Threshold Response factor decreases.

Table 2-4. Recommended Fitness Level settings

Recommended Fitness Level setting	Patient activity level
Sedentary	Little to no physical activity
Active	Regular walking and low impact activities
Athletic	Moderate intensity, non-competitive jogging/biking
Endurance Sports	Strenuous, competitive activities such as marathons

The baseline (long-term average) is fixed for up to 4.5 hours. This allows active patients who exercise for a long duration (e.g., long-distance runners) to maintain an adequate sensor-driven rate throughout the exercise period. The baseline will be fixed when the sensor indicated rate is above 110 min^{-1} for the Fitness Level setting of Endurance Sports or 90 min^{-1} for the other three Fitness Level settings. After 4.5 hours, or when the sensor rate falls below 90 min^{-1} or 110 min^{-1} as defined above, baseline adaptation will be re-enabled.

Dual-Sensor Blending

Whenever both the Accelerometer and the MV sensor are programmed On for rate adaptive pacing, the two sensor-indicated rates are blended to produce a rate-dependent, weighted average response. As a result, the blended response will always be equal to one of the rates or between the two rates. Whenever the Accelerometer response is less than the MV response, the sensor blending will be 100% MV-based. If the Accelerometer response is greater than the MV response, the blending will range from approximately 80% Accelerometer and 20% MV when the Accelerometer rate is at LRL, to approximately 40% Accelerometer and 60% MV when the Accelerometer rate is at MSR.

The following examples illustrate the blending algorithm operation.

Example 1

The Accelerometer detects motion with a simultaneous MV increase (Figure 2-23 on page 2-30). Upon exercise, the blended response will promptly (within 4 seconds) increase the rate based on the Accelerometer response. As the rate continues to increase, the blended response will be moving toward the MV response, but will always remain between the Accelerometer and MV responses. At higher rates, the changes in Accelerometer input will have a lesser effect on the blended response (only 40% at MSR), whereas changes in MV will have a more significant effect. At cessation of exercise, the Accelerometer rate will decrease as prescribed by the Recovery Time parameter and, in this example, will drop below the MV response. As a result, the algorithm will switch over to a 100% MV blend during the recovery phase for as long as the Accelerometer response remains below the MV response. When using dual-sensor blending, retain the nominal Accelerometer value of 2 minutes. This allows the physiologic MV signal to control rate adaptive pacing in the exercise recovery phase.

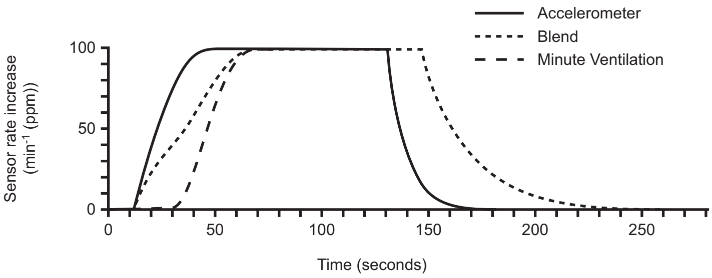


Figure 2-23. Blended response with an Accelerometer Reaction Time of 30 seconds

The aggressiveness of response at the onset of exercise can be controlled by programming a shorter Accelerometer Reaction Time (Figure 2-24 on page 2-30)

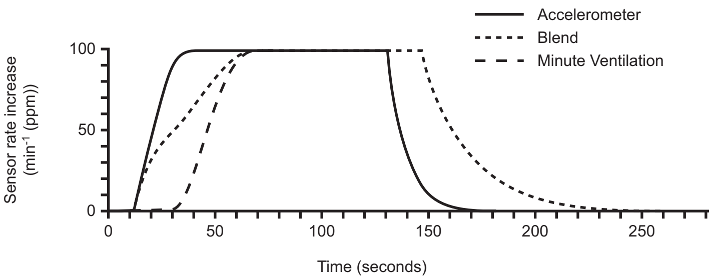


Figure 2-24. Blended response with an Accelerometer Reaction Time of 20 seconds

Example 2

The Accelerometer detects motion with little MV increase (Figure 2-25 on page 2-30). The response of the blended sensor will be limited to approximately 60% of the Accelerometer response. Once the Accelerometer response drops below the MV response during recovery, the blended response will be 100% MV-driven.

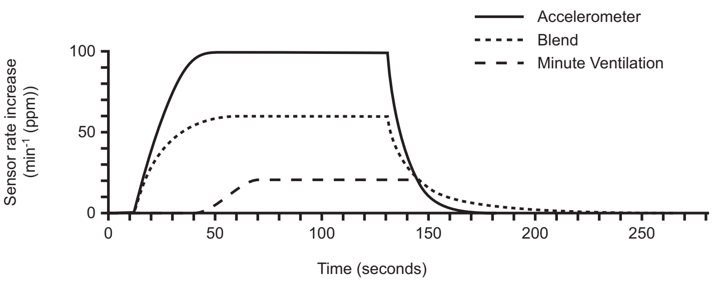


Figure 2-25. Blended response: Accelerometer detects motion with little or no increase in MV

Example 3

MV increases with little Accelerometer rate increase (Figure 2-26 on page 2-31). The blended response will initially increase with the Accelerometer response, but as the MV response increases over the Accelerometer response, the blended response will be 100% MV-driven. This provides adequate response during increases in metabolic demand under conditions of little or no upper body movement.

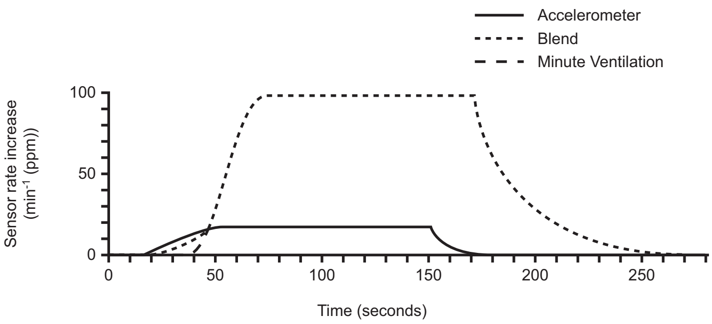


Figure 2-26. Blended response: MV increase with little or no motion detected by the Accelerometer

Sensor Trending

Sensor Trending provides a graphical display of the pulse generator's rate response to the patient's detected physiologic need and provides useful information during exercise testing. This allows the clinician to adapt the sensor-driven pacing rate to correspond to the patient's actual need.

The Sensor Trending graph and Sensor Trending Setup parameters are viewable via the Rate Adaptive Pacing screen.

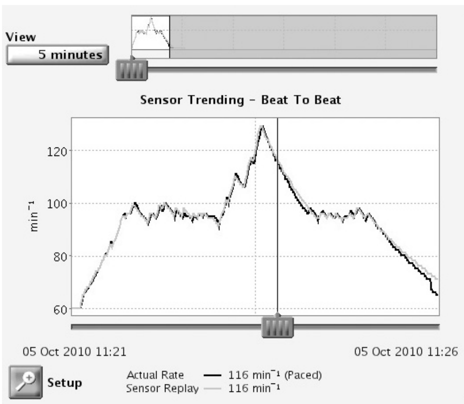


Figure 2-27. Sensor Trending graph

Setup includes the following options:

- Recording Method—programmable:
  - 30-Second Average—records and plots the average rate every 30 seconds.
  - Beat to Beat—records and plots the rate of every beat.

    NOTE: *Beat to Beat is recommended when using hall walks or shorter periods of activity to manually optimize sensor rates.*
  - Off—no trending data is gathered.

- Duration—non-programmable and based on the selected Recording Method:
  - When Recording Method is set to Off or 30-Second Average—Duration is approximately 25 hours.
  - When Recording Method is set to Beat to Beat—Duration is approximately 40 minutes at 75 min^{-1}.
- Data Storage—programmable:
  - Continuous—contains the most recent data available. Storage starts when setup is confirmed and continuously records the latest information, overwriting the oldest data until the information is retrieved. This option allows you to view data for the recording duration immediately prior to data retrieval.
  - Fixed—storage starts when setup is confirmed and continues until device memory storage is full. This allows you to view data from initial setup for a fixed amount of time.

The pulse generator collects and stores rate and sensor data which is then displayed on the PRM in a graphical format as the patient's Actual Rate and Sensor Replay during the recording time.

The Actual Rate (black line) indicates the patient's heart rate during activity (whether paced or sensed). The Sensor Replay (orange line) depicts the sensor-driven heart rate response with the current sensor parameter settings. As the slider along the horizontal axis of the graph is moved, actual and sensor-indicated heart rates are displayed for particular data points. Additionally, the atrial events represented by a particular data point (single beat or 30-second average) are classified and displayed next to the Actual Rate. Events are classified and displayed as one or more of the following: Paced, Sensed, Sensed in ATR. This event type will reflect ventricular events in VVI(R) modes.

Current sensor parameters can be adjusted to view the resulting change to sensor rate behavior without having to repeat an exercise test.

The pulse generator can collect and store data in rate adaptive and non-rate adaptive modes. In non-rate adaptive modes, the trending is collected via the Passive sensor setting. Passive allows for sensor data collection that can be used to optimize the sensors in the absence of the sensor-driven rate response. However, when the sensor setting is Passive, Sensor Replay data will not be displayed on the graph until a rate responsive mode is selected.

The pulse generator will record Sensor Trending data while wanded or RF telemetry is active.

When the heart rate is completely sensor-driven, small differences between the Actual Rate and Sensor Replay may still be observed because they are calculated independently by slightly different methods.

Working with Trending Data

To use the Sensor Trending function, follow these steps:

1. Following an exercise session, navigate to the Sensor Trending graph and press Interrogate to update trending information. Trending data is retrieved on initial interrogation. If a session remains active while the patient performs a hall walk, press Interrogate again to update the trending information.

2. Select the View button to expand or compress the amount of data viewed at one time. The start and end dates and times at the bottom of the graph will change to reflect the time period represented on the graph. The 30-second Average Recording Method has options for 1 to 25 hours, and the Beat to Beat Recording Method has options for 5 to 40 minutes.

3. To adjust which data is displayed on the graph or to view particular data points, move the sliders along the horizontal axes at the bottom of the display windows.

4. Adjust the sensor parameters to the right of the graph to see how adjustments in the rate adaptive pacing parameters will affect the sensor response (orange line). As these parameters and/or the MSR and LRL are changed on the screen, the application will modify the graph to illustrate the resulting effects. If the patient's heart rate is appropriate for the activity performed, no sensor optimization is necessary.

5. When a patient's heart rate is within the desired range for the activity performed, select Program.

NOTE: *Sensor Trending results may be printed via the Reports tab. Both the Present (currently programmed) and Replay (clinician adjusted) parameters are provided in addition to the current graph as represented on the programmer screen.*

NOTE: *Sensor adjustments should not be based on data which is collected during the MV calibration time period.*

ATRIAL TACHY RESPONSE

ATR Mode Switch

ATR is designed to limit the amount of time that the ventricular paced rate is at the MTR or exhibits upper-rate behavior (2:1 block or Wenckebach) in response to a pathological atrial arrhythmia.

In the presence of detected atrial activity that exceeds the ATR Trigger Rate, the pulse generator switches the pacing mode from a tracking mode to a nontracking mode as follows:

- From DDD(R) to DDI(R) or VDI(R)
- From VDD(R) to VDI(R)

An example of ATR behavior is shown (Figure 2-28 on page 2-33).

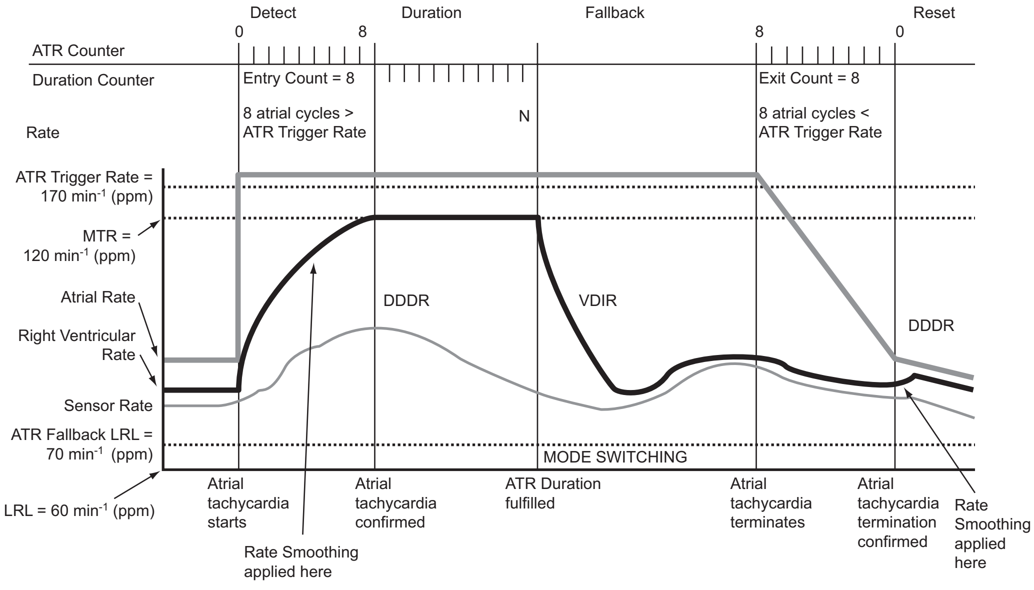


Figure 2-28. ATR behavior

NOTE: *Parameter settings that reduce the atrial sensing window may inhibit ATR therapy.*

ATR Trigger Rate

The ATR Trigger Rate determines the rate at which the pulse generator begins to detect atrial tachycardias.

The pulse generator monitors atrial events throughout the pacing cycle, except during the atrial blanking period and the noise rejection intervals. Atrial events faster than the Trigger Rate increase the ATR detection counter; atrial events slower than the Trigger Rate decrease the counter.

When the ATR detection counter reaches the programmed entry count, the ATR Duration begins. When the ATR detection counter counts down from the programmed Exit Count value to zero at any point in time, ATR Duration and/or fallback are terminated, and the ATR algorithm is reset. An event marker is generated whenever the ATR detection counter is incremented or decremented.

ATR Duration

ATR Duration is a programmable value that determines the number of ventricular cycles during which the atrial events continue to be evaluated after initial detection (entry count) is met. This feature is intended to avoid mode switching due to short, nonsustained episodes of atrial tachycardia. If the ATR counter reaches zero during ATR Duration, the ATR algorithm will be reset, and no mode switch will occur.

If the atrial tachycardia persists for the programmed ATR Duration, then mode switching occurs and the Fallback Mode and Fallback Time begin.

Entry Count

The Entry Count determines how quickly an atrial arrhythmia is initially detected.

The lower the programmable value, the fewer the fast atrial events required to fulfill initial detection. Once the number of fast atrial events detected equals the programmable Entry Count, ATR Duration begins, and the Exit Count is enabled.

CAUTION: Exercise care when programming the Entry Count to low values in conjunction with a short ATR Duration. This combination allows mode switching with very few fast atrial beats. For example, if the Entry Count was programmed to 2 and the ATR Duration to 0, ATR mode switching could occur on 2 fast atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.

Exit Count

The Exit Count determines how quickly the ATR algorithm is terminated once the atrial arrhythmia is no longer detected.

The lower the programmed value, the more quickly the pulse generator will return to an atrial tracking mode once an atrial arrhythmia terminates. Once the number of slow atrial events detected equals the programmable Exit Count, ATR Duration and/or Fallback will be terminated, and the ATR algorithm will be reset. The ATR Exit Count is decremented by atrial events slower than the ATR Trigger Rate or by any ventricular event that occurs more than two seconds after the last atrial event.

CAUTION: Exercise care when programming the Exit Count to low values. For example, if the Exit Count was programmed to 2, a few cycles of atrial undersensing could cause termination of mode switching.

Fallback Mode

Fallback Mode is the nontracking pacing mode that the pulse generator automatically switches to when ATR Duration is fulfilled.

After switching modes, the pulse generator gradually decreases the ventricular paced rate. This decrease is controlled by the Fallback Time parameter.

NOTE: *Dual-chamber pacing fallback mode values are only available when the Normal pacing mode is also set to dual-chamber.*

NOTE: *ATR Fallback mode may be programmed rate responsive even if the permanent brady mode is non-rate responsive. In this scenario, the sensor parameters will indicate "ATR Only".*

Fallback Time

Fallback Time controls how quickly the paced rate will decrease from the MTR to the ATR Fallback LRL during fallback. The paced rate will decrease to the higher of the sensor-indicated rate or the ATR Fallback LRL.

During fallback, the following features are disabled:

- Rate Smoothing—disabled until fallback reaches the ATR Fallback LRL or the sensor-indicated rate
- Rate Hysteresis
- AV Search +
- PVARP Extension

Fallback LRL

The ATR Fallback LRL is the programmed lower rate to which the rate decreases during mode switching. The ATR Fallback LRL may be programmed higher or lower than the permanent brady LRL.

The rate will decrease to the higher of the sensor-indicated rate (when applicable) and the ATR Fallback LRL.

End of ATR Episode

The End of ATR Episode identifies the point when the pulse generator reverts to AV-synchronous operation because the atrial arrhythmia is no longer detected.

With the termination of the arrhythmia, the ATR Exit Count decrements from its programmed value until it reaches 0. When the ATR Exit Count reaches 0, the pacing mode automatically switches to the programmed tracking mode, and AV-synchronous operation is restored.

PMT Termination

PMT Termination detects and attempts to interrupt pacemaker-mediated tachycardia (PMT) conditions.

AV synchrony may be lost for many reasons, including atrial fibrillation, PVCs, PACs, atrial oversensing, or loss of atrial capture. If the patient has an intact retrograde conduction pathway when AV synchrony is lost, the unsynchronized beat may conduct retrograde to the atrium, resulting in premature atrial depolarization. In DDD(R) and VDD(R) pacing modes, the device may detect and track retrograde conducted P-waves that fall outside of PVARP. The repeated cycle of sensing and tracking retrograde conduction is known as PMT, which can result in triggered ventricular pacing rates as high as the MTR. Programming certain refractory periods (e.g., PVARP After PVC) can reduce the likelihood of tracking retrograde events. Rate Smoothing can also be useful in controlling the pulse generator’s response to retrograde conduction.

When the pulse generator’s response to retrograde conduction has not been controlled by device programming, PMT Termination (when programmed to On) is used to detect and terminate PMT within 16 cycles of onset when the following conditions have been met:

- 16 successive ventricular paces are counted at the MTR following atrial sensed events
- All 16 V–A intervals are within 32 ms (preceding or following) of the second V–A interval measured at MTR during the 16 ventricular paced events (to distinguish Wenckebach behavior from PMT)

When both conditions are met, the pulse generator sets the PVARP to a fixed setting of 500 ms for one cardiac cycle in an attempt to break the PMT. If both conditions are not met, the pulse generator continues to monitor successive ventricular paces for the presence of a PMT.

When PMT Termination is programmed to On, the pulse generator stores PMT episodes in the Arrhythmia Logbook.

NOTE: *Although the V–A interval evaluation helps discriminate true PMT (stable V–A intervals) from upper rate behavior due to sinus tachycardia or normal exercise response (typically unstable V–A intervals), it is possible that a patient’s intrinsic atrial rate can meet PMT detection criteria. In such cases, if PMT Termination is programmed On, the algorithm will declare the rhythm a PMT and extend PVARP on the 16th cycle.*

NOTE: *Because retrograde conduction times may vary over a patient’s lifetime due to their changing medical condition, occasional programming changes may be necessary.*

If retrograde conduction is evident in a stored EGM, you can evaluate the electrogram and/or perform a threshold test to confirm appropriate atrial pacing and sensing. If stored EGMs are not available for review, follow these steps to use the PRM to assist in V–A interval evaluation:

1. From the Tests screen, select the Temp Brady tab.
2. Program an appropriate atrial sensing mode that provides atrial markers (VDD, DDD, or DDI).
3. Program the maximum PVARP to a value shorter than the average retrograde conduction time.

   NOTE: *Scientific literature suggests that the average retrograde conduction time is 235 ± 50 ms (with a range of 110–450 ms)[1].*

4. Program the LRL to ensure pacing above the intrinsic atrial rate (e.g., 90, 100, 110…).
5. Begin printing the real-time ECG.
6. Select the Start button to activate the temporary parameters.
7. When testing is complete for the specified LRL value, select the Stop button.
8. Stop printing the real-time ECG.

1. Furman S, Hayes D.L., Holmes D.R., A Practice of Cardiac Pacing. 3rd ed. Mount Kisco, New York: Futura Publishing Co.; 1993:74-75.

9. Evaluate the ECG strip for V–A conduction (VP followed by an AS). Look for stable and consistent intervals suggestive of retrograde conduction.

    - If retrograde conduction was identified, compare the retrograde V–A interval time to the programmed refractory period. Consider programming PVARP to the appropriate value so that the retrograde event is not tracked.

    - If retrograde conduction was not identified, the PMT episode may be a result of normal upper rate behavior. Review Histograms to see how often the rate is at the MTR, and consider raising the MTR (if clinically appropriate).

10. If necessary, repeat this procedure with different LRL values, as retrograde conduction may occur at different rates.

RATE ENHANCEMENTS

Rate Hysteresis

Rate Hysteresis can improve device longevity by reducing the number of pacing stimuli. In dual-chamber models, this feature is available in DDD, DDI, VVI, and AAI modes. In single-chamber models, this feature is available in VVI and AAI modes. In DDD, DDI, and AAI modes, Rate Hysteresis is activated by a single nonrefractory atrial sensed event.

NOTE: *Rate Hysteresis is activated and deactivated by ventricular events in VVI mode (e.g., intrinsic activity, paced activity).*

In DDD, DDI, and AAI modes, Hysteresis is deactivated by a single atrial pace at the hysteresis rate. In DDD mode, Hysteresis is deactivated by an atrial rate above the MTR.

When Rate Smoothing Down is enabled, Rate Hysteresis remains in effect until pacing occurs at the hysteresis rate. This allows Rate Smoothing to control the transition to the hysteresis rate.

Hysteresis Offset

Hysteresis Offset is used to lower the escape rate below the LRL when the pulse generator senses intrinsic atrial activity.

If intrinsic activity below the LRL occurs, then Hysteresis Offset allows inhibition of pacing until the LRL minus Hysteresis Offset is reached. As a result, the patient might benefit from longer periods of sinus rhythm.

Search Hysteresis

When Search Hysteresis is enabled, the pulse generator periodically lowers the escape rate by the programmed Hysteresis Offset in order to reveal potential intrinsic atrial activity below the LRL. The programmed number of search cycles must be consecutively atrial paced for a search to occur.

Example: At a rate of 70 min^{-1} and a search interval of 256 cycles, a search for intrinsic atrial activity would occur approximately every 3.7 minutes (256 ÷ 70 = 3.7).

During Search Hysteresis, the pacing rate is lowered by the Hysteresis Offset for up to 8 cardiac cycles. If intrinsic activity is sensed during the search period, Hysteresis will remain active until an atrial pace occurs at the hysteresis offset rate.

Rate Smoothing is disabled during the search cycles. If no intrinsic atrial activity is detected during the 8-cycle search, the pacing rate is brought up to the LRL. Rate Smoothing Up, if enabled, controls the pacing rate increase.

Rate Smoothing

Rate Smoothing controls the pulse generator's response to atrial and/or ventricular rate fluctuations that cause sudden changes in pacing intervals. Rate Smoothing is an important enhancement to ATR because it can significantly reduce the rate fluctuations associated with the onset and cessation of atrial arrhythmias.

Without Rate Smoothing, a sudden, large atrial rate increase will cause a simultaneous sudden increase in the paced ventricular rate as high as the programmed MTR. Patients who experience large variations in their ventricular paced rate can feel symptomatic during these episodes. Rate Smoothing can prevent these sudden rate changes and the accompanying symptoms (such as palpitations, dyspnea, and dizziness).

In a normal conduction system, limited cycle-to-cycle rate variations occur. However, the paced rate can change dramatically from one beat to the next in the presence of any of the following:

- Sinoatrial disease such as sinus pause or arrest, sinoatrial block, and brady-tachy syndrome
- PACs and/or PVCs
- Pacemaker Wenckebach
- Intermittent, brief, self-terminating SVTs, and atrial flutter/fibrillation
- Retrograde P-waves
- Pulse generator sensing of myopotential signals, EMI, crosstalk, etc.

In single-chamber modes, Rate Smoothing operates between:

- The LRL and the MPR when programmed VVI or AAI
- The LRL and the MSR when programmed VVIR or AAIR

In dual-chamber modes, Rate Smoothing operates between:

- The LRL and the greater of the MSR or MTR when programmed DDD(R) or VDD(R)
- The LRL and MPR when programmed to DDI
- The LRL and MSR when programmed to DDIR

Rate Smoothing is also applicable between the hysteresis rate and LRL when hysteresis is active, except during Search Hysteresis.

When Rate Smoothing is programmed to On, it is functional except:

- During the 8 cycles of rate Search Hysteresis
- During ATR Fallback until fallback reaches the ATR LRL or the sensor-indicated rate
- Upon triggering PMT Termination
- Immediately following programmed LRL increases
- When the intrinsic rate is above the MTR

Programmable Values

Rate Smoothing values are a percentage of the RV R–R interval (3% to 25% in 3% increments) and can be independently programmed for:

- Increase—Rate Smoothing Up
- Decrease—Rate Smoothing Down
- Off

The pulse generator stores the most recent R–R interval in memory. R-waves may be either intrinsic or paced. Based on this R–R interval and the programmed Rate Smoothing value, the device limits the variation in paced rate on a beat to beat basis.

It is important to ascertain the patient's physiologic cycle-to-cycle variation and program the Rate Smoothing parameter to a value that protects against pathologic interval changes, yet allows physiologic interval changes in response to increases in activity or exercise.

Rate Smoothing Up

Rate Smoothing Up controls the largest pacing rate increase allowed when the intrinsic or sensor rate is increasing.

Rate Smoothing Down

Rate Smoothing Down controls the largest pacing rate decrease allowed when the intrinsic or sensor rate is decreasing.

NOTE: *When Rate Smoothing Down is programmed on and Rate Smoothing Up is programmed Off, the pulse generator will automatically prevent fast intrinsic beats (e.g., PVCs) from resetting the Rate Smoothing Down escape rate any faster than 12% per cycle.*

Rate Smoothing Maximum Pacing Rate (MPR)

The Rate Smoothing Maximum Pacing Rate places a limit on the maximum pacing rate that Rate Smoothing can reach.

The Rate Smoothing Down parameter requires a programmed MPR when in AAI, VVI, or DDI. Rate Smoothing will then be used only between the MPR and the LRL or the hysteresis rate (if applicable).

Rate Smoothing Example Based on a Dual-Chamber Tracking Mode

Based on the most recent R–R interval stored in memory and the programmed Rate Smoothing value, the pulse generator sets up the two synchronization windows for the next cycle: one for the atrium and one for the ventricle. The synchronization windows are defined below:

Ventricular synchronization window: previous R–R interval ± Rate Smoothing value

Atrial synchronization window: (previous R–R interval ± Rate Smoothing value) - AV Delay

The following example explains how these windows are calculated (Figure 2-29 on page 2-40):

- Previous R–R interval = 800 ms
- AV Delay = 150 ms
- Rate Smoothing Up = 9%

- Rate Smoothing Down = 6%

The windows would be calculated as follows:

Ventricular Synchronization Window = 800 - 9% to 800 + 6% = 800 ms - 72 ms to 800 ms + 48 ms = 728 ms to 848 ms

Atrial Synchronization Window = Ventricular Synchronization Window - AV Delay = 728 ms - 150 ms to 848 ms - 150 ms = 578 ms to 698 ms

The timing for both windows is initiated at the end of every ventricular event (R–R interval).

If paced activity is to occur, it must occur within the appropriate synchronization window.

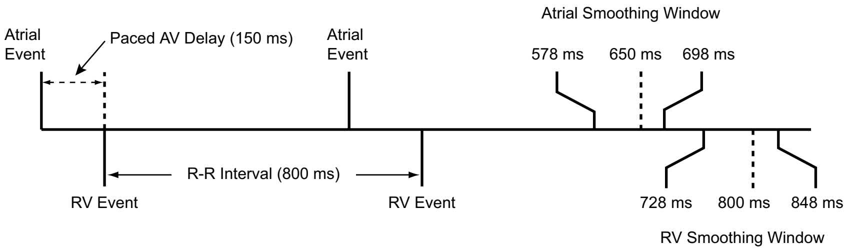


Figure 2-29. Rate smoothing synchronization window

LEAD CONFIGURATION

The pulse generator has independently programmable lead configurations for the following:

- Atrium (in dual-chamber models)
- Right Ventricle

The atrial and RV leads may be set to Unipolar and/or Bipolar pacing and sensing. Additionally, the atrial lead can be programmed to a Bipolar or Unipolar pacing lead configuration with the atrial sensing lead configuration Off.

The input impedance is > 100 KΩ for each sense/pace electrode pair.

In dual-chamber devices programmed to AAI(R), the ventricular sensing lead configuration is available to facilitate VT detection. This parameter will be available unless the Ventricular Tachy EGM Storage parameter is set to Off.

If the atrial or ventricular lead type is specified as Unipolar on the Patient Information screen, programming to Bipolar configuration for either pacing or sensing is not allowed. Certain features and programming options require a bipolar lead to be identified either in Patient Information or with a bipolar lead configuration. Therefore, if Patient Information is not entered, unipolar programming may result in a parameter interaction.

NOTE: *If a unipolar pacing configuration is required at implant, ensure that the configuration is programmed to Unipolar before implant.*

CAUTION: If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.

NOTE: *If a separate ICD is present, programming the pacemaker lead configuration to unipolar is contraindicated.*

When the pacing configuration is programmed to Unipolar, the pacing stimulus will be applied between the lead tip and the pacemaker case. When the pacing configuration is programmed to Bipolar, the stimulus will be applied between the lead tip and the lead ring. In the Unipolar pacing configuration, the pacing artifact should be clearly visible on the surface ECG, which will assist in its interpretation. However, unipolar pacing at high outputs is more likely than bipolar pacing to cause muscle stimulation.

When the sensing configuration is programmed to Unipolar, cardiac signals are detected between the lead tip and the pacemaker case. In the Unipolar sensing configuration, the pacemaker can generally discern smaller intrinsic cardiac signals than in the Bipolar configuration. However, the Unipolar configuration is also more sensitive to myopotentials which can cause pacemaker inhibition. When the sensing configuration is programmed to Bipolar, because of the relatively short distance between the tip and ring electrodes, sensitivity is highest for signals originating in the proximity of the lead tip and ring. As a result, the pacemaker is less likely to sense myopotentials and other signals unrelated to cardiac depolarization.

NOTE: *Blanking Period behavior will vary slightly depending on which lead configuration is selected ("Cross-Chamber Blanking" on page 2-49).*

Use of Atrial Information

The pulse generator will respond to atrial sensing regardless of whether an atrial lead is implanted.

There may be clinical situations in which atrial lead information is not useful (e.g., chronic atrial fibrillation, faulty or dislodged atrial lead, plugged atrial port).

CAUTION: If an atrial lead is not implanted (port is plugged instead), or an atrial lead is abandoned but remains connected to the header, device programming should be consistent with the number and type of leads actually in use.

If an atrial lead will not be used, use the following programming recommendations to ensure appropriate device behavior:

- Program the atrial sensing lead configuration to Off to prevent atrial sensing and minimize accrual of atrial counters. This will also disable the V>A detection enhancement [all tachy events will be labeled as VT (V>A)].

NOTE: *When atrial sensing is programmed to Off (Bipolar/Off or Unipolar/Off) in a DDI(R) or DDD(R) mode, any atrial pacing that occurs will be asynchronous. Additionally, features that require atrial sensing may not function as expected.*

NOTE: *An atrial EP test should not be performed if the atrial sensing lead configuration is programmed to Off.*

- Program the Brady Mode to VVI or VVI(R), to prevent atrial pacing and ensure that atrial information is not used to drive brady pacing.

- Program the Atrial Intrinsic Amplitude and Atrial Pace Impedance daily lead measurements to Off to disable atrial diagnostics (e.g., atrial amplitude and impedance).

- During follow-up visits, consider deselecting the atrial real-time EGM.

If an atrial lead is used in the future, these programming adjustments should be reevaluated, and the pulse generator should be programmed appropriately for use with an atrial lead.

Lead Safety Switch

The Lead Safety Switch feature allows the pacemaker to monitor lead integrity and to switch the pacing and sensing lead configuration from Bipolar to Unipolar if the impedance criteria indicate unacceptably high or low lead impedances.

Lead integrity is monitored once per day by measuring lead impedance. The Safety Switch feature may be programmed to On in either the Atrium or Right Ventricle.

When the measured impedance is ≤ 200 or ≥ 2000 Ω for any daily measurement, both pacing and sensing configurations will automatically be switched to Unipolar for that chamber. Once the configuration has switched, it will remain Unipolar until it is manually reprogrammed back to Bipolar.

NOTE: *Reprogramming back to Bipolar may result in unexpected behavior due to the lead integrity issue that triggered the Safety Switch.*

If a Safety Switch has occurred, information is presented in the following locations on the programmer:

- Summary dialog on initial interrogation
- Lead section of the summary tab
- Daily Measurement graph regardless of the horizontal cursor position
- Safety Switch Details button from the Lead Setting screen

The date on which the Safety Switch occurred as well as the out of range lead impedance value measured are provided. Additionally, an attention symbol is displayed next to the Pace and Sense lead configuration for the affected lead, with Unipolar displayed as the currently programmed parameter for that lead.

The Safety Switch lead alert messages will remain on the PRM screen until the session is ended and will not be present on subsequent sessions unless an additional Safety Switch occurs.

Further testing of lead integrity and performance may be carried out via the Lead Tests screen. Testing will be performed in Unipolar until the lead configuration is manually reprogrammed back to Bipolar.

CAUTION: If leads with measured impedance values approaching 200 or 2000 Ω are used, consider programming Lead Safety Switch Off.

NOTE: *Disabling daily lead impedance measurements in a given chamber also disables the Lead Safety Switch feature in that chamber.*

WARNING: In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of ≤ 200 or ≥ 2000 Ω. Unipolar pacing is contraindicated for patients with an ICD.

AV DELAY

AV Delay is the programmable time period from the occurrence of either a paced or sensed right atrial event to a paced RV event.

AV Delay is designed to help preserve the heart’s AV synchrony. If a sensed right ventricular event does not occur during the AV delay following an atrial event, the pulse generator delivers a ventricular pacing pulse when the AV Delay expires.

AV Delay can be programmed to one or both of the following operations:

- Paced AV Delay
- Sensed AV Delay

AV Delay is applicable in DDD(R), DDI(R), DOO or VDD(R) modes.

NOTE: *The PaceSafe Right Ventricular Automatic Capture feature may lengthen the programmed AV Delay in order to distinguish a fusion beat or noise from ventricular capture.*

NOTE: *Long fixed AV intervals may be selected to avoid unnecessary RV pacing. However, programming long fixed AV intervals, in some cases, may be associated with PMT, diastolic mitral insufficiency, or pacemaker syndrome. As an alternative to programming long fixed AV intervals, consider AV Search+ to avoid unnecessary RV pacing.*

Paced AV Delay

Paced AV Delay corresponds to the AV Delay following an atrial pace.

When the minimum AV Delay value is less than the maximum AV Delay value, then the Paced AV Delay is scaled dynamically according to the current pacing rate. Dynamic AV Delay provides a more physiologic response to rate changes by automatically shortening the Paced AV Delay or Sensed AV Delay with each interval during an increase in atrial rate. This helps minimize the occurrence of large rate changes at the upper rate limit and allows one-to-one tracking at higher rates.

The pulse generator automatically calculates a linear relationship based on the interval length of the previous A–A or V–V cycle (depending on the previous event type) and the programmed values for the following:

- Minimum AV Delay
- Maximum AV Delay
- LRL
- MTR
- MSR
- MPR

The dynamic AV Delay is not adjusted following a PVC or when the previous cardiac cycle was limited by the MTR.

If the atrial rate is at or below the LRL (e.g., hysteresis), the maximum AV Delay is used. If the atrial rate is at or above the higher of the MTR, MSR, or MPR, the programmed minimum AV Delay is used.

When the atrial rate is between the LRL and the higher of the MTR, MSR, and MPR, the pulse generator calculates the linear relationship to determine the Dynamic AV Delay.

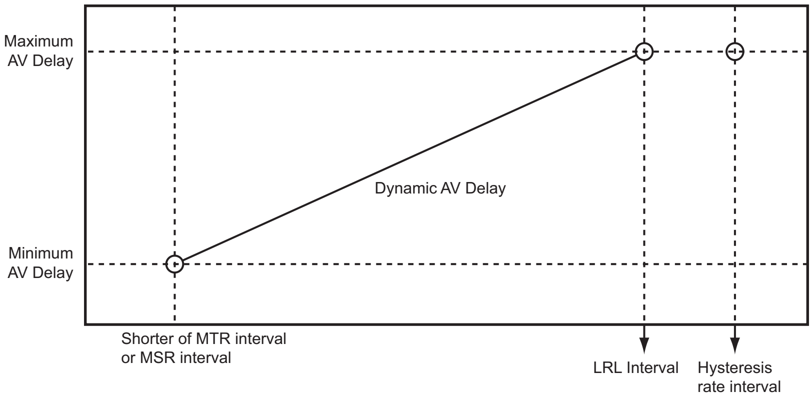


Figure 2-30. Dynamic AV Delay

The AV delay may be programmed to either a fixed or dynamic value as follows:

- Fixed AV Delay—occurs when Paced AV Delay minimum and maximum values are equal
- Dynamic AV Delay—occurs when Paced AV Delay minimum and maximum values are not equal

Sensed AV Delay

Sensed AV Delay corresponds to the AV Delay after a sensed atrial event.

Sensed AV Delay may be programmed to a value shorter than or equal to the Paced AV Delay. A shorter value is intended to compensate for the difference in timing between paced atrial events and sensed atrial events (Figure 2-31 on page 2-44).

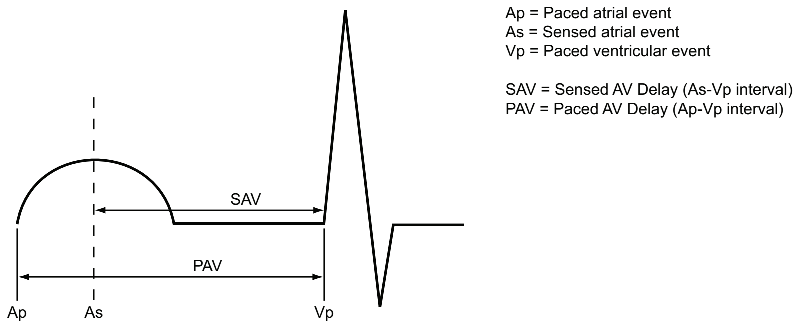


Figure 2-31. Sensed AV Delay

The hemodynamic impact of the Sensed AV Delay depends on the appropriateness of the timing between the atrial and ventricular contractions. Atrial pacing initiates atrial electrical excitation, whereas atrial sensing can only occur after the onset of spontaneous atrial excitation. The delay between initiation and sensing depends on the lead location and conduction. As a result, when Sensed AV Delay is programmed to the same value as Paced AV Delay, the hemodynamic AV interval will differ between paced and sensed atrial events.

When the device is programmed to DDD(R), it is recommended that the patient be tested to determine the optimal AV Delay during atrial sensing and atrial pacing. If the optimal AV Delays are different, this can be reflected by programming different Paced AV Delay and Sensed AV Delay parameter settings.

Using Sensed AV Delay with Paced AV Delay—Fixed

When Paced AV Delay is programmed to a fixed value, then the Sensed AV Delay will be fixed at the programmed Sensed AV Delay value.

Using Sensed AV Delay with Paced AV Delay—Dynamic

When Paced AV Delay is programmed as dynamic, then the Sensed AV Delay will also be dynamic.

Dynamic Sensed AV Delay and Paced AV Delay are based on the atrial rate. To reflect the shortening of the PR interval during periods of increased metabolic demand, the AV Delay shortens linearly from the programmed (maximum) value at the LRL (or hysteresis rate) to a value determined by the ratio of minimum and maximum AV Delay at the higher of the MTR, MSR, or MPR(Figure 2-32 on page 2-45). When Dynamic AV Delay is used, if the maximum Sensed AV Delay value is programmed as shorter than the maximum Paced AV Delay value, then the minimum Sensed AV Delay value will also be shorter than the minimum Paced AV Delay value.

NOTE: *The minimum Sensed AV Delay value is programmable only in VDD(R) mode.*

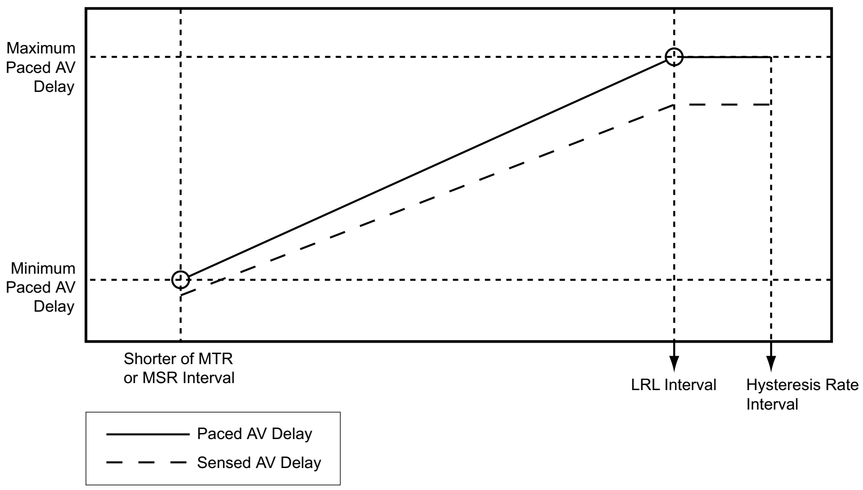


Figure 2-32. Dynamic and Sensed AV Delay function

AV Search+

AV Search+ is designed to promote intrinsic A–V conduction if present by allowing AV conduction to occur beyond the programmed AV Delay. In patients with exercise-dependent, first degree or second degree AV nodal block, this intrinsic AV conduction can improve hemodynamic performance and increase device longevity by reducing the amount of ventricular pacing pulses.

When AV Search+ is enabled, the AV Delay is lengthened periodically (Search Interval) for up to 8 consecutive paced or sensed cardiac cycles. The AV Search+ AV delay remains active as long as the intrinsic PR intervals are shorter than the programmed Search AV Delay value.

The pulse generator reverts to the programmed AV Delay at the following points:

- When the 8-cycle search expires without sensing intrinsic ventricular activity
- When two ventricular paced events occur within a 10-cycle moving window

Search AV Delay

The Search AV Delay parameter determines the length of the sensed and paced AV delays during the search cycles and during the AV hysteresis period.

The PaceSafe Right Ventricular Automatic Capture feature may lengthen the programmed AV Delay in order to distinguish a fusion beat or noise from ventricular capture.

NOTE: *The Search AV Delay value must be programmed to longer than the maximum Paced AV Delay. Dynamic AV Delay and Sensed AV Delay are not applied during AV Search+.*

The PRM does not consider the AV Delay associated with AV Search+ when calculating the TARP interval. This is so that longer AV Delays, without interactions, can be programmed for patients with intact AV conduction. Note that if AV Search+ is utilized in this manner, Wenckebach-like behavior may occur at rates lower than the MTR if conduction is lost.

NOTE: *Long fixed AV intervals may be selected to avoid unnecessary RV pacing. However, programming long fixed AV intervals, in some cases, may be associated with PMT, diastolic mitral insufficiency or pacemaker syndrome. As an alternative to programming long fixed AV intervals, consider AV Search+ to avoid unnecessary RV pacing.*

Search Interval

The Search Interval controls the frequency at which AV Search+ will attempt a search.

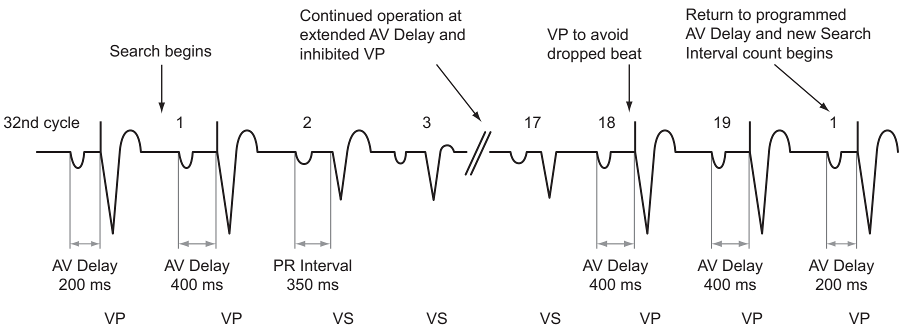


Figure 2-33. AV Search +

REFRACTORY

Refractory periods are the intervals following paced or sensed events during which the pulse generator is not inhibited or triggered by detected electrical activity. They suppress (or prevent) oversensing of pulse generator artifacts and evoked responses following a pacing pulse. They also promote appropriate sensing of a single, wide, intrinsic complex and prevent the sensing of other intrinsic signal artifacts (e.g., a T-wave or far-field R-wave).

NOTE: *Rate adaptive pacing is not inhibited during refractory periods.*

NOTE: *Single-chamber devices programmed to VVI(R) will automatically load ventricular-specific refractory periods, and single-chamber devices programmed to AAI(R) will automatically load atrial-specific refractory periods. As discussed below, the atrial refractory periods used in a single-chamber device are different from those used in a dual-chamber device.*

A-Refractory - PVARP

PVARP is defined according to the pacing mode:

- Dual-chamber device programmed AAI(R)—the time period after a sensed or paced atrial event when an atrial sense event does not inhibit an atrial pace.

- Dual-chamber modes: DDD(R), DDI(R), VDD(R)—the time period after a sensed or paced RV event when an atrial event does not inhibit an atrial pace or trigger a ventricular pace. The atrial refractory period prevents the tracking of retrograde atrial activity initiated in the ventricle.

In DDD(R) and VDD(R) pacing modes, the pulse generator may detect retrograde conduction in the atrium, causing triggered ventricular pacing rates as high as the MTR (i.e., PMT). Retrograde conduction times may vary over a patient's lifetime as a function of changing autonomic tone. If testing does not reveal retrograde conduction at implantation, it may still occur at a later time. This problem can usually be avoided by increasing the atrial refractory period to a value that exceeds the retrograde conduction time.

In controlling the pulse generator's response to retrograde conduction, it may also be useful to program the following:

- PVARP after PVC
- PMT Termination
- Rate Smoothing

PVARP after PVC

PVARP after PVC is designed to help prevent PMT due to retrograde conduction, which can occur due to a PVC.

When the pulse generator detects a sensed RV event without detecting a preceding atrial sensed event (refractory or non-refractory) or delivering an atrial pace, the atrial refractory period automatically extends to the programmed PVARP after PVC value for one cardiac cycle. After a PVC is detected, the timing cycles reset automatically. PVARP extends no more frequently than every other cardiac cycle.

The pulse generator automatically extends the PVARP to the PVARP after PVC value for one cardiac cycle in these additional situations:

- After a ventricular escape pace that is not preceded by an atrial sense in VDD(R) mode

- When the device transitions from a non-atrial tracking mode to an atrial tracking mode (e.g., exits ATR Fallback, transitions from temporary non-atrial tracking mode to permanent atrial tracking mode)

- When the device returns from magnet operation to an atrial tracking mode

- When the device returns from Electrocautery Protection to an atrial tracking mode

A Refractory - same chamber

Dual-chamber Modes

Atrial refractory provides an interval following an atrial paced or sensed event when additional atrial sensed events do not impact the timing of pacing delivery.

The following are nonprogrammable intervals for dual-chamber modes:

- 85 ms atrial refractory following an atrial sensed event
- 150 ms atrial refractory following an atrial pace in DDD(R) and DDI(R) modes

Single-chamber Device

In a single-chamber device programmed to AAI(R), there is a programmable refractory period following atrial events. This is applied to both atrial pace and atrial sense events to ensure there is a long enough refractory period to prevent oversensing of a far-field ventricular event. Any sensed event which falls into refractory is not detected or marked, and does not impact timing cycles, unless it occurs within the noise window.

NOTE: *If prolonged intrinsic conduction is present, a longer refractory may be needed to avoid oversensing a far-field R-wave.*

RV-Refractory (RVRP)

The programmable RVRP provides an interval following an RV pace event during which RV sensed events do not impact the timing of pacing delivery.

Additionally, a 135 ms nonprogrammable refractory period provides an interval following an RV sensed event during which further RV sensed events do not impact the timing of pacing delivery.

The programming and function of the ventricular refractory period in VVI(R) mode is the same in dual- and single-chamber devices. Any event which falls into VRP is not detected or marked (unless it occurs within the noise window), and does not impact timing cycles.

RVRP is available in any mode where ventricular sensing is enabled, and RVRP can be programmed to a fixed or dynamic interval (Figure 2-34 on page 2-48):

- Fixed—RVRP remains at the programmed, fixed RVRP value between the LRL and the applicable upper rate limit (MPR, MTR or MSR).
- Dynamic—RVRP shortens as ventricular pacing increases from the LRL to the applicable upper rate limit, allowing adequate time for RV sensing.
  – Maximum—if the pacing rate is less than or equal to the LRL (i.e., hysteresis), the programmed Maximum VRP is used as the RVRP.
  – Minimum—if the pacing rate is equal to the applicable upper rate limit, the programmed Minimum VRP is used as the RVRP.

NOTE: *Dynamic Refractory is not available in single-chamber devices programmed to VVI if there is no Max Pacing Rate to apply the minimum value, or any time in single-chamber devices programmed to AAI(R).*

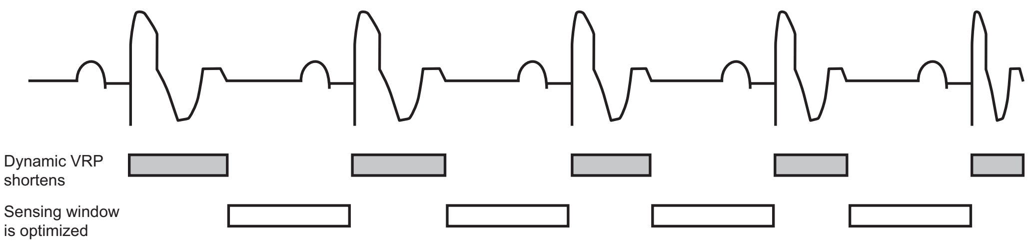


Figure 2-34. Relationship between ventricular rate and refractory interval

To provide an adequate sensing window, the following refractory value (fixed or dynamic) programming is recommended:

- Single-chamber modes—less than or equal to one-half the LRL in ms
- Dual-chamber modes—less than or equal to one-half the applicable upper rate limit in ms

The use of a long RVRP shortens the ventricular sensing window.

Programming the Ventricular Refractory period to a value greater than PVARP can lead to competitive pacing. For example, if the Ventricular Refractory is longer than PVARP, an atrial event can be appropriately sensed following PVARP and intrinsic conduction to the ventricle falls into the Ventricular Refractory period. In this case, the device will not sense the ventricular depolarization and will pace at the end of the AV Delay, resulting in competitive pacing.

Cross-Chamber Blanking

Cross-chamber blanking periods are designed to promote appropriate sensing of in-chamber events and prevent oversensing of activity in another chamber (e.g., cross-talk, far-field sensing).

Cross-chamber blanking periods are initiated by paced and/or sensed events in an adjacent chamber. For example, a blanking period is initiated in the right ventricle each time a pacing pulse is delivered to the right atrium; this prevents the device from detecting the atrial paced event in the right ventricle.

Cross-chamber blanking can be programmed to Smart (when available) or a fixed value. Smart Blanking is designed to promote appropriate sensing of in-chamber events by shortening the cross-chamber blanking period (37.5 ms following paced events and 15 ms following sensed events) and prevent oversensing of cross-chamber events by automatically raising the AGC threshold for sensing at the expiration of the Smart Blanking period.

Smart Blanking does not change the programmed AGC or Fixed sensitivity settings.

NOTE: *Smart Blanking periods will be lengthened to 85 ms if a same-chamber blanking period or a retriggerable noise window is active when the Smart Blanking period begins. For example, if an RV sense occurs within the atrial refractory period, the A blank after RV sense cross chamber blank will be 85 ms.*

NOTE: *Sensitivity adjustments associated with Smart Blanking may not be sufficient to inhibit detection of cross-chamber artifacts if the cross-chamber artifacts are too large. Consider other factors that impact the size/amplitude of cross-chamber artifacts including lead-placement, pacing output, and programmed sensitivity settings.*

Blanking period nominals and programmable options will automatically change in certain situations in order to ensure that cross-chamber artifacts are not detected:

- If the AGC Sensing method is selected, Smart Blanking is the nominal setting (except for V-blank after A-pace) and Fixed Blanking is also available.

  NOTE: *If AGC is used with a Unipolar Atrial Sense Lead Configuration, Fixed atrial blanking is the nominal setting but Smart Blanking is available.*

- If the Fixed Sensing method is selected, Fixed Blanking is the nominal setting and Smart Blanking is not available for any chamber.

- When a change to the Sensing method occurs, blanking periods will automatically revert to the nominal value associated with that Sensing method unless the blanking period was previously reprogrammed. If the blanking period was previously reprogrammed for a Sensing method, the period will revert to the last programmed value.

RV-Blank after A-Pace

RV-Blank after A-Pace is a cross-chamber blanking period designed to promote the appropriate sensing of RV events and prevent oversensing of cross-chamber events following an atrial pace.

The pulse generator will not respond to RV events for the duration selected following an atrial pace.

NOTE: *Smart Blanking is not available for the V-Blank after A-Pace parameter.*

When adjusting blanking, consider the following:

- To promote continuous pacing for pacemaker-dependent patients, it may be preferable to lessen the potential for ventricular oversensing of atrial paced artifacts by programming a longer blanking period. However, programming a longer blanking period may increase the likelihood of undersensing R-waves (e.g., PVCs, should they occur within the RV-Blank after A-Pace cross-chamber blanking period).

- For patients with a high percentage of atrial pacing and frequent PVCs who are not pacemaker-dependent, it may be preferable to shorten the blanking period to lessen the potential for undersensing a PVC (should it occur in the cross-chamber blanking period following an atrial paced event). However, a shorter blanking period may increase the likelihood for ventricular oversensing of an atrial paced event.

Certain programmed combinations of dual-chamber pacing parameters may interfere with ventricular tachy detection. For example, when dual-chamber pacing occurs, RV undersensing due to the refractory period caused by an atrial pace (V-Blank after A-Pace) could occur. In certain usage scenarios, if a pattern of atrial pacing and VT beats is detected, the AV Delay is automatically shortened to facilitate confirmation of a suspected VT. If no VT is present, the AV Delay is returned to the programmed value. For programming scenarios where the automatic AV Delay adjustment may occur, a specific Parameter Interaction Attention will not be displayed. For discussion of details, please contact Boston Scientific using the information on the back cover.

A-Blank after V-Pace

A-Blank after V-Pace is a cross-chamber blanking period designed to promote the appropriate sensing of P-waves and prevent oversensing of cross-chamber events following a ventricular pace.

A-Blank after V-Pace may be programmed to a Fixed or Smart (available with the AGC Sensing method) value.

If the value is programmed to Smart, the pulse generator automatically raises the AGC threshold for sensing at the expiration of the Smart Blanking period in order to aid rejection of cross-chamber ventricular events. This promotes sensing of P-waves that may have otherwise fallen in the cross-chamber blanking period. Smart Blanking does not change the programmed sensitivity settings.

A-Blank after RV-Sense

A-Blank after RV-Sense is a cross-chamber blanking period designed to promote appropriate sensing of P-waves and prevent oversensing of cross-chamber events following an RV-sensed event.

A-Blank after RV-Sense may be programmed to a Fixed or Smart (available with the AGC Sensing method) value.

If the value is programmed to Smart, the pulse generator automatically raises the AGC threshold for sensing at the expiration of the Smart Blanking period in order to aid rejection of cross-chamber RV events. This promotes sensing of P-waves that may have otherwise fallen in the cross-chamber blanking period. Smart Blanking does not change the programmed sensitivity settings.

Refer to the following illustrations:

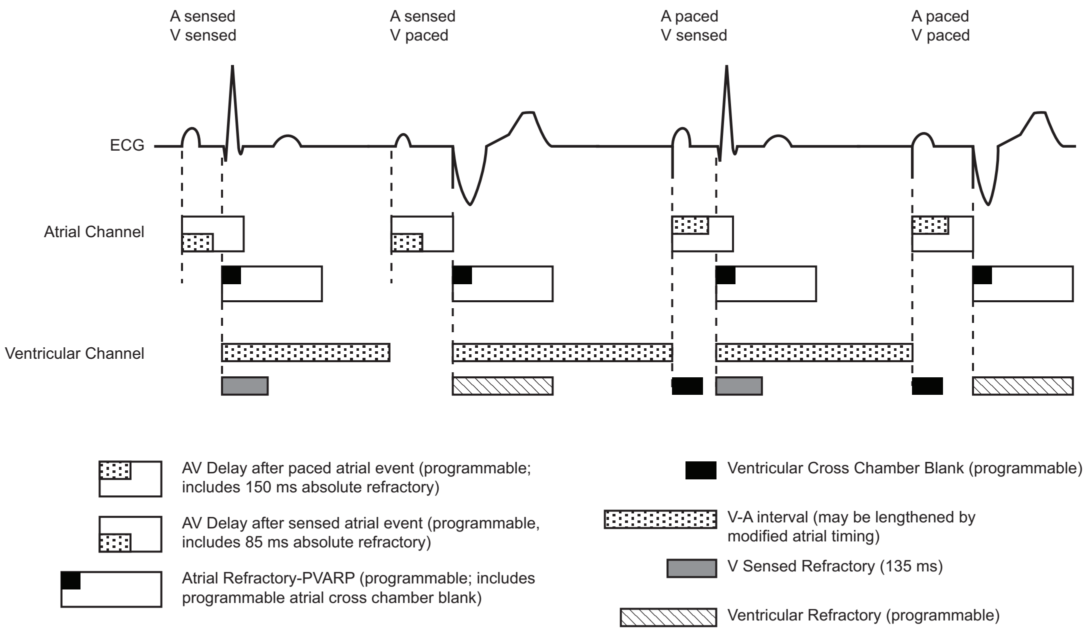


Figure 2-35. Refractory periods, dual-chamber pacing modes

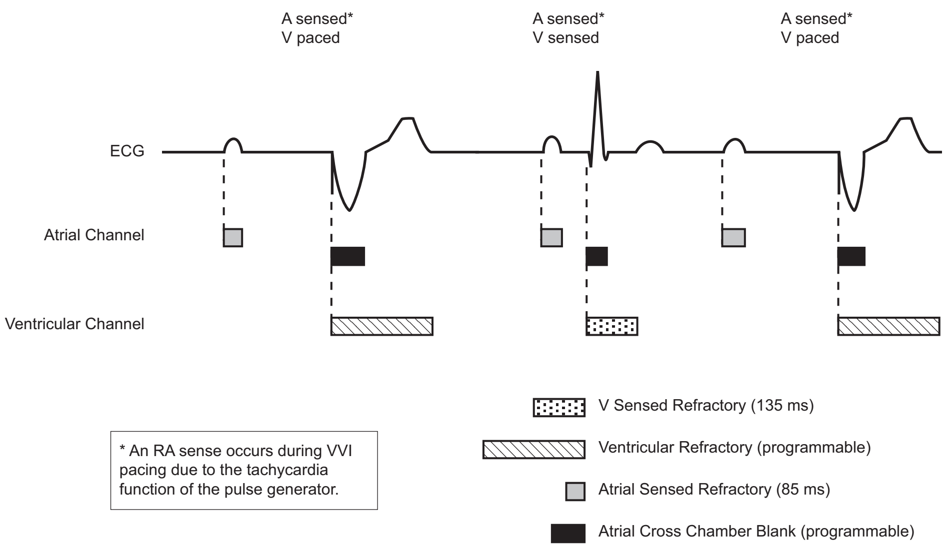


Figure 2-36. Refractory periods, VVI pacing mode

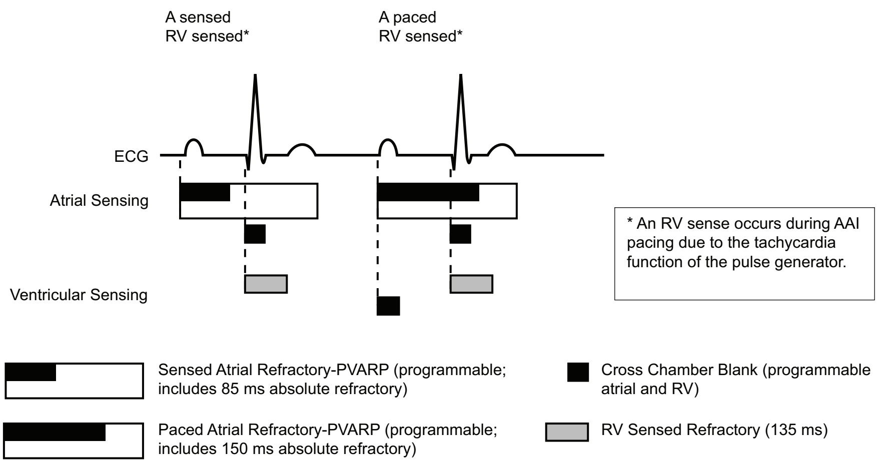


Figure 2-37. Refractory periods, AAI pacing mode; DR

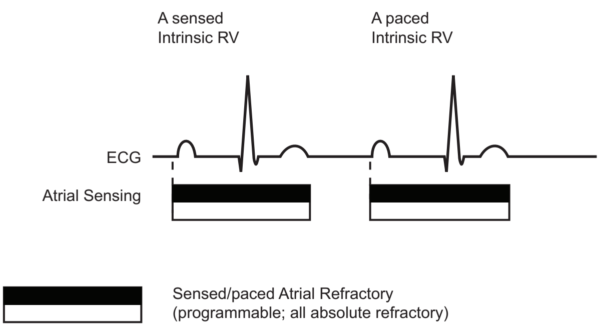


Figure 2-38. Refractory periods, AAI pacing mode; SR

NOISE RESPONSE

Noise windows and blanking periods are designed to prevent pacing inhibition due to cross-chamber oversensing.

Noise Response allows the clinician to choose whether to pace or inhibit pacing in the presence of noise.

A retriggerable, 40-ms noise window exists within each refractory and fixed (non-smart) cross-chamber blanking period. The window is initiated by either a sensed or paced event. Both the noise window and the refractory period must be completed for each cardiac cycle in one chamber before the next event restarts the timing in the same chamber. Recurrent noise activity may cause the noise window to restart, extending the noise window and possibly the effective refractory period or blanking period.

The Noise Response parameter can be programmed to Inhibit Pacing or an asynchronous mode. The available asynchronous mode will automatically correspond to the permanent Brady Mode (i.e., VVI permanent mode will have VOO noise response). If Noise Response is programmed to an asynchronous mode and the noise persists so that the noise window is extended longer than the programmed pacing interval, the pulse generator paces asynchronously at the programmed pacing rate until the noise ceases. If Noise Response is programmed to Inhibit Pacing and persistent noise occurs, the pulse generator will not pace in the noisy chamber until after the noise ceases. The Inhibit mode is intended for patients whose arrhythmias may be triggered by asynchronous pacing.

Refer to the following illustrations.

RA refractory periods may be programmable or nonprogrammable depending on the mode (single- vs dual-chamber). Refer to Figure 2-40 on page 2-53.

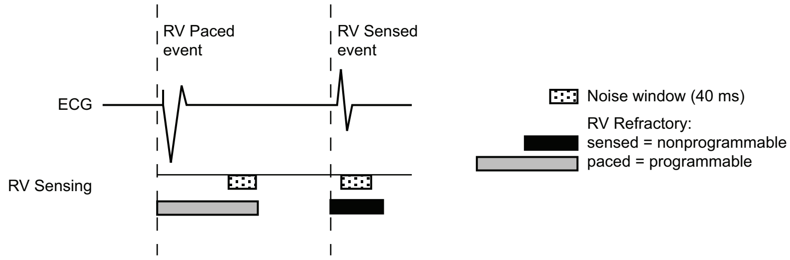


Figure 2-39. Refractory periods and noise windows, RV

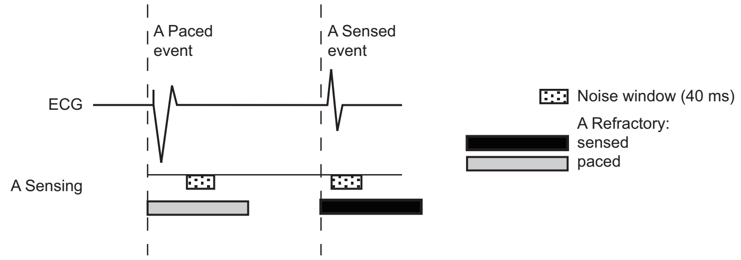


Figure 2-40. Refractory periods and noise windows, RA

In addition, a nonprogrammable Dynamic Noise Algorithm is active in rate channels where AGC Sensing is used.

The Dynamic Noise Algorithm uses a separate noise channel to continuously measure the baseline signal and adjust the sensing floor to avoid noise detection. This algorithm is intended to help prevent oversensing of myopotential signals and the problems associated with oversensing.

The following noise event markers are generated:

Single-Chamber

Depending on which mode is selected:

- The marker [AS] or [VS] occurs when the noise window is initially triggered following an A pace or a V pace, respectively
- If retriggered for 340 ms, the marker AN or VN occurs
- With continuous retriggers, the marker AN or VN occurs frequently
- If asynchronous pacing occurs due to continuous noise, the marker AP-Ns or VP-Ns will occur

Dual-Chamber

- Depending on the chamber where noise is occurring, the marker [AS] or [VS] occurs when the noise window is initially triggered following a pace
- If retriggered for 340 ms, the marker AN or VN occurs
- With continuous retriggers, the marker AN or VN occurs frequently
- If asynchronous pacing occurs due to continuous noise, the markers AP-Ns, VP-Ns will occur

NOTE: *In pacer-dependent patients, use care when considering setting Noise Response to Inhibit as pacing will not occur in the presence of noise.*

Noise Response example

Cross-chamber sensing that occurs early in the AV Delay may be detected by the RV sense amplifiers during the fixed blanking period, but is not responded to except to extend the noise rejection interval. The 40 ms noise rejection interval continues to retrigger until the noise is no longer detected, up to the length of the AV Delay. If noise continues throughout the duration of the AV Delay, the device will deliver a pacing pulse when the AV Delay timer expires, preventing ventricular inhibition due to noise. If a ventricular pacing spike is delivered under conditions of continuous noise, a VP-Ns marker notation appears on the intracardiac electrogram (Figure 2-41 on page 2-54).

If noise ceases prior to the expiration of the AV Delay, the device can detect an intrinsic beat that occurs at any time beyond the 40 ms retriggerable noise interval and initiate a new cardiac cycle.

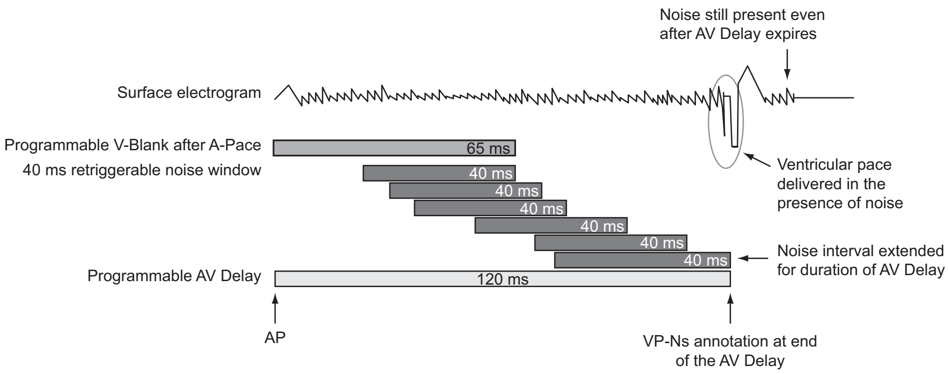


Figure 2-41. Noise Response (fixed blanking)

SYSTEM DIAGNOSTICS

CHAPTER 3

This chapter contains the following topics:

SUMMARY DIALOG

Upon interrogation, a Summary dialog is displayed. It includes Leads and Battery status indications, approximate time to explant, and an Events notification for any episodes since the last reset. In addition, a magnet notification will appear if the pulse generator detects the presence of a magnet.

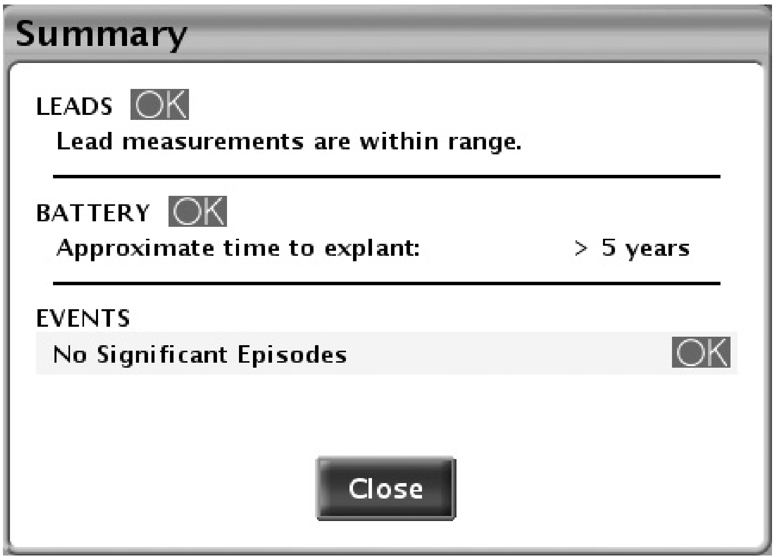


Figure 3-1. Summary dialog

Potential status symbols include OK, Attention, or Warning ("Use of Color" on page 1-6). Potential messages are described in the following sections:

- Leads—"Leads Status" on page 3-6
- Battery—"Battery Status" on page 3-2
- Events—"Therapy History" on page 4-2

Once the Close button is selected, the Warning or Attention symbols for Leads and Battery will not appear on subsequent interrogations until additional events triggering an alert condition occur. Events will continue to appear until any history counter Reset button is selected.

BATTERY STATUS

The pulse generator automatically monitors battery capacity and performance. Battery status information is provided via several screens:

- Summary dialog—displays a basic status message about remaining battery capacity ("Summary Dialog" on page 3-2).
- Summary tab (on the Main Screen)—displays the same basic status message as the Summary dialog, along with the battery status gauge ("Main Screen" on page 1-2).
- Battery Status Summary screen (accessed from the Summary tab)—displays additional battery status information about remaining battery capacity and current magnet rate ("Battery Status Summary Screen" on page 3-3).

- Battery Detail screen (accessed from the Battery Status Summary screen)—provides detailed information about battery use, capacity, and performance ("Battery Detail Summary Screen" on page 3-5).

Battery Status Summary Screen

The Battery Status Summary screen provides the following key information about battery capacity and performance.

Time Remaining

This section of the screen displays the following items:

- Battery status gauge—displays a visual indication of the battery capacity status.

  NOTE: *Battery status can be assessed using a manually applied external magnet stronger than 70 gauss. The pacing rate activated by magnet application provides an indication of battery status on the Battery Status Summary screen. For details, refer to "Magnet Rate" below.*

- Approximate time to explant—displays the estimate of calendar time remaining until the pulse generator reaches the Explant status.

  This estimate is calculated using battery capacity consumed, charge remaining, and power consumption at current programmed settings.

  When insufficient usage history is available, Approximate time to explant may change between interrogation sessions. This fluctuation is normal, and occurs as the pulse generator collects new data and can calculate a more stable prediction. Approximate time to explant will be more stable after several weeks of usage. Causes of fluctuation may include the following:

  – If certain brady features that affect pacing output are reprogrammed, the Approximate time to explant will be forecasted based on the expected changes in power consumption from the reprogrammed features. The next time the pulse generator is interrogated, the PRM will resume displaying Approximate time to explant based on recent usage history. As new data is collected, Approximate time to explant will likely stabilize near the initial forecast.

  – For several days post-implant, the PRM will display a static Approximate time to explant based on model-dependent data. Once enough usage data has been collected, device-specific predictions will be calculated and displayed.

Magnet Rate

When the Magnet Response is programmed to Pace Async, magnet application converts the pulse generator Brady Mode to an asynchronous mode with a fixed pacing rate and magnet AV Delay of 100 ms.

The asynchronous pacing rate will reflect the current battery status and is displayed on the Battery Status Summary screen:

More than One Year Remaining	100 min^{-1}
One Year or Less Remaining	90 min^{-1}
Explant	85 min^{-1}

Additional information about Pace Async and the Magnet Feature is available ("Magnet Feature" on page 4-11).

Battery Detail icon

When selected, this icon displays the Battery Detail Summary screen ("Battery Detail Summary Screen" on page 3-5).

Battery Status Indicators

The following battery status indicators appear in the battery status gauge. The indicated Approximate time to explant is calculated based on the pulse generator's current programmed parameters.

One Year Remaining—approximately one year of full pulse generator function remains (Approximate time to explant is one year).

Explant—The battery is nearing depletion, and pulse generator replacement must be scheduled. Once Explant status is reached, there is sufficient battery capacity to pace 100% under existing conditions for three months. When Explant status is reached, 1.5 hours of ZIP telemetry remain. Consider using wanded telemetry.

Battery Capacity Depleted—pulse generator functionality is limited, and therapies can no longer be guaranteed. This status is reached three months after Explant status is reached. The patient should be scheduled for immediate device replacement. Upon interrogation, the Limited Device Functionality screen is displayed (all other screens are disabled). This screen provides battery status information and access to remaining device functionality. ZIP telemetry is no longer available.

When the device reaches Battery Capacity Depleted status, functionality is limited to the following:

- Brady Mode will be changed as described below:

Brady Mode prior to Battery Capacity Depleted Indicator	Brady Mode after Battery Capacity Depleted Indicator
DDD(R), DDI(R), VDD(R), VVI(R)	VVI
AAI(R)	AAI
Off	Off
DOO, VOO	VOO
AOO	AOO

- Brady Mode can be programmed to Off; no other parameters are programmable
- Wanded telemetry only (RF telemetry is disabled)
- An LRL of 50 min^{-1}

At Battery Capacity Depleted status, the following features are disabled:

- Daily measurement trends
- Brady enhancements (e.g., rate response, rate smoothing)
- PaceSafe Automatic Capture (the output is fixed at 2X the last measurement but not more than 5 V or less than 3.5 V)
- Lead Safety Switch (the lead configuration remains at its pre-explant value)
- Episode storage
- Diagnostic and EP tests

- Real-time EGMs
- MV sensor and Accelerometer

If the device reaches a point where insufficient battery capacity is available for continued operation, the device will revert to Storage Mode. In Storage Mode, no functionality is available.

NOTE: *The device uses the programmed parameters and recent usage history to predict Approximate time to explant. Greater than normal battery usage may result in the subsequent day's Approximate time to explant to appear less than expected.*

Battery Detail Summary Screen

The Battery Detail summary screen provides the following information about pulse generator battery status (Figure 3-2 on page 3-5):

- Charge Remaining (measured in ampere-hours)—the amount of charge remaining based on the pulse generator's programmed parameters until the battery is depleted.

- Power Consumption (measured in microwatts)—the average daily power being used by the pulse generator, based on currently programmed parameters. Power consumption is included in the calculations that determine Approximate time to explant and the needle position on the battery status gauge.

- Power Consumption Percentage—compares the power consumption at the pulse generator's currently programmed parameters with the power consumption of the standard parameters used to quote device longevity.

If any of the following parameters (which affect pacing output) are changed, the Power Consumption and Power Consumption Percentage values are adjusted accordingly:

- Amplitude
- Pulse Width
- Brady Mode
- LRL
- MSR
- PaceSafe

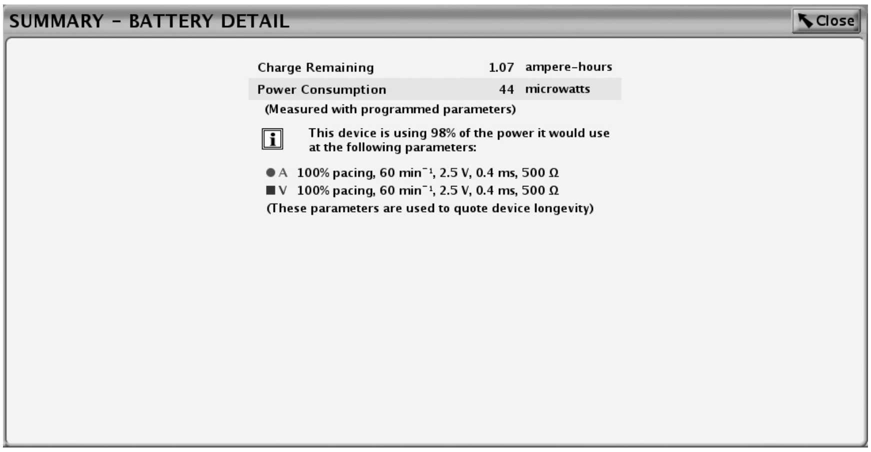


Figure 3-2. Battery Detail summary screen

LEADS STATUS

Daily Measurements

The device performs the following measurements every 21 hours and reports them daily:

- Daily intrinsic amplitude measurement: the device will automatically attempt to measure the intrinsic P- and R- wave amplitudes for each cardiac chamber in which the daily intrinsic amplitude measurement is enabled regardless of the pacing mode. This measurement will not affect normal pacing. The device will monitor up to 255 cardiac cycles to find a sensed signal to obtain a successful measurement.
- Daily lead impedance measurement:
  - Pace lead(s)—the device will automatically attempt to measure the pace lead impedance for each chamber in which the daily pace impedance test is enabled, regardless of the pacing mode. To conduct the lead impedance test the device utilizes a sub-pacing threshold signal that will not interfere with normal pacing or sensing.
- PaceSafe daily threshold measurements—when PaceSafe is programmed to Auto or Daily Trend, the device will automatically attempt to measure the pacing threshold in the chamber for which PaceSafe is programmed. To conduct the test, the device adjusts the necessary parameters to facilitate the test.

Basic lead status information is displayed on the Summary screen. Detailed data are displayed in a graphical format on the Leads Status summary screen, which can be accessed by selecting the leads icon on the Summary screen (Figure 3-3 on page 3-7).

Possible leads status messages are as follows (Table 3-1 on page 3-6):

- Lead measurements are within range.
- Check Lead (message will specify which lead)—indicates daily lead measurement(s) are out of range. To determine which measurement is out of range, evaluate the corresponding lead's daily measurement results.

NOTE: *Out-of-range lead impedance measurements may cause the lead configuration to change to Unipolar ("Lead Safety Switch" on page 2-42).*

NOTE: *A detailed description of PaceSafe–specific messages including notification of lead test failures and lead alerts is available ("PaceSafe" on page 2-11)*

Table 3-1. Lead measurement reporting

Lead Measurement	Reported Values	Out-of-Range Limits
A Pace Impedance (Ω)	200 to 2000	Low: ≤ 200 High: ≥ 2000
RV Pace Impedance (Ω)	200 to 2000	Low: ≤ 200 High: ≥ 2000
P-Wave Amplitude (mV)	0.1 to 25.0	Low: 0.5 High: none
R-Wave (RV) Amplitude (mV)	0.1 to 25.0	Low: 3.0 High: none

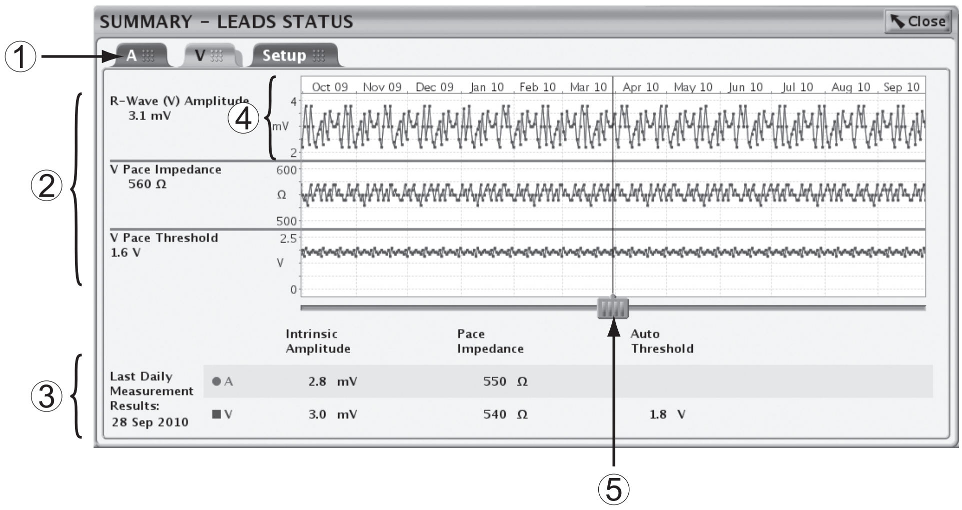
NOTE: *For single-chamber devices, the Amplitude and Impedance values reported and out of range limits applied correspond to the selected lead position and mode.*

The Leads Status summary screen provides daily measurement details for applicable leads (Figure 3-3 on page 3-7):

- The graph shows daily measurements from the past 52 weeks.
- Use the tabs across the top of the screen to view data for each lead. Select the Setup tab to enable or disable specific daily lead measurements.

  NOTE: *Disabling daily lead impedance measurements in a given chamber also disables the Lead Safety Switch feature in that chamber.*

- Each data point represents the daily measurement for a given day. To view specific results for a day, move the horizontal slider over the corresponding data point or gap.
- An out-of-range measurement will either plot a point at the corresponding maximum or minimum value or leave a gap (depending on how far out of range).
- A gap may also be generated if the device is unable to obtain a valid measure for that day.
- The most recent daily measurements are displayed at the bottom of the screen.



[1] Use tabs to select the appropriate lead [2] Results for the selected day [3] Results for most recent day [4] Y-axis adjusts based on measured results [5] Use horizontal slider to view data for a specific day

Figure 3-3. Leads Status summary screen

If the device is unable to obtain one or more daily measurements at the scheduled time, up to three re-attempts will be performed at one-hour intervals. Re-attempts do not change the timing of daily measurements. The next day's measurement will be scheduled 21 hours from the initial attempt.

If a valid measure is not recorded after the initial attempt plus three re-attempts, or is not recorded at the end of a 24-hour time block, the measurement will be reported as Invalid Data or No Data Collected (N/R).

Because eight measurements are recorded in seven days, one day will contain two measurements. For Amplitude and Impedance, if one measurement is valid and one invalid, the invalid measurement will be reported. If both measurements are valid, the second value will be reported. For Threshold, if one measurement is valid and one invalid, the valid measurement will be reported. If both measurements are valid, the highest value will be reported.

If the Summary screen indicates that a lead should be checked and the Intrinsic Amplitude and Impedance graphs do not show any out-of-range values or gaps, the test that resulted in the out-of-range value occurred within the current 24 hours and has not yet been saved with the daily measurements.

Table 3-2. Intrinsic Amplitude: Daily Measurement Conditions, Programmer Display, and Graphical Representation

Condition	Programmer Display	Graphical Representation
Electrode configuration is programmed to Off/None	No Data Collected	Gap
All events during the test period are paced	Paced	Gap
Noise detected during the test period	Noise	Gap
Sensed events defined as a PVC	PVC	Gap
Sensed events defined as a PAC	PAC	Gap
Out-of-range amplitude measurements	> 0.1 – < 0.5 mV (RA lead) > 0.1 – < 3.0 mV (ventricular lead)	Plotted point with attention icon
	= 0.1 mV	Plotted point at corresponding minimum with attention icon
	< 0.1 mV	Gap
	> 25 mV	Gap[a]

a. When the value measured is > 25 mV, an attention symbol is displayed on the graph even though no alert is generated on the summary screens.

Table 3-3. Lead Impedance: Daily Measurement Conditions, Programmer Display, and Graphical Representation

Condition	Programmer Display	Graphical Representation
Electrode configuration is programmed Off/None	Invalid Data	Gap
Noise detected during the test period	Noise	Gap
Out-of-range impedance measurements[a] (pace leads)	> 2000 Ω < 200 Ω	Plotted point at corresponding minimum or maximum OR gap[b]

a. If the measured value corresponds exactly to one of the out-of-range boundary values (200 or 2000 Ω), the numerical value is displayed and no attention icon is generated on the graphical representation screen. The summary screens do generate alerts for these values.
b. Selecting these points or gaps will not display the numerical value, but will indicate that the value is above the upper range limit or below the lower range limit, as appropriate.

Table 3-4. PaceSafe Automatic Threshold: Daily Measurement Conditions, Programmer Display, and Graphical Representation

Condition	Programmer Display	Graphical Representation
Feature is not enabled	No Data Collected	Gap
Test failures or out of range measurements	Various	Gap

NOTE: *See a detailed list of failure codes for PaceSafe Threshold tests ("PaceSafe" on page 2-11).*

Under the following conditions, Intrinsic Amplitude and Lead Impedance measurements will not be attempted. The programmer display will indicate No Data Collected or Invalid Data, and there will be a gap in the graphical representation:

- Telemetry is active
- Device battery capacity is depleted
- Pulse generator is in Electrocautery Protection Mode

See a detailed description of conditions under which PaceSafe measurements will not be attempted ("PaceSafe" on page 2-11).

LEAD TESTS

The following lead tests are available (Figure 3-4 on page 3-9):

- Pace Impedance
- Intrinsic Amplitude
- Pace Threshold

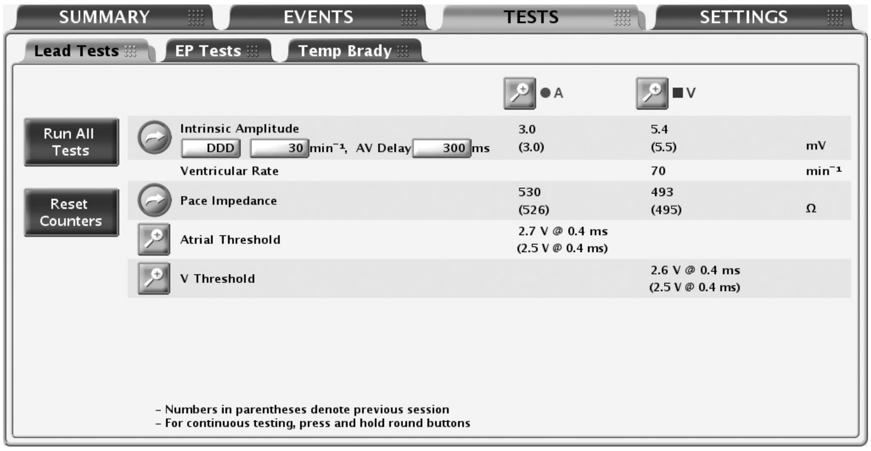


Figure 3-4. Lead Tests screen

Lead tests can be accessed by using the following steps:

1. From the main screen, select the Tests tab.

2. From the Tests screen, select the Lead Tests tab.

All lead tests may be performed following two different processes:

- Via the Lead Tests screen—allows you to perform the same lead tests across all chambers
- By selecting the desired chamber button—allows you to perform all tests on the same lead

Intrinsic Amplitude Test

The intrinsic amplitude test measures the intrinsic P- and R-wave amplitudes for the respective chambers.

An intrinsic amplitude test can be performed from the Lead Tests screen by completing the following steps:

1. You may change the following preselected values as necessary to elicit intrinsic activity in the chamber(s) being tested:
   - Programmed Normal Brady Mode
   - LRL at 30 min^{-1}
   - AV Delay at 300 ms

2. Select the Intrinsic Amplitude button. During the test, a window will display the test's progress. Selecting and holding the Intrinsic Amplitude Button will cause measurements to be repeated for up to 10 seconds or until the button is released. When the window closes,

the same test can be performed again by selecting the Intrinsic Amplitude button. To cancel the test, select the Cancel button or press the DIVERT THERAPY key on the PRM.

3. When the test is complete, the intrinsic amplitude measurement will be displayed as the current measurement (not in parentheses). If the test is repeated during the same session, the current measurement will be updated with the new result. Note that the previous session measurement (displayed in parentheses) is from the most recent past session during which this test was performed.

NOTE: *The test results from the last measurement are stored in pulse generator memory, retrieved during the initial interrogation, and displayed on the Lead Tests screen. The measurements are also provided on the Quick Notes report.*

Lead Impedance Test

A lead impedance test can be performed and used as a relative measure of lead integrity over time.

If the lead integrity is in question, standard lead troubleshooting tests should be used to assess the lead system integrity.

Troubleshooting tests include, but are not limited to, the following:

- Electrogram analysis
- X-ray or fluoroscopic image review
- EGM review with pocket manipulation and/or isometrics
- Invasive visual inspection

A test result of NOISE is reported if a valid measurement could not be obtained (likely due to EMI).

Pace lead impedance tests can be performed from the Lead Tests screen by completing the following steps:

1. Select the desired lead impedance test button. Selecting and holding a button will cause measurements to be repeated for up to 10 seconds or until the button is released.

2. During the test, a window will display the test progress. When the window closes, the same test can be performed by once again selecting the desired lead impedance test button. To cancel the test, select the Cancel button or press the DIVERT THERAPY key on the PRM.

3. When the test is complete, the impedance measurement will be displayed as the current measurement (not in parentheses). If the test is repeated during the same session, the current measurement will be updated with the new result. Note that the previous session measurement (displayed in parentheses) is from the most recent past session during which this test was performed.

4. If the test results in NOISE, consider the following mitigation options:

    - Repeat the test

    - Switch telemetry modes

    - Remove other sources of electromagnetic interference

NOTE: *The test results from the last measurement are stored in pulse generator memory, retrieved during the initial interrogation, and displayed on the Lead Tests screen. The measurements are also provided on the Quick Notes report.*

Pace Threshold Test

The Pace Threshold Test determines the minimum output needed for capture in a specific chamber.

The right ventricular pace amplitude threshold test can be performed manually or automatically. When PaceSafe is programmed to Auto, the result of the automatic amplitude test is used to adjust the PaceSafe output levels.

Ventricular and atrial pulse width threshold tests are performed manually by selecting the Pulse Width option on the Pace Threshold details screen.

Manual Pace Threshold Test

The minimum 2X voltage or 3X pulse width safety margin is recommended for each chamber based on the capture thresholds, which should provide an adequate safety margin and help preserve battery longevity. The test begins at a specified starting value and steps that value down (amplitude or pulse width) as the test progresses. The PRM beeps with each decrement. The values used during the threshold test are programmable. The parameters are only in effect during the test.

NOTE: *The starting values for Amplitude and Pulse Width values are automatically calculated. The device retrieves the stored results for the previous pace threshold measurement (for the parameter being tested) and sets the parameter at three steps above the previous threshold measurement. The LRL is preselected at 90 min^{-1}. For DDD mode, the LRL is further limited to 10 min^{-1} below the MTR.*

NOTE: *If DDD mode is chosen, selecting either the atrial or ventricular test will cause the pacing output to decrease only in the chamber selected.*

Once the test is started, the device operates with the specified brady parameters. Using the programmed number of cycles per step, the device then decrements (steps down) the selected test type parameter (Amplitude or Pulse Width) until the test is complete. Real-time electrograms and annotated event markers, which include the values being tested, continue to be available during threshold testing. The display will automatically adjust to reflect the chamber being tested.

During the threshold test, the programmer displays the test parameters in a window while the test is in progress. To pause the test or perform a manual adjustment, select the Hold button on the window. Select the + or − button to manually increase or decrease the value being tested. To continue the test, select the Continue button.

The threshold test is complete and all parameters are returned to the normal programmed values when any of the following occur:

- The test is terminated via a command from the PRM (e.g., pressing the End Test button or DIVERT THERAPY key).
- The lowest available setting for Amplitude or Pulse Width is reached and the programmed number of cycles has completed.
- Telemetry communication is interrupted.

A pace threshold test can be performed from the Lead Tests screen using the following steps:

1. Select the desired chamber to be tested.
2. Select the Pace Threshold details button.
3. Select the test type.

4. Change the following parameter values as desired to elicit pacing in the chamber(s) being tested:

   - Mode
   - LRL
   - Paced AV Delay
   - Pacing Lead Configuration
   - Amplitude
   - Pulse Width
   - Cycles per Step

   For DDD mode, the normal Brady MTR is used.

5. Watch the ECG display and stop the test by selecting the End Test button or pressing the DIVERT THERAPY key when loss of capture is observed. If the test continues until the programmed number of cycles at the lowest setting have occurred, the test is automatically terminated. The final threshold test value will be displayed (the value is one step above the value when the test was terminated).

NOTE: *The threshold test result can be edited by selecting the Edit Today's Test button on the Threshold Test screen*

6. When the test is complete, the threshold measurement will be displayed as the current measurement (not in parentheses). If the test is repeated during the same session, the current measurement will be updated with the new result. Note that the previous session measurement (displayed in parentheses) is from the most recent past session during which this test was performed.

7. To perform another test, make changes to the test parameter values if desired, then begin again. Results of the new test will be displayed.

NOTE: *The test results from the most recent measurement are stored in pulse generator memory, retrieved during initial interrogation, and displayed on the Lead Tests screen and on the Lead Status screen. The measurements are also provided on the Quick Notes report.*

Automatic Pace Threshold Test

Automatic pace threshold testing is available in devices with PaceSafe. When complete, the test automatically stops and displays the threshold, which is the last output level that demonstrated consistent capture.

Automatic threshold tests differ from the manual tests in the following ways:

- Automatic threshold tests are available for Amplitude, but not Pulse Width.

- The following parameters are fixed (vs. programmable in manual tests):

  – Paced AV Delay

  – Pulse Width

  – Cycles per step

  NOTE: *Change the programmable parameters as desired to elicit pacing in the chamber being tested.*

- Additional event markers are available including loss of capture, fusion, and backup pacing (where backup pacing is available).
- Once started, an automatic threshold test cannot be paused, only cancelled.
- PaceSafe automatically determines when the test is completed and automatically stops the test.
- Test results cannot be edited.

PATIENT DIAGNOSTICS AND FOLLOW UP

CHAPTER 4

This chapter contains the following topics:

THERAPY HISTORY

The pulse generator automatically records data that can be helpful when evaluating the patient's condition and the effectiveness of pulse generator programming.

Therapy history data can be reviewed at various levels of detail using the PRM:

- Arrhythmia Logbook—provides detailed information for each detected episode ("Arrhythmia Logbook" on page 4-2)
- Histograms and Counters—displays the total number and percentage of paced and sensed events during a particular recording period ("Histograms" on page 4-7 and "Counters" on page 4-7)
- Trends—provides a graphical view of specific patient, pulse generator, and lead data ("Trends" on page 4-8)

NOTE: *The Summary dialog and Summary tab display a prioritized list of events that have occurred since the last reset. This list will only include VT, SVT, Nonsustained and ATR (if it lasted more than 48 hours) episodes.*

ARRHYTHMIA LOGBOOK

The Arrhythmia Logbook provides access to the following detailed information about episodes of all types (Figure 4-1 on page 4-2):

- The number, date, and time of the event
- The type of event
- A summary of event details
- Duration of the event (when applicable)
- Electrograms with annotated markers
- Intervals

NOTE: *The data include information from all active electrodes. The device compresses the history data to store a maximum of 14 minutes of electrogram data (10 minutes with Patient Triggered Monitor enabled). However, the amount of time actually stored may vary based on the data being compressed (e.g., noise on the EGM or an episode of VT).*

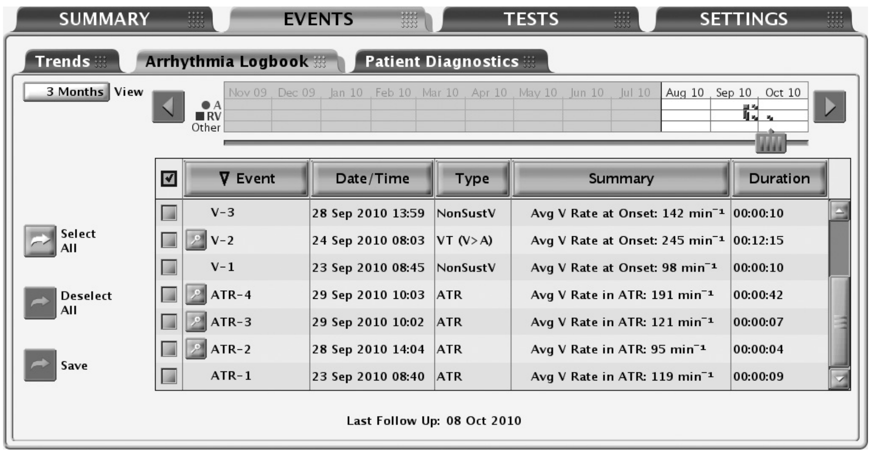


Figure 4-1. Arrhythmia Logbook screen

The priority, maximum number, and minimum number of episodes that the pulse generator stores under normal conditions varies by episode type (Table 4-1 on page 4-3). As long as device memory allocated for episode data is not full, the pulse generator stores up to the maximum number of episodes allowed for each episode type. The minimum number of episodes for each episode type ensures that all episode types are represented by protecting a few low priority episodes from being overwritten by high priority episodes when device memory is full.

Once device memory is full, the pulse generator attempts to prioritize and overwrite stored episodes according to the following rules:

- If device memory is full, and there are episode types that have more than the minimum number of episodes stored, then the oldest of the lowest priority episodes from these episode types will be deleted. In this case, the low priority episodes are not deleted if their number of stored episodes is less than the minimum number.

- If device memory is full, and there are no episode types that have more than the minimum number of episodes stored, then the oldest of the lowest priority episodes of all episode types will be deleted.

- If the maximum number of episodes has been reached within an episode type, the oldest episode of that type will be deleted.

- An episode in progress has the highest priority until its type can be determined.

NOTE: *Once history data is saved, it can be accessed at any time without device interrogation.*

Table 4-1. Episode Priority

Episode Type	Priority	Maximum number of stored episodes	Minimum number of stored episodes with detailed reports	Maximum number of stored episodes with detailed reports
VT (V>A)[b]	1	50	5	10
PTM (Patient Triggered Monitor)	1	5	1	1
SVT (V≤A) [a]	2	50	3	5
NonSustV	3	10	1	2
PaceSafe RVAC	3	1	1	1
ATR[a]	4	10	1	3
PMT[a]	4	5	1	3

a. Not available in SR models.
b. In an SR device, the episode type is Tachy.

To display Arrhythmia Logbook data, use the following steps:

1. From the Events tab, select Arrhythmia Logbook. If necessary, the pulse generator will be automatically interrogated and current data will be displayed. Saved patient data also can be displayed ("Data Storage" on page 1-12).

2. While retrieving the data, the programmer will display a window indicating the progress of the interrogation. No information will be displayed if you select the Cancel button before all of the stored data are retrieved.

3. Use the slider and View button to control the range of dates for the events you want to display in the table.

4. Select the Details button of an event in the table to display the event details. Event details, available if the details button is present, are useful in evaluating each episode.

The Stored Event screen will appear, and you can browse between the following tabs for more information about the event:

- Events Summary
- EGM
- Intervals

5. Select a column header button to sort the events by that column. To reverse the order, select the column header again.

6. To save specific events, select the event and choose the Save button. To print specific events, select the event and choose Reports from the toolbar. Choose the selected Episodes Report and select the Print button.

NOTE: *An "in-progress" episode will not be saved; an episode must be complete before it will be saved by the application.*

To view episode details, select the Details button next to the desired episode on the Arrhythmia Logbook screen. The Stored Event screen will appear, and you can browse between the Summary, EGM, and Intervals tabs.

Events Summary

The Events Summary screen displays additional details about the selected episode corresponding to the Arrhythmia Logbook.

The summary data include the following:

- Episode number, date, time, type (e.g., VT, SVT, or PTM)
- Average atrial and ventricular rates
- Duration
- Average Ventricular Rate in ATR (ATR events only; may help determine if the patient's ventricular response to atrial arrhythmias is adequately controlled)
- Atrial rate at PMT start (PMT events only)

Stored Electrograms with Annotated Markers

The pulse generator can store annotated electrograms sensed from the following channels:

- RV pace/sense lead
- Atrial pace/sense lead
- PaceSafe Evoked Response (ER)

The particular annotated electrograms stored depend upon the episode type. In this section, EGM refers to both electrograms and the associated annotated markers. The EGM storage capacity varies depending on EGM signal condition and heart rate. The total amount of stored EGM data associated with an episode may be limited; EGMs from the middle of the episode may be removed for episodes greater than 4 minutes in duration.

When the memory allocated to EGM storage is full, the device overwrites older EGM data segments in order to store the new EGM data. The EGM is recorded in segments consisting of episode Onset and End EGM storage. Detailed information for the Onset segment can be viewed when the left caliper is in that section.

Episode Onset refers to the period of time (measured in seconds) of EGM prior to event declaration.

Onset includes the following information:

- Type of event
- Average RA Rate at the start of Event
- Average RV Rate at the start of Event
- Average V rate during ATR (ATR episodes only)

To view the EGM data, select the Details button of the desired episode on the Arrhythmia Logbook screen.

Use the following steps to view specific details about each episode:

1. Select the EGM tab.

    - EGM strips for the appropriate sources are displayed. Each strip includes the EGMs sensed during the episode with the corresponding annotated markers. Blue vertical bars indicate the segment (Onset, End) boundaries.

    NOTE: *For marker definitions, select the Reports button on the PRM and view the Marker Legend Report.*

    - Use the slider under the upper display window to view different sections of the stored EGM.
    - Improve visibility of EGM traces by adjusting the amplitude of each EGM. The adjustment controls and amplitude gain values are located on the right side of the trace display.
    - Move the calipers along the trace to display the time interval between the calipers.
    - As the left caliper is moved, the stored EGM voltage amplitude at the location of the caliper for each EGM is displayed along the left edge of the trace display. The EGM voltage amplitude is correct regardless of the amplitude gain value.
    - A speed button changes the trace speed in millimeters/seconds.

2. Select the Previous Event or Next Event button to display a different event strip.
3. To print the entire episode report, select the Print Event button. To save the entire episode report, select the Save button.

Intervals

The pulse generator stores event markers and associated time stamps. The PRM derives event intervals from the event markers and time stamps.

To view the episode intervals, use the following steps:

1. From the Stored Event screen, select the Intervals tab. If all of the episode data is not visible in the window, use the scroll bar to view more data.

2. Select the Previous Event or the Next Event button to display a previous or more current episode, one episode at a time.

3. Select the Print Event button to print the entire episode report.

4. Select the Save button to save the entire episode report.

Ventricular Tachy EGM Storage

The Ventricular Tachy EGM Storage feature will detect and store an Arrhythmia Logbook episode when the patient's intrinsic ventricular rate rises above a programmable threshold. In response to 3 consecutive fast beats, the device will begin storing an episode which will ultimately be classified as: VT (V>A), SVT (V<A) or a Nonsustained episode. The pulse generator will not provide any tachy therapy (e.g., shocks or ATP).

NOTE: *In a single-chamber device, these types of episodes will be classified as Tachy or Nonsustained.*

This feature is available in any Brady mode. In a dual-chamber device programmed to AAI(R), ventricular sensing for VT detection is used in addition to atrial sensing unless the VT EGM Storage parameter is set to Off.

Tachy EGMs will be stored under the following conditions:

1. To begin storing an episode, 3 consecutive fast beats must occur above the VT Detection Rate. The episode Onset EGM segment will start 5 seconds before the third fast beat, and stop 10 seconds after the third fast beat.

2. The pulse generator then uses a sliding detection window to monitor for 8 out of 10 fast beats. The detection window is the 10 most recently detected ventricular intervals. As a new interval occurs, the window slides to encompass it and the oldest interval is eliminated.

3. Once 8 out of 10 fast beats have been detected, a V-Epsd marker is displayed and a nonprogrammable 10 second Duration begins.

   NOTE: *For single-chamber devices, an Epsd marker is displayed instead.*

4. A sustained VT episode is declared if 6 out of 10 fast beats are maintained throughout Duration. At the end of Duration, if the rate is still fast, the pulse generator applies the V>A detection enhancement to determine if the episode is VT (V>A) or SVT (V≤A):

   a. At the end of Duration, the pulse generator calculates averages of the last 10 V–V intervals and the last 10 A–A intervals.

      NOTE: *If there are fewer than 10 atrial intervals available, the available intervals will be used to determine the average atrial rate. There will always be at least 10 ventricular intervals.*

   b. These averages are compared. If the average ventricular rate is 10 min^{-1} or more faster than the average atrial rate, the episode is declared as VT. Otherwise, it is declared as SVT.

   NOTE: *The pulse generator will respond to atrial sensing regardless of whether an atrial lead is implanted. If an atrial lead is not implanted, or is not sensing adequately, program the atrial sensing lead configuration to Off ("Lead Configuration" on page 2-40).*

5. A Nonsustained episode is declared if 8 out of 10 fast beats are not detected, or if 6 out of 10 fast beats are not maintained during Duration. The episode will be classified as NonSustV.

6. End of episode is declared under the following conditions:

   - End of Episode timer expires. Once 8 out of 10 fast beats have been detected, a nonprogrammable 10 second End of Episode timer begins whenever fewer than 6 out 10 beats are fast. The timer is only cleared if 8 out of 10 fast beats are once again detected before the timer expires. If the timer expires, End of Episode is declared, and a V-Epsd End marker is displayed.

     NOTE: *For single-chamber devices, an Epsd End marker is displayed instead.*

   - 10 consecutive slow beats are detected below the VT Detection Rate. No end of episode marker is provided in this scenario.

   - Any Temp Brady function is initiated.

   - Ventricular Tachy EGM Storage is reprogrammed.

The episode End EGM segment will start 20 seconds before the end of the episode (may be less than 20 seconds if the Onset and End segments overlap), and stops at the end of the episode.

NOTE:

For single-chamber pulse generators programmed to AAI(R) mode, all references to ventricular events or intervals described above actually refer to atrial events or intervals, and the resulting stored atrial tachy episodes are labeled as ventricular episodes in the Logbook.

HISTOGRAMS

The Histograms feature retrieves information from the pulse generator and displays the total number and percentage of paced and sensed events for the chamber.

Histograms data can provide the following clinical information:

- The distribution of the patient's heart rates
- How the ratio of paced to sensed beats varies by rate
- How the ventricle responds to paced and sensed atrial beats across rates

Use the following steps to access the Histograms screen:

1. From the Events screen, select the Patient Diagnostics tab.
2. The initial display shows the paced and sensed data since the last time the counters were reset.
3. Select the Details button to display the data type and time period.
4. Select the Rate Counts button on the Details screen to view rate counts by chamber.

All Histograms and Counters can be reset by selecting the Reset button from any Patient Diagnostics Details screen.

COUNTERS

The following counters are recorded by the pulse generator and displayed on the Patient Diagnostics screen:

- Tachy
- Brady

Ventricular Tachy Counters

Information about Ventricular Episode Counters is available by selecting the Tachy Counters Details button. For each counter, the number of events since last reset and device totals are displayed. Ventricular Episode counters contains the following data:

- Total episodes
- VT Episodes (V>A)
- SVT Episodes (V≤A)
- Nonsustained Episodes

Brady Counters

Information about Brady Counters is displayed by selecting the Brady Counters button. This screen displays the brady episode counters. For each counter, the number of events since last reset and reset before last are displayed. Brady counters contains the following details:

- Percent of atrial paced
- Percent of RV paced
- Intrinsic Promotion—includes Rate Hysteresis % successful and AV Search+ % successful
- Atrial burden—includes Episodes by Duration and Total PACs
- Ventricular counters—includes total PVCs and Three or More PVCs

All Histograms and Counters can be reset by selecting the Reset button from any Patient Diagnostic Details screen.

TRENDS

Trends provide a graphical view of specific patient, device, and lead data. This data can be useful when evaluating your patient’s condition and the effectiveness of programmed parameters. Unless otherwise noted below, data for all trends is reported every 24 hours and is available for up to 1 year. For many trends, a value of “N/R” is reported if there is insufficient or invalid data for the collection period.

The following trends are available:

- Events—displays both atrial and ventricular events stored in the Arrhythmia Logbook, organized by date and type ("Arrhythmia Logbook" on page 4-2). This trend is updated whenever an episode is completed, and may contain data that is older than 1 year.
- Atrial Burden—displays a trend of the total number of ATR Mode Switch events and the total amount of time spent in an ATR Mode Switch per day.

- Heart Rate—displays a trend of the patient's daily maximum, mean, and minimum heart rate. Intervals used in this calculation must be valid sinus rhythm intervals.

  The validity of an interval and the Heart Rate Trend data for the 24-hour collection period is determined by the Heart Rate Trend collection criteria.

- Lead impedance and amplitude—displays trends of the daily intrinsic amplitude and lead impedance measurements ("Leads Status" on page 3-6).

- RV Pace Threshold—displays a trend of the daily right ventricular pacing thresholds

Follow the steps below to access Trends:

1. From the Events screen, select the Trends Tab.

2. Choose the Select Trends button to specify the trends you want to view. You can choose from the following categories:

   - Atrial Arrhythmia—includes Events, Heart Rate, and Atrial Burden trends

   - Custom—allows you to select various trends to customize the information displayed on the Trends screen

The display on the screen can be viewed in the following manner:

- Select the desired time on the View button to choose the length of visible trend data.

- Adjust the start and end dates by moving the horizontal slider at the top of the window. You can also adjust these dates using the scroll left and scroll right icons.

- Move the vertical axis across the graph by moving the horizontal slider at the bottom of the display window.

Heart Rate Trend Collection Criteria

Only valid sinus rhythm intervals are used in the Heart Rate Trend data calculations. Valid intervals are those which include only valid Heart Rate Trend events.

Valid Heart Rate Trend events are listed below:

- AS with an interval not faster than MTR, followed by a VS

- AS followed by VP at the programmed AV Delay

Invalid Heart Rate Trend events are listed below:

- AP/VS or AP/VP
- AS with an interval faster than MTR
- Non-tracked VP events
- Consecutive AS events (no intervening V event)
- VP-Ns
- Rate Smoothing events (e.g., RVP↑)
- PVC

Heart Rate Trend data may not be reported for a variety of reasons; the most common are listed below:

- Less than 67% of the 24-hour collection period (approximately 16 hours) contains valid Heart Rate Trend events
- Brady parameters were programmed within the last 24 hours

POST IMPLANT FEATURES

Patient Triggered Monitor

Patient Triggered Monitor allows the patient to trigger the storage of EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device. Instruct the patient to place the magnet on the device briefly and one time only.

Patient Triggered Monitor is enabled by selecting Store EGM as the desired Magnet Response. This can be found in the Timing, Rate Enhancements, Magnet, Noise section on the Brady Settings screen. When enabled, the device will store up to 2 minutes of patient monitor data prior to and up to 1 minute after triggering the monitoring. The stored data include the episode number, the rates at magnet application, and the start time and date of magnet application.

Once PTM is programmed on, only one EGM can be generated and stored. To store another EGM, the PTM feature must be re-enabled using the programmer.

When data are stored, the corresponding episode type is recorded as PTM in the Arrhythmia Logbook.

Use care when enabling Patient Triggered Monitor, because the following conditions will exist:

- All other magnet features are disabled, including asynchronous pacing (until the EGM is stored). The Magnet feature will not indicate magnet position.
- Device longevity is impacted. Once the patient has triggered this feature to store episode data or the feature is disabled, the impact on device longevity is no longer present. To help reduce the longevity effect, this feature is automatically disabled after 60 days from the day it was enabled.
- Once the EGM is stored, the device Magnet Response automatically will be set to Pace Async. However, the pulse generator will not revert to asynchronous operation until the magnet is removed for 3 seconds and placed on the device again.

To program the Patient Triggered Monitor feature, follow these steps:

1. From the Settings tab on the main screen, select Settings Summary.
2. From the Settings Summary tab, select Brady Settings.
3. From Brady settings, select Timing, Rate Enhancements, Magnet, Noise.
4. Program the Magnet Response to Store EGM.

   CAUTION: Determine if the patient is capable of activating this feature prior to being given the magnet and prior to enabling Patient Triggered Monitor. Remind the patient to avoid strong magnetic fields so the feature is not inadvertently triggered.

CAUTION: Consider having the patient initiate a stored EGM at the time Patient Triggered Monitor is enabled to assist with patient education and feature validation. Verify the activation of the feature on the Arrhythmia Logbook screen.

NOTE: *Ensure that Patient Triggered Monitor is enabled prior to sending the patient home by confirming the Magnet Response is programmed to Store EGM. If the feature is inadvertently left in the Pace Async setting, the patient could potentially cause the device to pace asynchronously by applying the magnet.*

NOTE: *Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the Magnet Response programming automatically will be set to Pace Async.*

5. Patient Triggered Monitor can only be enabled for a 60-day period of time. To disable the feature within the 60-day time period, reprogram the Magnet Response to a setting other than Store EGM. When 60 days have passed since enabling Patient Triggered Monitor, the feature will automatically disable itself and the Magnet Response will revert to Pace Async. To re-enable the feature, repeat these steps.

For additional information, contact Boston Scientific using the information on the back cover.

Magnet Feature

The magnet feature allows certain device functions to be triggered when a magnet is placed in close proximity to the pulse generator (Figure 4-2 on page 4-11).

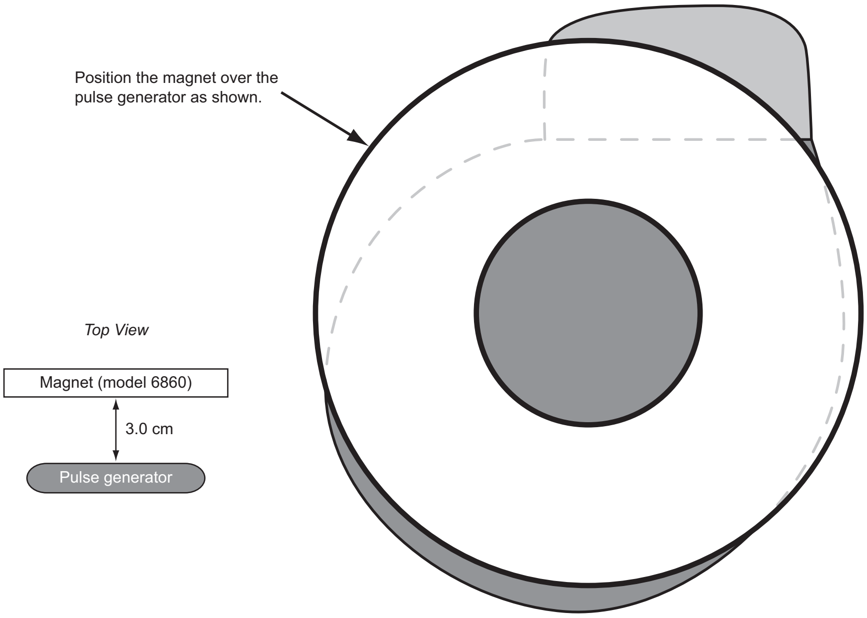


Figure 4-2. Proper position of magnet Model 6860 to activate the pulse generator magnet feature

The pulse generator Magnet Response settings can be programmed to control the behavior of the pulse generator when a magnet is detected. The Magnet Response settings are located in the Timing, Rate Enhancements, Magnet, Noise section of the Brady Settings screen.

The following Magnet Response settings are available:

- Off—no response
- Store EGM—patient monitoring data will be stored

- Pace Async—pacing will occur asynchronously at a rate reflective of the current battery status ("Battery Status Summary Screen" on page 3-3)

Off

When the Magnet Response is programmed to Off, application of the magnet will have no effect on the pulse generator.

Store EGM

When the Magnet Response is programmed to Store EGM, application of the magnet will activate the patient triggered monitor functionality ("Patient Triggered Monitor" on page 4-10).

Pace Async

When the Magnet Response is programmed to Pace Async, magnet application converts the pulse generator Brady Mode to an asynchronous mode, with a fixed pacing rate that reflects battery status ("Battery Status Summary Screen" on page 3-3) and magnet AV Delay of 100 ms.

If Magnet Response is programmed to Off, the pulse generator will not revert to asynchronous operation in the presence of magnet. If Magnet Response is programmed to Store EGM, the pulse generator will not revert to asynchronous operation until the magnet is removed for 3 seconds and placed on the device again.

Initial Brady Modes and their corresponding magnet Modes are listed below:

- Brady Modes DDD, DDDR, DDI, and DDIR convert to Magnet Mode DOO
- Brady Modes VDD, VDDR, VVI, and VVIR convert to Magnet Mode VOO
- Brady Modes AAI and AAIR convert to Magnet Mode AOO

The third pulse during the Pace Async Magnet Response will be issued at 50% of the programmed Pulse Width. If loss of capture is observed at the third beat after magnet application, consider re-assessing the safety margin.

The pulse generator remains in Magnet Response as long as the magnet is positioned over the middle of the pulse generator, parallel to the device header. When the magnet is removed, the pulse generator automatically resumes operating according to previously programmed parameters.

NOTE: *If rate adaptive pacing or PaceSafe Right Ventricular Automatic Capture has been programmed, it is suspended for the duration of magnet application. Output is set to twice the last threshold measurement and there is no beat to beat capture verification for the duration of magnet application.*

ELECTROPHYSIOLOGIC TESTING

CHAPTER 5

This chapter contains the following topics:

EP TEST FEATURES

Electrophysiologic (EP) Testing features enable you to induce and terminate arrhythmias noninvasively.

WARNING: Always have external defibrillation protection available during implant and electrophysiologic testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.

The features allowing noninvasive EP testing of arrhythmias include the following:

- Programmed electrical stimulation (PES) induction/termination
- Manual Burst pacing induction/termination

EP Test Screen

The EP Test screen displays the real-time status of the episode detection and brady pacing therapy of the pulse generator when telemetry communication is occurring.

Refer to the EP Test screen (Figure 5-1 on page 5-2):

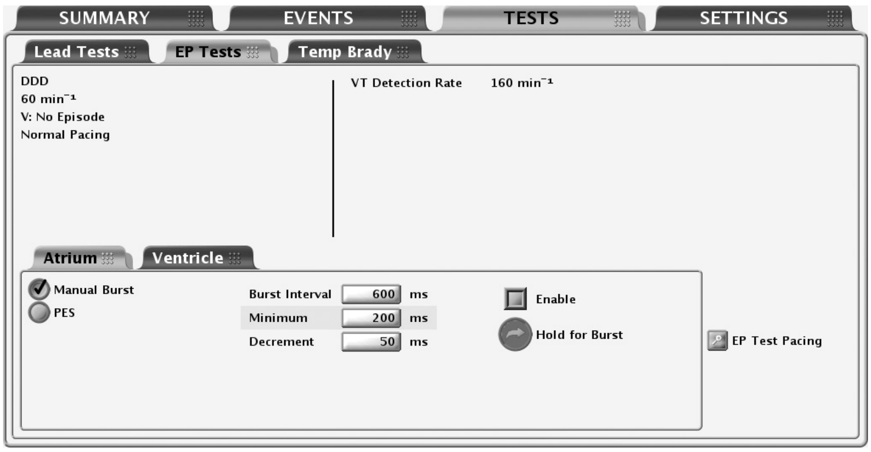


Figure 5-1. EP Test Screen

The screen provides the following information:

- Ventricular episode status—if an episode is occurring, the duration of the episode is displayed (if it is greater than 10 minutes, then it is displayed as > 10:00 m:s)
- Atrial episode status—if an episode is occurring, the duration of the episode is displayed (if it is greater than 100 minutes, then it is displayed as > 99:59 m:s)

  NOTE: *Single-chamber devices use ventricular-based episode reporting*

- Brady pacing status

Follow the steps below to perform EP Test functions:

1. Select the Tests tab, then select the EP Tests tab.
2. Establish telemetry communication. Telemetry communication between the programmer and the pulse generator should be maintained throughout all EP test procedures.

3. Set backup pacing and EP Test Pacing outputs as desired.

   NOTE: *Backup pacing during EP testing is not available in single-chamber devices.*

INDUCTION METHODS

Each EP test method available from the EP Test screen is described below with instructions. During any type of induction/termination, the pulse generator performs no other activity until the test has ceased, at which time the programmed mode will take effect and the pulse generator will respond accordingly.

Consider the following information when using these methods:

- Pacing pulses during induction are delivered at the programmed EP Test pacing parameters

Backup Ventricular Pacing During Atrial EP Testing

Backup ventricular pacing is available during atrial EP testing (PES, Manual Burst) regardless of the programmed Normal Brady mode.

NOTE: *Backup pacing is performed in VOO mode.*

NOTE: *Backup pacing during EP testing is not available in single-chamber devices.*

In dual-chamber devices, program the backup pacing parameters by selecting the EP Test Pacing button. Backup pacing parameters are independently programmable from the permanent pacing parameters. Backup pacing can also be disabled by programming the Backup Pacing Mode to Off.

Programmed Electrical Stimulation (PES)

PES induction allows the pulse generator to deliver up to 30 equally timed pacing pulses (S1) followed by up to 4 premature stimuli (S2–S5) to induce or terminate arrhythmias. Drive pulses, or S1 pulses, are intended to capture and drive the heart at a rate slightly faster than the intrinsic rate. This ensures that the timing of the premature extra stimuli will be accurately coupled with the cardiac cycle (Figure 5-2 on page 5-4).

The initial S1 pulse is coupled to the last sensed or paced beat at the S1 interval. All pulses are delivered in XOO modes (where X is the chamber) at the programmed EP Test pacing parameters.

For Atrial PES, backup pacing parameters are provided.

NOTE: *Backup pacing during EP testing is not available in single-chamber devices.*

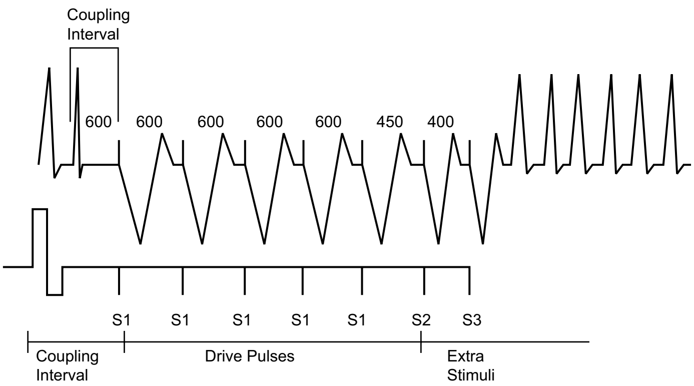


Figure 5-2. PES induction drive train

Performing PES Induction

1. In a dual-chamber device, choose the Atrium or Ventricle tab, depending on which chamber you want to pace.

2. Select the PES option. Buttons for the S1–S5 pulses and the corresponding burst cycle lengths are displayed.

3. Select the desired value for the S1–S5 intervals (Figure 5-3 on page 5-4). You can either select a value box for the desired S interval and choose a value from the box or use the plus or minus symbols to change the value visible in the value box.

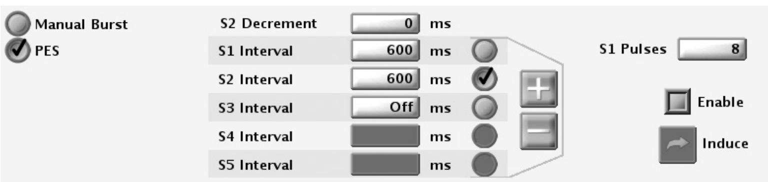


Figure 5-3. PES induction options

4. Select the Enable checkbox.

5. Select (do not hold) the Induce button to begin delivery of the drive train. When the programmed number of S1 pulses is delivered, the pulse generator will then deliver the programmed S2–S5 pulses. The pulses are delivered in sequence until a pulse is encountered that is set to Off (e.g., if S1 and S2 are set to 600 ms, and S3 is Off, then S3, S4, and S5 will not be delivered). Once induction is initiated, the PES delivery will not stop if you interrupt telemetry communication. (While telemetry is active, pressing the DIVERT THERAPY key will stop induction delivery.)

6. PES induction is complete when the drive train and extra stimuli are delivered, at which time the pulse generator automatically restarts detection.

NOTE: *Ensure the PES induction is complete before beginning another induction.*

NOTE: *When PES is used to terminate an arrhythmia that has been detected (and an episode declared), the episode is terminated when the PES is commanded regardless of whether it is successful or not. A new episode can be declared after the PES induction is completed. The PES itself is not recorded in therapy history; this may result in several episodes being counted in therapy history.*

NOTE: *Real-time EGMs and annotated event markers will continue to be displayed during the entire test sequence.*

Manual Burst Pacing

Manual Burst pacing is used to induce or terminate arrhythmias when delivered to the desired chamber. Pacing parameters are programmable for Manual Burst.

Manual Burst pacing pulses are delivered in XOO mode (where X is the chamber) at the programmed EP Test pacing parameters. For Atrial Manual Burst, backup pacing parameters are provided.

NOTE: *Backup pacing during EP testing is not available in single-chamber devices.*

Performing Manual Burst Pacing

1. In a dual-chamber device, choose the Atrium or Ventricle tab, depending on which chamber you want to pace.

2. Select the Manual Burst option.

3. Select the desired value for the Burst Interval, Minimum, and Decrement. This indicates the cycle length of the intervals in the drive train.

4. Select the Enable checkbox.

5. To deliver the burst, select and hold the Hold for Burst button.

   The ventricular Manual Burst will be delivered up to 30 seconds as long as the Hold for Burst button is held and the telemetry link is maintained.

   The atrial Manual Burst will be delivered up to 45 seconds as long as the Hold for Burst button is held and the telemetry link is maintained.

   The intervals will continue to be decremented until the Minimum interval is reached, then all further pulses will be at the Minimum interval.

   NOTE: *In single-chamber devices, the 30 second burst time limit is used.*

6. To stop the burst delivery, release the Hold for Burst button. The Hold for Burst button will become dimmed again.

7. To deliver additional Manual Burst pacing, repeat these steps.

NOTE: *Real-time EGMs and annotated event markers will continue to be displayed during the entire test sequence.*

PROGRAMMABLE OPTIONS

APPENDIX A

Table A-1. ZIP Telemetry settings

Parameter	Programmable Values	Nominal[a]
Communication Mode	Enable use of ZIP telemetry (May require limited use of wand), Use wand for all telemetry	Enable use of ZIP telemetry (May require limited use of wand)

a. If the Communication Mode is selected via the Utilities button on the PRM Startup screen, the Nominal setting within the ZOOMVIEW Programmer software application will correspond to the value chosen on the Startup screen.

Table A-2. Device Mode

Parameter	Programmable Values	Nominal
Device Mode	Exit Storage, Enable Electrocautery Protection	Storage

Table A-3. Pacing therapy parameters (specified into a 750 Ω load)

Parameter	Programmable Values	Nominal
Mode[a b d]	DDD(R), DDI(R), DOO, VDD(R), VVI(R), VOO, AAI(R), AOO, Off; Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off	Dual Chamber: DDD; Single Chamber: VVI
Lower Rate Limit (LRL)[a c d] (min^{-1})	30, 35, …, 185	60 (Tolerance ± 5 ms)
Maximum Tracking Rate (MTR)[a d] (min^{-1})	50, 55, …, 185	130 (Tolerance ± 5 ms)
Maximum Sensor Rate (MSR)[f] (min^{-1})	50, 55, …, 185	130 (Tolerance ± 5 ms)
Pulse Amplitude (dual chamber, atrium)[a d e] (V)	0.1, 0.2, …, 3.5, 4.0, …, 5.0	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude (dual chamber, right ventricle)[a d e] (V)	Auto, 0.1, 0.2, …, 3.5, 4.0, …, 7.5; Temporary: 0.1, 0.2, …, 3.5, 4.0, …, 7.5	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude (single chamber)[a d e] (V)	Auto, 0.1, 0.2, …, 3.5, 4.0, …, 7.5; Temporary: 0.1, 0.2, …, 3.5, 4.0, …, 7.5	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude Daily Trend[g]	Disabled, Enabled	Disabled
Pulse Width (atrium, right ventricle)[a d e h] (ms)	0.1, 0.2, …, 2.0	0.4 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Accelerometer[f]	On, Passive	Passive
Accelerometer Activity Threshold	Very Low, Low, Medium Low, Medium, Medium High, High, Very High	Medium
Accelerometer Reaction Time (sec)	10, 20, …, 50	30
Accelerometer Response Factor	1, 2, …, 16	8
Accelerometer Recovery Time (min)	2, 3, …, 16	2
Minute Ventilation[f]	On, Passive, Off	Passive
Minute Ventilation Response Factor	1, 2, …, 16	3
Minute Ventilation Fitness Level	Sedentary, Active, Athletic, Endurance Sports	Active
Patient's Age	≤5, 6–10, 11–15, …, 91–95, ≥ 96	56–60
Patient's Gender	Male, Female	Male
Ventilatory Threshold (min^{-1})	30, 35, …, 185	120 (Tolerance ± 5 ms)
Ventilatory Threshold Response (%)	Off, 85, 70, 55	70
Rate Hysteresis Hysteresis Offset[f] (min^{-1})	-80, -75, …, -5, Off	Off (Tolerance ± 5 ms)
Rate Hysteresis Search Hysteresis[f] (cycles)	Off, 256, 512, 1024, 2048, 4096	Off (Tolerance ± 1 cycle)
Rate Smoothing (up, down)[f] (%)	Off, 3, 6, 9, 12, 15, 18, 21, 25	Off (Tolerance ± 1%)

Table A-3. Pacing therapy parameters (specified into a 750 Ω load) (continued)

Parameter	Programmable Values	Nominal
Rate Smoothing Maximum Pacing Rate (min^{-1})	50, 55, …, 185	130 (Tolerance ± 5 ms)
Atrial Pace/Sense Configuration (dual chamber)[a d]	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off	Unipolar
Right Ventricle Pace/Sense Configuration (dual chamber)[a d]	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar	Unipolar
Pace/Sense Configuration (single chamber)[a d]	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar	Unipolar
Safety Switch (independently programmable in each chamber)	Off, On	On
Maximum Paced AV Delay[a d] (ms)	30, 40, …, 400	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay[a d] (ms)	30, 40, …, 400	80 (Tolerance ± 5 ms)
Maximum Sensed AV Delay[a d] (ms)	30, 40, …, 400	150 (Tolerance ± 5 ms)
Minimum Sensed AV Delay[a d] (ms)	30, 40, …, 400	65 (Tolerance ± 5 ms)
AV Search +[f]	Off, On	Off
AV Search + Search AV Delay (ms)	30, 40, …, 400	300 (Tolerance ± 5 ms)
AV Search + Search Interval (cycles)	32, 64, 128, 256, 512, 1024	32 (Tolerance ± 1 cycle)
A-Refractory (PVARP)[a d] (ms)	150, 160, …, 500	250 (Tolerance ± 5 ms)
Maximum V-Refractory (VRP) (dual chamber)[a d](ms)	150, 160, …, 500	250 (Tolerance ± 5 ms)
Minimum V-Refractory (VRP) (dual chamber)[a d] (ms)	150, 160, …, 500	230 (Tolerance ± 5 ms)
Maximum Refractory (single chamber)[a d] (ms)	150, 160, …, 500	250 (Tolerance ± 5 ms)
Minimum Refractory (single chamber)[a d] (ms)	150, 160, …, 500	250 (Tolerance ± 5 ms)
PVARP After PVC[a] (ms)	Off, 150, 200, …, 500	400 (Tolerance ± 5 ms)
V-Blank after A-Pace[a d] (ms)	45, 65, 85	65 (Tolerance ± 5 ms)
A-Blank after V-Pace[a d] (ms)	Smart, 45, 65, 85, 105, 125, 150, 175, 200	125 (Tolerance ± 5 ms)
A-Blank after V-Sense[a d] (ms)	Smart, 45, 65, 85	45 (Tolerance ± 5 ms)
Noise Response[a]	AOO, VOO, DOO, Inhibit Pacing	DOO for DDD(R) and DDI(R) modes; VOO for VDD(R) and VVI (R) modes; AOO for AAI(R) mode
Magnet Response	Off, Store EGM, Pace Async	Pace Async

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
b. Refer to the NASPE/BPEG codes below for an explanation of the programmable values. The identification code of the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG) is based on the categories listed in the table.
c. The basic pulse period is equal to the pacing rate and the pulse interval (no hysteresis). Runaway protection circuitry inhibits bradycardia pacing above 205 min^{-1}. Magnet application may affect pacing rate (test pulse interval).
d. Separately programmable for Temporary Brady.
e. Values are not affected by temperature variation within the range 20°C – 43°C.
f. This parameter is disabled during Temporary Brady.
g. This parameter is automatically enabled if Auto is selected for the Pulse Amplitude.
h. When the Pulse Amplitude is set to Auto or Pulse Amplitude Daily Trend is enabled the Pulse Width is fixed at 0.4 ms.

Table A-4. Brady Mode values based on NASPE/BPEG codes

Position	**I**	**II**	**III**	**IV**	**V**
Category	**Chambers Paced**	**Chambers Sensed**	**Response to Sensing**	**Programmability, rate modulation**	**Antitachyarrhythmia Functions**
Letters	0–None	0–None	0–None	0–None	0–None
	A–Atrium	A–Atrium	T–Triggered	P–Simple Programmable	P–Pacing (Antitachyarrhythmia)
	V–Ventricle	V–Ventricle	I–Inhibited	M–Multiprogrammable	S–Shock

Table A-4. Brady Mode values based on NASPE/BPEG codes (continued)

Position	I	II	III	IV	V
	D–Dual (A&V)	D–Dual (A&V)	D–Dual (T&I)	C–Communicating	D–Dual (P&S)
				R–Rate Modulation	
Mfrs. Designation Only	S–Single (A or V)	S–Single (A or V)			

Table A-5. Sensor Trending

Parameter	Programmable Values	Nominal
Recording Method	Beat To Beat, Off, 30 Second Average	30 Second Average
Data Storage	Continuous, Fixed	Continuous

Table A-6. Ventricular Tachy EGM Storage

Parameter	Programmable Values	Nominal
Tachy EGM Storage (single chamber models)	Off, On	On
Ventricular Tachy EGM Storage (dual chamber models)	Off, On	On
Tachy Detection Rate [a] (single chamber models) (min^{-1})	90, 95, …, 210, 220	160 (Tolerance ± 5 ms)
VT Detection Rate [b] (dual chamber models) (min^{-1})	90, 95, …, 210, 220	160 (Tolerance ± 5 ms)

a. The Tachy Detection Rate must ≥ 5 min^{-1} higher than the Maximum Sensor Rate and the Maximum Pacing Rate, and must be ≥ 15 min^{-1} higher than the Lower Rate Limit.
b. The VT Detection Rate must be ≥ 5 min^{-1} higher than the Maximum Tracking Rate, Maximum Sensor Rate, and the Maximum Pacing Rate, and must be ≥ 15 min^{-1} higher than the Lower Rate Limit.

Table A-7. Atrial Tachy Parameters

Parameter	Programmable Values	Nominal
ATR Mode Switch[a]	Off, On	On
ATR Trigger Rate[a] (min^{-1})	100, 110, ..., 300	170 (Tolerance ± 5 ms)
ATR Duration[a] (cycles)	0, 8, 16, 32, 64, 128, 256, 512, 1024, 2048	8 (Tolerance ± 1 cardiac cycle)
Entry Count[a] (cycles)	1, 2, ..., 8	8
Exit Count[a] (cycles)	1, 2, ..., 8	8
ATR Fallback Mode [c]	VDI, DDI, VDIR, DDIR	DDI
ATR Fallback Time[a] (min:sec)	00:00, 00:15, 00:30, 00:45, 01:00, 01:15, 01:30, 01:45, 02:00	00:30
ATR Fallback LRL[a] (min^{-1})	30, 35, ..., 185	70 (Tolerance ± 5 ms)
PMT Termination [b]	Off, On	On

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
b. This parameter gets disabled during Temporary Brady.
c. If Normal Brady ATR Fallback Mode is DDIR or DDI, then Temporary Brady ATR Fallback Mode is DDI and If Normal Brady ATR Fallback Mode is VDIR or VDI, then Temporary Brady ATR Fallback Mode is VDI.

Table A-8. Sensitivity

Parameter[a b c]	Programmable Values	Nominal
Sensing Method[d]	AGC, Fixed	Fixed
Atrial Sensitivity (AGC)	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, …, AGC 1.0, AGC 1.5	AGC 0.25
Right Ventricular Sensitivity (AGC)	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, …, AGC 1.0, AGC 1.5	AGC 0.6

Table A-8. Sensitivity (continued)

Parameter[a b c]	Programmable Values	Nominal
Atrial Sensitivity (Fixed)	Fixed 0.15, Fixed 0.25, Fixed 0.5, Fixed 0.75, Fixed 1.0, Fixed 1.5, …, Fixed 8.0, Fixed 9.0, Fixed 10.0	Fixed 0.75
Right Ventricular Sensitivity (Fixed)	Fixed 0.25, Fixed 0.5, Fixed 0.75, Fixed 1.0, Fixed 1.5, …, Fixed 8.0, Fixed 9.0, Fixed 10.0	Fixed 2.5

a. Separately programmable for Temporary Brady.
b. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
c. In single-chamber models, the chamber chosen determines the nominal value.
d. The programmed value for Sensing Method determines the applicable values (AGC or Fixed) in each chamber.

Table A-9. Backup EP Test

Parameter	Programmable Values	Nominal
Backup Pacing Mode[a c]	Off, On	On
Backup Pacing Lower Rate Limit[a b c] (min^{-1})	30, 35, …, 185	60 (Tolerance ± 5 ms)
Backup Pacing V Refractory[a b c] (ms)	150, 160, …, 500	250 (Tolerance ± 5ms)
EP Test Pacing Outputs Atrial Amplitude (dual-chamber models when test is in the atrium) (V)	Off, 0.1, 0.2, …, 3.5, 4.0, …, 5.0	5.0 (Tolerance ± 15% or 100 mV, whichever is greater)
EP Test Pacing Outputs Amplitude (single-chamber models) (V)	Off, 0.1, 0.2, …, 3.5, 4.0, …, 7.5	7.5 (Tolerance +/- 15% or 100 mV, whichever is greater)
EP Test Pacing Outputs V Amplitude (dual chamber models) (V)	Off, 0.1, 0.2, …, 3.5, 4.0, …, 7.5	7.5 (Tolerance ± 15% or 100 mV, whichever is greater)
EP Test Pacing Outputs Atrial Pulse Width (dual-chamber models when test is in the atrium) (ms)	0.1, 0.2, …, 2.0	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
EP Test Pacing Outputs Pulse Width (single-chamber models) (ms)	0.1, 0.2, …, 2.0	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
EP Test Pacing Outputs V Pulse Width (dual-chamber models) (ms)	0.1, 0.2, …, 2.0	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)

a. This parameter only applies when the test is in the atrium.
b. The programmed Normal Brady value will be used as the nominal value.
c. Not applicable to single-chamber models.

Table A-10. PES (Programmed Electrical Stimulation)

Parameter[a]	Programmable Values	Nominal
Number of S1 Intervals (pulses)	1, 2, ..., 30	8
S2 Decrement (ms)	0, 10, ..., 50	0
S1 Interval (ms)	120, 130, ..., 750	600 (Tolerance ± 5 ms)
S2 Interval (ms)	Off, 120, 130, ..., 750	600 (Tolerance ± 5 ms)
S3 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)
S4 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)
S5 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)

a. Applied to the atrium or ventricle as commanded by the programmer.

Table A-11. Manual Burst Pacing

Parameter[a]	Programmable Values	Nominal
Burst Interval (ms)	100, 110, ..., 750	600 (Tolerance ± 5 ms)
Minimum Interval (ms)	100, 110, ...,750	200 (Tolerance ± 5 ms)
Decrement (ms)	0, 10, ..., 50	50 (Tolerance ± 5 ms)

a. Applied to the atrium or ventricle depending on the chamber selected.

SYMBOLS ON PACKAGING

APPENDIX B

SYMBOLS ON PACKAGING

The following symbols may be used on packaging and labeling (Table B-1 on page B-1):

Table B-1. Symbols on packaging

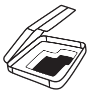
Symbol	Description
REF	Reference number
	Package contents
	Pulse generator
	Torque wrench
	Literature enclosed
SN	Serial number
	Use by
LOT	Lot number
	Date of manufacture
	Non-ionizing electromagnetic radiation
STERILE EO	Sterilized using ethylene oxide
	Do not resterilize
	Do not reuse
	Do not use if package is damaged
	Consult instructions for use
	Temperature limitation
CE0086	CE mark of conformity with the identification of the notified body authorizing use of the mark
	RTTE designation for radio equipment with a use restriction

Table B-1. Symbols on packaging (continued)

Symbol	**Description**
	Wand placement indicator for interrogation
	Opening instruction
EC REP	Authorized Representative in the European Community
	Manufacturer
 N 20593 Z 1088	C-Tick with supplier codes
AUS	Australian Sponsor Address

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Technical Communications
Final Literature Approval

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Information Product Type: systemguide

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