Boston Scientific

REFERENCE GUIDE

ACCOLADE™
ACCOLADE™ MRI
PROPONENT™
PROPONENT™ MRI
ESSENTIO™
ESSENTIO™ MRI
ALTRUA™ 2
FORMIO™
FORMIO™ MRI
VITALIO™
VITALIO™ MRI
INGENIO™
INGENIO™ MRI
ADVANTIO™
ADVANTIO™ MRI

PACEMAKER

REF L300, L301, L321, L310, L311, L331, L200, L201, L209, L221, L210, L211, L231, L100, L101, L121, L110, L111, L131, S701, S702, S722, J278, J279, J272, J273, J274, J275, J276, J277, J172, J173, J174, J178, J175, J176, J177, J062, J063, J064, J065, J066, J067

ABOUT THIS MANUAL

INTENDED AUDIENCE

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

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 Physician Technical Manual, used in conjunction with the ZOOMVIEW software, is intended to provide information most relevant for implanting the pulse generator. The Physician Technical Manual also contains information such as warnings/cautions, potential adverse events, mechanical specifications, longevity, hyperbaric therapy, and programming considerations. This Reference Guide provides further descriptions of programmable features and diagnostics.

For information about MRI scanning, refer to the ImageReady MR Conditional Pacing System MRI Technical Guide.

To view and download any of these documents, go to www.bostonscientific-elabeling.com.

NOTE: *Multiple Programming Systems are available for use based on software and regional availability, and they include different programming devices such as the Model 3120 Programmer/Recorder/Monitor (PRM) and the Model 3300 Programmer. In this manual, the terms PRM and Programmer are used interchangeably to refer to the programming device.*

The Model 3300 Programming System has the same basic capabilities and intended use as the Model 3120 Programming System. Differences between the programming systems include software application model numbers, networking and printing capabilities, on-device keys, and data storage options. Refer to the 3300 Programming System's family of operator's manuals for specific information.

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.

The following new or enhanced features apply to ACCOLADE, PROPONENT, ESSENTIO, and/or ALTRUA 2 devices.

User Experience

- EasyView header with port identifiers: increased header transparency is designed to provide enhanced visibility of the lead ports and ease of individual port identification.

- MICS Telemetry: RF telemetry band utilized is MICS (Medical Implant Communication Service).

Patient Diagnostics

- Programmable Lead Impedance Limits for daily measurements: the High Impedance Limit is programmable between 2000 and 3000 Ω and the Low Impedance Limit is programmable between 200 and 500 Ω.

- Snapshot: up to 6 unique traces of the ECG/EGM display can be stored at any time by pressing the Snapshot button. The traces are 10 seconds pre-activation and 2 seconds post-activation. A 10 second trace will automatically be stored at the end of Pace Threshold tests, which counts as one of the 6 snapshots.

- Atrial Arrhythmia Report: AT/AF % and Total Time in AT/AF Counters are provided. AT/AF Burden, RV Rate during AT/AF, Pacing Percent, Heart Rate, Activity Level and Respiratory Rate Trends are provided. Histograms are provided for RV Rate during AT/AF. A timeline history of interrogations, programming, and counter resets for one year is collected. The Longest AT/AF, Fastest RVS rate in AT/AF, and most recent episode information is also collected.

- POST (Post-Operative System Test): provides an automatic device/lead check at a pre-determined time post-implant to help document proper system functionality without requiring manual system testing.

The following new or enhanced features apply to FORMIO, VITALIO, INGENIO, and/or ADVANTIO devices.

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.

- Indications-Based Programming (IBP): allows you to set up programming parameters based on the patient's clinical needs and indications.

- 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.

- PDF versions of reports are available.

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.

- PaceSafe RA Automatic Threshold: automatically performs atrial threshold testing every 21 hours and sets a 2:1 output safety margin.

- 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.

- RYTHMIQ: designed to reduce unnecessary right ventricular (RV) pacing for patients with intact atrioventricular (AV) conduction by providing mode switching between AAI(R) pacing with ventricular backup pacing rate support and DDD(R).

- 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.

- MRI Protection Mode: a device mode that modifies certain pulse generator functions in order to mitigate risks associated with exposing the pacing system to the MRI environment.

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

- Programmable Lead Impedance Limits for daily measurements: the Low Impedance Limit is programmable between 200 and 500 Ω.

- Snapshot: up to 6 unique traces of the ECG/EGM display can be stored at any time by pressing the Snapshot button. The traces are 10 seconds pre-activation and 2 seconds post-activation. A 10 second trace will automatically be stored at the end of Pace Threshold tests, which counts as one of the 6 snapshots.

- A counter for Total Time in AT/AF is provided.

- Trends: expanded set of trends is provided including:
  - Heart Rate
  - Respiratory Rate
  - AP Scan
  - AT/AF Burden (including total number of episodes)
  - Events

- Heart Rate Variability: heart failure diagnostics including HRV Footprint, SDANN, and ABM trends.

- 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.

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).

This guide may contain reference information for model numbers that are not currently approved for sale in all geographies. For a complete list of model numbers approved in your geography, consult with your local sales representative. Some model numbers may contain fewer features; for those devices, disregard descriptions of the unavailable features. Descriptions found within

this manual apply to all device tiers unless otherwise noted. References to names of non-MRI devices also apply to the corresponding MRI devices. References to “ICD” include all types of ICDs (e.g., ICD, CRT-D, S-ICD).

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.

LATITUDE NXT is a remote monitoring system that provides pulse generator data for clinicians. These pulse generators are designed to be LATITUDE NXT enabled; availability varies by region.

LATITUDE NXT is available for the following devices: ACCOLADE, PROPONENT, ESSENTIO MRI, FORMIO, VITALIO, INGENIO, and ADVANTIO.

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 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.

The following acronyms may be used in this manual:

A	Atrial
ABM	Autonomic Balance Monitor
AF	Atrial Fibrillation
AFR	Atrial Flutter Response
AGC	Automatic Gain Control
ALR	Automatic Lead Recognition
APP	Atrial Pacing Preference
AT	Atrial Tachycardia
ATP	Antitachycardia Pacing
ATR	Atrial Tachy Response
AV	Atrioventricular
BPEG	British Pacing and Electrophysiology Group
BTR	Brady Tachy Response
CPR	Cardiopulmonary Resuscitation
CRT-D	Cardiac Resynchronization Therapy Defibrillator
EAS	Electronic Article Surveillance
ECG	Electrocardiogram
EF	Ejection Fraction
EGM	Electrogram
EL	Extended Longevity
EMI	Electromagnetic Interference
EP	Electrophysiology; Electrophysiologic
HRV	Heart Rate Variability
IBP	Indications-Based Programming
IC	Industry Canada
ICD	Implantable Cardioverter Defibrillator
LRL	Lower Rate Limit
MI	Myocardial Infarction
MICS	Medical Implant Communication Service

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
POST	Post-Operative System Test
PRM	Programmer/Recorder/Monitor
PSA	Pacing System Analyzer
PTM	Patient Triggered Monitor
PVARP	Post-Ventricular Atrial Refractory Period
PVC	Premature Ventricular Contraction
RAAT	Right Atrial Automatic Threshold
RADAR	Radio Detection and Ranging
RF	Radio Frequency
RRT	Respiratory Rate Trend
RV	Right Ventricular
RVAC	Right Ventricular Automatic Capture
RVRP	Right Ventricular Refractory Period
SAM	Signal Artifact Monitor
SBR	Sudden Bradycardia Response
SCD	Sudden Cardiac Death
SDANN	Standard Deviation of Averaged Normal-to-Normal R-R intervals
S-ICD	Subcutaneous Implantable Cardioverter Defibrillator
SVT	Supraventricular Tachycardia
TARP	Total Atrial Refractory Period
TENS	Transcutaneous Electrical Nerve Stimulation
V	Ventricular
VF	Ventricular Fibrillation
VRP	Ventricular Refractory Period
VRR	Ventricular Rate Regulation
VT	Ventricular Tachycardia

TABLE OF CONTENTS

USING THE PROGRAMMER

CHAPTER 1

This chapter contains the following topics:

LATITUDE PROGRAMMING SYSTEM

The LATITUDE Programming System is the external portion of the pulse generator system.

The 3120 ZOOM LATITUDE Programming System includes:

- Model 3120 Programmer/Recorder/Monitor (PRM)
- Model 3140 ZOOM Wireless Transmitter
- Model 2869 ZOOMVIEW Software Application
- Model 6577 Accessory Telemetry Wand

The 3300 LATITUDE Programming System includes:

- Model 3300 Programmer
- Model 3869 Software Application
- Model 6395 Accessory Telemetry Wand

The 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 LATITUDE Programming 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
- Store a 12 second trace of the ECG/EGM display from any screen
- 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

You can program the pulse generator using two methods: automatically using IBP or manually.

For more detailed information about using the PRM or ZOOM Wireless Transmitter, refer to the PRM Operator's Manual or ZOOM Wireless Transmitter Reference Guide.

Refer to the 3300 Programming System's family of operator's manuals for specific information about the 3300 Programmer, its PSA, patient data management, and networking and connectivity.

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 Main Screen on page 1-3).

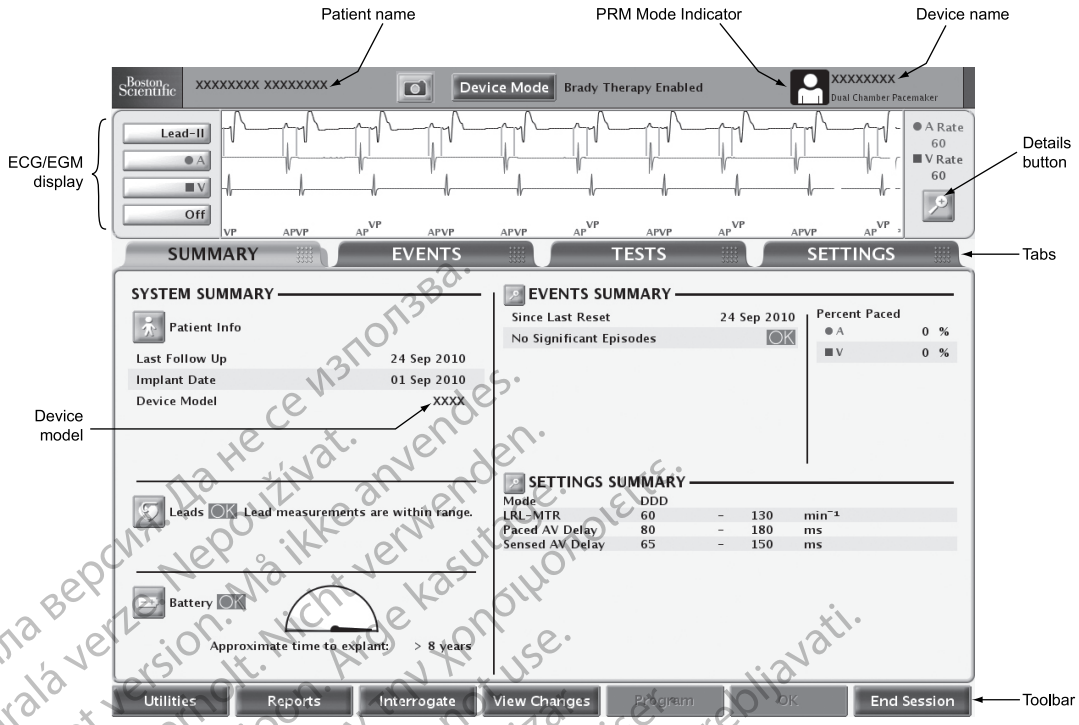


Figure 1–1. Main Screen

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).

- At any time, a 12 second trace of the ECG/EGM display can be stored by pressing the Snapshot button from any screen.

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
- Trace Speed—adjusts the speed of the trace (0, 25, or 50 mm/s). As the speed is increased, the time/horizontal scale is expanded
- Gain—adjusts the amplitude/vertical scale (AUTO, 1, 2, 5, 10, or 20 mm/mV) for each channel. As the gain is increased, the amplitude of the signal is enlarged

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.

Information—indicates information that is provided for reference.

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.

Snapshot—causes the programmer to store a 12 second trace of the ECG/EGM display from any screen.

POST Complete—opens the Reports window to print POST information on the Quick Notes or Follow-Up Reports.

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

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 available in ACCOLADE, PROPONENT, and ESSENTIO devices and operates with a transmit frequency of 402 to 405 MHz. ZIP telemetry is available in FORMIO, VITALIO, INGENIO, and ADVANTIO devices and operates with a transmit frequency of 869.85 MHz.

ZIP telemetry is a wandless, two-way RF communication option that allows the PRM system to communicate with these RF capable pulse generators.

- For ACCOLADE, PROPONENT, and ESSENTIO devices, RF communication is enabled by the ZOOM Wireless Transmitter unit connected to the PRM. When initiating communication, wanded telemetry is needed. When ZIP telemetry is ready for use, a message will display on the PRM screen indicating that the wand can be removed. Otherwise, the session will continue with wanded telemetry.
- For FORMIO, VITALIO, INGENIO, and ADVANTIO devices, 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

- Allows the physician to continue with the operating procedure while the device is being programmed for the patient

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. For ACCOLADE, PROPONENT, and ESSENTIO devices, verify that the ZOOM Wireless Transmitter is connected to the PRM via the USB cable and that the green light on top of the transmitter is illuminated (indicating the transmitter is ready for use).
2. 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.
3. 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 following ZIP Telemetry Security information applies to devices operating with a transmit frequency of 402 to 405 MHz.

The pulse generator contains 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 for the PRM is enabled
- The ZOOM Wireless Transmitter is connected to the PRM via the USB cable
- The indicator light on top of the ZOOM Wireless Transmitter is green; indicating the transmitter is ready 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
- Pulse generator is not in MRI Protection Mode

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–45°C (68°F–113° F).

Communication can be supported between multiple PRMs and pulse generators at a time, as independent sessions. Signals from other sessions using RF communication or interference from other RF sources may interfere with or prevent ZIP telemetry communication.

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 in the 869.85 MHz frequency band 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 due to interference or if the ZOOM Wireless Transmitter is unplugged or not functioning properly, 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
- The green indicator light on the ZOOM Wireless Transmitter is off
- If event markers and/or EGMs are activated, transmission of the event markers and/or EGMs will be 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 ZOOM Wireless Transmitter attached to the PRM or by 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, set the Communication Mode (accessed via the Utilities button) to use the wand for all telemetry.*

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 (or 73 minutes if the device was in Storage Mode at interrogation). Wanded telemetry must be used to re-establish communication with the pulse generator after this period has elapsed.*

Considerations for Reducing Interference

Increasing the distance from the source of interfering signals may enable the use of the ZIP telemetry channel.

Repositioning the ZOOM Wireless Transmitter may improve ZIP telemetry performance. If ZIP telemetry performance is not satisfactory, the option of using wanded telemetry is available.

Depending on the environment and PRM orientation relative to the pulse generator, the system is capable of maintaining ZIP telemetry communication at distances up to 3 m (10 ft). For optimum ZIP telemetry communication, position the ZOOM Wireless Transmitter within 3 m (10 ft) of the pulse generator and remove any obstruction between the ZOOM Wireless Transmitter and the pulse generator.

Positioning the ZOOM Wireless Transmitter 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.

Avoid placing the ZOOM Wireless Transmitter in close proximity to monitors, high-frequency electrosurgical equipment, or strong magnetic fields since the telemetry link may be impaired.

Ensuring there are no obstructions (e.g., equipment, metal furniture, people, or walls) between the ZOOM Wireless Transmitter and pulse generator may improve signal quality. Personnel or objects that momentarily move between the ZOOM Wireless Transmitter 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.

ZIP Telemetry Security

The following ZIP Telemetry Security information applies to devices operating with a transmit frequency of 869.85 MHz.

The pulse generator contains 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 for the PRM is enabled
- 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
- Pulse generator is not in MRI Protection Mode

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 one PRM and one pulse generator at a time. If there is a PRM–pulse generator communication session already occurring in the vicinity, a second 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 in the 869.85 MHz frequency band 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, set the Communication Mode (accessed via the Utilities button) to use the wand for all telemetry.*

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 (or 73 minutes if the device was in Storage Mode at interrogation). Wanded telemetry must be used to re-establish communication with the pulse generator after this 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.

INDICATIONS-BASED PROGRAMMING (IBP)

This feature is available in ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices.

IBP is a tool that provides specific programming recommendations based on the patient's clinical needs and primary indications.

IBP is a clinical approach to programming that was developed based on physician consultation and case studies. The intent of IBP is to enhance patient outcomes and save time by providing base programming recommendations that you can customize as needed. IBP systematically

presents the specific features intended for use with the clinical conditions you identify in the IBP user interface, and allows you to take maximum advantage of the pulse generator's capabilities.

IBP can be accessed from the Settings tab on the main application screen (Figure 1–2 Indications-based Programming screen on page 1-14).

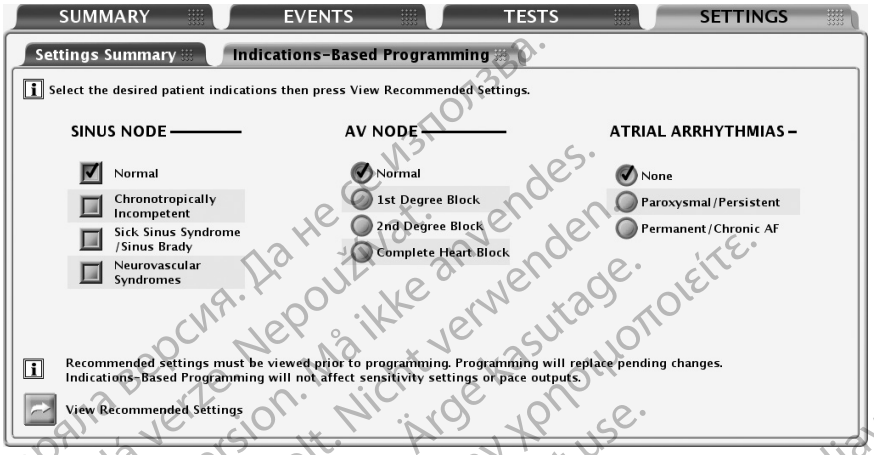


Figure 1–2. Indications-based Programming screen

Indications are clustered in general categories as illustrated above. The intent for each category of indications is described below:

- Sinus Node
  - If Normal is selected, the intent is to allow intrinsic atrial events and provide RV pacing when necessary.
  - If Chronotropically Incompetent is selected, the intent is to provide rate-adaptive pacing.
  - If Sick Sinus Syndrome is selected, the intent is to provide atrial pacing support.
  - If Neurovascular Syndromes is selected, the intent is to provide Sudden Brady Response.
- AV Node
  - If Normal or 1st Degree Block is selected, the intent is to allow intrinsic AV conduction and provide RV pacing when necessary.
  - If 2nd Degree Block is selected, the intent is to allow intrinsic AV conduction and provide AV sequential pacing when conduction is not present.
  - If Complete Heart Block is selected, the intent is to provide AV sequential pacing.

  NOTE: *The selected settings for AF and Sinus Node may affect the suggested value for the Normal/1st Degree Block setting of AV Node.*
- Atrial Arrhythmias
  - If Paroxysmal/Persistent is selected, the intent is to avoid tracking atrial arrhythmias by using ATR Mode Switch when a dual-chamber pacing mode is suggested.
  - If Permanent/Chronic AF is selected, the intent is to provide rate-adaptive RV pacing and set atrial sensing to Off.

After choosing appropriate patient indications, select the View Recommended Settings button to view a summary of the programming recommendations (Figure 1–3 Proposed Settings Summary screen on page 1-15).

NOTE: *You must view the recommended settings before you can program them. Selecting the View Recommended Settings button allows you to view the settings that are recommended based on the indications that you selected. Viewing the recommended settings does not overwrite any pending (i.e., not yet programmed) parameter changes. You must choose to program or reject the recommended settings after viewing them. If you choose to reject the recommended settings, all of your pending settings will be restored. If you choose to program the recommended settings, any pending parameter changes will be overwritten, with the exception of sensitivity and therapy outputs, which are independent of IBP.*

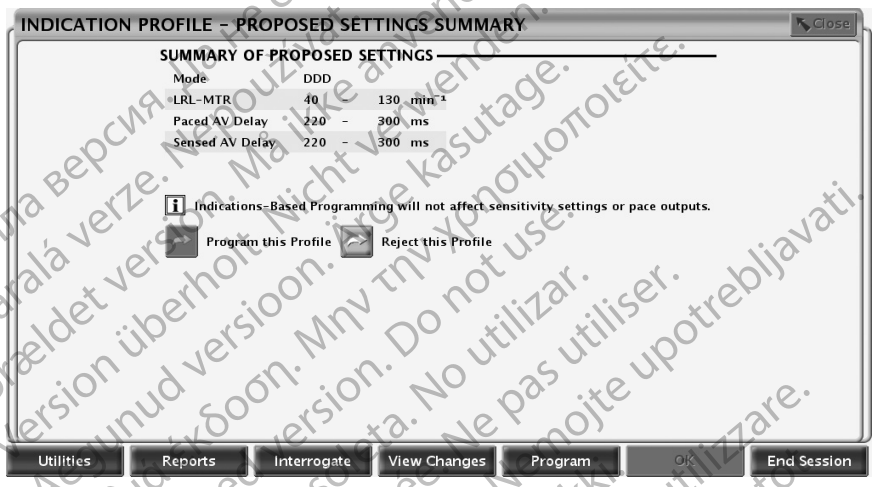


Figure 1–3. Proposed Settings Summary screen

The Proposed Settings Summary screen displays the primary programming recommendations. Additional details about all changed parameters are available by selecting the View Changes button from the toolbar. You have the option to program the proposed settings or reject them, as long as telemetry is still engaged:

- Program—select the Program this Profile button to accept the proposed settings.
- Reject—select the Reject this Profile button to reject the proposed settings; this action will return you to the main IBP screen with no changes made.

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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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

The DIVERT THERAPY key can also be used to terminate MRI Protection Mode.

STAT PACE

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 and MRI 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 STAT PACE Parameter Values on page 1-16).

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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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.*

NOTE: *The data entered for patient Sleep Schedule is used for the AP Scan trend.*

Data Storage

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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
- HRV
- 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. Reports are available in PDF format. 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 can be encrypted before it is transferred to a USB pen drive.

Device Memory

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 1-17).*

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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 for communicating with the PRM when Safety Mode is active; wanded telemetry must be used instead.
- LATITUDE NXT will alert that Safety Mode has been activated.
- 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.*

WARNING: If the pulse generator enters Safety Mode from MRI Protection Mode, backup pacing will not occur in the following scenarios:

- if a functional bipolar right ventricular pacing lead is not present
- if the Pacing Mode under MRI Protection Mode settings is programmed to Off; the pulse generator will continue permanently with the Pacing Mode programmed to Off, and the patient will not receive pacing therapy until the pulse generator is replaced

CAUTION: If the MR Conditional Pacing System enters Safety Core Operation during MRI Protection Mode and the pacing mode was set to a value other than Off, MRI Protection Mode pacing will be automatically switched to VOO mode, RV bipolar configuration (sensing and pacing), 5.0 V pace pulse amplitude, 1.0 ms pulse width, and 72.5 min^{-1} pacing rate as the safety mode.

PACING THERAPIES

CHAPTER 2

This chapter contains the following topics:

PACING THERAPIES

WARNING: During MRI Protection Mode, if Brady Mode is programmed to Off, Bradycardia therapy is suspended. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only program Brady Mode to Off during MRI Protection Mode if the patient is judged to be clinically capable of tolerating no Bradycardia therapy (including pacing-dependence or need for overdrive pacing) for the entire duration in which the pulse generator is in MRI Protection Mode.

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 activity levels and/or 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 2-25).
- STAT PACE—initiates emergency ventricular pacing at high output settings when commanded via the PRM using telemetry communication ("STAT PACE" on page 1-16).
- Electrocautery Protection—provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer ("Electrocautery Protection Mode" on page 2-3).
- MRI Protection—modifies certain pulse generator functions in order to mitigate risks associated with exposing the pacing system to the MRI environment ("MRI Protection Mode" on page 2-3).

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.

- MRI Protection Mode—modifies certain pulse generator functions in order to mitigate risks associated with exposing the pacing system to the MRI environment. 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 1-18).

Electrocautery Protection Mode

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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.

MRI Protection Mode

This feature is available in ACCOLADE MRI, PROPONENT MRI, ESSENTIO MRI, FORMIO MRI, VITALIO MRI, INGENIO MRI, and ADVANTIO MRI devices.

For a complete description of MRI Protection Mode, as well as additional information about the ImageReady MR Conditional Pacing System, refer to the ImageReady MR Conditional Pacing System MRI Technical Guide.

WARNING: ACCOLADE MRI, PROPONENT MRI, ESSENTIO MRI, FORMIO MRI, VITALIO MRI, INGENIO MRI, and ADVANTIO MRI devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the

patient and/or damage to the implanted system may result. *All other devices covered by this manual are not MR conditional.* Do not expose patients with non-MR Conditional devices to MRI scanning. Strong magnetic fields may damage the pulse generator and/or lead system, possibly resulting in injury to or death of the patient.

For additional warnings, precautions, Conditions of Use, and potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide.

MRI Protection Mode provides asynchronous pacing (or pacing Off) with the following fixed and programmable parameters:

- Pacing mode options include asynchronous pacing or no pacing (DOO, AOO, VOO, or Off).
- The Lower Rate Limit is nominally set to 20 min^{-1} above the starting LRL, and is programmable in normal increments. For both the nominal setting based on the LRL and the programmable setting, the maximum value is 100 min^{-1}.
- Atrial pulse amplitude and ventricular pulse amplitude are nominally set to 5.0 V and are programmable in normal increments between 2.0 V and 5.0 V.
- AV Delay is fixed at 100 ms.
- Pulse Width is fixed at 1.0 ms for both chambers.
- A Time-out feature is nominally set to 24 hours, with programmable values of Off, 3, 6, 9, 12, 24, and 48 hours.

When MRI Protection Mode is active, the following features and functions are suspended:

- PaceSafe
- Cardiac sensing
- Daily diagnostics (Lead Impedance, Intrinsic Amplitude, Pace Threshold)
- Motion and respiratory sensors
- Magnet Response
- ZIP Telemetry
- Battery voltage monitoring

The following device conditions will preclude the user from having the option to enter MRI Protection Mode:

- Battery capacity status is Depleted
- Pulse generator is in Storage Mode
- Pulse generator is in Electrocautery Protection Mode
- Pulse generator is in Safety Core operation (Safety Mode)
- Diagnostic test is in progress
- EP Test is in progress

Certain conditions in the pulse generator and/or system will cause a user request to enter MRI Protection Mode to be rejected. These include:

- A ventricular episode as detected and recognized by the pulse generator is in progress
- Magnet presence is detected by the magnet sensor
- Pulse generator is in STAT PACE mode
- Unipolar pacing configuration in the RA or RV chamber(s) where pacing will occur in MRI Protection Mode

MRI Protection Mode is terminated by manual exit or by setting a user-programmed automatic Time-out period (refer to the MRI Technical Guide for MRI Protection Mode programming instructions). STAT PACE and DIVERT THERAPY will also terminate MRI Protection Mode.

MRI Protection Mode is accessed via the Device Mode button. Choosing MRI Protection Mode will initiate a sequence of dialog boxes to assess the eligibility and readiness of the patient and the patient's pacing system to undergo an MR Conditional MRI scan. Detailed programming instructions, the Conditions for Use, and a comprehensive list of MRI-related warnings and precautions are provided in the MRI Technical Guide.

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 1-7).

Brady Mode

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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.

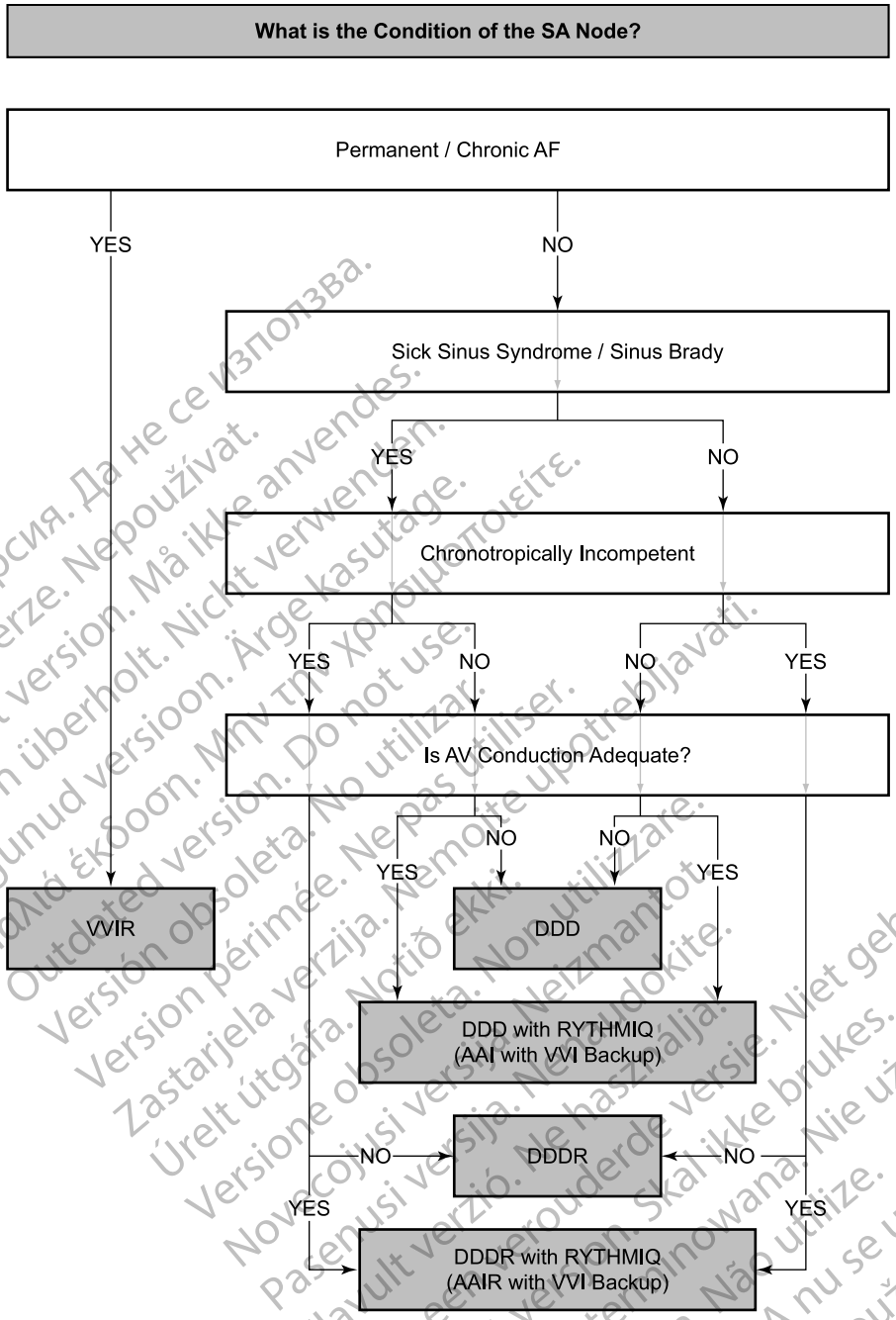


Figure 2–1. Optimal pacing mode decision tree

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)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 LRL timing transitions on page 2-9). 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.

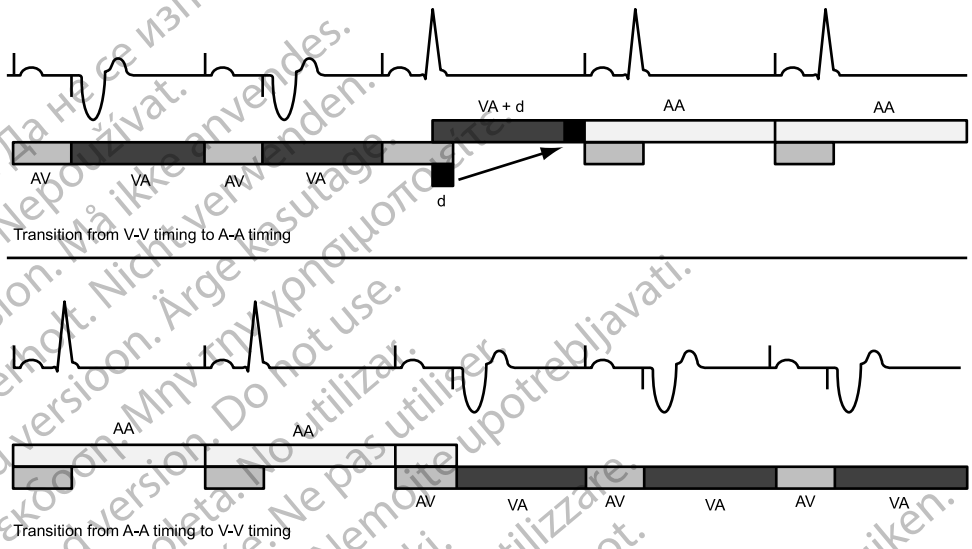


Illustration of timing transitions (d = the difference between AV Delay and the AV interval in the first cycle during which intrinsic conduction occurs. The value of d is applied to the next V–A interval to provide a smooth transition without affecting A–A intervals).

Figure 2–2. LRL timing transitions

Maximum Tracking Rate (MTR)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 Dynamic PVARP, 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 2-70).

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:

- AFR
- ATR
- APP/ProACt
- 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 Wenckebach behavior at MTR on page 2-10). 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).

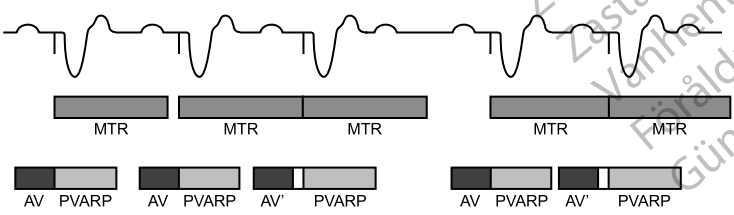


Figure 2–3. Wenckebach behavior at MTR

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 Pacemaker 2:1 block on page 2-11). 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.

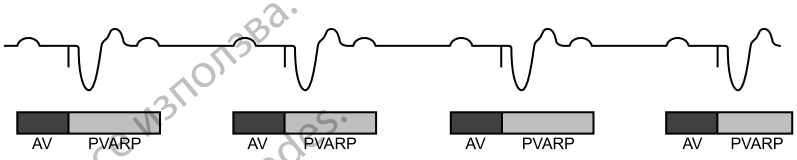


Illustration of pacemaker 2:1 block, in which every other P-wave falls inside the PVARP interval.

Figure 2–4. Pacemaker 2:1 block

Maximum Sensor Rate (MSR)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

MSR is the maximum pacing rate allowed as a result of rate-adaptive sensor control.

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

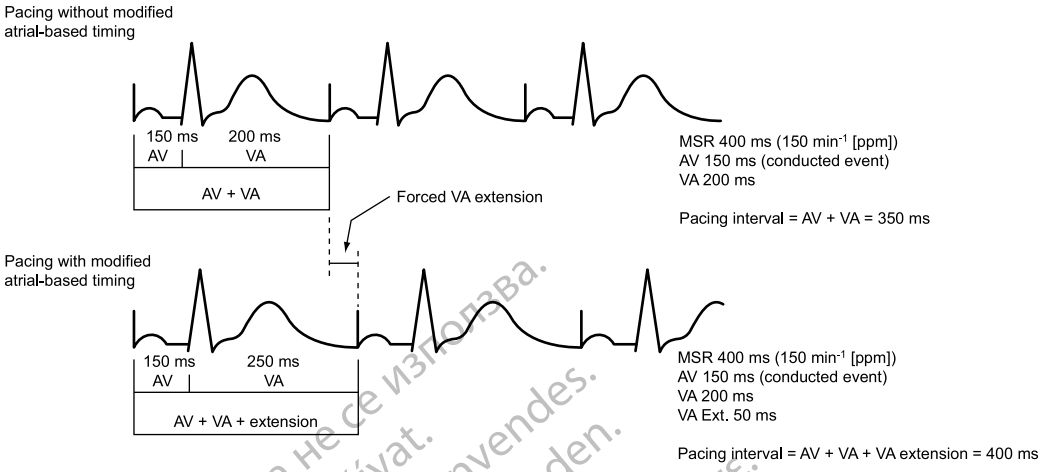
NOTE: *If the pulse generator is operating in DDDR or VDDR mode, the MSR and MTR may be programmed independently to different values.*

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 since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic PVARP to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.

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 VA interval extension and MSR on page 2-12).



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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 Pulse waveform on page 2-13).

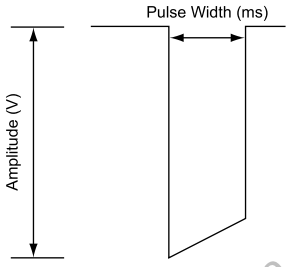


Figure 2–6. Pulse waveform

Amplitude

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

The pulse amplitude, or voltage of the output pulse, is measured at the leading edge of the output pulse (Figure 2–6 Pulse waveform on page 2-13).

Consider the following when programming Amplitude:

- Amplitudes are independently programmable for 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.
- The programmed Amplitude is recommended to be a minimum of 2X the capture threshold to provide adequate safety margin. Lower pace amplitudes will preserve/extend longevity. The programmed Amplitude should be a balance of adequate safety margin and effect upon battery longevity. If PaceSafe is programmed On, it will automatically provide an adequate safety margin and may help extend 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 Atrial Automatic Threshold (RAAT)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, and VITALIO devices.

PaceSafe RAAT is designed to dynamically adjust the atrial pacing output to ensure capture of the atrium by optimizing the output voltage to 2X the capture threshold to provide adequate safety margin (for thresholds less than or equal to 2.5 V). RAAT will measure pacing thresholds between 0.2 V and 4.0 V at 0.4 ms and the output will be a minimum of 2.0 V and a maximum of 5.0 V with a fixed pulse width of 0.4 ms.

NOTE: *To function properly, RAAT requires a functional RV lead and a bipolar atrial lead. It is important to indicate on the Patient Information screen that a bipolar lead is present, particularly if the Atrial Pace and Sense Lead Configurations are programmed to Unipolar.*

NOTE: *RAAT is only available in pulse generators programmed to DDD(R) and DDI(R) modes as well as DDI(R) Fallback Mode.*

RAAT can be programmed on by selecting Auto from the Atrial Amplitude parameter options. Programming the atrial output to Auto will automatically adjust the Pulse Width to 0.4 ms and set the atrial voltage output to an initial value of 5.0 V unless there is a successful test result within the last 24 hours.

NOTE: *Prior to programming RAAT on, consider performing a Commanded Atrial Automatic Threshold Measurement to verify that the feature functions as expected. RAAT testing is performed in a unipolar configuration and there may be a discrepancy between unipolar and bipolar thresholds. If the bipolar threshold is greater than the unipolar threshold by more than 0.5 V, consider programming a fixed Atrial Amplitude or programming the Atrial Pace Lead Configuration to Unipolar.*

RAAT is designed to work with typical lead implant criteria and an atrial threshold between 0.2 V and 4.0 V at 0.4 ms.

The RAAT algorithm then measures the atrial pacing threshold each day and adjusts the voltage output. During testing, RAAT measures an evoked response signal to confirm that each atrial pacing output captures the atrium. If the device is unable to repeatedly measure an evoked response signal of sufficient amplitude, a “Low ER” or “Noise” message may be displayed and the algorithm will default to 5.0 V pacing amplitude. Consider programming a fixed atrial pacing amplitude in these situations and re-check with a Commanded RAAT test at a later follow-up; maturation of the lead-tissue interface may improve the performance of RAAT.

If testing is successful, the Atrial Amplitude is adjusted to 2X the highest measured threshold of the last 7 successful ambulatory tests (output Amplitude between 2.0 V and 5.0 V). Seven tests are used to account for circadian cycle effects on threshold and ensure an adequate safety margin. This also allows for a rapid increase in output due to a sudden rise in threshold while requiring consistently lower threshold measurements to decrease output (i.e., one low threshold measurement will not cause a decrease in output) (Figure 2–7 Effect of threshold change on RAAT pacing output on page 2-14).

NOTE: *Since output is set to 2X the capture threshold to provide adequate safety margin and RV pacing occurs shortly after atrial pacing, there is no beat-to-beat capture verification or backup atrial pacing at any time.*

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

The RAAT feature is designed to operate with a large range of pacing leads (e.g., high impedance, low impedance, tined fixation, or positive fixation).

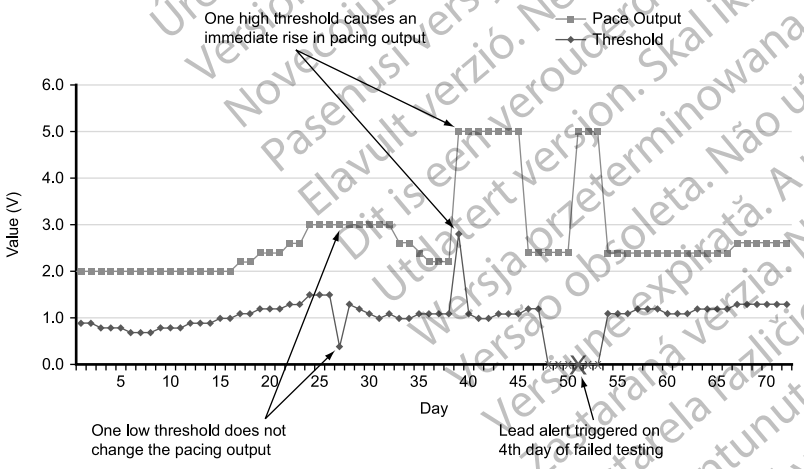


Figure 2–7. Effect of threshold change on RAAT pacing output

Ambulatory Atrial Automatic Threshold Measurement

Testing uses an RA tip >> can (unipolar) pacing vector and an RA ring >> can (unipolar) sensing vector whether the lead is programmed to Unipolar or Bipolar Pace/Sense.

When RAAT is set to Auto or Daily Trend, ambulatory atrial automatic threshold measurements are conducted every 21 hours and the following parameters are adjusted to ensure a valid measurement is obtained:

- Mode remains unchanged from current mode unless RYTHMIQ is on and in AAI(R) mode; in that case the mode will switch to DDD(R) for testing.
- Starting atrial pacing amplitude is the output that RAAT is currently using. If that Amplitude value fails or if no previous results are available, the starting Amplitude is 4.0 V.
- The pacing amplitude will decrement in 0.5 V steps above 3.5 V and in 0.1 V steps at or below 3.5 V.
- Paced AV Delay is fixed at 85 ms.
- Sensed AV Delay is fixed at 55 ms.
- Initial pacing rate is set to the average atrial rate, the LRL or sensor-indicated rate, whichever is faster.
- If there are an insufficient number of atrial paces or if fusion occurs, the atrial pacing rate will be increased by 10 min^{-1} (it may be increased a second time), but will not exceed the lowest of the MTR, MSR, MPR, 110 min^{-1}, or 5 min^{-1} below the VT Detection Rate.

Following initialization paces, the pulse generator will decrement the atrial output every 3 paces until a threshold is determined. If loss of capture occurs twice at a particular output level, threshold is declared as the previous output level that demonstrated consistent capture. If 3 captured beats occur at any particular output level, output decrements to the next level.

NOTE: *To ensure that loss of capture during RAAT does not encourage PMT (and also end the test prematurely due to too many atrial senses), the pulse generator uses a PMT algorithm. Following the loss of capture of any atrial beat, the PVARP following that ventricular event is extended to 500 ms to prevent tracking of a subsequent P-wave.*

If daily testing is unsuccessful, RAAT will return to the previously determined output and the pulse generator will 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 RAAT will enter Suspension.

Right Atrial Automatic Threshold Suspension

If ambulatory testing fails in Auto mode for 4 consecutive days, RAAT will go into a Suspension mode and the pacing output will operate at 5.0 V and 0.4 ms. Testing will continue each day with up to 3 re-attempts to evaluate thresholds and the pulse generator will adjust to a lower output setting when indicated by a successful test.

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

Commanded Atrial Automatic Threshold Measurement

An automatic threshold measurement can be commanded via the Threshold Tests screen by selecting Auto Amplitude as the Test Type. If testing completes successfully and RAAT is programmed on, the output will automatically be set to 2X that test's measured threshold (between 2.0 V and 5.0 V). The last 7 successful daily measurements are cleared and the current commanded test result is used as the first successful test of a new 7 test cycle. This is to ensure that there will be an immediate output adjustment based on the current commanded test result

rather than on older ambulatory test data. This can be confirmed by observing the output voltage on the Brady Settings screen, which will show the actual operating voltage of the RAAT algorithm.

If testing is unsuccessful, the Threshold Tests screen will display a failure code indicating the reason the test was not successful, and the output will return to the previously set level (Table 2–1 Threshold Test Codes on page 2-16).

NOTE: *For the initial Atrial 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.*

NOTE: *Commanded testing requires a functional bipolar atrial lead and may be performed in AAI mode.*

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 threshold test does not complete successfully. Threshold Test Failure Codes are listed below (Table 2–1 Threshold Test Codes on page 2-16).

The following scenarios will trigger the Check Atrial Lead alert:

- Threshold > Programmed Amplitude will be displayed if RAAT is in Daily Trend mode and the ambulatory test results of the last 4 consecutive days exceed the manually programmed fixed output.
- Automatic Threshold Suspension will be displayed if no successful tests are performed for 4 consecutive days in Auto or Daily Trend mode.

Table 2–1. Threshold Test Codes

Code	Reason
N/R: device telem.	Telemetry started during an ambulatory test
N/R: comm. lost	Telemetry was lost during a commanded test
N/R: no capture	Capture was not obtained at the starting amplitude for a commanded test or capture is > 4.0 V for an ambulatory test
N/R: mode switch	ATR mode switch either started or stopped
N/R: fusion events	Too many consecutive or too many total fusion events occurred
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 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	Incompatible Brady mode was present (e.g. VDI Fallback Mode, Magnet Mode) or a Lead Safety Switch occurred
N/R: rate too high	Rate was too high at the start of the test, a rate increase would raise the rate too high or more than 2 rate increases were required

Table 2–1. Threshold Test Codes (continued)

Code	Reason
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, MRI Protection Mode, or RAAT was turned on while the device remained in Storage mode
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

PaceSafe Right Ventricular Automatic Capture (RVAC)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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. RVAC will measure pacing thresholds 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 on 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.

For information about resumption of RVAC after exit from MRI Protection Mode, refer to the MRI Technical Guide.

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 and will decrement in 0.1 V steps.
- 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 and will decrement in 0.1 V steps.
- 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 fusion (which could potentially be a noise 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 2–2 Pacing output during Automatic Capture Suspension on page 2-19). 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 2–2. 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 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 2–3 Threshold Test Failure Codes on page 2-20).

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 2–3 Threshold Test Failure Codes on page 2-20).

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 2–3. 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, MRI Protection Mode, or RVAC was turned on while the device remained in Storage mode
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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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)

CAUTION: 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.

NOTE: *Use of VDD leads is inconsistent with the Conditions of Use required for MR Conditional status. Refer to the MRI Technical Guide for warnings, precautions, and other information about MRI scanning.*

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: *Consider using Fixed Sensing instead of AGC for patients who are pacemaker-dependent or have leads programmed to unipolar.*

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 2-76).*

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 2–8 AGC sensing on page 2-24).

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 2-72).

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 2–8 AGC sensing on page 2-24):

- 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.*

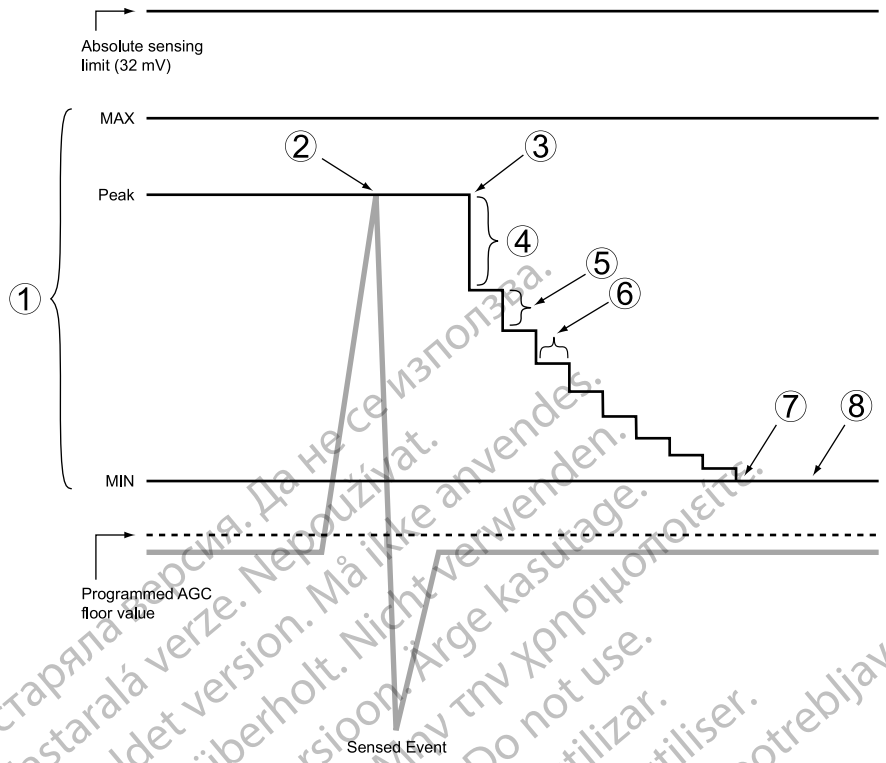


Figure 2–8. AGC sensing

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 2-79).

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 2-79). 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, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, 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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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

   NOTE: *Temporary Brady interactive limits must be corrected before Temporary pacing 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.

MINUTE VENTILATION / RESPIRATORY SENSOR AND SIGNAL ARTIFACT MONITOR

Minute Ventilation/Respiratory Sensor (MV/Respiratory Sensor)

The PG uses the Minute Ventilation (MV)/Respiratory Sensor to measure transthoracic impedance. The resulting transthoracic impedance measurements are used for two purposes:

- To collect respiration-related data for use in generating trends, such as the Respiratory Rate trend.
- To measure minute ventilation (MV), the product of respiration rate and tidal volume. MV can be used to increase the pacing rate to meet the patient's corresponding physiologic need. Refer to Minute Ventilation ("Minute Ventilation" on page 2-37) for more information.

ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices include the Respiratory Rate trend and MV rate responsive pacing. On the programmer screen, the sensor is referred to as the Minute Ventilation or MV Sensor, and it is programmable from the Brady Settings screen and the Minute Ventilation Sensor Details screen (Figure 2–10 Minute Ventilation Sensor Details on page 2-29).

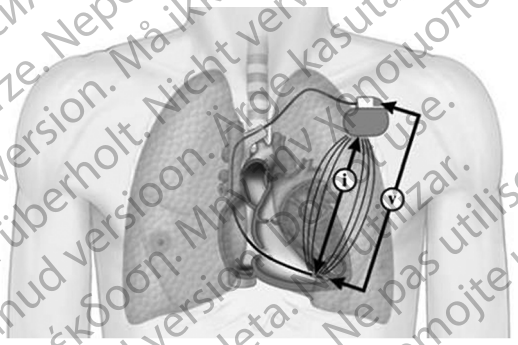
ESSENTIO, ALTRUA 2, and ADVANTIO devices include MV rate responsive pacing. On the programmer screen, the sensor is referred to as the Minute Ventilation or MV Sensor, and it is

programmable from the Brady Settings screen and the Minute Ventilation Sensor Details screen (Figure 2–10 Minute Ventilation Sensor Details on page 2-29).

When the MV/Respiratory Sensor is programmed to On or Passive (MV), approximately every 50 ms (20 Hz), the device will deliver a subthreshold excitation current waveform between the RA or RV Ring electrode and Can (the MV/Respiratory Sensor signal).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 measures the resulting voltage modulations between the lead tip electrode and the Can.

NOTE: *If an RA lead is not used, only the RV vector is available.*

NOTE: *Leads may be programmed to Unipolar or Bipolar, but a functioning bipolar lead must be present.*



i represents excitation output (current), V represents measurement of resulting voltage (volts)

Figure 2–9. Measurement of transthoracic impedance using the RV lead

When the RA/RV pacing leads and lead terminal connections are operating as intended, the MV/Respiratory Sensor signal is appropriately filtered and therefore is not detected by the pacemaker or displayed on electrograms (EGMs). However, intermittency related to integrity of the lead or pacemaker-lead connection has the potential to create a transient high impedance condition. A high impedance condition may result in the MV/Respiratory Sensor signal becoming visible on EGMs and potentially subject to oversensing on the RA and/or RV channels.

The MV/Respiratory Sensor provides two mechanisms for measuring the integrity of the sensor vectors (ring to Can and tip to Can):

- When the Signal Artifact Monitor (SAM) device diagnostic is programmed to On, the SAM continually monitors the EGM for sensor artifacts. For details, see "Device Behavior when SAM is On" on page 2-29.

- When the SAM is programmed to Off, the device performs MV/Respiratory Sensor vector impedance measurements approximately every hour to assess lead and lead connection integrity. For details, see "Device Behavior when SAM is Off" on page 2-30.

CAUTION: For maximum sensitivity in detecting and preventing potential signal artifact-generated oversensing, it is recommended that the Signal Artifact Monitor (SAM) is programmed On any time the MV/Respiratory Sensor is programmed to On or Passive. Turning the Signal Artifact Monitor Off may put the patient at increased risk of oversensing, unless the MV/Respiratory Sensor is also programmed Off.

MV/Respiratory Sensor Programmable Parameters

The following parameters for the MV/Respiratory Sensor are programmable.

For devices where MV rate responsive pacing is available, the MV Sensor can be programmed to On, Passive, Off, or ATR Only:

- On: enables RightRate pacing and respiration-related trending. If the device is programmed to a non-rate adaptive mode, the On setting is not available.
- Passive: enables respiration-related trending only.
- ATR Only: enables rate responsive pacing only during ATR Fallback. 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.
- Off: no rate-responsive pacing or respiration-related trending is available.

Excitation Current controls the amplitude of the MV/Respiratory Sensor signal and can be set to 80uA or 320uA.

Vector Selection controls how the active MV/Respiratory Sensor vector is determined by the device, and can be set to:

- A Only: the MV/Respiratory Sensor is restricted to RA vectors.
- RV Only: the MV/Respiratory Sensor is restricted to RV vectors.
- Auto Select: either A or RV will be automatically determined by the device. The vector selection behavior when set to Auto Select depends on whether the Signal Artifact Monitor is On or Off. Refer to SAM Device Diagnostic ("Signal Artifact Monitor Device Diagnostic" on page 2-28) for more details.

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

- Inappropriate MV Sensor-driven rate
- Misleading respiration-based trending

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:
  - Inappropriate MV Sensor-driven rate (up to maximum sensor-driven rate)
  - Misleading respiration-based trending

To resolve suspected interactions with MV rate driving and/or MV/Respiratory Sensor-based diagnostics, deactivate the MV/Respiratory Sensor by programming it to Off. 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.

MV/Respiratory Sensor Status

The MV/Respiratory Sensor initiates calibration when initially activated after device implant and after sensor suspension due to noise or other conditions. Refer to additional information about

calibration in "Minute Ventilation" on page 2-37. The status of the sensor is indicated by the appropriate MV/Respiratory Sensor status message, as summarized in MV/Respiratory Sensor Status Messages (Table 2–4 MV/Respiratory Sensor Status Messages on page 2-28). Sensor status is reported on the Minute Ventilation Sensor Details screen (devices with MV rate responsive pacing (Figure 2–10 Minute Ventilation Sensor Details on page 2-29)) or Respiratory Sensor Details screen (devices without MV rate responsive pacing).

The messages are all updated in real-time for ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices. The messages of Suspended: Noise Detected, Suspended: Telemetry, and Rate Hold: Telemetry are updated real-time while the remainder are updated upon interrogation for FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

Table 2–4. MV/Respiratory Sensor Status Messages

Sensor Status	MV Sensor Driven Pacing	MV/Respiratory Sensor Data Collection for Trending[a]
Off	No	No
Initializing (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices)	No	No
Auto Calibration in Progress	No	Yes
Calibrated	Yes[b]	Yes
Suspended	No	No
Suspended: No Valid Lead (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices)	No	No
Suspended: Noise Detected	No	Yes
Suspended: Telemetry	No[c]	Yes
Disabled by device diagnostic	No	No
Rate Hold: Telemetry	No[c d e]	Yes
Manual Calibration in Progress	No[e]	Yes

a. Individual Trends determine if data collected during Suspension is valid and incorporated into Trend results.
b. If the MV/Respiratory Sensor is programmed to Passive, MV/Respiratory Sensor-driven pacing will not occur.
c. Inductive (wanded) telemetry may interfere with the device's MV/Respiratory sensor function. MV driven pacing rates may hold at the current rate and Respiratory Rate Trend data collection is suspended for approximately one minute immediately following any interrogation or programming command (Rate Hold). Longer delays (up to several minutes) will be indicated by a status of Suspended: Telemetry. 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.
d. 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.
e. Status applies to MV rate responsive pacing devices only.

Signal Artifact Monitor Device Diagnostic

The Signal Artifact Monitor (SAM) is a device diagnostic that monitors the EGM for MV/Respiratory Sensor signal artifacts and measures MV/Respiratory Sensor vector lead impedance values. If artifacts are detected or a MV/Respiratory Sensor vector lead impedance value is out of range, SAM either switches the MV/Respiratory Sensor vector, or disables the sensor (Figure 2–10 Minute Ventilation Sensor Details on page 2-29). In addition, an episode is created that includes EGMs and diagnostic lead impedance data.

The SAM is nominally On when MV/Respiratory Sensor is programmed to On or Passive (MV). Signal artifacts can be generated when the MV/Respiratory Sensor is set to any value except Off. Therefore, it is recommended to keep SAM On unless the MV/Respiratory Sensor is programmed to Off. Recommended SAM Settings are listed below (Table 2–5 Recommended Signal Artifact Monitor (SAM) Settings on page 2-29).

CAUTION: Turning the Signal Artifact Monitor Off may put the patient at increased risk of oversensing, unless the MV/Respiratory Sensor is also programmed to Off.

Table 2–5. Recommended Signal Artifact Monitor (SAM) Settings

MV Sensor Setting	Possible to generate Signal Artifact	Recommended SAM Setting
On	Yes	On
Passive	Yes	On
ATR Only	Yes	On
Off	No	N/A

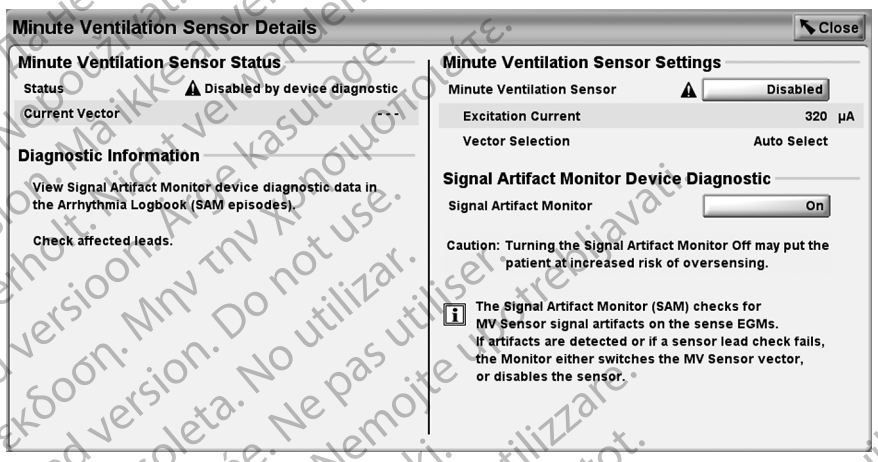


Figure 2–10. Minute Ventilation Sensor Details

Device Behavior when SAM is On

The SAM continuously monitors the EGM for MV/Respiratory Sensor signal artifacts that may result in oversensing. At the time of artifact detection, impedance values for the MV/Respiratory Sensor vectors are measured, and paced lead impedances are also measured. A SAM episode is created that records the EGM with artifact and all associated vector and lead impedance values.

Depending on the setting of the MV/Respiratory Sensor Vector Selection parameter, two outcomes are possible (as described in Table 2–6 Result of EGM artifact detection by SAM on page 2-30):

- The active sensor vectors switch from A to V, or
- The sensor is disabled by SAM.

NOTE: *Impedance measurements recorded by SAM are independent of daily lead impedance measurements. They do not appear on the daily lead impedance trend graphs and will not trigger Lead Safety Switch (Refer to "Lead Safety Switch" on page 2-65).*

Table 2–6. Result of EGM artifact detection by SAM

If MV/Respiratory Sensor Vector Selection is set to	And the active vector was	Device response to EGM artifact being detected
Auto Select	A	SAM episode created Measure MV/Respiratory Sensor RV vector's impedance values: • **If in range**: Switch the active sensor vector to RV[a b] • **If out of range**: second SAM episode created and MV/Respiratory Sensor is Disabled
Auto Select	RV	**SAM episode created and MV/Respiratory Sensor Disabled**
A Only	A	
RV Only	RV	

a. If a MV/Respiratory Sensor vector switch occurs, an automatic 6-hour calibration will occur (no MV rate responsive pacing occurs during the 6-hour calibration period).
b. Acceptable MV/Respiratory Sensor vector impedance values are 100-1500 Ω for the ring to Can vector and 200-2000 Ω for the tip to Can vector. These values are not affected by impedance alert limits programmed for Daily lead impedance measurements.

During a programmer session, active monitoring for artifacts is not performed. However, programming the MV/Respiratory Sensor settings may trigger a sensor vector impedance measurement. If the resulting MV/Respiratory Sensor vector impedance is out of range, a SAM episode is created, and the sensor vector may be switched or the sensor may be disabled depending on vector selection settings.

A disabled MV/Respiratory Sensor will remain in that state until manually reprogrammed from the MV Sensor Details screen (Figure 2–10 Minute Ventilation Sensor Details on page 2-29). No MV rate-responsive pacing and no respiratory-related trending will occur while the sensor is disabled.

Device Behavior when SAM is Off

If SAM is programmed to Off, MV/Respiratory Sensor vector impedance measurements are performed hourly (Table 2–7 Device response to out-of-range impedance value found during hourly lead check on page 2-30). When the Vector Selection parameter is set to Auto Select, if the measured impedance for the currently utilized vector (for example, RA) is out of range, the impedance for the alternate vector (for example, RV) is evaluated to determine if that vector can be utilized. If the measured impedance for the alternate vector is in range, then the alternate vector becomes the active vector. If both vectors are out of range, the sensor is suspended for one hour. Lead integrity will continue to be tested every hour to evaluate if the MV/Respiratory Sensor can resume using one of the vectors or remain suspended. If a MV/Respiratory Sensor vector switch occurs, an automatic 6-hour calibration will occur (no MV rate responsive pacing occurs during the 6-hour calibration period).

Table 2–7. Device response to out-of-range impedance value found during hourly lead check

If MV/Respiratory Sensor Vector Selection is set to	And the active vector is	Then the device response to an out-of-range impedance is
Auto Select	A or RV	Switch to the alternate vector if alternate vector impedance is in range[a] If the alternate vector impedance is out of range, the MV/Respiratory Sensor is suspended, re-test after one hour
A Only	A	MV/Respiratory Sensor suspended, re-test after one hour
RV Only	RV	

a. If a MV/Respiratory Sensor vector switch occurs, an automatic 6-hour calibration will occur (no MV rate responsive pacing occurs during the 6-hour calibration period).

Unlike when SAM is programmed to On, no monitoring for EGM artifacts occurs and no SAM episodes are created.

Signal Artifact Monitor Episodes

SAM episode details are recorded in the Arrhythmia Logbook ("Arrhythmia Logbook" on page 4-2). To view SAM episode details, select the desired episode on the Arrhythmia Logbook screen. The Event Summary screen displays details about the SAM episode (Figure 2–11 Signal Artifact Monitor Episode Summary on page 2-31).

The Summary tab provides a link to the screen where sensor details are found. The screen displays programming options for the MV/Respiratory Sensor and SAM (Figure 2–10 Minute Ventilation Sensor Details on page 2-29). Refer to MV/Respiratory Sensor Programmable Parameters ("MV/Respiratory Sensor Programmable Parameters" on page 2-27) for more information on programming options.

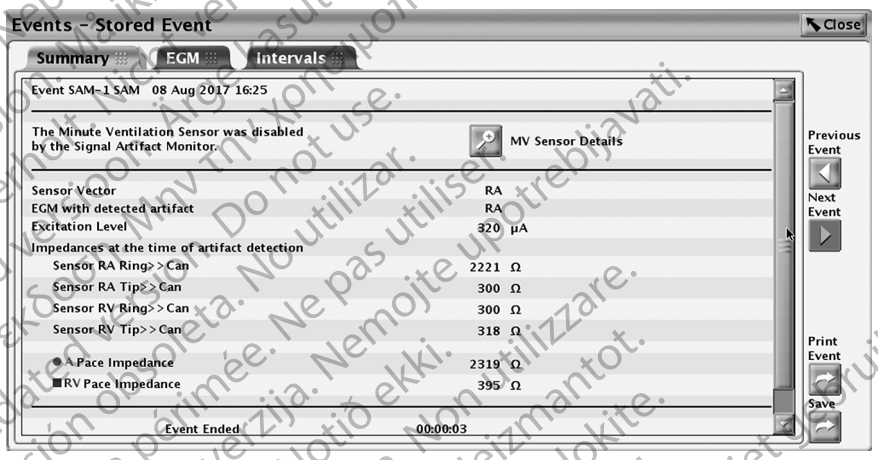


Figure 2–11. Signal Artifact Monitor Episode Summary

Two types of SAM episodes can be generated; MV/Respiratory Sensor Disabled, or MV/Respiratory Sensor Vector Switched. Both types include an EGM, as well as impedance values recorded at the time of episode creation for:

- Available MV/Respiratory Sensor vectors
- Pacing Leads

NOTE: *For VDD devices, MV/Respiratory Sensor does not operate on the RA lead and impedances for the RA sensor vector are not available in the SAM Episode.*

The EGM tab displays the EGM recorded at the time of SAM episode creation. When device conditions result in the sensor excitation signal being detected on the sense channel, the signal artifact is visible on the corresponding trace as a regular, rapidly repeating (20 Hz) pattern of peaks that may resemble non-physiologic noise (Figure 2–12 Signal Artifact Monitor Episode EGM on page 2-32). The amplitude and duration of the sensor signal artifact on the EGM can be variable, and may be modulated by postural, respiratory, or cardiac motion.

Some SAM episodes may generate EGMs with no visible signal artifact. This is the expected behavior when the sensor vector impedance measurement was triggered by something other than a detected signal artifact. For example, when SAM is On and the MV/Respiratory Sensor setting is changed from Off or Disabled to On or Passive, a sensor vector impedance measurement is triggered. If out-of-range impedance(s) are detected, a SAM episode will be created.

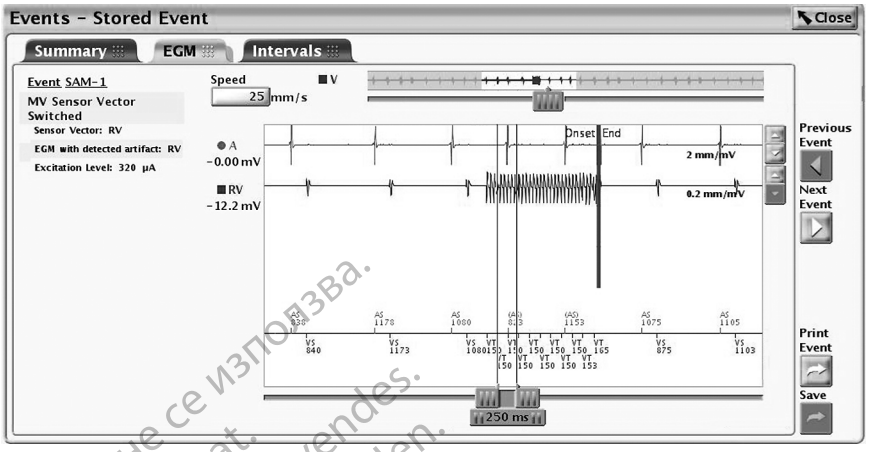


Figure 2–12. Signal Artifact Monitor Episode EGM

Signal Artifact Monitor Episode Data and Programming Considerations

SAM episode data (impedance values for the individual sensor vectors) may help in determining the source of transient high impedance conditions. In general, transient high impedance conditions may be caused by a lead conductor fracture, under-insertion of the lead terminal, or axial/radial motion of the lead terminal's ring electrode within the pacemaker header.

When the MV/Respiratory Sensor is disabled by the SAM:

- From the Leads Status Summary screen ("Leads Status" on page 3-6), check for transient high impedance conditions or significant changes over time in the daily lead impedance measurements.
- Perform lead testing from the Lead Tests screen ("Lead Tests" on page 3-10).

If a problem with the lead is suspected, to reduce the potential for MV/Respiratory Sensor signal artifact-generated oversensing, consider programming to the opposite Vector Selection parameter, or programming the MV/Respiratory Sensor to Off.

If daily lead impedance measurements and lead impedance trends look normal, consider the patient's need for MV/Respiratory Sensor-associated trends and/or MV rate responsive pacing. If not needed, turn the MV/Respiratory Sensor Off and continue to monitor the lead.

If respiration-related trend data and/or MV rate responsive pacing is desired, keep the SAM programmed to On. The Minute Ventilation Sensor Details screen may be used to adjust the MV/Respiratory Sensor Vector Selection parameter to use the opposite lead (Figure 2–10 Minute Ventilation Sensor Details on page 2-29). The Excitation Current controls the amplitude of the MV/Respiratory Sensor signal and can also be adjusted. Programming the Excitation Current to 80uA may reduce the amplitude of excitation pulses if they appear on the EGM, thereby decreasing the likelihood of artifacts being oversensed. However, a lower excitation pulse amplitude has the potential to result in more frequent suspension of the MV/Respiratory Sensor due to external noise interfering with the sensor's function.

For a more detailed discussion of Vector Selection and Excitation Current programming, please contact Boston Scientific using the information on the back cover.

All programming decisions should be based on the individual patient's indications and therapy needs.

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 activity level and/or 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 activity level and/or 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 a previous clinical study.

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 activity level and/or 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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 2–13 Response Factor and paced rate on page 2-34).

- 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

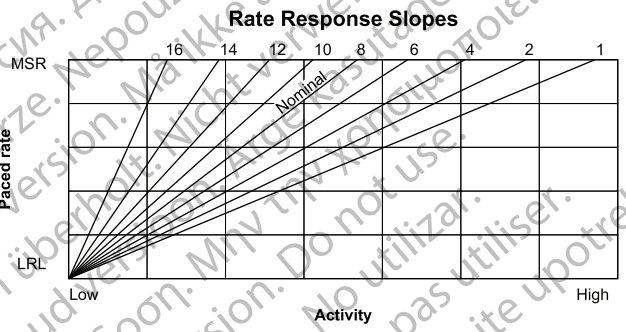
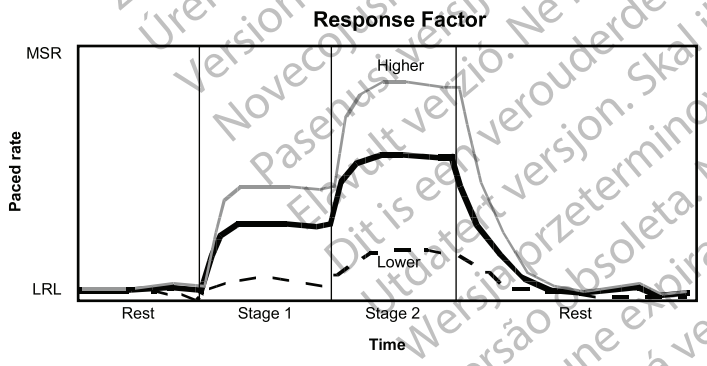


Figure 2–13. Response Factor and paced rate

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 2–14 Response Factor in exercise test on page 2-34). 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 2–14. 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 2–15 Activity Threshold and rate response on page 2-35 and Figure 2–16 Activity Threshold in exercise test on page 2-35).

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

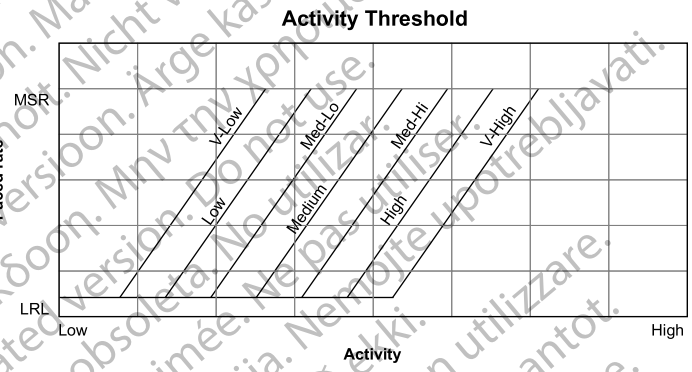
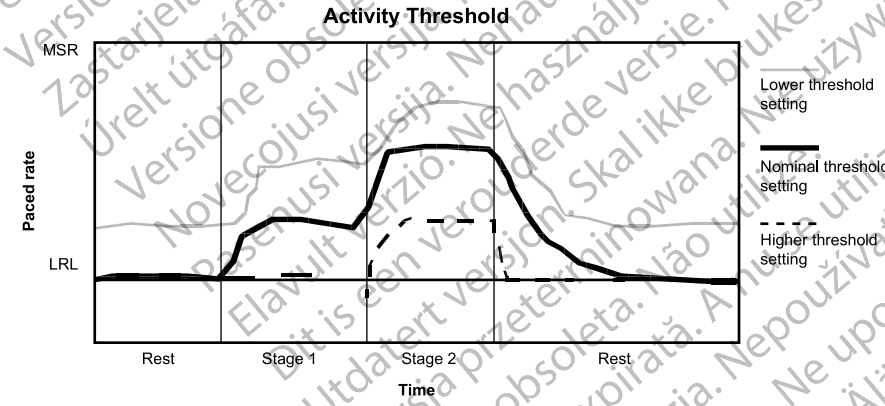


Figure 2–15. Activity Threshold and rate response



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

Figure 2–16. 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 2–17 Reaction Time and paced rate on page 2-36 and Figure 2–18 Reaction Time in exercise test on page 2-36).

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

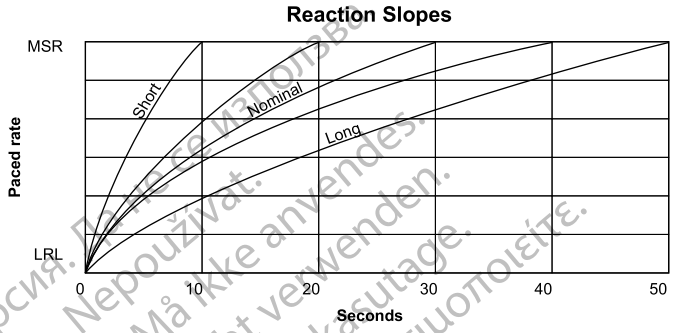


Figure 2–17. Reaction Time and paced rate

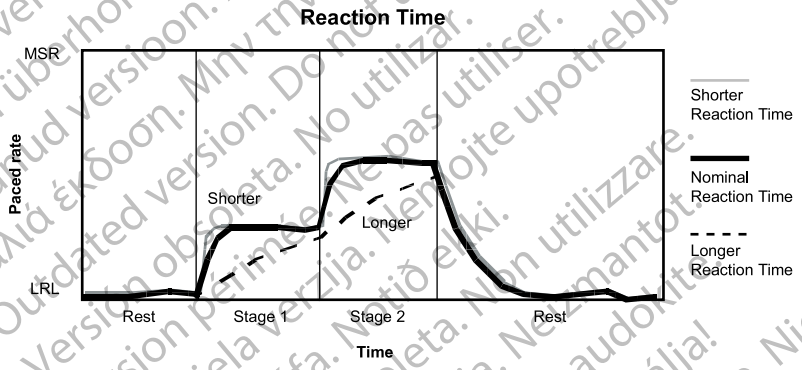
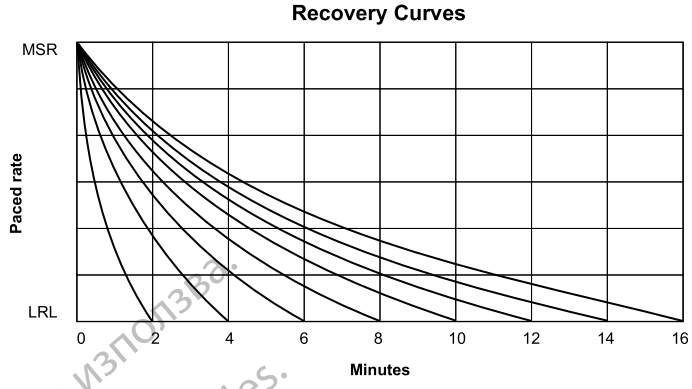


Figure 2–18. Reaction Time in exercise test

Recovery Time

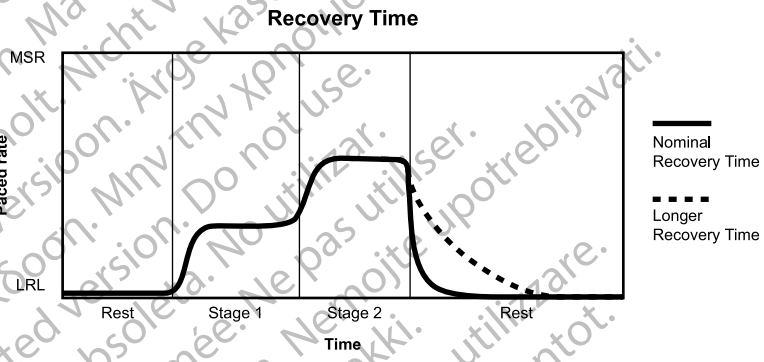
Recovery Time determines the time required for the paced rate to decrease from the MSR to the LRL in the absence of activity. When patient activity concludes, Recovery Time is used to prevent an abrupt decrease in pacing rate (Figure 2–19 Recovery Time and paced rate on page 2-37 and Figure 2–20 Recovery Time in exercise test on page 2-37).

- 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 2–19. Recovery Time and paced rate



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

Figure 2–20. Recovery Time in exercise test

Minute Ventilation (MV)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

The pulse generator uses the Minute Ventilation/Respiratory Sensor to evaluate transthoracic impedance and 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 pacing rate.

For a detailed description of Minute Ventilation/Respiratory Sensor function, refer to Minute Ventilation/Respiratory Sensor ("Minute Ventilation/Respiratory Sensor" on page 2-25). To enable MV-driven pacing, the pacing mode must be set to a rate-adaptive mode (any mode ending in R), and the Minute Ventilation/Respiratory Sensor must be programmed to On.

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.

CAUTION: For patients with respiratory disorders or abnormal breathing patterns, the physician should use medical judgment when programming the MV Sensor to On. To mitigate inappropriate sensor-driven rates, the physician may evaluate the rate response and consider a lower Response Factor.

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

- Inappropriate MV Sensor-driven rate
- Misleading respiration-based trending

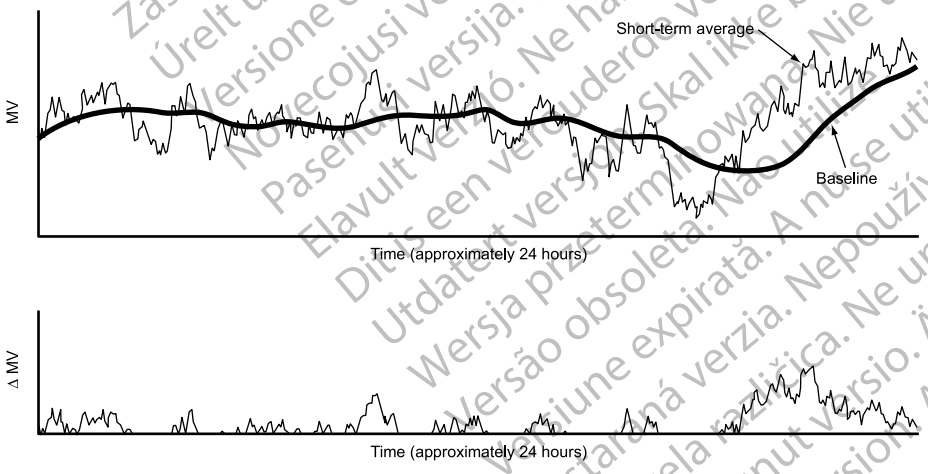
CAUTION: Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.

- External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may cause:
  - Inappropriate MV Sensor-driven rate (up to maximum sensor-driven rate)
  - Misleading respiration-based trending

To resolve suspected interactions with MV rate driving and/or MV/Respiratory Sensor-based diagnostics, deactivate the MV/Respiratory Sensor by programming it to Off. 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.

MV Rate Response Algorithm

The pulse generator keeps a long-term moving average (baseline) of these MV measurements (updated every 4 minutes) as well as a short-term (approximately 30-second) moving average, which is updated every 7.5 seconds. The difference between the short-term average and long-term baseline is used to determine the magnitude of the rate increase over the LRL, or decrease down to the LRL. Following a period of exertion and high MV rate drive, the patient's short-term average will decrease and eventually drop below the baseline. As it decreases, the MV Sensor-indicated rate decreases down to the LRL. The increase or decrease in the sensor-indicated rate occurs at a maximum of 2 min^{-1} per cycle (Figure 2–21 Difference between MV short-term average and MV baseline on page 2-38). The algorithm supports breathing rates up to 72 min^{-1}.



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 2–21. 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.*

To activate the MV Sensor, the system needs a measure of the baseline or resting MV (Sensor calibration). Methods for calibration include Manual and Automatic calibration.

Automatic Calibration

An automatic, 6-hour calibration will occur whenever MV is programmed to On or Passive. No MV-driven rate response or lead integrity checks will occur during the 6-hour calibration time.

- For ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices, at implant, either the first sensor lead integrity check with acceptable lead impedance values or an uncompleted Manual Calibration will begin a 2-hour wait period followed by the 6-hour calibration. This 2-hour period will be indicated by a sensor status of Initializing and is intended to allow the implantation procedure to be completed.

- For FORMIO, VITALIO, INGENIO, and ADVANTIO devices, 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.

NOTE: *If MV is programmed to On or Passive at the time of entry into MRI Protection Mode, upon exit from MRI Protection Mode, an automatic 6–hour calibration will begin. If MV-driven rate response is desired sooner, a manual calibration can be performed.*

Manual Calibration

Whenever MV is programmed On, the sensor can be calibrated manually. From the RightRate Pacing Details screen, select the Start Sensor Calibration button to initiate the Manual calibration process. 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.

- For ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices, when Manual calibration is initiated, a sensor lead integrity check is performed.

- For FORMIO, VITALIO, INGENIO, and ADVANTIO devices, when Manual calibration is initiated, a sensor lead integrity check is performed if the sensor status is currently Suspended. Otherwise, Manual calibration starts using the current MV vector.

If a sensor lead integrity check is performed, Manual calibration starts on the first MV vector with in-range impedances. If an MV vector with in-range impedances cannot be found, Manual calibration fails due to no valid MV lead vector.

The possible results of the Manual calibration and the corresponding MV behavior are described in Table 2–8 Manual Calibration Results on page 2-40 as follows:

Table 2–8. Manual Calibration Results

Manual Calibration Result	MV Behavior
Successful calibration	MV-driven rate response takes effect within one minute.
Calibration fails due to no valid MV lead vector	If SAM is On: • SAM episode(s) are created. • The MV Sensor is disabled. • The sensor status is Disabled by device diagnostic. If SAM is Off: • For ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices, the sensor status is Suspended: No Valid Lead. • For FORMIO, VITALIO, INGENIO, and ADVANTIO devices, the sensor status is Suspended. • The pulse generator checks hourly for a valid vector and starts the 6-hour calibration if a valid vector is detected.
Calibration fails due to noise	The sensor status is Suspended: Noise Detected. The 6-hour calibration automatically begins when noise is no longer 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 upon completion of calibration. Neither calibration method requires that telemetry communication be maintained for the duration of the calibration.

CAUTION: To obtain an accurate MV baseline following any surgical procedure involving the pulse generator or leads, a new, manual calibration should be performed. 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) require a new MV baseline for appropriate MV behavior.

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

- Response Factor
- Ventilatory Threshold
- Ventilatory Threshold Response
- Fitness Level

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 2–22 Relationship between the programmed Response Factor setting and rate response on page 2-41). 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 2–23 Effects of Response Factor settings in a two-stage exercise test on page 2-41).

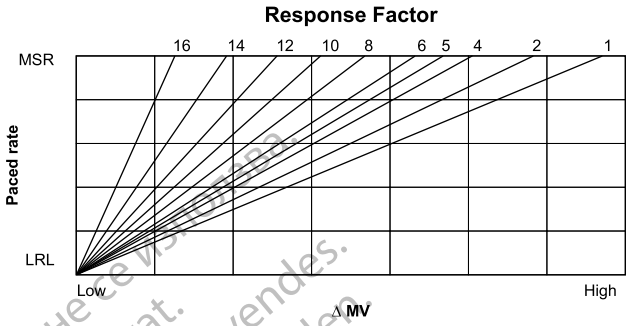


Figure 2–22. Relationship between the programmed Response Factor setting and rate response

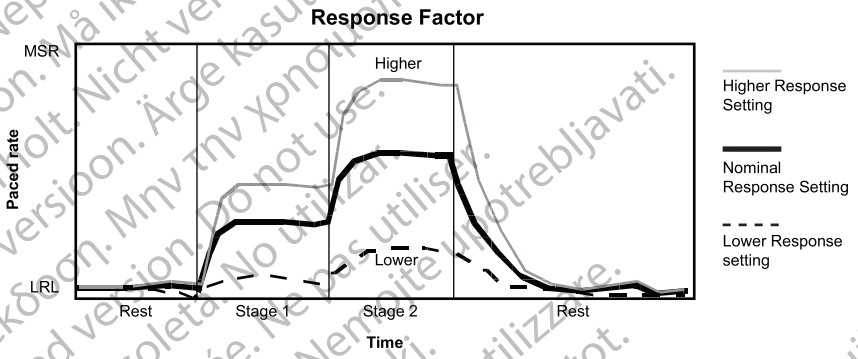


Figure 2–23. Effects of Response Factor settings in a two-stage exercise test

Ventilatory Threshold and Ventilatory Threshold Response

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.

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 2–24 Ventilatory Threshold and Ventilatory Threshold Response on page 2-42). 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.

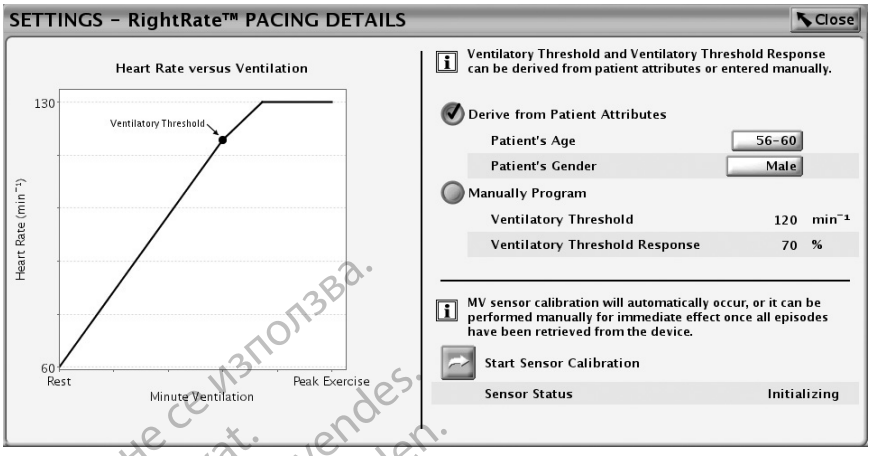
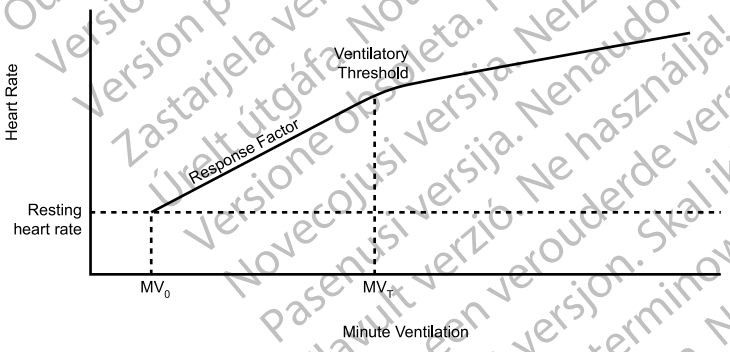


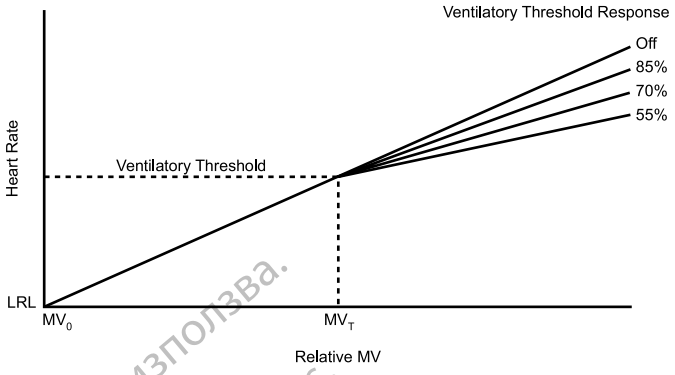
Figure 2–24. Ventilatory Threshold and Ventilatory Threshold Response

The physiologic relationship between MV and rate is approximately bilinear as shown (Figure 2–25 Typical physiologic relationship between MV and heart rate on page 2-42). 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 2–26 Ventilatory Threshold Response on page 2-43).



MV_0 = resting MV; MV_T = MV at the Ventilatory Threshold

Figure 2–25. 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 2–26. Ventilatory Threshold Response

Fitness Level

The selected Fitness Level will automatically determine an appropriate Ventilatory Threshold Response factor and rate at which the MV baseline will be fixed.

Table 2–9. 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 (Table 2–9 Recommended Fitness Level settings on page 2-43). 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.

Additionally, when Ventilatory Threshold and Ventilatory Threshold Response are programmed automatically by using the Derive from Patient Attributes selection on the programmer (Figure 2–24 Ventilatory Threshold and Ventilatory Threshold Response on page 2-42), the combination of Fitness Level, Patient Age, and Patient Gender determines the Ventilatory Threshold Response factor percentage.

Physical Activity Evaluation

Following medical judgment, health care professionals may ask patients to engage in light to moderate physical activity, such as a hall walk or walking up and down steps, to assess the pulse generator's rate response. This evaluation is used to inform the programming of rate adaptive pacing for the patient's detected activity level. For patients who engage in endurance sports, strenuous physical activity may result in a more accurate assessment of rate response.

Prior to starting the physical activity evaluation:

- Ensure that patients are healthy enough to participate.

- Review and consider printing the patient's previous 25-hour Sensor Trending data. For more information, refer to Sensor Trending ("Sensor Trending" on page 2-48).

- The Beat to Beat Recording Method (as described in "Sensor Trending" on page 2-48) is recommended during physical activity evaluations to manually optimize sensor rates.

NOTE: *Sensor Trending results may be printed via the Reports tab.*

After the physical activity evaluation, interrogate the patient's device as described in "Working with Trending Data" and review the rate response data. This rate response data can be compared to the previous 25-hour data printed prior to the test. It is recommended to reset the Recording Method to the mode used prior to the physical activity evaluation (e.g., 30-Second Average).

Optimizing Rate Response for Physical Activity

Sensor Trending provides a graphical display of the pulse generator's rate response to the patient's detected activity level during exercise ("Sensor Trending" on page 2-48). The Sensor Trending graph as shown (Figure 2–27 Rate Response before MV Sensor programmed to On on page 2-44) displays rate response data for a patient before programming the MV Sensor to On. The Actual Rate (black line) represents the patient's heart rate data in DDD mode when MV Sensor is programmed to Passive; the patient's heart rate was approximately 85 min^{-1} after engaging in physical activity.

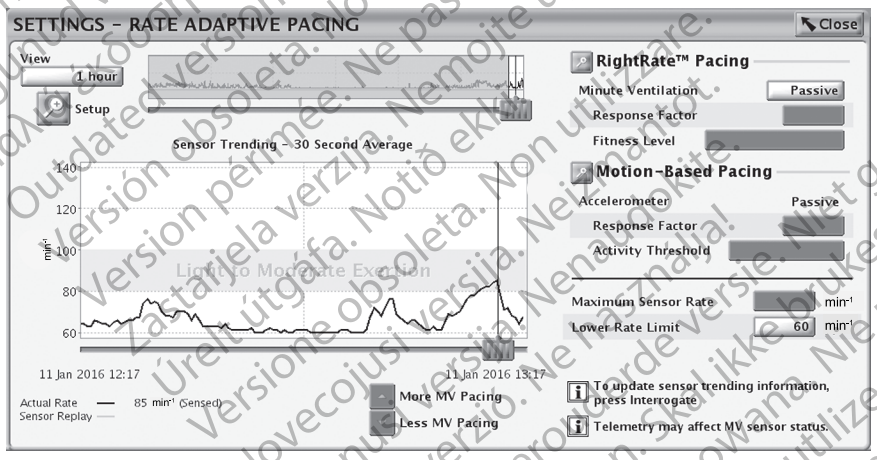


Figure 2–27. Rate Response before MV Sensor programmed to On

The second Sensor Trending graph (Figure 2–28 Rate Response after MV Sensor programmed to On on page 2-45) displays the heart rate response for the same patient after the MV Sensor was programmed to On. The Sensor replay (orange line) depicts the sensor-driven heart rate response that was approximately 105 min^{-1} after the patient engaged in physical activity.

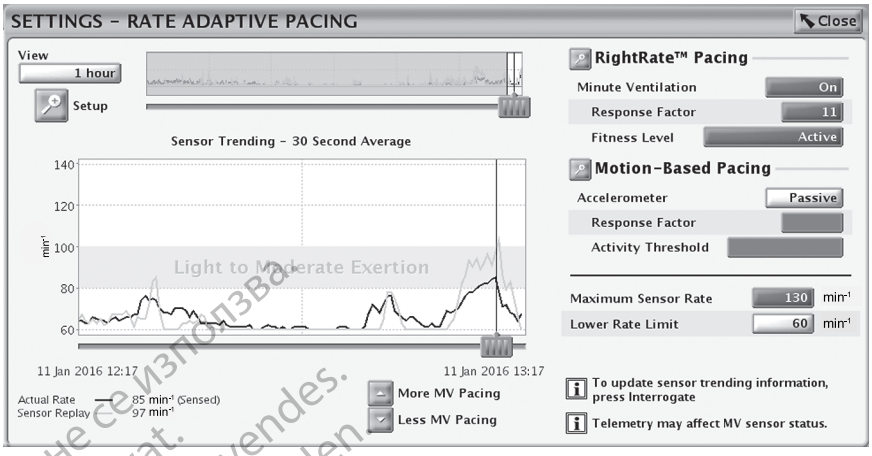


Figure 2–28. Rate Response after MV Sensor programmed to On

For patients who are chronotropically incompetent, consider programming the device to rate responsive mode (e.g., DDDR) with the MV Sensor to On. For example, chronotropically incompetent patients, such as those whose heart rate is < 100 min^{-1} during physical activity and the previous 24-hours, may benefit from device optimization for rate adaptive pacing.

After setting the MV Sensor to On, the rate response can be optimized to achieve an appropriate heart rate during future exercise. Consider programming the rate response factor to target a maximum Sensor Replay rate as appropriate based on the patient's clinical condition (e.g., 70% to 80% of the patient's age predicted maximal heart rate (APMHR)). This programming can be done incrementally according to the patient's clinical condition during clinical follow-up. Note that the sensor rate is limited by MSR and LRL. Therefore, when reprogramming the device, consider re-optimizing using these features.

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 2–29 Blended response with an Accelerometer Reaction Time of 30 seconds on page 2-46). 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.

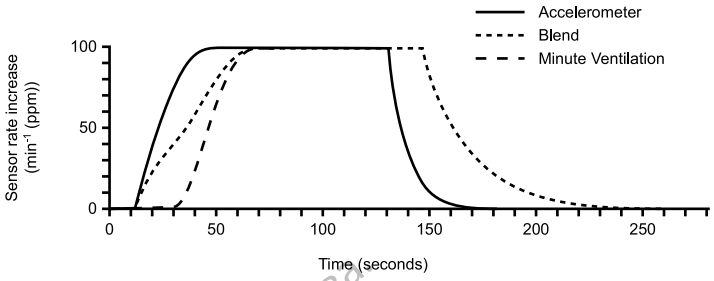


Figure 2–29. Blended response with an Accelerometer Reaction Time of 30 seconds

The aggressiveness of response at the onset of exercise can be controlled by programming a shorter Accelerometer Reaction Time (Figure 2–30 Blended response with an Accelerometer Reaction Time of 20 seconds on page 2-46).

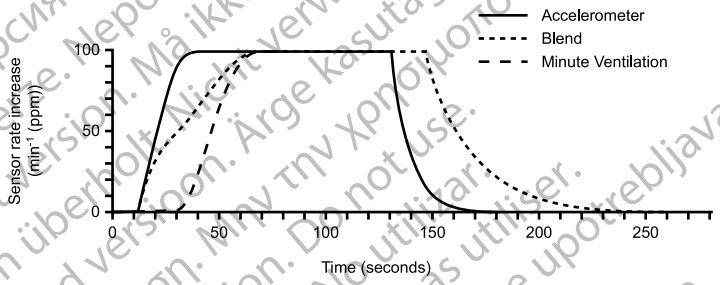


Figure 2–30. Blended response with an Accelerometer Reaction Time of 20 seconds

Example 2

The Accelerometer detects motion with little MV increase (Figure 2–31 Blended response: Accelerometer detects motion with little or no increase in MV on page 2-46). 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.

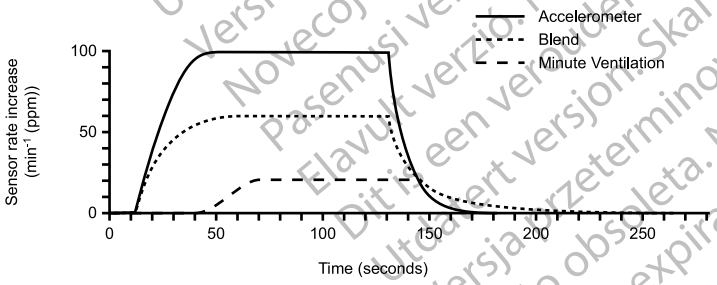


Figure 2–31. Blended response: Accelerometer detects motion with little or no increase in MV

Example 3

MV increases with little Accelerometer rate increase (Figure 2–32 Blended response: MV increase with little or no motion detected by the Accelerometer on page 2-47). 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.

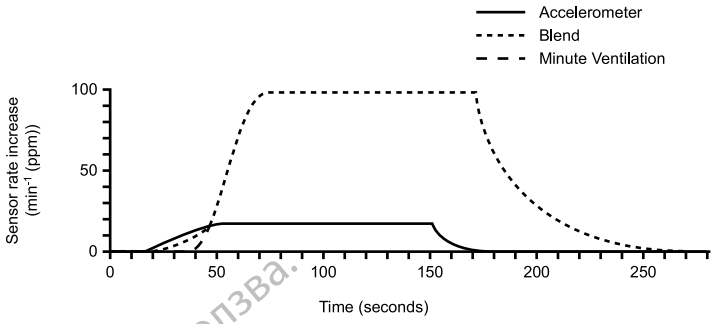


Figure 2–32. Blended response: MV increase with little or no motion detected by the Accelerometer

Follow-up Device Assessments

After programming the MV Sensor or Accelerometer, parameters associated with rate response can be adjusted at subsequent device checks. Consider checking histograms and adjusting parameters if patients complain of shortness of breath or tiredness while exercising, or report a high heart rate for prolonged periods of time. Also, consider resetting the Histograms whenever parameters associated with rate-response are adjusted (refer to "Histograms" on page 4-9).

Low and High Response Factor

Histograms may provide an indication that parameters associated with rate response (e.g. Response Factor, MSR, etc.) can be adjusted to achieve the desired heart rate. An increased amount of pacing at MSR may indicate that the Response Factor is set too high (Figure 2–33 High Response Factor on page 2-47) or the MSR is set too low as shown (Figure 2–34 Low Response Factor on page 2-48). In the histogram as shown in Figure 2–33 High Response Factor on page 2-47, consider whether it is appropriate to lower the Response Factor or raise the MSR.

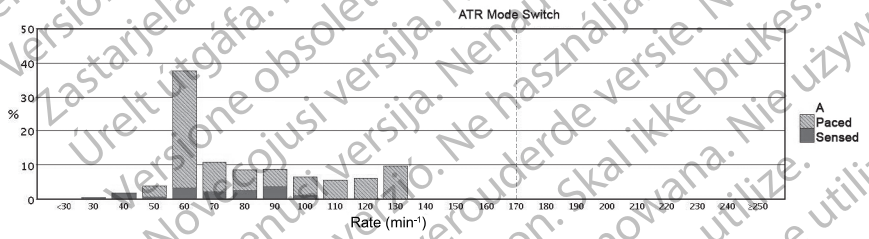


Figure 2–33. High Response Factor

In the histograms as shown in Figure 2–34 Low Response Factor on page 2-48, the Response Factor may be too low as indicated by a large percentage of beats in a single bin, e.g., > 70%. In this case, consider progressively increasing the programmed Response Factor.

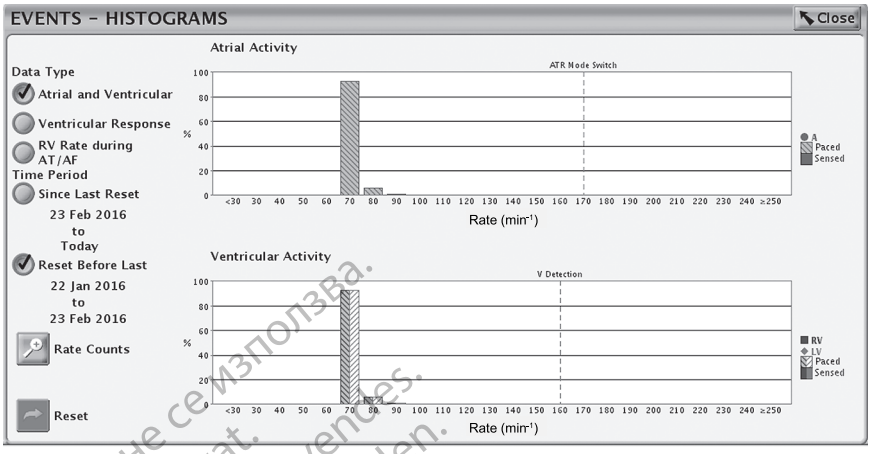


Figure 2–34. Low Response Factor

Sensor Trending

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

Sensor Trending provides a graphical display of the pulse generator's rate response to the patient's detected activity level and/or physiologic need and provides useful information during exercise testing. This data 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.

The Sensor Trending graph (Figure 2–35 Sensor Trending graph with exertion range on page 2-49) identifies a fixed range of heart rates (80–100 min^{-1}) for Light to Moderate Exertion. This range can be used as a guide for target heart rates corresponding to regular walking and other low impact activities and may help identify patients with chronotropic incompetence.[1] [2]This range may vary due to factors such as patient age and the type of exercise.[2]

The up and down buttons (Figure 2–35 Sensor Trending graph with exertion range on page 2-49) for More MV Pacing and Less MV Pacing are an alternate method to manually selecting the Response Factor. Each press of the button changes the Response Factor by one. The up button increases the Response Factor, and the down button decreases the Response Factor. For further information about sensor optimization, refer to the section about working with trending data below.

1. Scherr, J. et al., Associations between Borg's rating of perceived exertion and physiologic measures of exercise intensity. Eur J. Appl Physiol, Vol. 113 (1): 147-155, 2013.
2. Newman et al., Walking Performance and Cardiovascular Response: Associations with Age and Morbidity—The Health Aging and Body Composition Study. J. of Gerontology, Vol. 58A (8): 715-720, 2003.

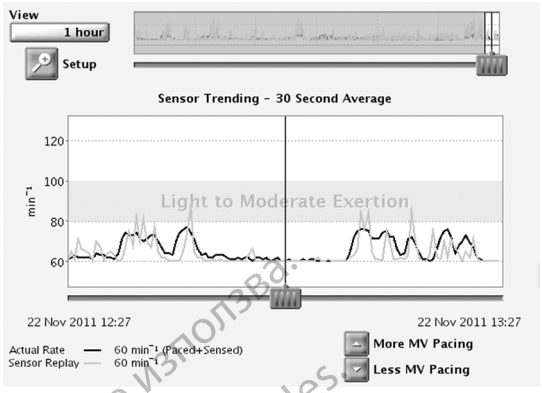


Figure 2–35. Sensor Trending graph with exertion range

Setup of Sensor Trending 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 Sensor 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 engages in light to moderate physical activity, 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 slider(s) 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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 2–36 ATR behavior on page 2-51).

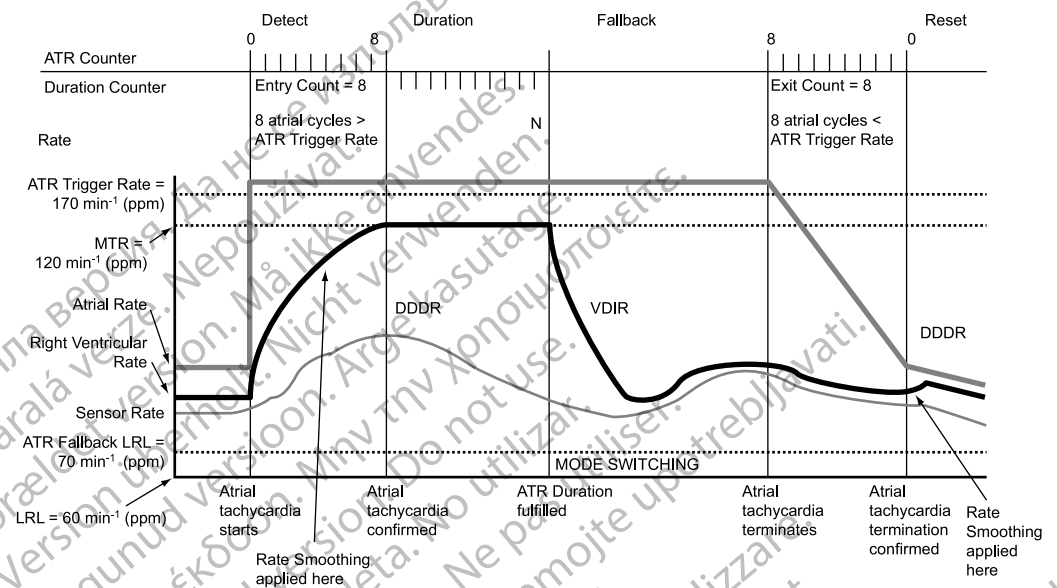


Figure 2–36. ATR behavior

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 highest of the sensor-indicated rate, VRR 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. If VRR is enabled, then Rate Smoothing is disabled throughout the mode switch
- Rate Hysteresis
- AV Search +

- APP/ProACt
- 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 highest among the sensor-indicated rate (when applicable), the VRR rate (if enabled), 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.

NOTE: *If RYTHMIQ is enabled, the pacing mode automatically switches back to the mode that was present prior to the ATR mode switch [AAI(R) or DDD(R) mode].*

Ventricular Rate Regulation (VRR)

This feature is available in ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices.

VRR is designed to reduce the V–V cycle length variability during partially conducted atrial arrhythmias by modestly increasing the ventricular pacing rate.

The VRR algorithm calculates a VRR-indicated pacing interval based on a weighted sum of the current V–V cycle length and the previous VRR-indicated pacing intervals.

- Paced intervals have more influence than sensed intervals such that paced events cause a decrease in the VRR-indicated rate.
- For sensed intervals, the VRR-indicated rate may be increased; however, the influence is tempered by the previous history.
- The VRR-indicated rate is further bound by the LRL and the VRR MPR.

When VRR is programmed on in tracking modes, it is only active when an ATR mode switch has occurred. Once the tracking mode operation resumes at the termination of the atrial arrhythmia, VRR becomes inactive. In tracking modes where both Rate Smoothing and VRR are programmed on, Rate Smoothing is disabled when VRR is active during ATR and re-enabled once the ATR terminates.

When programmed on in nontracking modes, VRR is continually active and updates the VRR-indicated pacing rate and the smoothed average on each cardiac cycle.

Ventricular Rate Regulation Maximum Pacing Rate (VRR MPR)

The VRR MPR limits the maximum pacing rate for VRR.

VRR operates between the LRL and the MPR.

Atrial Flutter Response (AFR)

This feature is available in ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices.

Atrial Flutter Response is designed to:

- Prevent pacing into the vulnerable period following an atrial sense. Pacing into the vulnerable period could occur if an atrial pace is scheduled soon after a refractory atrial sense.
- Provide immediate nontracking of atrial rates higher than the AFR Trigger Rate.

The nontracking behavior is maintained for as long as atrial events continually exceed the AFR Trigger Rate.

Example: When AFR is programmed to 170 min^{-1}, a detected atrial event inside the PVARP or a previously triggered AFR interval starts an AFR window of 353 ms (170 min^{-1}). Atrial detection inside the AFR is classified as a sense within the refractory period and is not tracked. Atrial tracking may only occur after both PVARP and the AFR window expire. Paced atrial events scheduled inside an AFR window are delayed until the AFR window expires. If there are fewer than 50 ms remaining before the subsequent ventricular pace, the atrial pace is inhibited for the cycle.

Ventricular pacing is not affected by AFR and will take place as scheduled. The wide programmable range for AFR Trigger rates allows for appropriate sensing of slow atrial flutters. High-rate atrial sensing may continuously retrigger the AFR window, effectively resulting in behavior similar to the VDI(R) fallback mode.

NOTE: *For atrial arrhythmias that meet the programmed AFR rate criteria, using the AFR feature will result in slower ventricular pacing rates.*

NOTE: *When both AFR and ATR are active in the presence of atrial arrhythmias, nontracking ventricular paced behavior may occur sooner, but the ATR Mode Switch may take longer. This is because the ATR Duration feature counts ventricular cycles for meeting duration and the AFR feature slows the ventricular paced response to fast atrial arrhythmias.*

PMT Termination

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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).*[3]

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.
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).

3. 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.

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

Atrial Pacing Preference (APP) and ProACt

This feature is available in ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices.

The Atrial Pacing Preference (APP) and ProACt features are designed to promote atrial pacing by increasing the pacing rate. APP and ProACt use algorithms that function similarly, but the ProACt algorithm reacts to premature atrial contractions (PACs) while the APP algorithm reacts to non-PAC atrial senses.

APP and ProACt are designed to decrease the number of atrial arrhythmic episodes.

PAC Determination

The pulse generator determines a PAC occurrence by calculating the average of 4 A–A intervals prior to an atrial sensed event. Both atrial paced and atrial sensed events are used in determining the A–A intervals (Figure 2–37 PAC detection on page 2-56). When an atrial sensed event occurs, it is classified as a PAC if the previous A–A interval is less than 75% of the average interval (calculated on the previous 4 intervals) and is less than 600 ms. An atrial paced event is not classified as a PAC.

NOTE: *PACs are not detected if an ATR Mode Switch is in progress.*

NOTE: *If any of the A–A intervals used in the average interval computation are longer than 2000 ms, the interval length used in the computation is 2000 ms.*

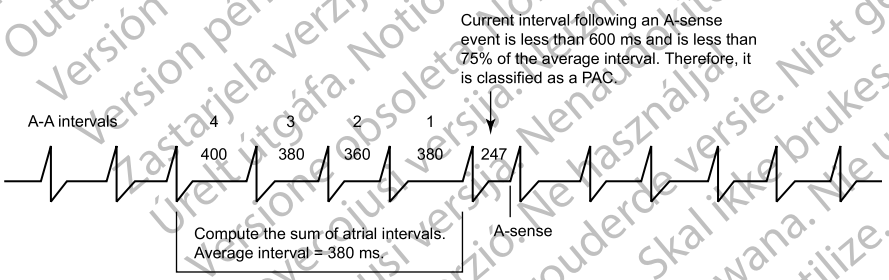


Figure 2–37. PAC detection

Atrial Pacing Preference (APP)

Atrial Pacing Preference is an algorithm designed to promote atrial pacing by increasing the atrial pacing rate when non-PAC, nonrefractory atrial sensed events occur.

When an AS–VS event occurs, APP shortens the A–A interval for the next cycle by 10 ms to help ensure atrial pacing. When an AS–VP event occurs, APP shortens the V–V interval for the next cycle by 10 ms.

Additionally, the pacing rate is gradually decreased back down to the LRL by lengthening the V–A interval by 10 ms if 4 consecutive cardiac cycles occur where each cycle falls into one of the following categories:

- A refractory atrial sense as the only atrial event
- No atrial event
- A PAC

- An atrial pace
- Multiple atrial events where the last atrial event is a nonrefractory atrial sense preceded by at least one PAC

This new V–A interval is used until either an intrinsic atrial sensed event occurs and the algorithm shortens the A–A or V–V interval or the V–A interval is again lengthened by 10 ms as described.

When APP/ProACt is active, SBR, and Rate Hysteresis are not allowed. In addition, Rate Smoothing Up will be ignored at pacing rates less than the APP/ProACt Max Pacing Rate.

An example of the APP/ProACt operation is shown below (Figure 2–38 Atrial Pacing Preference on page 2-57).

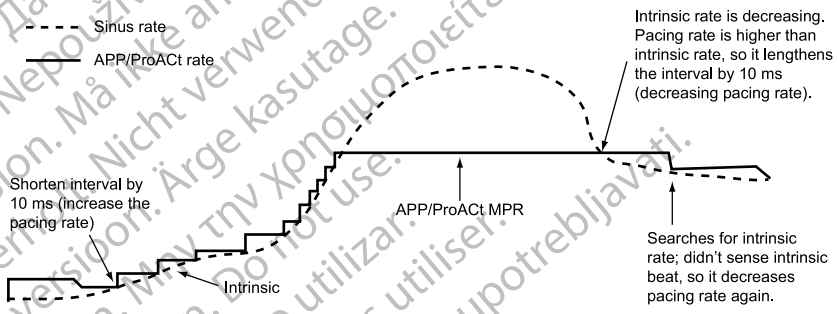


Figure 2–38. Atrial Pacing Preference

APP is available in DDI(R) and DDD(R) modes. The APP/ProACt pacing rate is limited by the programmable APP/ProACt MPR.

ProACt

ProACt increases the pacing rate in the presence of PACs in order to increase the likelihood of atrial pacing.

If the previous atrial event was a PAC, the ProACt algorithm calculates 75% of the V–V interval prior to the PAC and applies this calculated V–V interval to the next cycle to promote atrial pacing. The pacing rate is gradually decreased back down to the LRL by lengthening the V–V interval by 10 ms if 4 consecutive cycles occur with a non-PAC sense, no atrial event, or an atrial pace. This new V–V interval is used until either a PAC occurs and the algorithm shortens the V–V interval or the V–V interval is again lengthened by 10 ms as described.

APP/ProACt Maximum Pacing Rate (MPR)

The APP/ProACt indicated rate is limited by the programmable APP/ProACt Max Pacing Rate (MPR) value.

RATE ENHANCEMENTS

Rate Hysteresis

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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, the sensor-indicated rate, or the VRR interval
- During VRR when active
- Upon triggering PMT Termination
- Immediately following programmed LRL increases
- When the intrinsic rate is above the MTR
- When APP/ProACt is active, Rate Smoothing Up is not applied for pacing rates below the APP/ProACt Maximum Pacing Rate

NOTE: *Rate Smoothing cannot be programmed to On when Sudden Brady Response is programmed to On.*

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).

When both VRR and Rate Smoothing are programmed on in the VVI(R) or DDI(R) mode, VRR will have priority.

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 2–39 Rate smoothing synchronization window on page 2-61):

- 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.

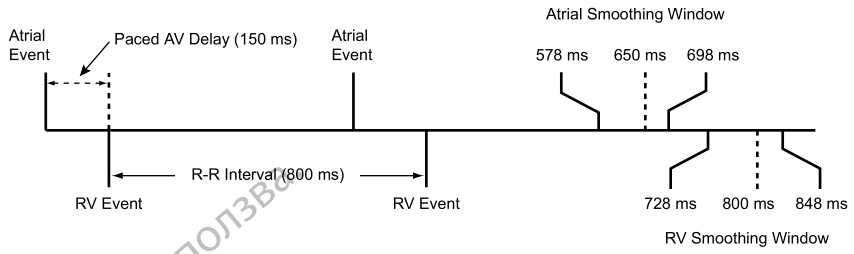


Figure 2–39. Rate smoothing synchronization window

Sudden Brady Response

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, and INGENIO devices.

Sudden Brady Response (SBR) is designed to respond to sudden decreases in intrinsic atrial rates by applying pacing at an elevated rate.

SBR is available in DDD(R) modes. SBR is declared when the atrial chamber has been continuously sensed for one minute (nonprogrammable), followed by a sudden decrease in atrial rate such that atrial pacing occurs at the LRL or the sensor-indicated rate for a programmable number of cycles. The decrease in atrial rate preceding the paced events must exceed 10 min^{-1} (nonprogrammable).

The SBR algorithm continually monitors the average of the atrial rate and this average is updated each cardiac cycle. This average rate is used both to determine if the atrial rate has decreased more than 10 min^{-1} and to determine the rate of SBR therapy.

NOTE: *Sudden Brady Response is not available when Rate Smoothing and/or APP/ProACt are enabled.*

NOTE: *Sudden Brady Response will not be activated based on an atrial rate decrease during ATR Fallback.*

NOTE: *Sudden Brady Response will not be activated based on an atrial rate decrease while RYTHMIQ is operating in AAI(R) mode. Likewise, SBR therapy will be terminated when a RYTHMIQ mode change from DDD(R) to AAI(R) with VVI backup occurs.*

SBR Atrial Paces Before Therapy

The SBR Atrial Paces Before Therapy criteria are applied once the decrease in atrial rate has been detected and LRL or sensor-indicated rate pacing begins. Atrial pacing must occur for the programmable number of consecutive intervals before the SBR criteria are met. This parameter is used to ensure that the rate stays at the LRL or sensor-indicated rate prior to delivering therapy. If atrial senses occur during these intervals, the algorithm is reset and SBR therapy is not applied.

SBR Atrial Pacing Rate Increase

SBR Atrial Pacing Rate Increase is calculated by using the patient's average atrial rate before the drop in rate and adding a programmable positive offset (Figure 2–40 Sudden Brady Response on page 2-62).

Pacing is applied in the DDD(R) mode at whichever of the following rates is higher:

- The previous average atrial rate plus the SBR Atrial Pacing Rate Increase (not to exceed the MTR), or
- The sensor-indicated rate (DDDR mode only)

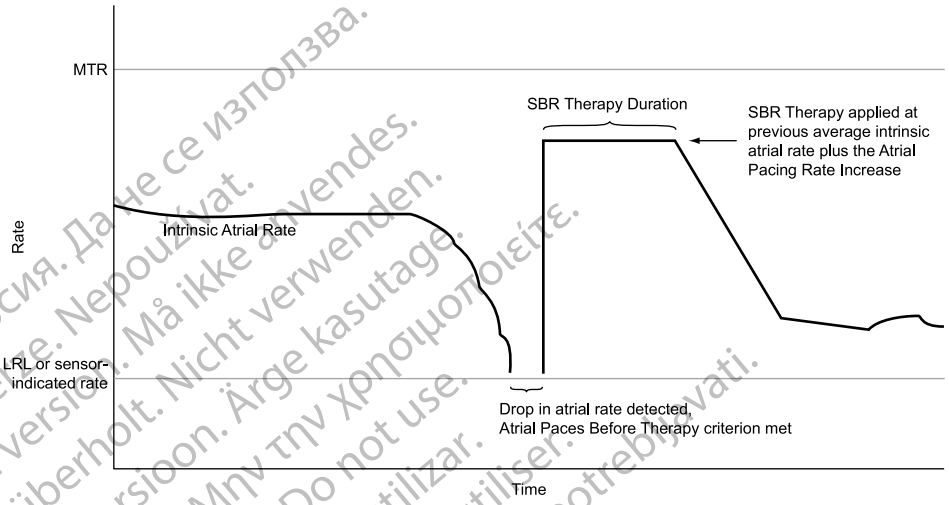


Figure 2–40. Sudden Brady Response

SBR Therapy Duration

SBR Therapy Duration is the programmable time interval during which the SBR pacing therapy rate will be applied. Once pacing therapy has been delivered, the atrial pacing rate will be decreased using a 12% Rate Smoothing Down factor (nonprogrammable) until the LRL or sensor-indicated rate is reached.

NOTE: *Rate Hysteresis is not active during SBR Therapy Duration.*

NOTE: *SBR Therapy Duration will end if a manual or PaceSafe Threshold Test is performed.*

SBR Inhibit During Rest

SBR Inhibit During Rest is designed to distinguish between a natural drop in rate (sleep) and a pathologic drop. It provides the ability to inhibit SBR therapy when the SBR rate and duration criteria are met, but the patient's current MV/Respiratory Sensor measurement is lower than a derived MV/Respiratory Sensor comparison value. The MV/Respiratory Sensor must be set to On (or Passive for the MV Sensor) for the SBR Inhibit During Rest to be programmed On. When the MV/Respiratory Sensor is activated, the pulse generator determines the lowest measured baseline value for each day over a 1-week period (rolling 7-day window). The MV/Respiratory Sensor comparison value is then set to 50% above that lowest weekly baseline. Each day, this MV/Respiratory Sensor comparison value is updated so that the algorithm adjusts to long-term changes in the patient's baseline. In the event the SBR atrial rate and duration criteria are met, the current MV/Respiratory Sensor measurement is compared to the comparison value. If the current MV/Respiratory Sensor measurement is less than the comparison value, SBR therapy is inhibited (Figure 2–41 SBR Therapy Inhibited by Sensor Comparison on page 2-63). If the present MV/Respiratory Sensor measurement is greater than or equal to the comparison value, SBR therapy is initiated (Figure 2–42 SBR Therapy Delivered after Sensor Comparison on page 2-63).

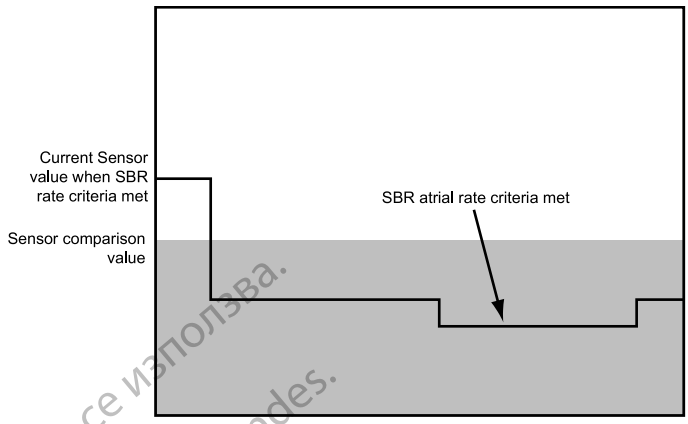


Figure 2–41. SBR Therapy Inhibited by Sensor Comparison

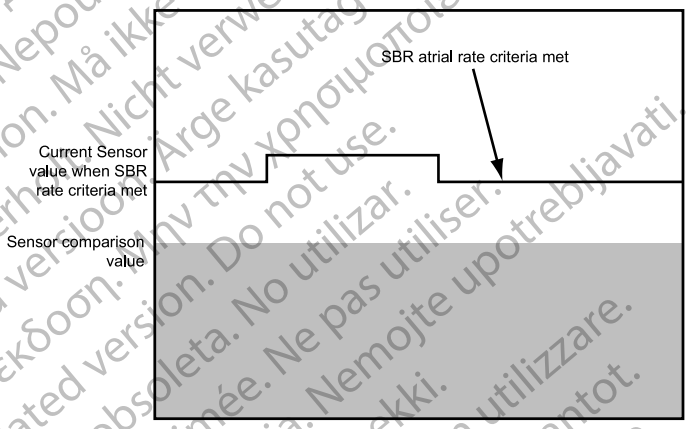


Figure 2–42. SBR Therapy Delivered after Sensor Comparison

LEAD CONFIGURATION

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 2-76).*

Use of Atrial Information

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

Atrial sensing can be programmed to On or Off in any dual or single chamber Brady Mode. 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 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 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)].

  CAUTION: Sensing high atrial rates may impact device longevity. Therefore, the Atrial Sense lead configuration will be seeded to Off when programming from an atrial sensing mode to a non-atrial sensing mode.

CAUTION: When atrial sensing is programmed to 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 MV/Respiratory Sensor Vector Selection parameter to RV Only.
- 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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 Lead Safety Switch feature may be programmed to On in either the Atrium or Right Ventricle.

When the measured Impedance is less than or equal to the programmed Low Impedance Limit or greater than or equal to the programmed High Impedance Limit 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 Lead Safety Switch.*

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

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

The date on which the Lead 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 Lead 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 Lead 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 properly functioning leads with stable measured impedance values near the programmed impedance limits are used, consider programming Lead Safety Switch Off or changing the impedance limits to avoid undesirable switching to a Unipolar Lead Configuration.

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

WARNING: Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD.

Automatic Lead Recognition

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices.

Auto Lead Recognition (ALR) detects at implant if the inserted RV lead is unipolar or bipolar, then ensures that the RV Pace/RV Sense lead configuration matches the detected lead type.

ALR is nominally On and remains programmable to On/Off until a lead is detected. The ALR parameter can be set to On/Off using the Leads Setting screen or Change Device Mode dialog when manually exiting Storage Mode.

WARNING: Automatic Lead Recognition should be programmed to Off before implant for patients with an ICD. Unipolar pacing is contraindicated for patients with an ICD.

When ALR detects an in-range bipolar impedance measurement (200-2000 Ω), the Bipolar RV lead configuration is retained. If an out-of-range bipolar impedance measurement is detected, ALR configures the RV Pace and RV Sense parameters for Unipolar pacing and sensing. This allows RV sensing and pacing to begin without programmer interaction when the RV lead is attached.

The device continues to measure the bipolar RV lead impedance for a period of two hours to confirm recognition of a unipolar lead. This period allows for recognition of an implanted bipolar lead following resolution of possible lead integrity issues. Upon an in-range bipolar impedance measurement, the Bipolar configuration is restored, and ALR no longer evaluates RV lead impedance. If, however, the two-hour period elapses with no in-range bipolar RV lead impedance measurement, Unipolar RV Pace and RV Sense parameters are retained, and the RV lead configuration will remain Unipolar until it is manually reprogrammed.

NOTE: *If RV Pace is set to Unipolar, ALR is not applicable and will not be performed. In addition, if RV Lead Safety Switch is set to Off to prevent unipolar pacing, ALR will not be performed.*

Upon starting a session with wanded telemetry, if ALR confirms a Unipolar RV lead, related information is included in the following locations:

- Summary dialog on initial interrogation: displays the automatic Unipolar RV lead configuration
- Leads Setting screen
- Lead Switch Details screen
- Reports

After a lead has been detected, the Leads Setting screen displays the following ALR statuses:

- Completed: if ALR recognized a unipolar or bipolar lead at implant
- Off: if ALR was not used due to programming at implant

During a Programmer session, if ALR recognizes the insertion of a unipolar lead, a dialog indicates that ALR is in progress and provides the following selections:

- Confirm Unipolar: this setting retains the Unipolar RV Pace/RV Sense configuration
- Program Bipolar: this setting programs the RV Pace/RV Sense to Bipolar for lead troubleshooting

Selecting either option opens the Brady Settings screen for troubleshooting.

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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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.

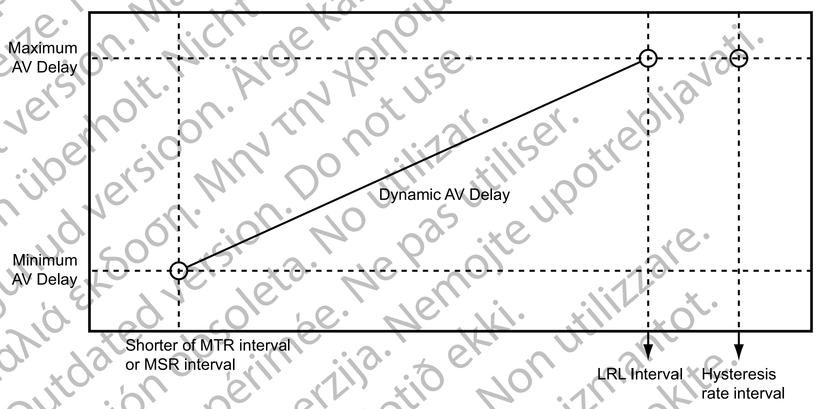


Figure 2–43. Dynamic AV Delay

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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 2–44 Sensed AV Delay on page 2-69).

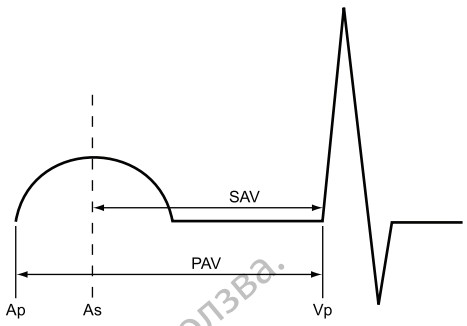


Figure 2–44. Sensed AV Delay

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 2–45 Dynamic and Sensed AV Delay function on page 2-70). 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.*

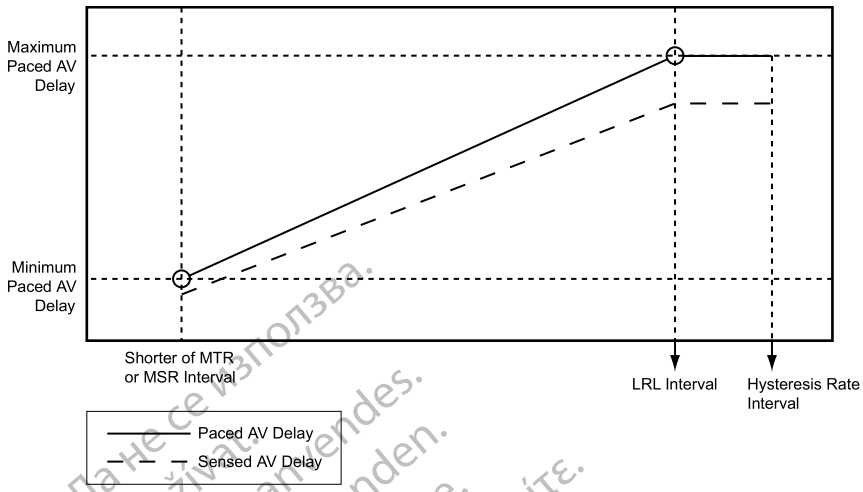


Figure 2–45. Dynamic and Sensed AV Delay function

AV Search +

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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.

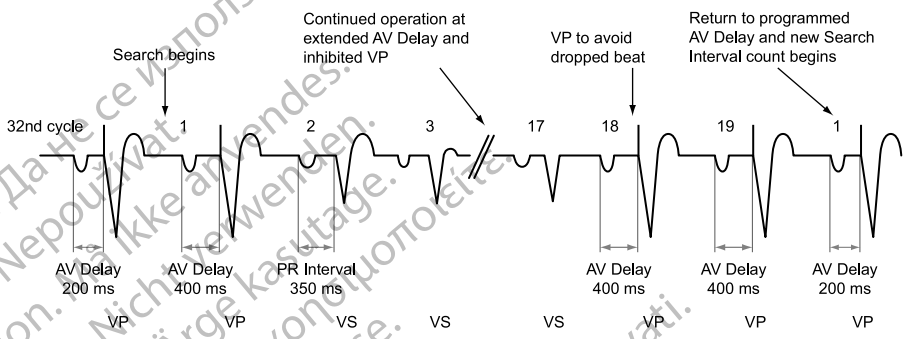


Figure 2–46. AV Search +

RYTHMIQ

This feature is available in ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices.

RYTHMIQ reduces unnecessary ventricular pacing[4] and prevents clinically significant pauses as defined by the 2008 ACC/AHA/HRS guidelines[5]. RYTHMIQ operates in an AAI(R) pacing mode with VVI backup during times of normal conduction. If loss of AV synchrony is detected, then the mode automatically switches to DDD(R) to restore AV synchrony. If normal conduction returns, then the mode automatically switches back to AAI(R) with VVI backup. RYTHMIQ does not require dropped ventricular beats to switch to DDD(R) pacing.

RYTHMIQ is available only when the Normal Brady Mode is programmed to DDD(R). If the Normal Brady Mode is DDD, then RYTHMIQ can be set to either AAI With VVI Backup or Off. If the Normal Brady Mode is DDDR, then RYTHMIQ can be set to either AAIR With VVI Backup or Off.

The following occurs during the RYTHMIQ stage of AAI(R) with VVI backup:

- The device provides AAI(R) pacing at the LRL and/or sensor indicated rate.
- The device provides backup VVI pacing at a rate of 15 min^{-1} slower than the LRL. The backup VVI pacing rate is limited to no slower than 30 min^{-1} and no faster than 60 min^{-1}. When there is consistent conduction, ventricular pacing does not occur as the VVI backup mode runs in the background at a reduced LRL.
- The device monitors for loss of AV synchrony. If 3 slow ventricular beats are detected in a window of 11 beats, then the device automatically switches to DDD(R) mode. A slow beat for RYTHMIQ is defined as a ventricular pace or ventricular sensed event that is at least 150 ms slower than the AAI(R) pacing interval.

4. Tolosana JM, Gras D, Le Polain De Waroux JB, et al. Reduction in right ventricular pacing with a new reverse mode switch algorithm: results from the IVORY trial. Europace. 2013;15 (suppl 2):P1036.
5. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. Journal of the American College of Cardiology, Vol. 51(21), May 27, 2008.

The following occurs during the RYTHMIQ stage of DDD(R):

- The device provides DDD(R) pacing according to the normal programmed parameters.
- The device uses AV Search + to periodically check for a return of intrinsic conduction. If AV Search + remains in AV hysteresis for at least 25 cardiac cycles, and less than 2 of the last 10 cycles are ventricular paced, then the device automatically switches the pacing mode back to AAI(R) with VVI backup.

When RYTHMIQ detects loss of AV synchrony, the device records a RYTHMIQ episode along with 20 seconds of electrogram data (10 seconds before the mode switch, 10 seconds after the mode switch). The RYTHMIQ episode will be noted by the PRM and can be inspected in detail by selecting the appropriate episode from the Arrhythmia Logbook screen. When the DDD(R) stage of RYTHMIQ is active, the RYTHMIQ episode is identified as “In Progress”.

Features available during the DDD(R) stage of RYTHMIQ may not be available during the AAI(R) stage of RYTHMIQ. The exceptions are ATR, Rate Adaptive Pacing, and Rate Smoothing. If ATR is programmed on for DDD(R), it will also be active during AAI(R), and may perform an ATR Mode Switch from either RYTHMIQ stage. When the atrial arrhythmia ends, the pacing mode will resume the RYTHMIQ stage that was active before the ATR Mode Switch. If Rate Smoothing is programmed On for DDD(R), then Rate Smoothing will be active during AAI(R); Rate Smoothing will not alter the VVI backup-pacing rate.

NOTE: *Sudden Brady Response will not be activated based on an atrial rate decrease while RYTHMIQ is operating in AAI(R) mode. If RYTHMIQ is operating in DDD(R) mode, a successful AV Search will terminate SBR therapy.*

If you want the switch from AAI(R) with VVI Backup to DDD(R) to only occur once, then program AV Search + to Off. In this case, the pulse generator remains in DDD(R) mode until reprogramming occurs.

REFRACTORY

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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.

PVARP can be programmed to a fixed value or to a dynamic value calculated based on the previous cardiac cycles. To program a fixed PVARP, set the minimum and maximum to the same value. PVARP will automatically be dynamic if the minimum value is less than the maximum value.

A long Atrial Refractory period shortens the brady atrial sensing window. Programming long Atrial Refractory periods in combination with certain AV Delay periods can cause 2:1 block to occur abruptly at the programmed MTR.

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

Dynamic PVARP

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

Programming of Dynamic PVARP and Dynamic AV Delay optimizes the sensing window at higher rates, allowing upper rate behavior (e.g., 2:1 block and pacemaker Wenckebach) in DDD(R) and VDD(R) modes to be significantly reduced, even at higher MTR settings. At the same time, Dynamic PVARP reduces the likelihood of PMTs at lower rates. Dynamic PVARP also reduces the likelihood of competitive atrial pacing.

The pulse generator automatically calculates the Dynamic PVARP using a weighted average of the previous cardiac cycles. This results in a shortening of the PVARP in a linear fashion as the rate increases. When the average rate is between the LRL and the MTR or applicable upper rate limit, the pulse generator calculates the Dynamic PVARP according to the linear relationship shown (Figure 2–47 Dynamic PVARP on page 2-74). This relationship is determined by the programmed values for Minimum PVARP, Maximum PVARP, the LRL, and the MTR or applicable upper rate limit.

CAUTION: Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a PMT.

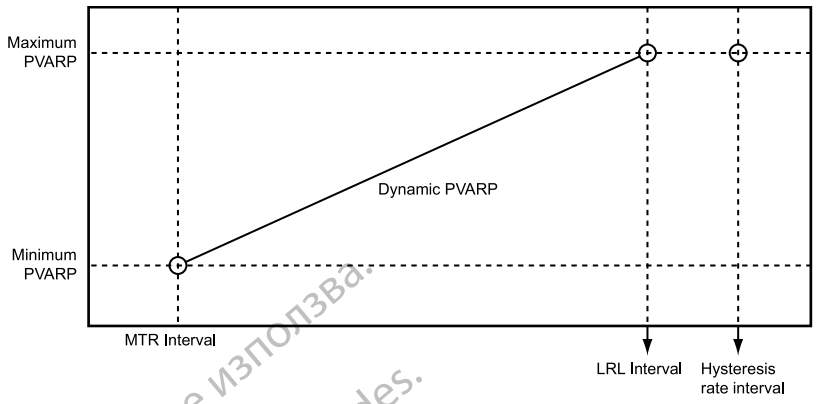


Figure 2–47. Dynamic PVARP

Maximum PVARP

If the average rate is equal to or lower than the LRL (e.g., hysteresis), the Maximum PVARP is used.

Minimum PVARP

If the average rate is equal to or higher than the MTR interval, the programmed Minimum PVARP is used.

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:

- If an atrial pace is inhibited due to Atrial Flutter Response
- 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 Mode or MRI Protection Mode 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 2–48 Relationship between ventricular rate and refractory interval on page 2-75):

- 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).*

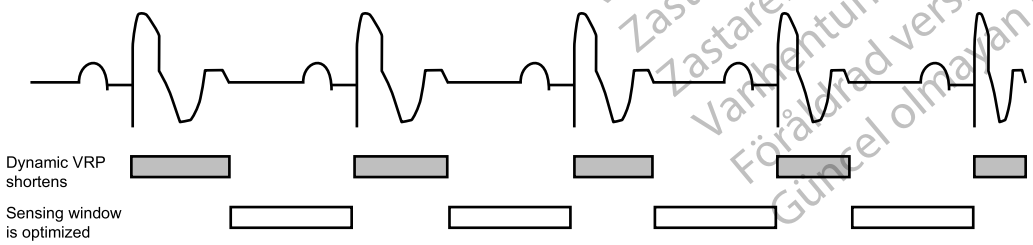


Figure 2–48. Relationship between ventricular rate and refractory interval

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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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.*

CAUTION: 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 RV-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 (RV-Blank after A-Pace) could occur. In certain usage scenarios, if a pattern of atrial pacing and VT beats is detected, the Brady Tachy Response (BTR) feature will automatically adjust the AV Delay 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:

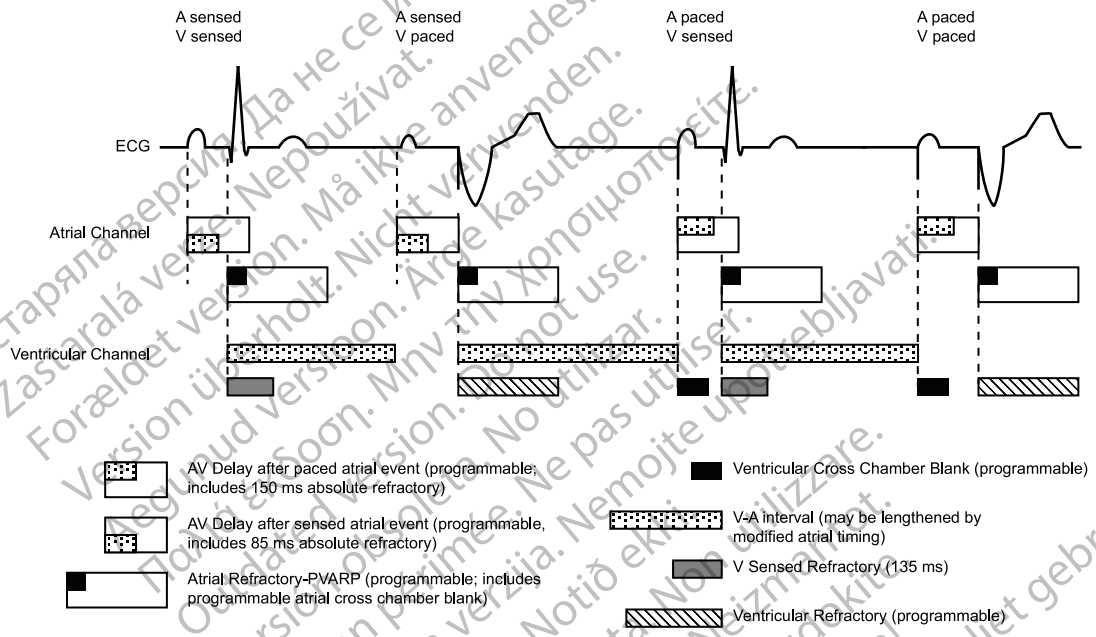


Figure 2–49. Refractory periods, dual-chamber pacing modes

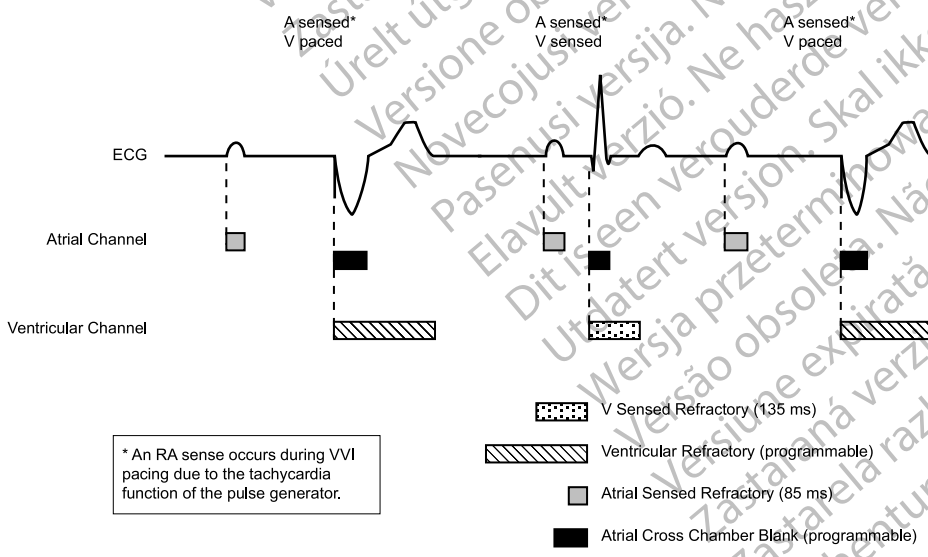


Figure 2–50. Refractory periods, VVI pacing mode

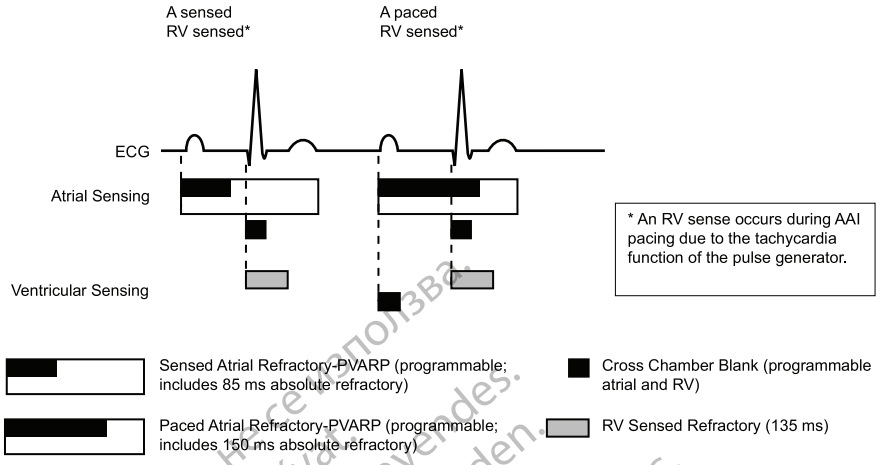


Figure 2–51. Refractory periods, AAI pacing mode; DR

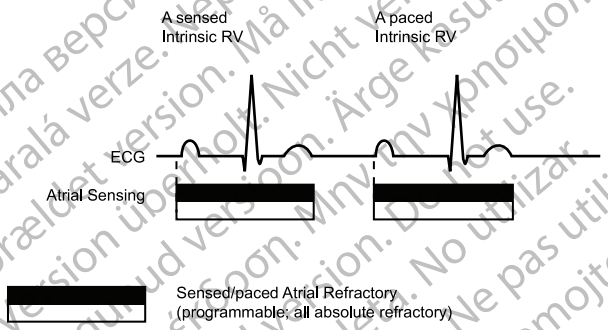


Figure 2–52. Refractory periods, AAI pacing mode; SR

NOISE RESPONSE

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 Pacing 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 2–54 Refractory periods and noise windows, RA on page 2-80.

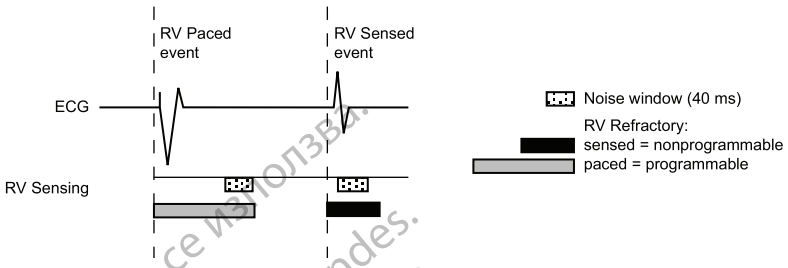


Figure 2–53. Refractory periods and noise windows, RV

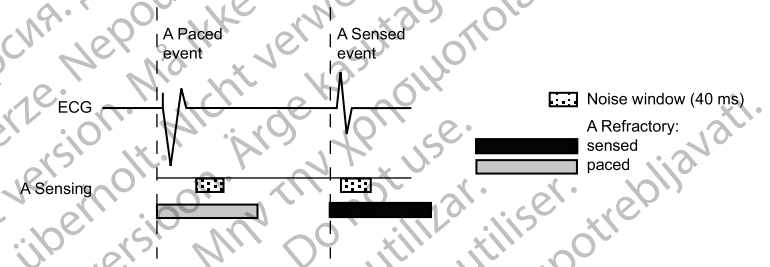


Figure 2–54. Refractory periods and noise windows, RA

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 Pacing 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 2–55 Noise Response (fixed blanking) on page 2-81).

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.

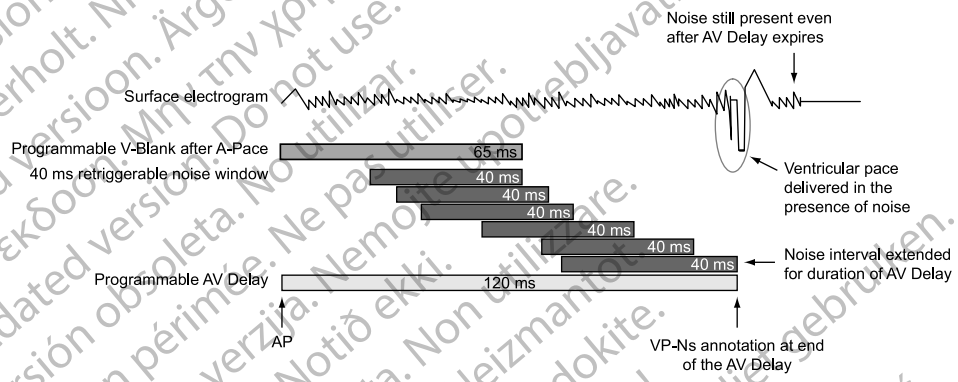


Figure 2–55. Noise Response (fixed blanking)

SYSTEM DIAGNOSTICS

CHAPTER 3

This chapter contains the following topics:

SUMMARY DIALOG

Upon interrogation, a Summary dialog is displayed. It includes Leads and POST information, 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.

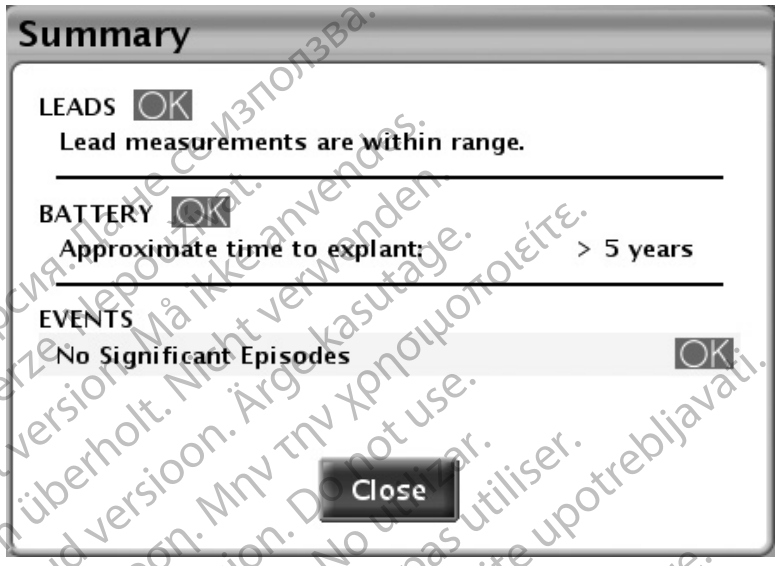


Figure 3–1. Summary dialog

Potential status symbols include OK, Attention, or Warning ("Use of Color" on page 1-7). 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 time remaining to explant.

  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 4-18).

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.

NOTE: *When the 1.5 hours of telemetry are exhausted, a LATITUDE alert is generated.*

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.

NOTE: *A LATITUDE alert is generated, after which LATITUDE NXT ceases interrogations of the device.*

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 RV Automatic Capture (the output is fixed at 2X the last measurement but not more than 5 V or less than 3.5 V)

- PaceSafe RA Automatic Threshold (the output is fixed at the current output value)
- Lead Safety Switch (the lead configuration remains as it was programmed when the device reached Battery Capacity Depleted status)
- Episode storage
- Diagnostic and EP Tests
- Real-time EGMs
- MV sensor
- 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.

WARNING: MRI scanning after Explant status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of pacing. After performing an MRI scan on a device that has reached Explant status, verify pulse generator function and schedule device replacement.

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 Battery Detail summary screen on page 3-6):

- 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 reprogrammed, the Power Consumption and Power Consumption Percentage values are adjusted accordingly:

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

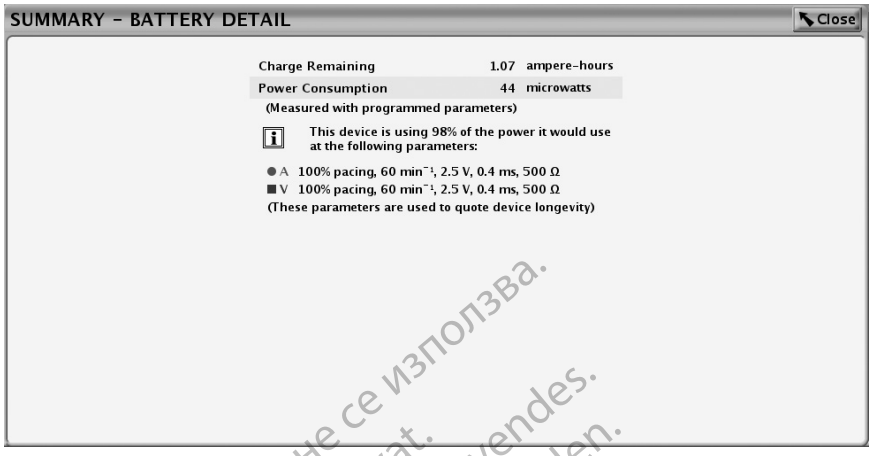


Figure 3–2. Battery Detail summary screen

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 (Pace 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.
  - For ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices, the High Impedance Limit is nominally set to 2000 Ω, and is programmable between 2000 and 3000 Ω in 250 Ω increments. The Low Impedance Limit is nominally set to 200 Ω, and is programmable between 200 and 500 Ω in 50 Ω increments.

    For FORMIO, VITALIO, INGENIO, and ADVANTIO devices, the High Impedance Limit is nominally set to 2000 Ω, and is programmable between 2000 and 2500 Ω in 250 Ω increments. The Low Impedance Limit is nominally set to 200 Ω, and is programmable between 200 and 500 Ω in 50 Ω increments.

    Consider the following factors when choosing a value for the Impedance Limits:

    - For chronic leads, historical impedance measurements for the lead, as well as other electrical performance indicators such as stability over time
    - For newly implanted leads, the starting measured impedance value

    NOTE: *Depending on lead maturation effects, during follow-up testing the physician may choose to reprogram the Impedance Limits.*

    - Pacing dependence of the patient
    - Recommended impedance range for the lead(s) being used, if available

- 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 Leads Status summary screen on page 3-8).

Possible leads status messages are as follows (Table 3–1 Lead measurement reporting on page 3-7):

- 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 2-65).*

NOTE: *A detailed description of PaceSafe–specific messages including notification of lead test failures and lead alerts is available ("PaceSafe" on page 2-13).*

Table 3–1. Lead measurement reporting

Lead Measurement	Reported Values	Out-of-Range Limits
A Pace Impedance (Ω)	200 to maximum programmable High Impedance Limit[a]	Low: ≤ programmed Atrial Low Impedance Limit High: ≥ programmed Atrial High Impedance Limit
RV Pace Impedance (Ω)	200 to maximum programmable High Impedance Limit[a]	Low: ≤ programmed Right Ventricular Low Impedance Limit High: ≥ programmed Right Ventricular High Impedance Limit)
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

a. The maximum programmable High Impedance Limit is 2500 or 3000 Ω depending on the pulse generator model.

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.*

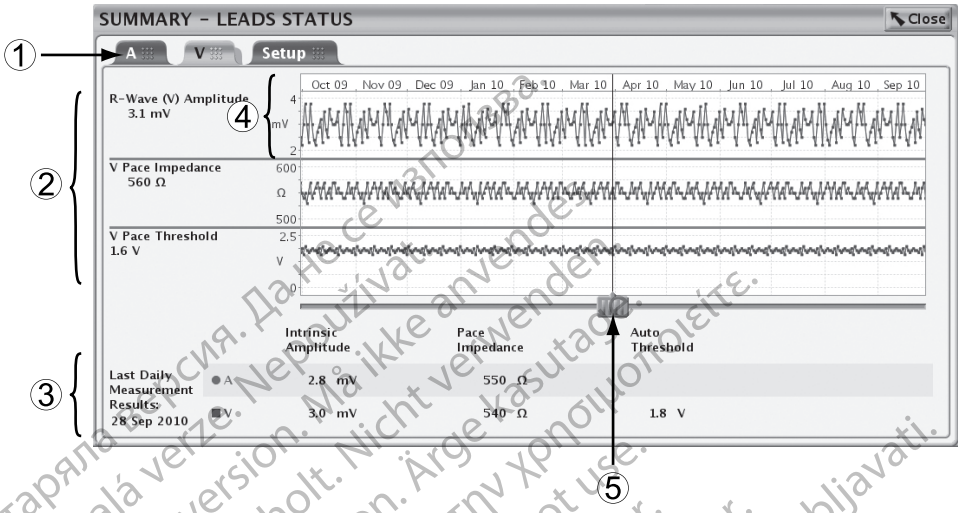
The Leads Status summary screen provides daily measurement details for applicable leads (Figure 3–3 Leads Status summary screen on page 3-8):

- 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 or to set the Impedance Limit values.

  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 or POST results 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 plot a point at the corresponding maximum or minimum value.

- A gap will be generated if the device is unable to obtain a valid measurement for that day.
- The most recent daily measurements or POST results 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).

When more than one measurement occurs in one day, only one will be reported. For Amplitude and Impedance, if one of the measurements is valid and one invalid, the invalid measurement will be reported. If both measurements are valid, the most recent 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
In-range amplitude measurement	Measurement value	Plotted point
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

Table 3–2. Intrinsic Amplitude: Daily Measurement Conditions, Programmer Display, and Graphical Representation (continued)

Condition	Programmer Display	Graphical Representation
Sensed events defined as a PAC	PAC	Gap
Out-of-range amplitude measurements (mV)	0.1, 0.2, ..., 0.5 (RA lead) with attention icon 0.1, 0.2, ..., 3.0 (ventricular lead) with attention icon	Plotted point
	< 0.1 with attention icon	Plotted point at corresponding minimum
	> 25 with attention icon	Plotted point at corresponding maximum[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
In-range impedance measurement	Measurement value	Plotted point
Electrode Configuration is programmed Off/ None	Invalid Data	Gap
Noise detected during the test period	Noise	Gap
Out-of-range impedance measurements (pace leads) (Ω)	Measured value greater than or equal to the Pace High Impedance Limit with attention icon Measured value less than or equal to the Pace Low Impedance Limit with attention icon	Plotted point
	> Maximum Pace High Impedance Limit with attention icon < Minimum Pace Low Impedance Limit with attention icon	Plotted point at corresponding minimum or maximum[a]

a. Selecting these points 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
In-range threshold measurement	Measurement value	Plotted point
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 2-13).*

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
- LATITUDE interrogation is in progress
- Pulse generator is in Electrocautery Protection Mode
- Pulse generator is in MRI Protection Mode
- Magnet is placed on the pulse generator (when Magnet Response set to Pace Async)

See a detailed description of conditions under which PaceSafe measurements will not be attempted ("PaceSafe" on page 2-13).

POST-OPERATIVE SYSTEM TEST (POST)

This feature is available in ACCOLADE, PROPONENT, and ESSENTIO devices.

The POST feature provides an automatic device/lead check at a pre-determined time post-implant. This helps document proper system functionality without requiring manual system testing, which helps facilitate same-day discharge. The clinician can select the amount of time after lead attachment when automatic lead test results are desired. Any adjustments to the nominal test results time must be programmed prior to lead attachment.

If enabled, automatic Intrinsic Amplitude, Impedance, and Pace Threshold testing will be attempted one hour prior to the desired test results time. Upon interrogation, status of the testing (scheduled to run, in-progress, complete) will be provided on the Summary dialog and Summary screen for the first 48 hours following lead attachment. Test results can be printed on Quick Notes and Follow-Up Reports.

NOTE: *Pacing parameters may be temporarily adjusted to help ensure a valid measurement is obtained.*

If the device is unable to obtain one or more valid measurements on the initial attempt, re-attempts will be performed to help facilitate a measurement. Testing may complete up to one hour after the test results time if re-attempts are required. If a valid measurement is not obtained, and/or if automatic daily measurements occur prior to printing the report, the daily measurement result may be recorded ("Leads Status" on page 3-6).

LEAD TESTS

The following lead tests are available (Figure 3–4 Lead Tests screen on page 3-10):

- Pace Impedance
- Intrinsic Amplitude
- Pace Threshold

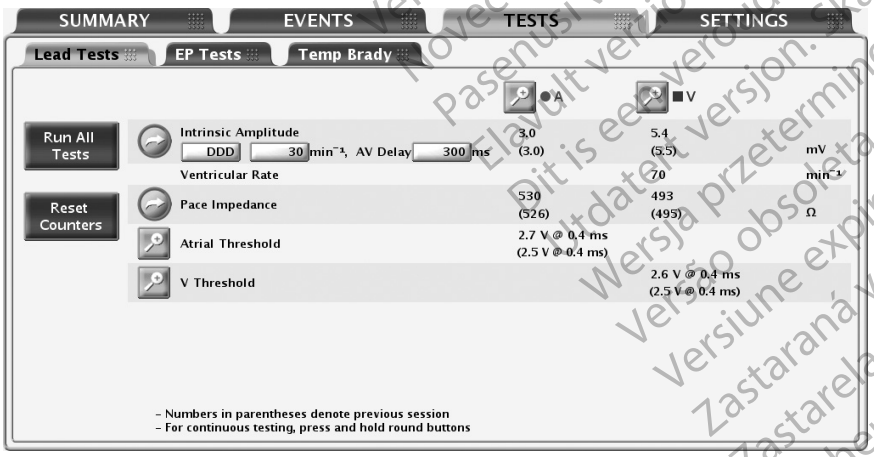


Figure 3–4. Lead Tests screen

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 three 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
- By selecting the Run All Tests button—automatically performs Intrinsic Amplitude and Lead Impedance tests and allows you to perform Pace Threshold tests

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 with pocket manipulation and/or isometrics
- X-ray or fluoroscopic image review
- 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 ventricular and atrial pace amplitude threshold tests can be performed manually or automatically. When PaceSafe is programmed to Auto, the results of the commanded automatic amplitude tests may be 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

A minimum 2X voltage capture threshold or 3X pulse width capture threshold for each chamber is recommended to provide an adequate safety margin and help preserve battery longevity. The starting parameter values are automatically calculated prior to testing. 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: *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). A 10 second trace (prior to loss of capture) is automatically stored and can be displayed and analyzed by selecting the Snapshot tab ("Snapshot" on page 4-8).

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 Leads Status screen. The measurements are also provided on the Quick Notes report.*

Commanded Automatic Pace Threshold Test

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

Commanded automatic threshold tests differ from the manual tests in the following ways:

- Commanded 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
  - Pacing Lead Configuration (RAAT)

  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, a commanded automatic threshold test cannot be paused, only cancelled.
- PaceSafe automatically determines when the test is completed and automatically stops the test.
- When complete, the test automatically stops and displays the threshold, which is the last output level that demonstrated consistent capture. A 10 second trace (prior to loss of capture) is automatically stored and can be displayed and analyzed by selecting the Snapshot tab ("Snapshot" on page 4-8).
- Test results cannot be edited.

NOTE: *No backup atrial pacing is provided during a commanded automatic right atrial threshold test.*

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 4-9 and "Counters" on page 4-9)
- Heart Rate Variability (HRV)—measures changes in the patient's intrinsic heart rate within a 24-hour collection period ("Heart Rate Variability" on page 4-10)
- Trends—provides a graphical view of specific patient, pulse generator, and lead data ("Trends" on page 4-13)

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, ATR (if it lasted more than 48 hours), and MRI episodes.*

ARRHYTHMIA LOGBOOK

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

The Arrhythmia Logbook provides access to the following detailed information about episodes of all types (Figure 4–1 Arrhythmia Logbook screen on page 4-3):

- 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).*

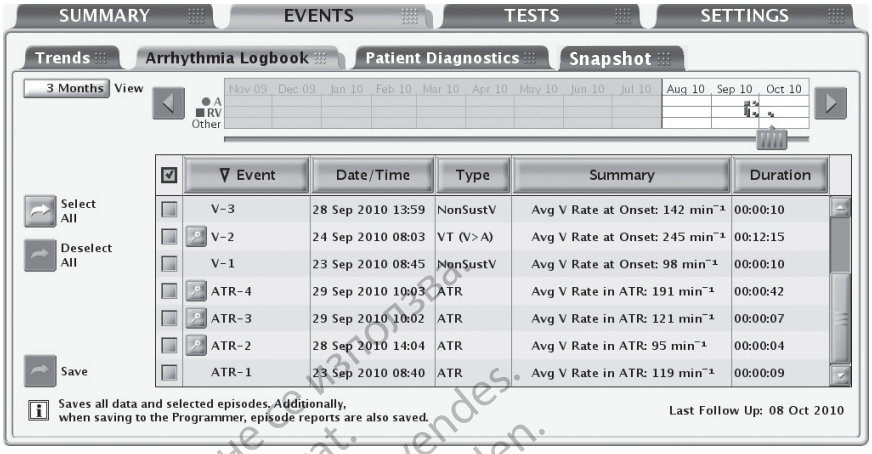


Figure 4–1. Arrhythmia Logbook screen

The priority, maximum number, and minimum number of episodes that the pulse generator stores under normal conditions varies by episode type (Table 4–1 Episode Priority 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:

1. If device memory is full, and there are episodes older than 18 months, then the oldest of the lowest priority episodes from these episode types will be deleted (regardless if the minimum number of episodes are stored) (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices).

2. 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.

3. 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.

4. 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)[C]	1	50	5	10
MRI	1	10	1	5
PTM (Patient Triggered Monitor)	1	5	1	1

Table 4–1. Episode Priority (continued)

Episode Type	Priority	Maximum number of stored episodes	Minimum number of stored episodes with detailed reports	Maximum number of stored episodes with detailed reports
SAM (Signal Artifact Monitor)	1	2	1	2
SVT (V≤A) [a]	2	50	3	5
NonSustV	3	10	1	2
RA Auto[a]	3	1	1	1
RV Auto	3	1	1	1
ATR [a]	4	10	1	3
PMT [a]	4	5	1	3
SBR[a]	4	10	1	3
APM RT[b]	4	1	1	1
RYTHMIQ [a]	4	10	1	3

a. Not available in SR models.
b. Advanced Patient Management real time (APM RT) events are presenting EGMs, captured and stored on the pulse generator during LATITUDE Communicator follow-ups.
c. 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 1-17).

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 (MRI events do not include EGM data)
   - Intervals (MRI events do not include Interval data)

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 may 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) (PaceSafe episodes only)

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.

   - Adjust the trace Speed as needed (10, 25, 50, 100 mm/s). As the Speed is increased, the time/horizontal scale is expanded.

   NOTE: *Adjusting the trace Speed is for on-screen viewing only; the print speed of a stored EGM is set to 25 mm/s.*

   - Use the electronic caliper (slider bar) to measure the distance/time between signals as well as measure the amplitude of signals.

     – The distance between signals can be measured by moving each caliper to the desired points on the EGM. The time (in milliseconds or seconds) between the two calipers will be displayed.

     – The amplitude of the signal can be measured by moving the left-hand caliper over the peak of the desired signal. The value (in millivolts) of the signal will be displayed on the left side of the EGM. The signal is measured from baseline to peak, either positive or negative. Adjust the trace Speed and/or amplitude scale as needed to help facilitate an amplitude measurement.

   - Adjust the amplitude/vertical scale as needed (0.2, 0.5, 1, 2, 5 mm/mV) for each channel using the up/down arrow buttons located on the right side of the trace display. As the gain is increased, the amplitude of the signal is enlarged.

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. ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices will begin storing an episode in response to 8 out of 10 fast beats. FORMIO, VITALIO, INGENIO, and ADVANTIO devices will begin storing an episode in response to 3 consecutive fast beats. The episode 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 ("Use of Atrial Information" on page 2-64).*

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-EpsdEnd marker is displayed.

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

- If 8 out of 10 fast beats have not been detected, but 10 consecutive slow beats are detected below the VT Detection Rate. No end of episode marker is provided in this scenario.
- EP testing 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.*

SNAPSHOT

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

A 12 second trace of the ECG/EGM display can be stored at any time by pressing the Snapshot button from any screen. A trace is also automatically stored following a Pace Threshold Test. After a trace has been stored, it can be displayed and analyzed by selecting the Snapshot tab.

The traces which are currently selected on the ECG/EGM display as well as annotated markers will be captured for up to 10 seconds before and up to 2 seconds after the Snapshot button was selected. If a Snapshot was automatically stored during a Pace Threshold Test, it will be 10 seconds long, ending with the termination of the test.

NOTE: *The Snapshot length will be reduced if the traces on the ECG/EGM display are changed or the session started within 10 seconds of selecting the Snapshot button.*

Up to 6 time-stamped Snapshots will be stored in the PRM memory for the current session only. Once the session has been terminated by exiting the application software or by interrogating a new patient, the data will be lost. If more than 6 Snapshots are stored in one PRM session, the oldest will be overwritten.

Use the following steps to view a stored Snapshot:

1. From the Events tab, select the Snapshot tab.
2. Select the Previous Snapshot or Next Snapshot button to display a different trace.
3. Use the slider under the upper display window to view different sections of the stored Snapshot.
4. Adjust the Speed as needed (10, 25, 50, 100 mm/s). As the Speed is increased, the time/horizontal scale is expanded.

   NOTE: *Adjusting the Speed is for on-screen viewing only; the print speed of a stored Snapshot is set to 25 mm/s.*

5. Use the electronic caliper (slider bar) to measure the distance/time between signals as well as measure the amplitude of signals.

- The distance between signals can be measured by moving each caliper to the desired points on the Snapshot. The time (in milliseconds or seconds) between the two calipers will be displayed.

- The amplitude of the signal can be measured by moving the left-hand caliper over the peak of the desired signal. The value (in millivolts) of the signal will be displayed on the left side of the Snapshot. The signal is measured from baseline to peak, either positive or negative. Adjust the Speed and/or amplitude scale as needed to help facilitate an amplitude measurement.

6. Adjust the amplitude/vertical scale as needed (0.2, 0.5, 1, 2, 5 mm/mV) for each channel using the up/down arrow buttons located on the right side of the trace display. As the gain is increased, the amplitude of the signal is enlarged.

7. To print the Snapshot that is currently being viewed, select the Print button. To save the Snapshot that is currently being viewed, select the Save button. Select Save All Snapshots to save all stored Snapshot traces.

HISTOGRAMS

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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
- The RV Rate during AT/AF events (ACCOLADE and PROPONENT devices)

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 as well as RV rate counts during AT/AF events (ACCOLADE and PROPONENT devices).

All Histograms can be reset by selecting the Reset button from any Patient Diagnostics Details screen. Histogram data can be saved to the PRM and printed via the Reports tab.

COUNTERS

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 Details 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 Arrhythmia—includes percentage of time in AT/AF, Total Time in AT/AF (min, hr, or days), Episodes by Duration and Total PACs. When at least one ATR event has been stored since the last reset, data for the Longest AT/AF and Fastest VS Rate in AT/AF is presented on the Summary screen and on printed reports (ACCOLADE and PROPONENT devices).

  NOTE: *AT/AF % and Total Time in AT/AF records and displays data for a maximum of one year.*

- Ventricular Counters—includes Total PVCs and Three or More PVCs

All Counters can be reset by selecting the Reset button from any Patient Diagnostics Details screen. Counter data can be saved to the PRM and printed via the Reports tab.

HEART RATE VARIABILITY (HRV)

This feature is available in ACCOLADE and FORMIO devices.

Heart Rate Variability (HRV) is a measure of the changes in a patient's intrinsic heart rate within a 24-hour collection period.

HRV data are collected only in dual chamber devices.

This feature can assist in evaluating the clinical status of heart failure patients.

HRV, as measured by SDANN and HRV Footprint, is an objective, physiological measure that can identify heart failure patients at higher risk of mortality. Specifically, depressed HRV can be

used as a predictor of risk of mortality after an acute myocardial infarction.[1] A normal SDANN value is 127 plus or minus 35 ms.[1] Higher SDANN values (indicating greater variability of heart rate) have been associated with lower risk of mortality.[2 3 4] Similarly, a larger HRV Footprint also indicates greater heart rate variability and has been associated with lower mortality risk.[2 3 4]

The HRV monitor feature provides the following information using the intrinsic interval data from the 24-hour collection period that meets the HRV collection criteria (Figure 4–2 Heart Rate Variability display on page 4-11):

- Date and time the 24-hour collection period was completed.
- % of Time Used—displays the percentage of time during the 24-hour collection period in which there are valid intrinsic beats. If the % of Time Used falls below 67%, data will not be displayed for that collection period.
- HRV Footprint plot—shows the percentage of the graph area used by the HRV plot. The graph area portrays an “at-a-glance snapshot” of the distribution of variability versus heart rate over a 24-hour period. The trended percentage is a normalized score based on the footprint in the graph.
- Standard Deviation of Averaged Normal R to R intervals (SDANN)—the HRV collection period comprises 288 5-minute segments (24-hours) of intrinsic intervals. The SDANN is the standard deviation of the averages of intrinsic intervals in the 288 5-minute segments. This measurement is also available in the Trends.
- Current Normal Brady parameters—Mode, LRL, MTR, and Sensed AV Delay.
- An HRV plot for current and previous collection periods including a line that shows the mean heart rate. The HRV plot summarizes the cardiac variation on a cycle-to-cycle basis. The x-axis shows the heart rate range; the y-axis shows the beat-to-beat variability displayed in milliseconds. The color indicates the frequency of beats at any particular heart rate and heart rate variability combination.

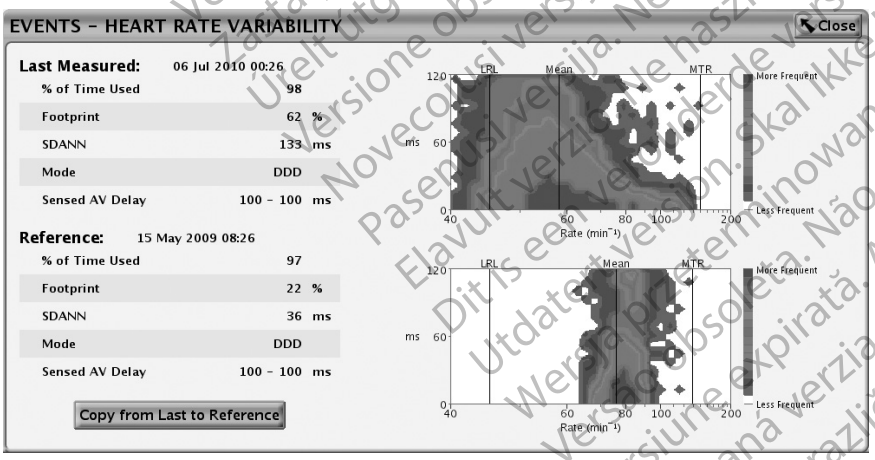


Figure 4–2. Heart Rate Variability display

Consider the following information when using HRV:

- The cardiac cycle (R–R interval) in HRV is determined by RV sensed and paced events.

1. Electrophysiology Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Circulation, 93:1043-1065, 1996.
2. F.R. Gilliam et al., Journal of Electrocardiology, 40:336-342, 2007.
3. F.R. Gilliam et al., PACE, 30:56-64, 2007.
4. J.P. Singh et al., Europace, 12:7–8, 2010.

- Programming the pacing parameters causes the data acquired for the current 24-hour collection period to be invalid.
- The device saves only one set of values and corresponding HRV plot for the Reference portion of the screen. Once the values are copied from Last Measured to Reference, older data cannot be retrieved.
- The first time the HRV feature is used, the Reference screen will show the data from the first valid 24-hour collection period.

Follow the steps below to view HRV:

1. To access the HRV monitor screen, select the Events tab.
2. From the Events screen, select the Patient Diagnostics tab.
3. Select the Heart Rate Variability Details button to view the Last Measured and Reference data.
4. To copy the Last Measured HRV measurements into the Reference section, select the Copy From Last to Reference button.

The HRV monitor screen displays a set of measurements and a HRV plot based on the most recent 24-hour collection period in the Last Measured portion of the screen; measurements from a previously saved collection period are displayed in the Reference portion of the screen. Both collection periods can be viewed simultaneously to compare data that could show trends in the patient's HRV changes over a period of time. By saving the Last Measured values to the Reference portion of the screen, you can view the last measured data during a later session.

HRV Collection Criteria

Only valid sinus rhythm intervals are used in the HRV data calculations. For HRV, valid intervals are those which include only valid HRV events.

Valid HRV 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 HRV events are as follows:

- 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

HRV data may not be reported for a variety of reasons; the most common are as follows:

- Less than 67% of the 24-hour collection period (approximately 16 hours) contains valid HRV events
- Brady Parameters were programmed within the last 24 hours

An example of how HRV data is recorded is shown (Figure 4–3 Example of HRV data collection on page 4-13). In this example, the HRV data in the first collection period is invalid because the Brady Parameters were programmed after the device was taken out of Storage. HRV data is successfully calculated and reported at the end of the second 24-hour collection period. Subsequent HRV data is not reported until the end of Collection Period 5.

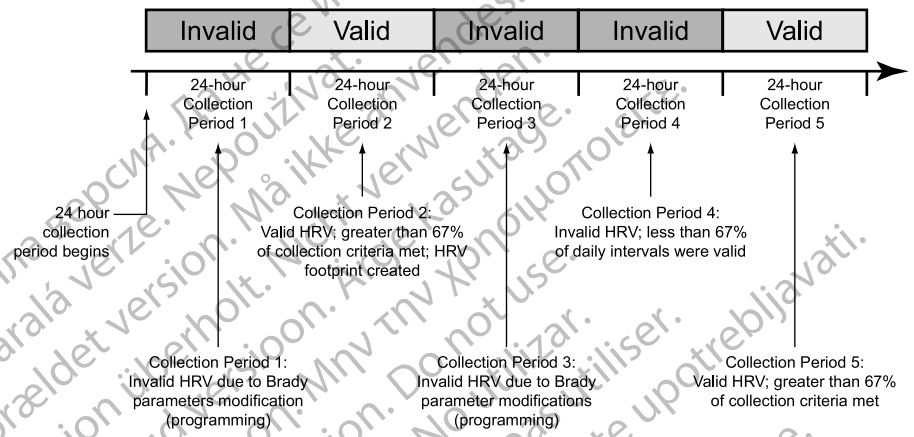


Figure 4–3. Example of HRV data collection

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.
- Activity Level (ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices)—displays a measure of the patient's daily activity represented by the “Percent of Day Active”.
- AT/AF 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.
- RV Rate during AT/AF (ACCOLADE and PROPONENT devices)—displays a trend of the patient’s Mean and Maximum RV rate during ATR events. The Mean rate is calculated using both paced and sensed beats while the Maximum rate is a rolling average of sensed beats. In some cases, the Mean rate may be higher than the Maximum rate.
- Pacing Percent (ACCOLADE and PROPONENT devices)—displays the percentage of paced events for each chamber.
- Respiratory Rate—displays a trend of the patient's daily minimum, maximum, and median respiratory rate values ("Respiratory Rate Trend" on page 4-15).

- AP Scan—displays a trend of the average number of respiratory disturbance events as measured by the pulse generator that the patient experiences per hour during the programmed sleep period ("AP Scan" on page 4-15).

- 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 HRV collection criteria ("Heart Rate Variability" on page 4-10).

- SDANN (Standard Deviation of Averaged Normal-to-Normal R-R intervals)—displays a trend of the standard deviation of the averages of intrinsic intervals over the 24-hour collection period (which is comprised of 288 5-minute segments). Only intervals that meet the HRV collection criteria are considered valid.

  A normal SDANN value is 127 plus or minus 35 ms.[5]

- HRV Footprint—displays the percentage of the graph area used by the HRV Footprint plot, illustrating the distribution of variability versus heart rate over a 24-hour period. The trended percentage is a normalized score based on the footprint in the graph. Refer to additional information about HRV ("Heart Rate Variability" on page 4-10).

- ABM (Autonomic Balance Monitor)—displays a trend of the LF/HF ratio.[6] Normal range for the LF/HF ratio is 1.5 - 2.0.[7] ABM is a device calculation based on R–R interval measurements, which mathematically functions as a surrogate measurement for LF/HF ratio. Intervals used in the calculation must be valid sinus rhythm intervals as determined by the HRV collection criteria. If the HRV data is invalid for the 24-hour collection period, then the ABM is not calculated and a value of "N/R" is displayed.

- Lead impedance and amplitude—displays trends of the daily intrinsic amplitude and lead impedance measurements ("Leads Status" on page 3-6).

- A Pace Threshold—displays a trend of the daily right atrial pacing thresholds.

- 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:

   - Heart Failure—includes Heart Rate, SDANN, and HRV Footprint trends.

   - Atrial Arrhythmia—includes AT/AF Burden, RV Rate during AT/AF, and Respiratory Rate (ACCOLADE and PROPONENT devices). For other models, the Atrial Arrhythmia category includes Events, Heart Rate, and AT/AF Burden trends.

   - Activity—includes Heart Rate, Activity Level, and Respiratory Rate trends.

5. Electrophysiology Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Circulation, 93:1043-1065, 1996.
6. Parasympathetic tone is primarily reflected in the high-frequency (HF) component of spectral analysis. The low-frequency (LF) component is influenced by both the sympathetic and parasympathetic nervous systems. The LF/HF ratio is considered a measure of sympathovagal balance and reflects sympathetic modulations. (Source: ACC/AHA Guidelines for Ambulatory Electrocardiography—Part III, JACC VOL. 34, No. 3, September 1999:912–48).
7. Electrophysiology Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Circulation, 93:1043-1065, 1996.

- 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.

Trends data can be saved to the PRM and printed via the Reports tab. Printed Trends display a timeline which shows PRM and device interactions including programming, office interrogations, and counter resets (ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2).

Respiratory Rate Trend

This feature is available in ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices.

The Respiratory Rate trend displays a graph of the patient's daily minimum, maximum, and median respiratory rate values. These daily values are stored for up to one year to create a longitudinal display of physiological data.

NOTE: *The American College of Cardiology (ACC)/American Heart Association (AHA) guidelines recommend the measurement and documentation of physiological vital signs including respiratory rate for cardiac patients.*[8]

The MV Sensor must be programmed to On or Passive for Respiratory Rate trend data to be collected and displayed.

For a detailed description of the Minute Ventilation/Respiratory Sensor function, refer to Minute Ventilation/Respiratory Sensor ("Minute Ventilation/Respiratory Sensor" on page 2-25).

Move the horizontal slider over a data point to view the values for a given date. At least 16 hours of data must be collected for values to be calculated and plotted to the Respiratory Rate trend. If insufficient data was collected, no data point will be plotted and there will be a gap in the trend line. This gap will be labeled as N/R to indicate that insufficient or no data was collected.

AP Scan

This feature is available in ACCOLADE, FORMIO, and VITALIO devices.

AP Scan is a trend of the average number of respiratory disturbance events as measured by the pulse generator that the patient experiences per hour during the programmed sleep period. This trend is not intended to diagnose patients with sleep apnea. Standard clinic methods such as polysomnogram should be used for actual diagnosis. Data provided by this trend can be used along with other clinical information to follow changes in patients who may be at high risk for sleep-disordered breathing.

AP Scan is modeled after accepted sleep clinic scoring methodologies for detection of apnea and hypopnea.[9] The pulse generator considers a respiratory disturbance event to be a 26% or greater reduction in respiratory signal amplitude, lasting at least 10 seconds. The average is calculated by dividing the total number of respiratory disturbance events observed during the

8. ACC/AHA Heart Failure Clinical Data Standards. Circulation, Vol. 112 (12), September 20, 2005.
9. Meoli et al., Sleep, Vol. 24 (4), 469–470, 2001.

programmed sleep period by the number of hours in the sleep period. These averages are plotted once a day to the AP Scan trend.

Consider the following when using AP Scan:

- To aid in interpreting the trend, a threshold is displayed on the graph at 32 average events per hour. This threshold is intended to approximately correlate to a clinical threshold for severe apnea. Data points above this threshold may indicate the need to further investigate the presence of severe sleep-disordered breathing.
- Respiratory signal amplitude can be affected by factors such as patient posture or movement.
- The accuracy of the AP Scan trend can be diminished under any of the following conditions:
  - The patient is not asleep during part or all of the defined sleep period
  - The patient experiences milder sleep-disordered breathing that the pulse generator cannot accurately detect
  - The patient has low respiratory signal amplitudes, making it difficult for the pulse generator to detect respiratory disturbance events
  - The patient is receiving treatment for sleep apnea (e.g., continuous positive airway pressure therapy)

To activate AP Scan, perform the following steps:

1. Program the MV Sensor to On or Passive ("Minute Ventilation/Respiratory Sensor" on page 2-25).
2. Program the following Sleep Schedule parameters (available on the General tab of the Patient Information screen):
   - Sleep Start Time—time when you expect the patient to typically fall asleep each night
   - Sleep Duration—amount of time you expect the patient to typically sleep each night

NOTE: *You must program the MV Sensor to On or Passive to activate AP Scan. Programming the Sleep Schedule parameters will have no effect if the MV Sensor is Off.*

To increase the likelihood that the patient is sleeping during data collection, the pulse generator does not begin collecting data until 1 hour after the Sleep Start Time, and stops collecting data 1 hour before the Sleep Duration period would otherwise have expired.

Example: If you select a Sleep Start Time of 22:00 and a Sleep Duration of 8 hours, the pulse generator will monitor for respiratory disturbance events starting at 23:00 and stopping at 05:00.

Move the horizontal slider over a data point to view the average for a given date. At least 2 hours of data must be collected for an average to be calculated and plotted to the AP Scan trend. If insufficient data was collected, no data point will be plotted and there will be a gap in the trend line. This gap will be labeled as N/R to indicate that insufficient or no data was collected.

POST IMPLANT FEATURES

Patient Triggered Monitor (PTM)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

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 PTM is enabled, the patient can trigger data storage by holding a magnet over the device for at least 2 seconds. The device will store data for up to 2 minutes prior to and up to 1 minute after magnet application. The stored data include the episode number, rates at magnet application, and start time and date of magnet application. After one EGM is generated and stored, PTM is disabled. To store another EGM, the PTM feature must be re-enabled using the programmer. If 60 days elapse and the patient did not trigger data storage, PTM is automatically disabled.

When data are stored, the corresponding episode type is recorded as PTM in the Arrhythmia Logbook.

CAUTION: Use care when using Patient Triggered Monitor, because the following conditions will exist while it is enabled:

- All other magnet features, including asynchronous pacing, are disabled. The Magnet feature will not indicate magnet position.
- Device longevity is impacted. To help reduce the longevity impact, PTM only allows storage of one episode, and PTM is automatically disabled after 60 days if data storage was never triggered.
- Once the EGM is stored (or 60 days elapses), PTM is disabled and the device Magnet Response automatically will be set to Pace Async. However, if a magnet is used, 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.
5. 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.
6. 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.*

7. 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

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

The magnet feature allows certain device functions to be triggered when a magnet is placed in close proximity to the pulse generator (Figure 4–4 Proper position of magnet Model 6860 to activate the pulse generator magnet feature on page 4-18).

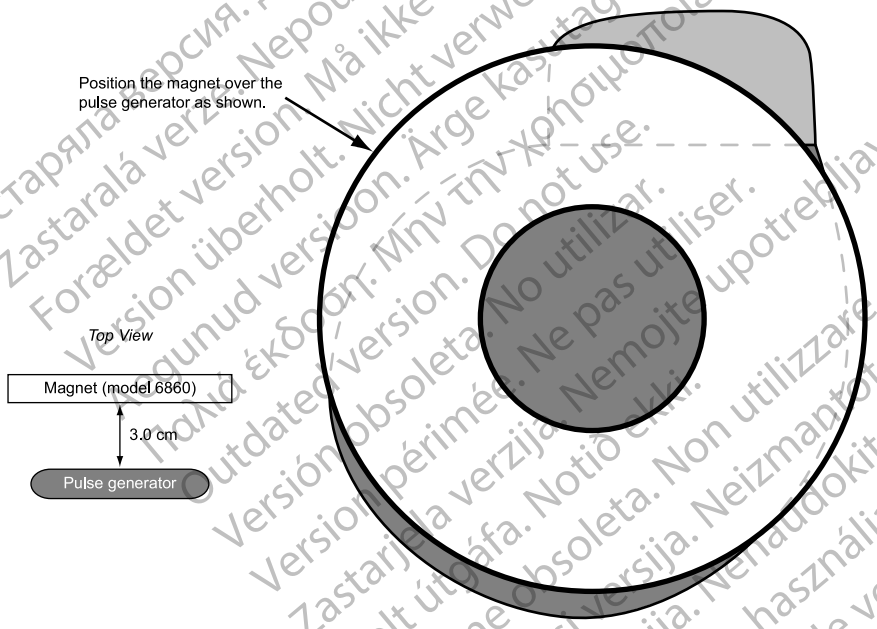


Figure 4–4. Proper position of magnet Model 6860 to activate the pulse generator magnet feature

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 4-16).

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.*

NOTE: *The magnet feature is suspended when the pulse generator is in MRI Protection Mode.*

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 equipment 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 EP Test Screen on page 5-2):

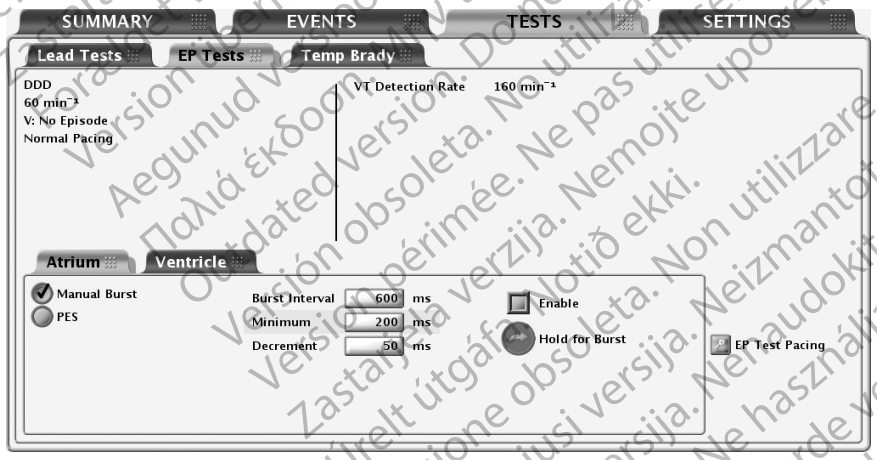


Figure 5–1. EP Test Screen

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 or VDDR 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 or VDDR devices.*

In dual-chamber, non-VDDR 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 PES induction drive train on page 5-3).

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 or VDDR devices.*

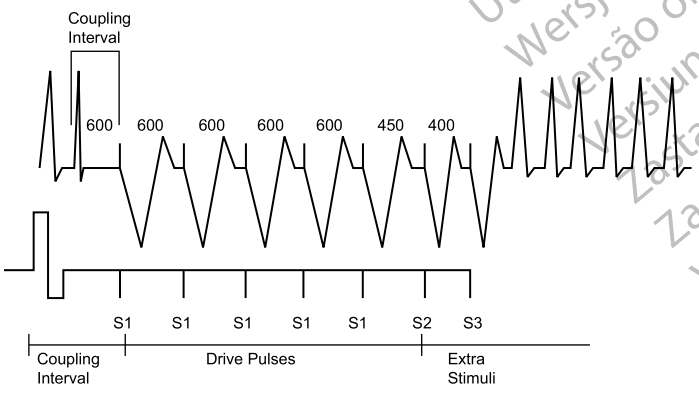


Figure 5–2. PES induction drive train

Performing PES Induction

1. In a dual-chamber, non-VDDR 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 PES induction options 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.

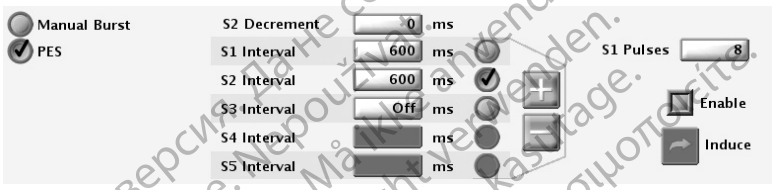


Figure 5–3. PES induction options

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 or VDDR devices.*

Performing Manual Burst Pacing

1. In a dual-chamber, non-VDDR 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 and VDDR 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; Enable MRI Protection[a]	Storage

a. Available in models with the MRI Protection Mode feature.

Table A–3. Pacing therapy parameters (specified into a 750 Ω load)

Parameter	Programmable Values	Nominal
Mode[a c]	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
Mode[a c] (VDDR model)	VDD(R); VVI(R); VOO; Off; Temporary: VDD; VVI; VOO; Off	VDD
Lower Rate Limit (LRL)[a b c] (min^{-1})	30; 35; …; 185	60 (Tolerance ± 5 ms)
Maximum Tracking Rate (MTR)[a c] (min^{-1})	50; 55; …; 185	130 (Tolerance ± 5 ms)
Maximum Sensor Rate (MSR)[e] (min^{-1})	50; 55; …; 185	130 (Tolerance ± 5 ms)
Pulse Amplitude[a c d h j] (dual chamber, atrium) (V)	Auto; 0.1; 0.2; …; 3.5; 4.0; …; 5.0; Temporary: 0.1; 0.2; …; 3.5; 4.0; …; 5.0	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude[a c d] (dual chamber, right ventricle) (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[a c d] (single chamber) (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[f] (independently programmable in each chamber that has the Pacesafe feature)	Disabled; Enabled	Enabled (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) Disabled (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)
Pulse Width[a c d g] (atrium, right ventricle) (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[e]	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[e]	On; Passive; Off	Passive
Minute Ventilation Response Factor	1; 2; …; 16	8
Minute Ventilation Fitness Level	Sedentary; Active; Athletic; Endurance Sports	Active

Table A–3. Pacing therapy parameters (specified into a 750 Ω load) (continued)

Parameter	Programmable Values	Nominal
Patient's Age[i]	≤ 5; 6–10; 11–15; …; 91–95; ≥ 96	56–60
Patient's Gender[i]	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[e] (min^{-1})	-80; -75; …; -5; Off	Off (Tolerance ± 5 ms)
Rate Hysteresis Search Hysteresis[e] (cycles)	Off; 256; 512; 1024; 2048; 4096	Off (Tolerance ± 1 cycle)
Rate Smoothing (Up, Down)[e] (%)	Off; 3; 6; 9; 12; 15; 18; 21; 25	Off (Tolerance ± 1%)
Rate Smoothing Maximum Pacing Rate (min^{-1})	50; 55; …; 185	130 (Tolerance ± 5 ms)
Sudden Brady Response (SBR)[e h]	Off; On	Off
SBR Atrial Paces Before Therapy[h]	1; 2; …; 8	3
SBR Atrial Pacing Rate Increase[h] (min^{-1})	5; 10; …; 40	20
SBR Therapy Duration[h] (min)	1; 2; …; 15	2
SBR Inhibit During Rest[h]	Off; On	On
Atrial Pace/Sense Configuration[a c h] (dual chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar; Unipolar/Off; Bipolar/Off	Bipolar (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) Unipolar (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)
Right Ventricle Pace/Sense Configuration[a c] (dual chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar	Bipolar (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) Unipolar (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)
Pace/Sense Configuration[a c] (single chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar	Bipolar (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) Unipolar (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)
Atrial Sense Configuration[a c] (VDDR model)	Unipolar; Bipolar; Off	Bipolar (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) Unipolar (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)
Safety Switch (independently programmable in each chamber)	Off; On	On
Automatic Lead Recognition	Off; On	On
Maximum Paced AV Delay[a c h] (ms)	30; 40; …; 400	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay[a c h] (ms)	30; 40; …; 400	80 (Tolerance ± 5 ms)
Maximum Sensed AV Delay[a c] (ms)	30; 40; …; 400	150 (Tolerance ± 5 ms)
Maximum Sensed AV Delay[a c] (VDDR model) (ms)	30; 40; …; 400	180 (Tolerance ± 5 ms)
Minimum Sensed AV Delay[a c] (ms)	30; 40; …; 400	65 (Tolerance ± 5 ms)
Minimum Sensed AV Delay[a c] (VDDR model) (ms)	30; 40; …; 400	80 (Tolerance ± 5 ms)
AV Search +[e]	Off; On	Off

Table A–3. Pacing therapy parameters (specified into a 750 Ω load) (continued)

Parameter	Programmable Values	Nominal
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)
RYTHMIQ[e h]	AAI(R) with VVI Backup; Off	Off
Maximum A-Refractory (PVARP)[a c] (dual chamber) (ms)	150; 160; …; 500	280 (Tolerance ± 5 ms)
Minimum A-Refractory (PVARP)[a c] (dual chamber) (ms)	150; 160; …; 500	240 (Tolerance ± 5 ms)
Maximum V-Refractory (VRP)[a c] (dual chamber) (ms)	150; 160; …; 500	250 (Tolerance ± 5 ms)
Minimum V-Refractory (VRP)[a c] (dual chamber) (ms)	150; 160; …; 500	230 (Tolerance ± 5 ms)
Maximum Refractory[a c] (single chamber) (ms)	150; 160; …; 500	250 (Tolerance ± 5 ms)
Minimum Refractory[a c] (single chamber) (ms)	150; 160; …; 500	250 (Tolerance ± 5 ms)
PVARP after PVC[a] (ms)	Off; 150; 200; …; 500	400 (Tolerance ± 5 ms)
A-Blank after V-Pace[a c k] (ms)	Smart; 45; 65; 85; 105; 125; 150; 175; 200	125 (Tolerance ± 5 ms)
A-Blank after V-Sense[a c k] (ms)	Smart; 45; 65; 85	45 (Tolerance ± 5 ms)
V-Blank after A-Pace[a c h] (ms)	45; 65; 85	65 (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
Noise Response[a] (VDDR model)	VOO; Inhibit Pacing	VOO
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. 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).
c. Separately programmable for Temporary Brady.
d. For FORMIO, VITALIO, INGENIO, and ADVANTIO devices, values are not affected by temperature variation within the range 20°C – 43°C. For ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices, values are not affected by temperature variation within the range 20°C – 45°C.
e. This parameter is disabled during Temporary Brady.
f. This parameter is automatically enabled if Auto is selected for the Pulse Amplitude.
g. When the Pulse Amplitude is set to Auto or Pulse Amplitude Daily Trend is enabled the Pulse Width is fixed at 0.4 ms.
h. Not applicable to VDDR models.
i. This parameter is used for calculating Ventilatory Threshold Response.
j. Auto is available in models which contain the Pacesafe feature.
k. Smart is available when AGC is selected as the Sensing Method.

Table A–4. MRI Protection parameters

Parameter	Programmable Values	Nominal
MRI Brady Mode	Off; VOO; AOO; DOO	DOO for DDD(R), DDI(R), or DOO normal Brady modes; VOO for VDD(R), VVI(R), or VOO normal Brady modes; AOO for AAI(R) or AOO normal Brady Mode; Off for Normal Brady Mode Off
MRI Lower Rate Limit (LRL) (min^{-1})	30; 35; ...; 100	20 min^{-1} above the normal mode LRL
MRI Atrial Amplitude (V)	2.0; 2.1; …; 3.5; 4.0; …; 5.0	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)[a]

Table A–4. MRI Protection parameters (continued)

Parameter	Programmable Values	Nominal
MRI Ventricular Amplitude (V)	2.0; 2.1; …; 3.5; 4.0; …; 5.0	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)[a]
MRI Protection Time-out (hours)	Off; 3; 6; 9; 12; 24; 48	24

a. During the transition into the MRI Protection Mode, it may take up to 6 cardiac pacing cycles for the pace amplitude to meet the specified tolerance range.

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] [c] (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)
ATR Entry Count[a] (cycles)	1; 2; ...; 8	8
ATR Exit Count[a] (cycles)	1; 2; ...; 8	8
ATR Fallback Mode [d]	VDI; DDI; VDIR; DDIR	DDI
ATR Fallback Mode[e] (VDDR model)	VDI; VDIR	VDI
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)
ATR Ventricular Rate Regulation (VRR)[a]	Off; On	On
ATR Maximum Pacing Rate (MPR)[a] (min^{-1})	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Atrial Flutter Response[b]	Off; On	On
Atrial Flutter Response Trigger Rate [c] (min^{-1})	100; 110; ...; 300	170 (Tolerance ± 5 ms)
PMT Termination [b]	Off; On	On
Ventricular Rate Regulation (VRR) [b]	Off; On	Off

Table A–7. Atrial Tachy Parameters (continued)

Parameter	Programmable Values	Nominal
VRR Maximum Pacing Rate (MPR) (min^{-1})	50; 55; ...; 185	130 (Tolerance ± 5 ms)
APP/ProACt[b]	Off; On	Off
APP/ProACt Max Pacing Rate (min^{-1})	50; 55; ...; 185	80 (Tolerance ± 5 ms)

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. ATR Trigger Rate and Atrial Flutter Response Trigger Rate are linked. If either of these rates is reprogrammed, the other will automatically change to the same value.
d. If Normal Brady ATR Fallback Mode is DDIR or DDI, then Temporary Brady ATR Fallback Mode is DDI. If Normal Brady ATR Fallback Mode is VDIR or VDI, then Temporary Brady ATR Fallback Mode is VDI.
e. 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) (mV)	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) (mV)	AGC 0.15; AGC 0.2; AGC 0.25; AGC 0.3; AGC 0.4; ...; AGC 1.0; AGC 1.5	AGC 0.6
Atrial Sensitivity (Fixed) (mV)	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) (mV)	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. Daily Lead Measurements

Parameter	Programmable Values	Nominal
Atrial Intrinsic Amplitude	On; Off	On
Ventricular Intrinsic Amplitude	On; Off	On
Intrinsic Amplitude (single-chamber models)	On; Off	On
Atrial Pace Impedance	On; Off	On
Ventricular Pace Impedance	On; Off	On
Pace Impedance (single-chamber models)	On; Off	On
Atrial Low Impedance Limit (Ω)	200; 250; ...; 500	200
Atrial High Impedance Limit (Ω)	2000; 2250;...; 3000 (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) 2000; 2250; 2500 (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)	2000
Ventricular Low Impedance Limit (Ω)	200; 250; ...; 500	200
Ventricular High Impedance Limit (Ω)	2000; 2250;...; 3000 (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices)	2000

Table A–9. Daily Lead Measurements (continued)

Parameter	Programmable Values	Nominal
	2000; 2250; 2500 (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)	
Low Impedance Limit (Ω) (single-chamber models)	200; 250; ...; 500	200
High Impedance Limit (Ω) (single-chamber models)	2000; 2250;...; 3000 (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) 2000; 2250; 2500 (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)	2000
Post-Operative System Test (POST) (hours)	Off; 2; 3; ...; 24	4

Table A–10. 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 ± 5 ms)
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 VDDR or single-chamber models.

Table A–11. 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–12. 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 Symbols on packaging 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
STERILE EO	Sterilized using ethylene oxide
	Do not resterilize
	Do not reuse
	Do not use if package is damaged
	Consult instructions for use on this website: www.bostonscientific-elabeling.com
	Temperature limitation
CE0086	CE mark of conformity with the identification of the notified body authorizing use of the mark
	Place telemetry wand here

Table B–1. Symbols on packaging (continued)

Symbol	Description
	Open here
EC REP	Authorized Representative in the European Community
	Manufacturer
N 20593 Z 1088	C-Tick with supplier codes
	Australian Communications and Media Authority (ACMA) radio compliance mark
R–NZ	New Zealand Radio Spectrum Management (RSM) radio compliance mark
AUS	Australian Sponsor Address
	MR Conditional
	Pacemaker RV
	Pacemaker RA, RV
	CRT-P RA, RV, LV
	Uncoated device
	RF Telemetry

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Authorized 2014 (ACCOLADE, ACCOLADE MRI, PROPONENT, PROPONENT MRI, ESSENTIO, ESSENTIO MRI, ALTRUA 2)

Products no longer placed on the EU market but continue to be supported. 2013 (FORMIO, FORMIO MRI, VITALIO, VITALIO MRI); 2012 (INGENIO MRI, ADVANTIO MRI); 2011 (INGENIO, ADVANTIO)