Boston Scientific

REFERENCE GUIDE

ALTRUA™ 20
ALTRUA™ 40
ALTRUA™ 60
INSIGNIA™ I Entra
INSIGNIA™ I Plus
INSIGNIA™ I Ultra

PACEMAKER

REF ALTRUA 20 - S201, S203, S204, S205, S208

ALTRUA 40 - S401, S402, S403, S404

ALTRUA 60 - S601, S602, S603, S604, S605, S606

INSIGNIA I Entra - 1195, 1198, 1294, 1295, 1296

INSIGNIA I Plus - 1194, 1297, 1298

INSIGNIA I Ultra - 1190, 1290, 1291

For the LATITUDE™ Programming System, Model 3300

CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

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 ALTRUA and INSIGNIA I System Guides provide information most relevant for implanting the pulse generator. These System Guides also contain information such as warnings, precautions, potential adverse events, mechanical specifications, longevity, hyperbaric therapy[1], and programming considerations.

This Reference Guide provides descriptions of pacing therapies, programmable features, and diagnostics.

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

NOTE: *The LATITUDE Programming System is available for use based on software and regional availability, which includes the Model 3300 Programmer. In this manual, the term Programmer is used to refer to the programming device.*

NOTE: *The LATITUDE Programming System has the same basic capabilities and intended use as the ZOOM™ LATITUDE™ Programming System, which includes the Model 3120 Programmer/Recorder/Monitor. Differences between the programming systems include software application model numbers, networking and printing capabilities, on-device keys, and data storage options.*

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.

PATIENT DIAGNOSTICS

- Snapshot: 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.
  - Up to 100 individual recordings can be maintained during a session. In the event more than 100 are captured, the oldest will be deleted to accommodate newer. A Real-time Log is not retained from session to session; if not saved as a PDF or printed, it is deleted upon ending the current device session or starting a new device session.

USER EXPERIENCE

- USB storage devices are supported: pulse generator data can be saved and transferred to a USB pen drive.
- PDF versions of reports are available.

1 Hyperbaric therapy pertains only to the ALTRUA pacemakers.

BRADY THERAPY

This product family includes single- and dual-chamber models, with feature variations.

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.

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

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

ACRONYMS

The following acronyms may be used in this manual:

°C	Degrees Celsius
°F	Degrees Fahrenheit
Ω	Ohms
A	Atrial
A-pace	Atrial pacing
A-sense	Atrial sensing
ACC	Accelerometer
AF	Atrial Fibrillation
AFR	Atrial Flutter Response
AGC	Automatic Gain Control
Ah	Ampere Hour
APM RT	Advanced Patient Management Remote Transmission
APMHR	Age Predicted Maximum Heart Rate
AT	Atrial Tachycardia
ATA	Atmospheres Absolute
ATR	Atrial Tachy Response
AV	Atrioventricular
BOL	Beginning of Life
bpm	beats per minute
C-LOC	Confirmed Loss of Capture
cm	Centimeter

EAS	Electronic Article Surveillance
ECG	Electrocardiogram
EGM	Electrogram
EMI	Electromagnetic Interference
EP	Electrophysiology; Electrophysiologic
EOL	End of Life
ERN	Elective Replacement Near
ERT	Elective Replacement Time
HBOT	Hyperbaric Oxygen Therapy
HF	Heart Failure
ICD	Implantable Cardioverter Defibrillator
kPA	Kilo Pascal
LRL	Lower Rate Limit
mA	Millampere
min.	Minimum
mm/mV	Millimeters per Millivolt
mm/s	Millimeters per second
MPR	Maximum Pacing Rate
MRI	Magnetic Resonance Imaging
ms	Millisecond
MSR	Maximum Sensor Rate
MTR	Maximum Tracking Rate
mV	Millivolt
MV	Minute Ventilation
NSVT	Non-sustained Ventricular Tachycardia
P-wave	deflection in an electrocardiographic tracing that represents atrial activity of the heart
PAC	Premature Atrial Contraction
PAT	Paroxysmal Atrial Tachycardia
PDF	Portable Document Format
PES	Programmed Electrical Stimulation
PG	Pulse Generator
PMT	Pacemaker-Mediated Tachycardia
POST	Post-Operative System Test
ppm	pulses per minute
PR	duration from P-wave to R-wave
psia	pounds per square inch (absolute)

psig pounds per square inch (gauge)

PTM Patient Triggered Monitor

PVARP Post-Ventricular Atrial Refractory Period

PVC Premature Ventricular Contraction

R-wave first upward deflection after the P wave representing early ventricular depolarization

RF Radio Frequency

RV Right Ventricular

SAM Signal Artifact Monitor

SBR Sudden Brady Response

SVT Supraventricular Tachycardia

TARP Total Atrial Refractory Period

TENS Transcutaneous Electrical Nerve Stimulation

USB Universal Serial Bus

V Ventricular

V Volt

V-pace Ventricular pacing

V-sense Ventricular sensing

VRP Ventricular Refractory Period

VRR Ventricular Rate Regulation

VT Ventricular Tachycardia

XL Accelerometer

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WARNINGS AND PRECAUTIONS

Additional warnings and precautions are listed in the ALTRUA and INSIGNIA I System Guides.

LEAD EVALUATION

- Pacing and sensing safety margins. Consider lead maturation in choice of pacing amplitudes, pacing pulse widths, and sensing levels.
  - Acute pacing thresholds greater than 1.5 V or chronic pacing thresholds greater than 3 V can result in loss of capture because thresholds increase after implantation.
  - R-wave amplitude less than 5 mV or P-wave amplitude less than 2 mV can result in under-sensing because sensed amplitude decreases after implantation.
  - Pacing lead impedance should be within the range of 100 Ω and 2500 Ω.

CLINICAL CONSIDERATIONS

- STAT PACE will initiate unipolar pacing, which is contraindicated for patients with an ICD.

- Adaptive-rate pacing should be used with care in patients unable to tolerate increased pacing rates.
- Adaptive-rate modes based completely or in part on MV might be inappropriate for patients who can achieve respiratory cycles shorter than 1 second (greater than 60 breaths per minute). Higher respiratory rates attenuate the impedance signal, which diminishes the MV rate response (i.e., the pacing rate will drop toward the programmed Lower Rate Limit).
- Use of AAT or VVT modes outside of a diagnostic setting is not recommended due to the potential for triggered pacing in response to oversensing.
- Slow retrograde conduction combined with a short PVARP might induce pacemaker-mediated tachycardia.
- The safety and efficacy of the MV sensor modes have not been clinically established in patients with abdominal implant sites.
- Performance of the MV sensor may be adversely affected under transient conditions such as pneumothorax, pericardial effusion, or pleural effusion. Consider programming the MV sensor Off until these conditions are resolved.
- Adaptive-rate modes based completely or in part on MV should not be used for the following patients:
  - Those implanted with an ICD
  - Those with unipolar leads, because a bipolar lead is required in either the atrium or ventricle for minute ventilation detection
  - Those with epicardial ventricular leads, because MV measurement has only been tested with a bipolar transvenous lead
  - Those using a mechanical ventilator, because use of the ventilator might result in an inappropriate MV sensor-driven rate

PROGRAMMING AND PACEMAKER OPERATION

- Use the LATITUDE Programming System, Model 3300, which includes the Model 3892 Software Application to communicate with the ALTRUA and INSIGNIA I pacemakers.
- Telemetry communication can be interrupted by electrical noise, thus preventing improper interrogation or programming. If the message window appears indicating that the wand is out of range or there is telemetry noise, move the Programmer and/or the wand away from such electrical devices as electrosurgical and monitoring equipment and ensure that the wand cord and cables are not crossing one another. Telemetry communication will resume when the noise source is removed. The message window also has a Cancel button that, when selected, will stop the interrogation.
- A pacemaker programmed to STAT pacing, if not reprogrammed, will continue to pace in VVI mode (or SSI for single-chamber devices) at the high-energy STAT values. Reprogram the pacemaker to other parameter settings for alternative patient therapies or to extend pacemaker longevity.
- 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 the Amplitude is Off during Temporary Brady Mode programming, the pacemaker will not pace. Pacing with the permanently programmed parameters can be restored by breaking the telemetry link or by selecting the Cancel button on the Temporary Parameters Now in Use window.

ENVIRONMENTAL AND MEDICAL THERAPY HAZARDS

Patients should be directed to avoid devices that generate strong electromagnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

HOSPITAL AND MEDICAL ENVIRONMENTS

Confirm pacemaker operation after any of the following medical procedures.

- **Mechanical ventilators** might result in an inappropriate MV sensor-driven rate when MV is programmed On. Program the MV sensor Off during mechanical ventilation.
- **Electrical signals** introduced into the body by some hospital monitoring and/or diagnostic equipment may result in accelerated pacing, possibly up to the maximum sensor-driven rate, when MV is programmed On. Examples of this equipment include, but are not limited to, respiratory monitors, diagnostic echo imaging, surface ECG monitors, and hemodynamic monitors. Deactivate the MV sensor when interaction with this equipment is suspected.
- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, may cause asynchronous or inhibited pacemaker operation, or may trigger the EOL indicator. If electrocautery cannot be avoided, observe the following precautions to minimize complications:
  - Program the device to the VOO/AOO/DOO mode and avoid direct contact with the pacemaker or leads.
  - Position the ground plate so that the current pathway does not pass through or near the pacemaker system.
  - Use short, intermittent, and irregular bursts at the lowest feasible energy levels.
  - Use a bipolar electrocautery system where possible.
  - Have temporary pacing and defibrillation equipment available.
- **Radio-frequency (RF) ablation.** Exercise caution when performing radio frequency (RF) ablation procedures, or any other type of cardiac ablation procedure in patients with implanted devices. RF ablation may cause: asynchronous pacing or inhibition of pacing, pacemaker reset, ventricular pacing up to the MTR, ventricular fibrillation, and/or changes in pacing thresholds. RF noise can interfere with telemetry communication between the pulse generator and Programmer potentially preventing pacemaker interrogation or programming during RF ablation. Check pulse generator and lead function post ablation. Minimize risks by following these steps:
  - Monitor the patient and have temporary pacing and defibrillation equipment, and knowledgeable medical personnel available.
  - For pacemaker-dependent patients, consider the use of external pacing support (e.g., using internal or external pacing methods).
  - For pacemaker-dependent patients, program the pulse generator Brady Mode to DOO, VOO, or AOO, as appropriate, to prevent radio frequency noise from inhibiting pacing therapy. Alternatively, a magnet can be placed over the device to pace asynchronously at the magnet rate. Other options may be considered when the patient has intrinsic rhythm (e.g., programming the device to VVI at a rate below the intrinsic rate to avoid competitive pacing).
  - Avoid direct contact between the ablation catheter and the implanted lead. Radio frequency ablation close to the lead electrode may damage the lead tissue interface.
  - Position the ground plate so that the current pathway passes as far away from the pulse generator and leads as possible.

  - Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to verify lead-tissue interface and lead integrity. If any programming changes were made, the pulse generator should be programmed back to the appropriate settings following the procedure.

- **Magnetic resonance imaging** (MRI) for pacemaker patients has been contraindicated by MRI manufacturers. Clinicians should carefully weigh the decision to use MRI with pacemaker patients.

  - Magnetic and RF fields produced by MRI may increase ventricular pacing beyond the rate limit, result in total inhibition of pacing output, result in pacing at random rates, or result in asynchronous pacing.
  - Magnetic fields may activate magnet mode operation and cause asynchronous pacing.
  - MRI can irreversibly damage the pacemaker.
  - Pacemaker patients treated with MRI should be closely monitored and programmed parameters should be verified upon cessation of MRI.

- **Lithotripsy** may permanently damage the pacemaker if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, do not focus near the pacemaker site. The lithotriptor is designed to trigger off the R-wave on the ECG resulting in shock waves being delivered during the ventricular refractory period. Program to VVI/VOO mode because atrial pacing pulses can trigger the lithotriptor.

- **Therapeutic ultrasound energy** may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site.

- **Therapeutic diathermy** may cause fibrillation, burning of the myocardium, and irreversible damage to the pacemaker because of induced currents.

- **External defibrillation.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator, consider the following:

  - Avoid placing a pad (or paddle) directly over the pulse generator. Position the external defibrillation pads (or paddles) as far from the pulse generator as possible.
  - Position the external defibrillation pads (or paddles) in a 'posterior-anterior' orientation when the device is implanted in the right pectoral region or an 'anterior-apex' orientation when the device is implanted in the left pectoral region.
  - Set energy output of external defibrillation equipment as low as clinically acceptable.

Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. Interrogate the pulse generator, verify battery status, verify pacing, and ensure that programmable parameters did not change.

- **Transcutaneous electrical nerve stimulation (TENS)** may interfere with pacemaker function. If necessary, the following measures may reduce interference:

  - Place the TENS electrodes as close to each other as possible.
  - Place the TENS electrodes as far from the pacemaker/lead system as possible.
  - Monitor cardiac activity during TENS use.

- **Diagnostic x-ray and fluoroscopic radiation** should not affect the pacemaker. For high radiation sources, see ionizing radiation therapy warning below.

- **Ionizing Radiation.** Many sources of ionizing radiation are commonly used for the diagnosis and treatment of diseases; these sources vary significantly in their potential impact on an implanted pulse generator. Several therapeutic radiation sources are capable of interfering with or damaging an implanted pulse genera tor, including those used for the treatment of cancer, such as radioactive cobalt, linear accelerators, radioactive seeds, and betatrons.

Most diagnostic tools, such as radiography (X-ray) and fluoroscopy, have not been identified as sources of device interference or damage. The impact of ionizing radiation will also vary from one pulse generator to another and may range from no changes in function to a loss of pacing.

It is not possible to specify a 'safe' radiation dosage or guarantee proper pulse generator function following exposure to ionizing radiation. Multiple factors collectively determine the impact of radiation therapy on an implanted pulse generator, including proximity of the pulse generator to the radiation beam, type and energy level of the radiation beam, dose rate, total dose delivered over the life of the pulse generator, and shielding of the pulse generator.

Refer to the Post-Implant section of the System Guide for further details regarding advance planning and follow-up assessment of pulse generators exposed to ionizing radiation.

HOME AND OCCUPATIONAL ENVIRONMENTS

Patients should be advised of the following potential sources of EMI:

- **High-voltage power transmission lines** might generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Communication equipment** such as microwave transmitters, linear-power amplifiers, or high-powered amateur transmitting systems might generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders might generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Electronic article surveillance (EAS) equipment** such as retail theft prevention systems might interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than is necessary.
- **Home appliances** that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

CELLULAR PHONES

Patients having an implanted pacemaker who operate a cellular phone should observe the following precautions:

- Maintain a minimum separation of 15 cm (6 inches) between a handheld personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to handheld models. For phones transmitting above 3 watts, maintain a minimum separation of 30 cm (12 inches) between the antenna and the implanted device.
- Hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over or within 15 cm (6 inches) of the implanted device as some phones emit signals when they are turned On but not in use (e.g., in the listen or standby mode). Store the phone in a location opposite the side of the implant site.

ELEVATED PRESSURE

The information provided here is a summary of pressure testing completed by Boston Scientific; it should not be viewed as and is not an endorsement of HBOT treatment or SCUBA diving activities. During laboratory testing of ALTRUA, all devices in the test sample (statistically significant) continued to function as designed when exposed to more than 100 cycles at a pressure up to 5.0 ATA. Pressure for each test cycle

began at ambient/room pressure, increased to a high pressure level, and then returned to ambient pressure. Although dwell time (the amount of time under elevated pressure) may have an impact on human physiology, testing indicated it did not impact device performance.

Since our pressure testing was conducted in a laboratory environment, it did not characterize the impact of elevated pressure on device performance or physiological response while implanted in a human body. Prior to engaging in activities such as HBOT or SCUBA diving, a patient should consult their attending cardiologist or electrophysiologist to fully understand the potential consequences of these activities relative to their specific health condition.

Refer to the following table for pressure value equivalencies.

Table i-1. Pressure Value Equivalencies

Atmospheres Absolute (ATA)	Sea Water [a] Depth (feet)	Sea Water [a] Depth (meters)	Pounds per Square Inch Absolute (psia)	Pounds per Square Inch Gauge (psig)[b]	Bar	kPa Absolute
5.0	130	40	73.5	58.8	5.0	500

a. All pressures derived assuming sea water density of 1030 kg/m^3
b. Pressure as read on a gauge or dial (psia = psig + 14.7 psi)

If you have additional questions, please contact Boston Scientific Technical Services at the phone number on the back of this manual.

ADVERSE EVENTS

For adverse events, refer to the specific System Guide/Physician Technical Manual for the ALTRUA and INSIGNIA I pacemaker.

x

TABLE OF CONTENTS

ABOUT THIS MANUAL ..... **I**

INTENDED AUDIENCE ..... **I**

NEW OR ENHANCED FEATURES ..... **I**

Patient Diagnostics i

User Experience i

Brady Therapy ii

ACRONYMS ..... **II**

WARNINGS AND PRECAUTIONS ..... **IV**

Lead Evaluation iv

Clinical Considerations iv

Programming and Pacemaker Operation v

Environmental and Medical Therapy Hazards vi

Hospital and Medical Environments vi

Home and Occupational Environments viii

Elevated Pressure viii

Adverse Events ix

USING THE PROGRAMMER **1-1**

LATITUDE PROGRAMMING SYSTEM **1-1**

SOFTWARE TERMINOLOGY AND NAVIGATION **1-1**

Feature Name Changes 1-2

Model 2892 Software Application Features – No Longer Supported 1-2

Main Screen 1-2

Programmer Mode Indicator 1-3

ECG/EGM Display 1-3

Toolbar 1-4

Tabs 1-4

Buttons 1-4

Icons 1-5

Common Objects 1-6

Use of Color 1-6

COMMUNICATING WITH THE PULSE GENERATOR **1-7**

Starting a Wanded Telemetry Session 1-7

Ending a Telemetry Session 1-8

MANUAL PROGRAMMING **1-8**

STAT PACE **1-8**

DATA MANAGEMENT **1-9**

Patient Information 1-9

Data Storage 1-9

Device Memory 1-10

Print 1-10

THERAPY **2-1**

PACING THERAPIES **2-1**

Device Mode 2-1

Basic Parameters 2-2

Interactive Limits 2-2

MODELS **2-2**

BRADY MODE **2-2**

BRADY PARAMETERS SCREEN **2-5**
Brady Parameters 2-6
Modifying Parameter Values 2-6
Cancel Changes Button 2-6
Load Initials Button 2-6

BASIC BRADY PARAMETERS **2-7**
Mode 2-7
Lower Rate Limit (LRL) 2-7
Max Tracking Rate (MTR) 2-7
Maximum Sensor Rate (MSR) 2-10
Paced AV Delay 2-11
Pulse Width 2-12
Amplitude 2-12

AUTOMATIC CAPTURE **2-13**
Commanded Ventricular Automatic Threshold Measurement 2-14
Ambulatory Ventricular Automatic Threshold Measurement 2-15
Automatic Capture Retry 2-15

SENSITIVITY **2-16**
Auto Sense 2-16

REFRACTORY PERIODS **2-17**
Atrial Refractory Period 2-18
Post Ventricular Atrial Refractory Period (PVARP) 2-18
Ventricular Refractory Period 2-18

PACE/SENSE **2-18**

SENSORS **2-18**
Adaptive-Rate Pacing 2-18
Accelerometer 2-19
Response Factor (Accelerometer) 2-19
Advanced Accelerometer Parameters 2-20
Automatic Response Factor (Accelerometer) 2-23
Sensor Rate Target for Automatic Response Factor 2-24
Accelerometer (ACC) Initial Response Factor 2-24

TEMPORARY BRADY PACING **2-24**

MINUTE VENTILATION (MV) **2-24**
MV Initialization 2-25
Response Factor (Minute Ventilation) 2-26
Advanced Minute Ventilation Parameters 2-27

MANUAL OPTIMIZATION OF THE MV AND MV BLENDED SENSOR (MV AND ACCELEROMETER) **2-28**
Programming MV Blended Sensor to Passive (for Data Collection) 2-28
Retrieving Trending Data and Manually Optimizing MV Blended Sensor 2-29

DUAL SENSOR BLENDING **2-29**
Time Dependent Blend 2-31

AUTOLIFESTYLE **2-32**
Response Factor (MV) 2-32
MV Max Long Term 2-33
Sensor Rate Target for AutoLifestyle 2-33

ATR MODE SWITCH **2-34**
Trigger Rate 2-34
Entry Count 2-34
Exit Count 2-35
Duration 2-36
Fallback Mode 2-37

Fallback Time ... 2-37
ATR Lower Rate Limit ... 2-37
Ventricular Rate Regulation (VRR) ... 2-38
VRR Max Pacing Rate ... 2-38
Atrial Flutter Response (AFR) ... 2-38
PMT Termination ... 2-39

RATE ENHANCEMENTS ... 2-39
Rate Hysteresis ... 2-39
Rate Hysteresis in Nonadaptive Rate Modes ... 2-40
Rate Hysteresis in Adaptive Rate Modes ... 2-40
Search Hysteresis ... 2-41

RATE SMOOTHING ... 2-42
Rate Smoothing Up ... 2-43
Rate Smoothing Down ... 2-43
Max Pacing Rate (DDI and SSI) ... 2-43
Rate Smoothing Example ... 2-43

SUDDEN BRADY RESPONSE (SBR) ... 2-44
SBR Detect Time ... 2-44
SBR Number of Beats ... 2-44
SBR Therapy Rate Offset ... 2-44
SBR Therapy Duration ... 2-45
SBR MV Offset ... 2-45

LEAD CONFIGURATION ... 2-46
Bipolar Configuration Lock Out ... 2-46
Lead Configuration ... 2-46

SAFETY SWITCH (AUTOMATIC LEAD CONFIGURATION) ... 2-47

AV DELAY ... 2-48
Dynamic AV Delay ... 2-48
Paced AV Delay ... 2-49
Sensed AV Delay ... 2-50
AV Search Hysteresis ... 2-51
AV Search Interval ... 2-51
AV Increase ... 2-52

REFRACTORY ... 2-52
Dynamic PVARP ... 2-52
Maximum PVARP ... 2-53
Minimum PVARP ... 2-53
PVARP After PVC/PAC ... 2-53

BLANKING AND NOISE REJECTION ... 2-54
V-Blank After A-Pace (Ventricular Blanking) ... 2-54
A-Blank After V-Pace (Atrial Blanking) ... 2-54
Noise Rejection ... 2-54

MAGNET SETTINGS ... 2-55
Magnet Response ... 2-55

SYSTEM DIAGNOSTICS ... 3-1

SUMMARY DIALOG ... 3-1

BATTERY STATUS ... 3-1
Time Remaining ... 3-2
Magnet Rate ... 3-3

LEADS STATUS ... 3-4
Daily Measurements ... 3-4

LEAD TESTS 3-7
Intrinsic Amplitude Test 3-8
Lead Impedance Test 3-8
Pace Threshold Test 3-9
Manual Pace Threshold Test 3-10
Commanded Automatic Pace Threshold Test 3-10

PATIENT DIAGNOSTICS AND FOLLOW UP 4-1

THERAPY HISTORY 4-1

ARRHYTHMIA LOGBOOK 4-1
EGM Selections 4-3
Clearing Stored EGMs 4-3
Arrhythmia Logbook History 4-3
Arrhythmia Logbook Retrieval 4-4

SNAPSHOT 4-6

HISTOGRAMS 4-7

COUNTERS 4-7
Ventricular Counters 4-7
Brady Counters 4-7

TRENDS 4-7

POST-IMPLANT FEATURES 4-8
Patient Triggered Monitor (PTM) 4-8
Magnet Feature 4-9

ELECTROPHYSIOLOGIC TESTING 5-1

EP TEST FEATURES 5-1
EP Tests Screen 5-1

INDUCTION METHODS 5-2
Backup Ventricular Pacing During Atrial EP Testing 5-2
Programmed Electrical Stimulation (PES) 5-2
Manual Burst Pacing 5-4

APPENDIX A-1

PROGRAMMABLE OPTIONS AND PARAMETERS A-1
Pacing Therapy Parameters A-1
STAT, Reset, and SHIP Parameter Values A-4
Battery Information A-4

EVENT MARKERS A-5
DDD(R) Event Markers A-5
SSI(R) Event Markers A-12

SYMBOLS ON PACKAGING A-15

USING THE PROGRAMMER

CHAPTER 1

This chapter contains the following topics:

- "LATITUDE PROGRAMMING SYSTEM" on page 1-1
- "SOFTWARE TERMINOLOGY AND NAVIGATION" on page 1-1
- "COMMUNICATING WITH THE PULSE GENERATOR" on page 1-7
- "MANUAL PROGRAMMING" on page 1-8
- "STAT PACE" on page 1-8
- "DATA MANAGEMENT" on page 1-9

LATITUDE PROGRAMMING SYSTEM

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

- Model 3300 Programmer
- Model 3892 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
- Capture a snapshot or make a real-time recording of lead traces during ECG and PG activity
- Print patient data including pulse generator therapy options and therapy history data
- Save patient data

Refer to the LATITUDE Programming System's family of operator's manuals for specific information about the Programmer, Patient Data Management, and Networking and Connectivity.

SOFTWARE TERMINOLOGY AND NAVIGATION

This section provides an overview of the LATITUDE Programming System, Model 3300.

FEATURE NAME CHANGES

Some Model 2892 Software Application parameter names changed when implemented in the Model 3892 Software Application on the Model 3300 Programmer.

Table 1-1. Parameter and Trend Name Changes from the 2892 to 3892 Software Application

Model 2892	Model 3892
AV Delay (paced)	Paced AV Delay [a]
Sensed AV Offset	Max Sensed AV Delay [b] Max Paced AV Delay
High Rate Response Factor	Ventilatory Threshold Response
High Rate Break Point	Ventilatory Threshold
A-Tachy Response	ATR Mode Switch
Selected Duration	Duration
Setup Method	Data Storage
Application Version	Software Application and Software Version
PG Model	Device Model
Activity Log trend	Activity Level trend
Initiate Trend	Reset and Start Trending
V-Blanking after A-Pace	V-Blank after A-Pace
A-Blanking after V-Pace	A-Blank after V-Pace

a. In VDD mode Sensed AV Delay is used

b. Max Sensed AV Delay — Max Paced AV Delay = Sensed AV Offset

MODEL 2892 SOFTWARE APPLICATION FEATURES – NO LONGER SUPPORTED

The following features of the Model 2892 Software Application are not supported in the Model 3892 Software Application on the Model 3300 Programmer:

- Expert Ease
- Sensor Trending setup of Sensitivity trend, Timer, and Beat to Beat
- 4-minute fast walk within 30 minutes for AutoLifestyle (set to No after program operation)
- Exit Ship Mode
- Demo Mode
- Interrogation of devices with earlier versions of the Digital IC

NOTE: *For additional information, contact Boston Scientific using the information on the back cover of this manual.*

MAIN SCREEN

The main screen in “Figure 1-1. Main Screen” on page 1-3, is followed by a description of the components.

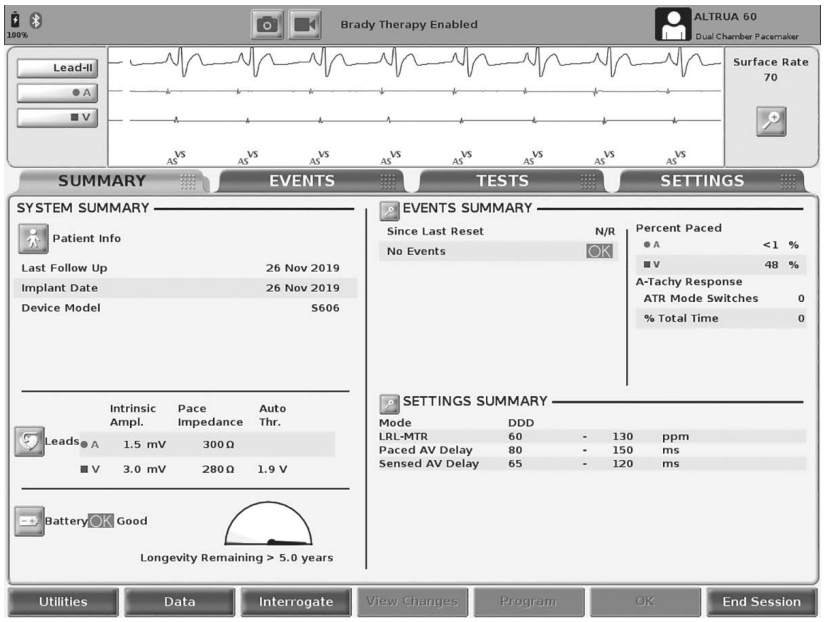


Figure 1-1. Main Screen

PROGRAMMER MODE INDICATOR

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



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

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 Programmer, 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 dislodgements.

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

- At any time, a 12-second trace of the ECG/EGM display can be stored by pressing the Snapshot button from any screen.
- At any time, 3-minute data segments can be continuously recorded and stored by pressing the Real-time Recorder button from any screen. Recording stops when the Real-time Recorder button is pressed again.

Refer to the *LATITUDE Programming System, Model 3300 Operator's Manual* for additional details about recordings.

NOTE: *If the Programmer is left idle for 15 minutes, real-time EGMs are shut off. The Programmer 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, 0.5, 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 reports and real-time EGMs, which include annotated event markers, by performing the following steps:

1. Select the Data button at the bottom of the Programmer screen to display the Data Management window.
2. Select the desired Report(s) and/or Real-time Log item.
3. If not already selected, choose the printer from the Printer list and select the number of copies.
4. Select the Print button.

You can print a full marker legend report containing the definitions of all of the annotated markers by performing the previous steps and selecting the Marker Legend report item as the desired report.

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 Programmer session

TABS

Tabs allow you to select Programmer 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

ICONS

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 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


Real-time Recorder—records continuously upon button press, and stores data in 3-minute segments until a second press ceases recording

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 Programmer screens (Table 1-2 on page 1-6).

Table 1-2. Programmer Color Conventions (Model 3300)

Color [a]	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.	

Table 1-2. Programmer Color Conventions (Model 3300)

Color [a]	Meaning	Examples	Symbol
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		

a. The Model 3120 Programmer displayed warnings in yellow and errors in red.

COMMUNICATING WITH THE PULSE GENERATOR

The Programmer communicates with the pulse generator using the Model 6395 telemetry wand.

Telemetry is required to:

- Direct commands from the Programming system, such as:
  - INTERROGATE
  - PROGRAM
  - STAT PACE
- Modify device parameter settings
- Conduct EP testing
- Conduct diagnostic tests including the following
  - Pacing impedance tests
  - Pacing threshold tests
  - Intrinsic amplitude tests

STARTING A WANDED TELEMETRY SESSION

Follow this procedure to begin a wanded telemetry communication session:

1. Position the Model 6395 telemetry wand over the pulse generator at a distance not greater than 5 cm (1.97 inches).

   NOTE: *The Model 6395 telemetry wand must remain in position with the pulse generator for the entire programming session to maintain telemetry communication in order to complete the pulse generator programming. During a programming sequence, the telemetry wand is positioned over the pacemaker. Allow all telemetry sequences to complete before removing the wand.*

   NOTE: *Status windows might appear on the screen during a communication session to indicate that the pacemaker is out of range. Reposition the telemetry wand to reestablish communication or try turning the telemetry wand over.*

CAUTION: Computerized systems can be subject to electrical interference, or "noise." In the presence of such interference, telemetry communication is interrupted and prevents improper interrogation or programming. If the message window appears indicating that the wand is out of range or there is telemetry noise, move the Programmer away from such electrical devices as electrosurgical and monitoring equipment and ensure that the wand cord and cables are not crossing one another. Telemetry communication will resume when the noise source is removed. The message window also has a Cancel button that, when selected, will stop the interrogation

2. Use the Programmer to Interrogate the pulse generator.
3. Retain the Model 6395 telemetry wand position whenever communication is required.

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 Programming system terminates all communication with the pulse generator.

MANUAL PROGRAMMING

Programming controls (such as sliders and menus) allow you to individually adjust pulse generator program settings. The programming controls 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 and Parameters" on page A-1 for detailed listings of available settings.

STAT PACE

Emergency bradycardia pacing using the STAT PACE command sets the bradycardia operation to high-energy values intended to ensure capture until reprogrammed.

1. If you are not already in a session, position the Model 6395 telemetry wand within range of the pulse generator.
2. Press the red STAT button  on the Programmer.
3. The Emergency Functions message window displays the STAT PACE selection.
4. Select the PG STAT PACE value. A message indicates that STAT PACE is being, programmed followed by the STAT PACE Programmed values.
5. Select the Close button on the message window.
6. To stop STAT PACE, reprogram the pulse generator.

WARNING: STAT PACE will initiate unipolar pacing, which is contraindicated for patients with an ICD.

The STAT PACE parameter values are listed below.

Table 1-3. STAT PACE Parameter Values

Parameter	Values
Mode	VVI
Lower Rate Limit	65 ppm
Interval	923 ms
Amplitude	5.0 V

Table 1-3. STAT PACE Parameter Values

Parameter	Values
Pulse Width	1.0 ms
Paced Refractory	320 ms
Lead Configuration (Pace/Sense)	Unipolar
Sensitivity	1.5 mV

NOTE: *STAT PACE pacing mode is SSI for single-chamber devices programmed to SSI(R), SOO(R), or SST.*

DATA MANAGEMENT

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

PATIENT INFORMATION

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

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

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

DATA STORAGE

The Programming system allows you to save pulse generator data to the Programmer hard drive. Data can also be saved to a removable USB pen drive or transfered to a previously authorized computer using Bluetooth.® [1]

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

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

Select the Data button to access the following options:

- Save—allows you to save pulse generator data to a USB drive or the Programmer's internal hard drive.
- Data Transfer—allows you to transfer pulse generator data to a previously authorized Bluetooth® device such as a personal computer.

1 Authorized Bluetooth® devices (e.g., personal computers, tablets) can receive Programmer data. Refer to the LATITUDE Programming System Networking and Connectivity Operator's Manual for authorizing Bluetooth® devices.

- Reports are available in PDF format. Refer to the Programmer Operator's Manual for more information.

NOTE: *While the data is being saved, 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 Programmer. When a pulse generator is interrogated, the Programmer 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 Programmer 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 a USB pen drive before returning a Programmer to Boston Scientific, as all patient and pulse generator data will be erased from the Programmer when it is returned.
- To protect patient privacy, pulse generator data can be encrypted before it is transferred to a USB pen drive.
- The Programmer erases all data older than 14 days. Refer to the LATITUDE Programming System Operator's Manual (Model 3300) for additional details.

DEVICE MEMORY

The Device Memory feature, a selection from the Utilities toolbar, allows retrieval and saving 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.

PRINT

NOTE: *Use the Data toolbar to access pulse generator data for clinician use (see "Data Storage" on page 1-9).*

You can print Programmer reports by connecting to an external printer. To print a report, select the Data toolbar at the bottom of the Programmer screen. Then select the report you wish to print from the following categories:

- Reports
  - QUICK NOTES Report
  - Device Follow-up Report
  - Combined Follow-up Report
  - Device Settings
  - Settings Changes
  - Patient Data
  - Arrhythmia Logbook
  - Marker Legend
  - Sensor Trending
- Episode reports
- Real-Time Log

THERAPY

CHAPTER 2

This chapter includes descriptions of the programmable therapy parameters available with the ALTRUA 20, 40, 60 pacemakers and INSIGNIA I Entra, Plus, and Ultra pacemakers.

The following therapy features and their programmable parameters are discussed in this chapter:

- PACING THERAPIES on page 2-1
- SENSORS on page 2-18
- ATR MODE SWITCH on page 2-34
- RATE ENHANCEMENTS on page 2-39
- LEAD CONFIGURATION on page 2-46
- AV DELAY on page 2-48
- REFRACTORY on page 2-52
- BLANKING AND NOISE REJECTION on page 2-54
- MAGNET SETTINGS on page 2-55

All parameters described in this chapter are accessible through the SETTINGS - BRADY screen. See Figure 2-1 on page 2-6.

PACING THERAPIES

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

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

The pulse generator provides the following types of therapies:

NORMAL BRADYCARDIA PACING

- If the intrinsic heart rate falls below the programmed pacing rate (i.e., LRL), the device delivers pacing pulses at the programmed settings.
- Adaptive-rate pacing allows the pulse generator to adapt the pacing rate to the patient's changing 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 2-24)
- STAT PACE—initiates emergency ventricular pacing at high output settings when commanded via the Programmer using telemetry communication ("STAT PACE" on page 1-8)

DEVICE MODE

Once the pulse generator has been programmed out of Storage Mode, Brady Therapy Enabled displays at the top of the Programmer screen, which indicates that the pulse generator is providing normal pacing therapy. This mode is not selectable; it is set automatically and remains On.

BASIC PARAMETERS

Normal Settings include the following:

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

INTERACTIVE LIMITS

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

MODELS

The following models are available for each family of pulse generators:

Table 2-1. Models

Family	Device Type	
	DDDR [a]	SSIR
ALTRUA 20	S203, S205, S208	S201, S204
ALTRUA 40	S402, S403, S404	S401
ALTRUA 60	S602[b], S603[b], S604, S605, S606[b]	S601
INSIGNIA I Entra	1294, 1295, 1296	1198, 1195
INSIGNIA I Plus	1297, 1298	1194
INSIGNIA Ultra	1290, 1291	1190

a. The use of sensors in DDD device types is limited to ATR fallback modes only

b. Models with 400 ms AV delay

BRADY MODE

The pacemakers can be programmed to the following modes, depending on the model. For a complete discussion of each of these modes, see "Programmable Options and Parameters" on page A-1.

Table 2-2. Available Modes By Model

MODE	Family	Device Type and Model	
		DDDR	SSIR
	ALTRUA	S203, S205, S208, S402, S403, S404, S602, S603, S604, S605, S606	S201, S204, S401, S601
	INSIGNIA	1290, 1291, 1294, 1295, 1296, 1297, 1298	1190, 1194, 1195, 1198
DDDR		X	
DDIR		X	
DOOR		X	

Table 2-2. Available Modes By Model

MODE	Family	Device Type and Model	
		DDDR	SSIR
	ALTRUA	S203, S205, S208, S402, S403, S404, S602, S603, S604, S605, S606	S201, S204, S401, S601
	INSIGNIA	1290, 1291, 1294, 1295, 1296, 1297, 1298	1190, 1194, 1195, 1198
VDIR		Fallback only	
VVIR		X	
AAIR		X	
SSIR			X
VOOR		X	
AOOR		X	
SOOR			X
DDD		X	
DDI		X	
DOO		X	
VDD		X	
VDI		Fallback only	
VVI		X	
AAI		X	
SSI			X
VOO		X	
AOO		X	
SOO			X
VVT		X	
AAT		X	
SST			X
OSO [a]			X
ODO [a]		X	
OOO [a]		X	X

a. Available only during Temporary programming.

The following 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

In the absence of sensed P- and R-waves, pacing pulses will be delivered to the ventricle at the LRL (VDD). 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.

AAT MODE

In the absence of sensed events, pacing pulses will be delivered to the atrium at the lower rate limit. Sensed events will trigger an atrial pulse and reset the escape interval of the pacemaker.

Using the AAT mode outside of a diagnostic setting is not recommended due to the potential for triggered pacing in response to oversensing.

VVT MODE

In the absence of sensed events, pacing pulses will be delivered to the ventricle at the lower rate limit. Sensed events will trigger a ventricular pulse and reset the escape interval of the pacemaker.

Using the VVT mode outside of a diagnostic setting is not recommended due to the potential for triggered pacing in response to oversensing.

DOO AND DOOR

Pacing pulses will be delivered asynchronously to the atrium and the ventricle at the LRL (DOO) or the sensor-indicated rate (DOOR), 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.*

The DOO mode may be used intraoperatively to reduce the likelihood of inhibition when sources of conducted electrical current are present.

VOO AND VOOR

Pacing pulses will be delivered asynchronously to the ventricle at the LRL (VOO) or the sensor-indicated rate (VOOR). Intrinsic events will neither inhibit nor trigger pacing in the ventricle.

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

The VOO mode may be used intraoperatively to reduce the likelihood of inhibition when sources of conducted electrical current are present.

AOO AND AOOR

Pacing pulses will be delivered asynchronously to the atrium at the LRL (AOO) or the sensor-indicated rate (AOOR). Intrinsic events will neither inhibit nor trigger pacing in the atrium.

NOTE: *AOO mode is the magnet mode of AAI(R), AOO(R), and AAT modes.*

The AOO mode may be used intraoperatively to reduce the likelihood of inhibition when sources of conducted electrical current are present.

SINGLE-CHAMBER MODES

Single-chamber pulse generators may be programmed to SSI(R) , SOO(R) or SST mode.

Some features may behave differently or become unavailable in a dual-chamber device programmed to a single-chamber mode.

DUAL-CHAMBER MODES

Do not use DDD(R) mode 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(R), AOO(R), and AAT 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.

WARNING: Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing, are contraindicated.

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

BRADY PARAMETERS SCREEN

The Brady Parameters screen (Figure 2-1) is divided into two areas: the basic Brady Parameters are displayed on the left, and Pacing and Sensing parameters are on the right side of the screen. To change the displayed values, select a value and a pop-up window displays the available values that can be selected. For additional parameters, select the magnify button for Leads or Rate Adaptive Pacing.

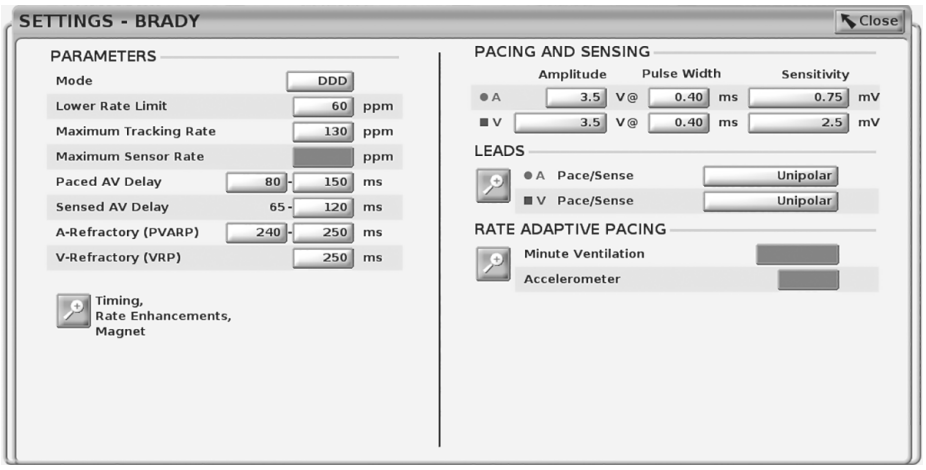


Figure 2-1. The Brady Parameters screen for dual chamber, adaptive rate pacemakers

BRADY PARAMETERS

Additional features are accessed via the magnify buttons. These features are displayed on the right side of the Brady Parameters screen (Figure 2-1). To display the parameter, select the button for that feature.

As with the basic Brady Parameters, availability of a feature is dependent on the selected mode. If a particular parameter is not applicable to the mode displayed, the parameter field will be grayed (see Minute Ventilation in Figure 2-1 for an example).

MODIFYING PARAMETER VALUES

Use the following procedure to make changes to the permanent pacing parameters:

1. Select the Settings button.
2. Select the parameter to change by touching parameter value next to the parameter name to display the range of values.
3. Select new parameter value by selecting the value from the displayed list. If additional parameters require reprogramming, repeat to achieve the desired values. Multiple parameter changes can be programmed at one time.

After the change(s) has been entered, make sure that the yellow attention icon or the red warning icon is not displayed next to the parameter. Warnings, indicated by the exclamation mark in the red diamond, should be carefully considered before continuing.

4. Press the Program button to program the changes in the pacemaker. These parameters now become the permanent pacing parameters.

CANCEL CHANGES BUTTON

To remove changes before they are programmed, select the View Changes button and then select the Cancel Changes button.

LOAD INITIALS BUTTON

Load Initials button is particularly helpful when mode changes have been made during a programming session because it ensures that all programmable settings, including lead polarity, are returned to initial values.

BASIC BRADY PARAMETERS

This section discusses the basic parameters appearing on the left half of the Programmer Brady Parameters screen. Each parameter is described, and the programmable values are listed.

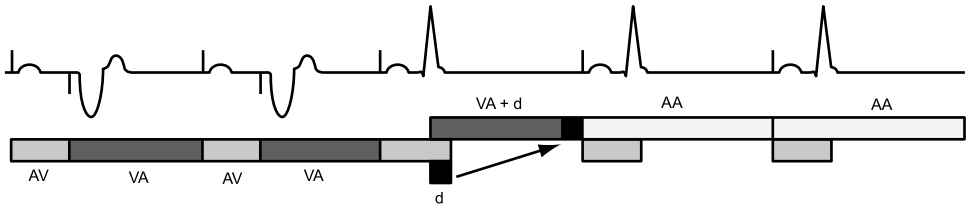
MODE

Refer to "Table 2-2. Available Modes By Model" on page 2-2 for modes available for each model.

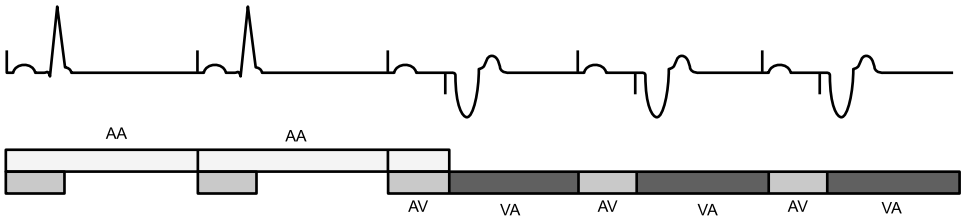
LOWER RATE LIMIT (LRL)

Lower Rate Limit (LRL) is the rate (pulses per minute) at which the pacemaker paces the atrium and/or ventricle in the absence of sensed intrinsic activity and the absence of sensor controlled pacing at a higher rate.

As long as the ventricle is being paced, the escape interval is timed from one ventricular event to the next. Whenever an event is sensed in the ventricle (i.e., intrinsic AV conduction occurs before the AV Delay elapses), the timing base switches from ventricular based timing to atrial based timing (Figure 2-2). This switching of timing base ensures accurate pacing rates even during intrinsic AV conduction.



Transition from V—V timing to A—A timing



Transition from A—A timing to V—V timing

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

MAX TRACKING RATE (MTR)

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

In AAT, VVT, and SST modes, the MTR determines the maximum rate at which sensed events (including externally applied stimuli) will trigger pacing.

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 VDD 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 Programmer 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 Programmer does not consider the AV Delay associated AV Search Hysterisis when calculating the TARP interval.

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
- 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). 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).

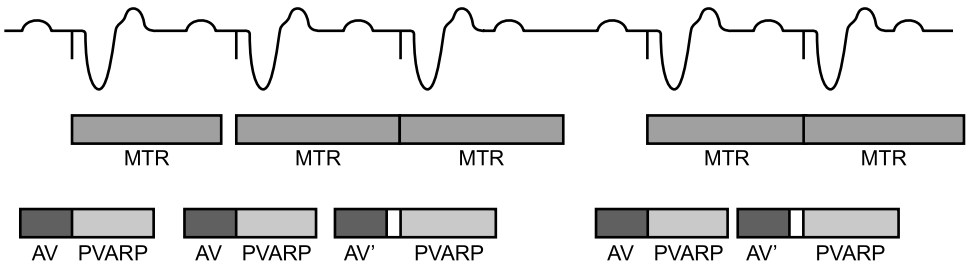


Figure 2-3. Wenckebach behavior at MTR

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 sensed (Figure 2-4). 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.

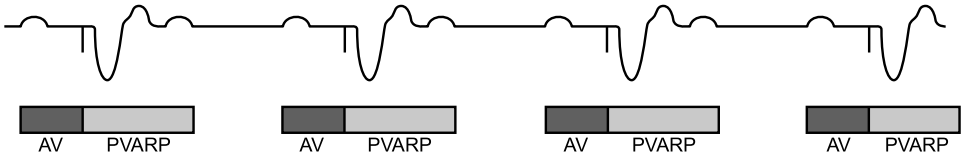


Figure 2-4. Pacemaker 2:1 block

CONVENTIONAL DDD BEHAVIOR

The following discussion assumes the following parameters are programmed to Off: ATR Mode Switch, Rate Smoothing, Dynamic AV Delay, and Dynamic PVARP.

One-to-one atrial tracked ventricular pacing will occur in the absence of a sensed ventricular event within the programmed AV Delay. When the sensed atrial rate exceeds the MTR, upper rate behavior in the form of pacemaker Wenckebach or 2:1 block may occur. High rate atrial tracking is limited by the programmed MTR and the total atrial refractory period [AV Delay + postventricular atrial refractory period (PVARP)].

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.*

As illustrated in "Figure 2-3. Wenckebach behavior at MTR" on page 2-9, if the atrial rate exceeds the MTR, the AV Delay will be progressively lengthened (AV') until an occasional P wave is not sensed because it falls into the atrial refractory period. This results in occasional loss of 1:1 tracking as the pacemaker synchronizes its paced ventricular rate to the next sensed P wave (pacemaker Wenckebach).

"Figure 2-4. Pacemaker 2:1 block" on page 2-9 illustrates another type of pacemaker upper rate behavior (2:1 block) that can occur when tracking high atrial rates. In this type of behavior, every other intrinsic atrial event occurs during PVARP and thus is not sensed, resulting 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 AV Delay + PVARP period, resulting in the pacemaker sensing only every third or fourth P wave. Block then occurs at rates such as 3:1 or 4:1.

Either Wenckebach or 2:1 block can occur at atrial rates above the MTR depending upon the programmed MTR, AV Delay, and PVARP.

In order to avoid complete closure of the sensing window at MTR resulting in 2:1 block, the Programmer does not allow programming to permanent modes with an MTR interval shorter than the sum of the AV Delay and the PVARP. 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.

Programming Rate Smoothing, Atrial Flutter Response, and/or ATR Mode Switch to On may reduce or eliminate rapid changes in the paced ventricular rate caused by sensed atrial rates above the MTR.

MAXIMUM SENSOR RATE (MSR)

Max Sensor Rate (MSR) is the maximum pacing rate allowed as a result of sensor control (either accelerometer, MV or the blend of both). The MSR parameter is independently programmable at, above, or below the MTR. It is possible to program the MSR greater than, equal to, or less than the ATR Trigger Rate unless the permanent mode is nonrate-adaptive and the ATR Fallback Mode is rate-adaptive, in which case the Programmer prevents the user from programming an MSR greater than the ATR Trigger Rate.

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 mode, the MSR and MTR may be programmed independently to different values.*

The MSR parameter is independently programmable at, above, or below the MTR. It is possible to program the MSR greater than, equal to, or less than the ATR Trigger Rate unless the permanent mode is nonrate-adaptive and the ATR Fallback Mode is rate adaptive, in which case the Programmer prevents the user from programming an MSR greater than the ATR Trigger Rate.

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.

- If the MSR setting is higher than the MTR, AV synchronous pacing above the MTR may occur if the sensor rate exceeds the MTR.
- If the MSR setting is lower than the MTR, ventricular pacing above the MSR can occur only in response to 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.

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).

EXAMPLES:

- An AV Delay setting of 200 ms combined with a PVARP of 300 ms will result in asynchronous atrial pacing at sensor indicated rates above 120 ppm in dual chamber adaptive rate pacemakers.
- A refractory period of 500 ms will result in asynchronous pacing at sensor indicated rates above 120 ppm in atrial adaptive rate pacemakers.

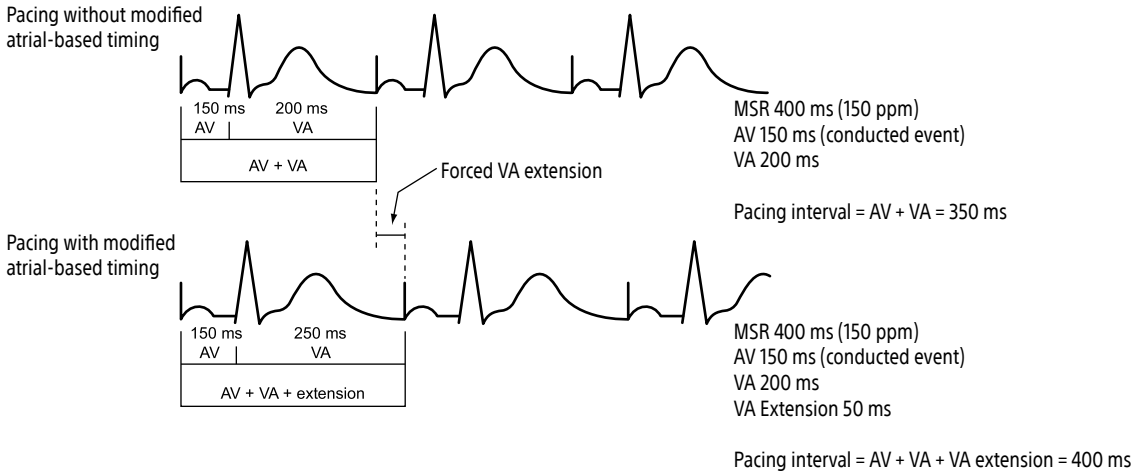


Figure 2-5. VA interval extension and MSR

PACED AV DELAY

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

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

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

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

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

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

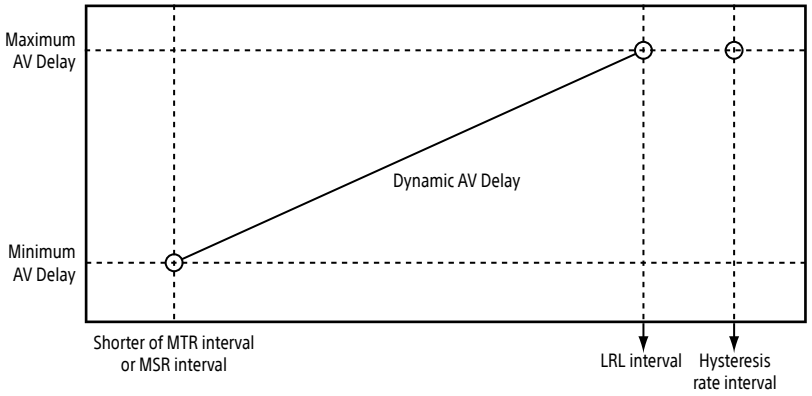


Figure 2-6. Dynamic AV Delay

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

NOTES:

- *The Automatic Capture feature may add an additional 64 ms AV Hysteresis in order to accommodate a fusion check for a maximum AV Hysteresis delay of 364 ms; for models S602, S603, and S606, the maximum AV Hysteresis delay is 464 ms.*
- *Long programmed AV intervals (≥250 ms) should be used with caution. The physician should evaluate the patient and weigh the potential benefit of promoting intrinsic conduction against the potential risk of hemodynamic compromise, such as pacemaker syndrome and diastolic mitral regurgitation.*

PULSE WIDTH

The Pulse Width, also referred to as pulse duration, determines how long the output pulse will be applied between the pacing electrodes. Atrial and ventricular pulse widths are independently programmable.

The energy delivered to the heart is proportional to the Pulse Width; doubling the Pulse Width doubles the energy delivered. Therefore, programming to a narrow (lower) Pulse Width while maintaining an adequate safety margin will increase pacemaker longevity.

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 2-7. Nominal pulse characteristics" on page 2-13).

AMPLITUDE

Amplitude is measured at the leading edge of the output pulse, and is measured in volts. Amplitude is independently programmable in the atrium and ventricle. During Temporary programming the mode may be programmed to OSO, ODO, or OOO (in effect, turning the Amplitude off) to monitor the patient's underlying rhythm.

The energy delivered to the heart is proportional to the square of the Amplitude. In other words, doubling the Amplitude quadruples the energy delivered, which will decrease pacemaker longevity (Figure 2-7). Programming to a lower Amplitude while maintaining an adequate safety margin will increase battery longevity.

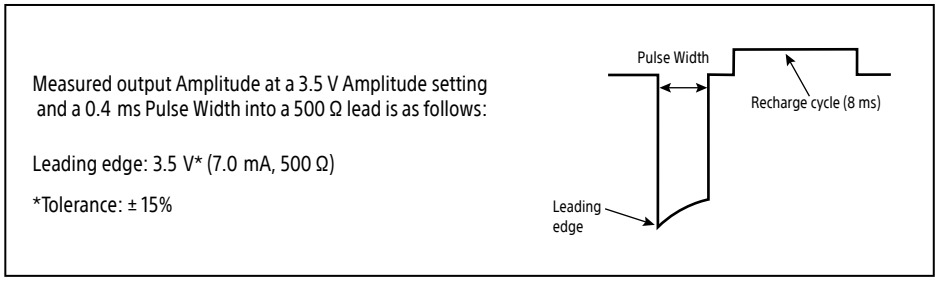


Figure 2-7. Nominal pulse characteristics

AUTOMATIC CAPTURE

The Automatic Capture feature is designed to dynamically adjust the ventricular pacing output to ensure capture of the ventricle while optimizing the output voltage by setting it to the capture threshold + 0.5 V. Automatic Capture maintains this output and confirms capture on a beat-to-beat basis.

The Ventricular Automatic Capture feature can be selected by choosing Auto from the Ventricular Amplitude parameter options. For more programming details, please refer to the section "Amplitude" on page 2-12".

Programming the ventricular output to Auto will automatically adjust the output Pulse Width to 0.4 ms and set the ventricular voltage output to an initial value of 3.5 V. The Automatic Capture algorithm then measures the ventricular pacing threshold and adjusts the voltage output to the threshold + 0.5 V. On a beat-to-beat basis, Automatic Capture confirms that each ventricular pacing output captures the ventricle. This is accomplished by observing the evoked response following each ventricular pacing output and determining if that pacing output captured the ventricle. If there is a Confirmed Loss of Capture (C-LOC), which is when 2 out of 4 cardiac cycles do not capture the ventricle, then the pacemaker will deliver a back-up pacing output within 100 ms of the primary pulse. The back-up safety pulse amplitude will be at least 1.5 V higher than the measured threshold, with a minimum of 3.5 V and a maximum of 4.5 V (see "Table 2-3. Back-up safety pulse values" on page 2-13).

Table 2-3. Back-up safety pulse values

Measured Threshold (V)	Backup Safety Pulse (V)
1.0	3.5
1.5	3.5
2.0	3.5
3.0	4.5

If C-LOC occurs and an Ambulatory or a Commanded Ventricular Threshold Test has been performed within the previous hour, Automatic Capture will enter Retry mode. See "Automatic Capture Retry" on page 2-15.

The Automatic Capture feature has been designed to operate with a large range of pacing leads (high impedance, low impedance, tined or positive fix). Also, Automatic Capture is independent of pacing and sensing lead polarity; the ventricular output and sensing can be programmed to Unipolar or Bipolar.

WARNING: Automatic Capture is intended for ventricular use only. Do not program Amplitude to Auto for single-chamber devices implanted in the atrium.

NOTES:

- Prior to programming Automatic Capture On, the clinician should consider performing a Commanded Ventricular Automatic Threshold Measurement to verify system compatibility.
- Automatic Capture is intended for ventricular use only. Do not program Amplitude to Auto for single-chamber devices implanted in the atrium.
- Automatic Capture is available in permanent DDD(R), VVI(R), and VDD mode. Automatic Capture is also available during VDI(R) and DDI(R) fallback modes.
- Automatic Capture's fusion management is enhanced with higher Maximum Tracking Rates and shorter AV Delays.
- When Automatic Capture is enabled, the minimum effective AV Delay allowed is 40 ms. For example if the AV Delay is 70 ms and the sensed AV offset is –30 ms, the effective AV delay is 40 ms (70 – 30 ms = 40 ms).
- If noise (which could potentially be a fusion beat) is detected in the evoked response signal, the AV interval (dual-chamber modes) or V–V interval (single-chamber modes) will be extended by 64 ms on the next cardiac cycle in an attempt to distinguish the fusion beat from a capture of the ventricle.
  - Automatic Capture is designed to work with typical lead implant criteria including:
  - Ventricular threshold between 0.1 V and 3.0 V at 0.4 ms
  - Lead impedance between 100 Ω and 2500 Ω
  - Ventricular intrinsic amplitude > 5 mV

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

COMMANDED VENTRICULAR AUTOMATIC THRESHOLD MEASUREMENT

The following models support automatic threshold measurement:

- ALTRUA 60: S601, S602, S603, S604, S605, S606
- INSIGNIA I Ultra: 1190, 1290, 1291

An automatic threshold measurement can be commanded via the Threshold Tests screen. If the ventricular auto threshold measurement completes successfully and Automatic Capture is programmed On, Automatic Capture will enter its beat-to-beat capture verification mode. This can be confirmed by observing the output Voltage on the Brady Parameters screen, which will show the actual operating Voltage of the Automatic Capture algorithm (the ventricular threshold + 0.5 V).

NOTE: *In order for the clinician to better recognize appropriate loss of capture, backup pacing is not active during a Commanded Ventricular Automatic Threshold Measurement except when the device confirms loss of capture.*

If an auto threshold measurement is not successfully completed and Automatic Capture is programmed On, the Threshold Tests screen will display the reason the test was not successful and Automatic Capture will enter Retry mode. See "Automatic Capture Retry" on page 2-15.

If an automatic threshold measurement is not commanded by the clinician, the algorithm will automatically try to measure the ventricular threshold within 10 minutes after the programming session is

completed. This is referred to as an ambulatory automatic threshold measurement and is described below.

AMBULATORY VENTRICULAR AUTOMATIC THRESHOLD MEASUREMENT

When Automatic Capture is On, ambulatory ventricular automatic threshold measurements are conducted by the pacemaker every 21 hours or when loss of capture is detected. As with the commanded auto threshold measurement, if the pacemaker cannot perform this test, Automatic Capture enters Retry mode. See "Automatic Capture Retry" on page 2-15.

In dual-chamber mode, the automatic threshold measurement adjusts the following parameters to help ensure a measurement:

- Paced AV Delay changes to 60 ms
- Sensed AV Offset changes to -30 ms
- Starting ventricular pacing output amplitude is 3.5 V
- Following every primary pacing pulse, a back-up pulse is delivered

In non-tracking modes VVI(R), VDI(R), and DDI(R), the automatic threshold measurement adjusts the following parameters to help ensure a measurement:

- Paced AV Delay changes to 60 ms
- Sensed AV Offset changes to -30 ms
- Starting ventricular pacing output amplitude is 3.5 V
- Following every primary pacing pulse, a back-up pulse is delivered
- The ventricular rate will be increased by a maximum of 10 ppm above the current rate (paced or intrinsic) and will not exceed the maximum sensor rate or maximum pacing rate

The pacemaker will apply at least 3 captured paced pulses at each output. With the occurrence of noisy evoked response or loss of capture, additional pace pulses will be issued. If at the beginning of the test, the current pacing rate is more than 50 ppm greater than the LRL, the pacemaker will postpone the test for one hour. The test will also be postponed if the device is being telemetered at the time of the test.

The ambulatory ventricular automatic threshold test may be delayed 1 hour or terminated mid-test if any of the following occur:

- Telemetry is initiated
- The magnet is applied
- ATR starts or is running

AUTOMATIC CAPTURE RETRY

Once the Automatic Capture feature is active, it remains active until the ventricular output is programmed to a manual Voltage setting or ERT is reached. If Automatic Capture is active but unable to determine the pacing threshold as described above, it will enter Retry mode. The pacing output will operate at twice the last measured threshold, but not > 5.0 V, and not < 3.5 V (See "Table 2-4. Pacing output during Automatic Capture retry" on page 2-16). Periodically, Automatic Capture will attempt to measure the ventricular threshold. If successful, Automatic Capture will return to the Beat-to-Beat mode.

How often Automatic Capture re-attempts the threshold measurement depends upon the reason the pacemaker entered Retry. For example, if the reason was noise detected on the evoked response channel or on the ventricular sense amplifier, the threshold test is attempted every hour. If the reason was inadequate evoked response signal, threshold not found at lowest pacing amplitude, or threshold > 3.0 V, the threshold test is attempted every 21 hours.

Table 2-4. Pacing output during Automatic Capture retry

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

Although Automatic Capture is designed to work with a wide range of pacemaker leads, in some patients the lead signals may hinder successful determination of the ventricular threshold. In these instances, Automatic Capture will continually operate in the Retry mode with a minimum ventricular output of 3.5 V and a maximum of 5.0 V.

Reasons for entering the Retry mode include an evoked response signal amplitude that is too small, a signal-to-artifact ratio that is too low, or the device is unable to measure loss of capture, the threshold is > 3.0 V, or there are insufficient paced events. For these patients, the clinician may choose to turn Automatic Capture Off by programming the ventricular output to Manual.

SENSITIVITY

The Sensitivity parameter allows the pacemaker to detect intrinsic cardiac signals that exceed the programmed value.

When Sensitivity is programmed to a very sensitive setting (i.e., a low value), the pacemaker may detect signals unrelated to cardiac depolarization (oversensing, such as sensing of Myopotential). When Sensitivity is programmed to a less sensitive setting (i.e., a higher value), the pacemaker may not detect the cardiac depolarization signal (undersensing). For manual programming, Sensitivity must be programmed to a value that prevents sensing of extraneous signals, but ensures accurate sensing of intrinsic cardiac signals. Intrinsic atrial signals are typically smaller than ventricular signals, so lower Sensitivity settings are typically programmed for the atrium. When a single pass VDD lead is used with a dual-chamber device, the atrial electrodes might not be in contact with the atrial wall. In this case, the measured depolarization signal has a relatively low Amplitude and could require a Sensitivity setting as low as 0.15 mV. P waves that are less than 0.25 mV and R waves that are less than 1.5 mV will not be sensed when Auto Sense is used. Careful consideration should be given to programming the sensing threshold below 0.3 mV (bipolar) and 2.0 mV (unipolar) due to the possibility of inappropriate far field sensing, myopotential sensing, and sensing of electromagnetic interference.

AUTO SENSE

Auto Sense is designed to automatically adjust pacemaker sensitivity to cardiac signal changes without clinician intervention. The sensitivity level is updated each cardiac cycle. The Auto Sense sensitivity range for the atrium is 0.25–4.0 mV and for the ventricle is 1.5–6.0 mV. For both Auto Sense and fixed programmed Sensitivity, the minimum recommended P wave is 2.0 mV and the minimum recommended R wave is 5.0 mV.

In dual-chamber applications, Auto Sense is a programmable option that can be used independently in each chamber. In single chamber applications, Auto Sense defaults to the ventricular algorithm; therefore, Auto Sense should be used only in the ventricle for single chamber uses. Auto Sense uses similar algorithms for atrial and ventricular sensing. When programmed On, the Auto Sense algorithm automatically adjusts the atrial and/or ventricular sensitivity levels based on the Amplitude of previously sensed events, the type of cardiac cycle (paced or sensed), and a measurement of the current myopotential/environmental noise level (see Figure 2-8 on page 2-17 and Figure 2-9 on page 2-17).

- Amplitude of Sensed Events—When Auto Sense is detecting intrinsic events, it will adjust the sensing threshold level based on a smoothed average of the measured intrinsic events.
- Type of Cardiac Signal (Sensed or Paced)—When sensing, Auto Sense uses the smoothed average of the measured intrinsic events to determine the sensitivity level. When pacing occurs, Sensitivity is slowly adjusted, becoming more sensitive each cardiac cycle until maximum sensitivity is reached at 0.25 mV in the atrium or 1.5 mV in the ventricle.
- Myopotential/Environmental Noise Level—In the ventricle, Auto Sense measures the myopotential/environmental noise level during the last 50 ms of ventricular refractory. In the atrium, Auto Sense determines the myopotential/environmental noise level by evaluating atrial senses during PVARP.

NOTE: *Auto Sense is disabled during PES and Burst pacing and nonpacing Temporary modes such as ODO. The sensing threshold remains at the level previously determined by Auto Sense for the duration of these temporary states.*

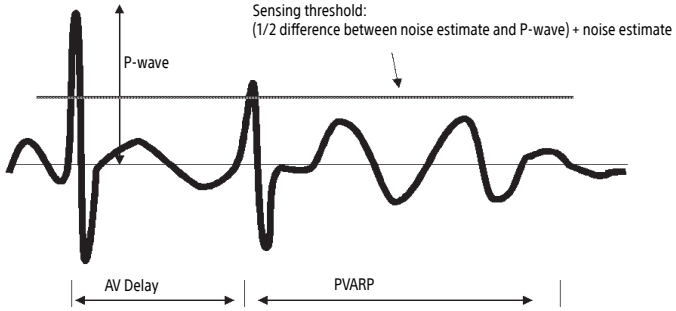


Figure 2-8. In the atrium, Auto Sense adjusts the Sensitivity levels based on the Amplitude of previously sensed P waves, myopotential/environmental noise detection during PVARP, and the type of cardiac cycle (paced or sensed). In this example, the myopotential/environmental noise level does not cause the Sensitivity level to be adjusted.

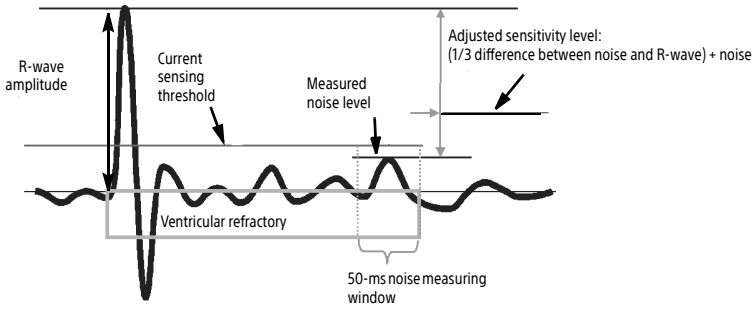


Figure 2-9. In the ventricle, Auto Sense adjusts the Sensitivity levels based on the Amplitude of previously sensed R waves, the myopotential/environmental noise level measured during the last 50 ms of ventricular refractory, and the type of cardiac cycle (paced or sensed). In this example, the sensing threshold is adjusted based on the measured myopotential noise level.

REFRACTORY PERIODS

The refractory period is the interval following a paced or sensed event during which the pacemaker is not inhibited or triggered by detected electrical activity. Refractory periods avoid triggering or inhibition of pacemaker events due to detection of inappropriate signals such as retrograde P waves, far field R waves, or noise.

ATRIAL REFRACTORY PERIOD

In three single-chamber atrial modes (AAT, AAI, AAIR), the Atrial Refractory period is defined as the period after an atrial event, either paced or sensed, when activity in the atrium does not inhibit or trigger an atrial stimulus.

Adaptive rate pacing is not inhibited during refractory periods. See "Maximum Sensor Rate (MSR)" on page 2-10 for further discussion.

POST VENTRICULAR ATRIAL REFRACTORY PERIOD (PVARP)

The post ventricular atrial refractory (PVARP) is defined as the period after a ventricular event, either paced or sensed, when activity in the atrium does not inhibit an atrial stimulus nor trigger a ventricular stimulus. It is designed to prevent the atrial channel from sensing the ventricular pacing pulse, the far field R waves, or retrograde P waves.

PVARP should be programmed to a value greater than the patient's V–A retrograde conduction time to prevent the atrial channel from sensing a retrograde atrial depolarization and possibly initiating pacemaker mediated tachycardia.

This parameter can be programmed to fixed value (PVARP) or can be calculated dynamically based on the previous cardiac cycles (Dynamic PVARP). Dynamic PVARP is nominally programmed On. See "Dynamic PVARP" on page 2-52.

Using a long PVARP shortens the atrial sensing window. Programming a long PVARP in combination with a long AV Delay can cause 2:1 block to occur abruptly at the programmed MTR. See "Max Tracking Rate (MTR)" on page 2-7 for further discussion.

VENTRICULAR REFRACTORY PERIOD

The ventricular refractory period is defined as the period following a ventricular event, either paced or sensed, when sensed electrical activity in the ventricle does not inhibit the pacemaker. This parameter is available in any mode in which ventricular sensing is enabled.

Use of a long Ventricular Refractory period 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 pacemaker will not sense the ventricular depolarization and will pace at the end of the AV Delay, resulting in competitive pacing.

Adaptive rate pacing is not inhibited during Refractory periods.

PACE/SENSE

The Pace/Sense field indicates the programmed lead polarity. The polarity cannot be changed from this screen; to change polarity, select the Leads button on the Settings - Brady screen.

SENSORS

ADAPTIVE-RATE PACING

In the adaptive rate modes (i.e., any mode ending with R), sensors are used to detect changes in metabolic demand and to increase the pacing rate accordingly. Adaptive rate pacing is available in the DDDR,

DDIR, DOOR, VVIR, AAIR, SSIR, VOOR, AOOR, and SOOR permanent modes as well as the DDIR and VDIR fallback modes. In these modes, the pacemaker will pace at the sensor indicated rate unless inhibited by sensed events.

ALTRUA 40 and 60 and INSIGNIA I Plus and Ultra models can be programmed to use the Accelerometer, or Minute Ventilation, or a blend of both the Accelerometer and Minute Ventilation.

ACCELEROMETER

The Accelerometer detects motion associated with physical activity and generates an electronic signal that is proportional to the magnitude of motion resulting from body movement.

Based on the accelerometer input, the pacemaker estimates the patient's energy expenditure as a result of exercise and then translates it into a rate increase. To measure acceleration, both the frequency and the amplitude of the sensor signal are evaluated during signal processing. Signal frequency reflects how often an activity occurs, such as the number of steps per minute taken during a brisk walk. Signal amplitude reflects the force of the motion—for example, the more deliberate steps taken while walking. Refer to the ALTRUA and INSIGNIA I System Guides for further discussion of the accelerometer function.

If the pacemaker is permanently programmed to a nonadaptive rate mode, it is possible to program ATR Fallback Mode to an adaptive rate mode using the Accelerometer sensor. In this case, on the Sensor screen, the Accelerometer field will display ATR Only.

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

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

RESPONSE FACTOR (ACCELEROMETER)

The Accelerometer Response Factor parameter determines the pacing rate that will occur above the LRL at various levels of patient activity. Figure 2-10 shows the relationship of the Response Factor settings.

NOTE: *Automatic Response must be Off or set to Reset before changing the Response Factor setting.*

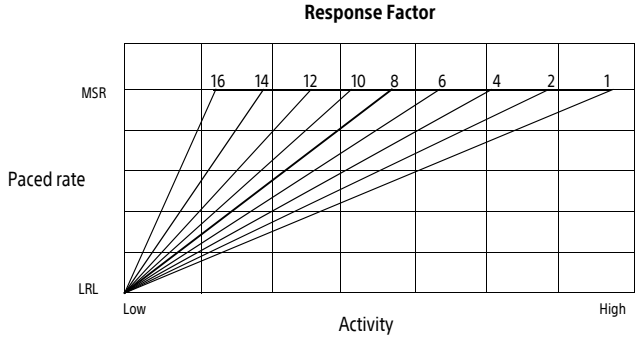


Figure 2-10. The relationship between the programmed Response Factor setting and the rate response

Setting the Response Factor to a higher value will enable the rate to reach the MSR with a lower level of activity than will a low value. Figure 2-11 illustrates the effect of higher and lower settings during a theoretical two stage exercise test.

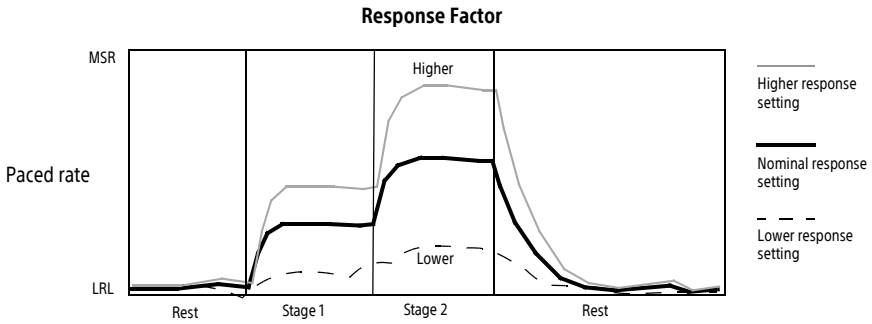


Figure 2-11. Effects of Response Factor settings in a two-stage exercise test

The pacing rate achieved can be limited either by the detected level of activity or by the programmed MSR. If the detected activity level results in a steady state rate below the MSR, pacing rate can still increase when the detected activity levels increase.

Programming the LRL up or down will move the entire response up or down without changing its shape. The steady state response is independent of the programmed reaction and recovery times.

The nominal setting has been shown to be appropriate for the majority of the patients in a previous study we conducted, and therefore is recommended for use in monitoring the rate response prior to programming changes.

The Passive setting can be used to allow accelerometer trending without a rate response.

ADVANCED ACCELEROMETER PARAMETERS

ACTIVITY THRESHOLD

The Activity Threshold prevents the pacemaker from increasing the rate due to low intensity extraneous motion (e.g., motion caused by respiration, heart beat, or, in some cases, tremor associated with Parkinson's disease). The pacemaker will not increase the paced rate above the LRL until the accelerometer signal has increased above the Activity Threshold. Select an Activity Threshold setting that allows a rate increase with minor activity (such as walking), but high enough so that the pacing rate will not increase inappropriately when the patient is inactive. A lower Activity Threshold setting will be easily exceeded by a minimum of motion, while a higher setting will require a greater amount of motion to result in an increased pacing rate (Figure 2-12). The nominal setting has been shown to be appropriate for the majority of the patients in a previous study we conducted, and therefore is recommended for use in monitoring the rate response prior to programming changes.

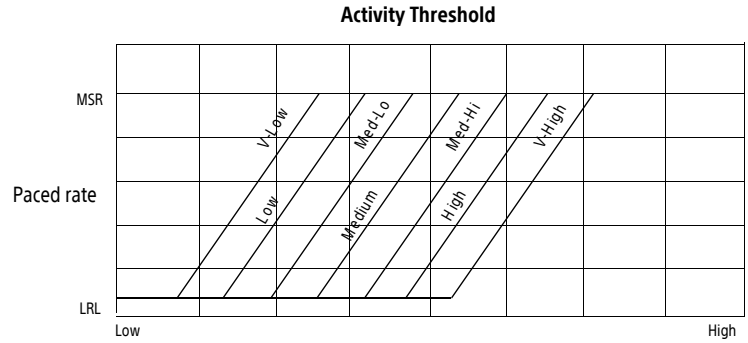


Figure 2-12. Relationship between the programmed Activity Threshold and the rate response

Increasing the Activity Threshold reduces the response to a theoretical two-stage exercise test as shown in Figure 2-13. Decreasing the Activity Threshold increases the response.

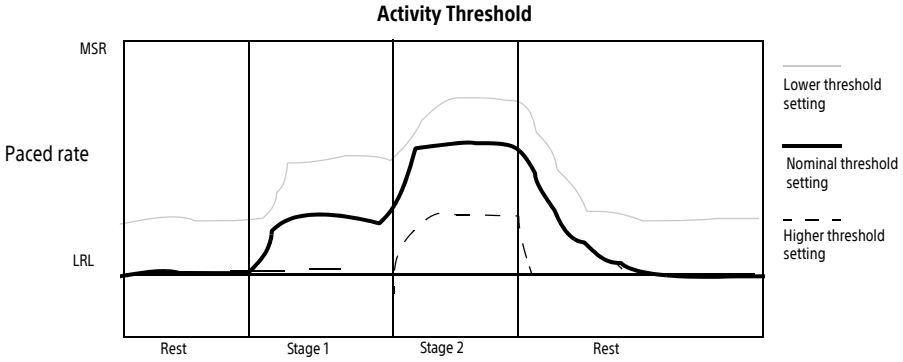


Figure 2-13. Effects of Activity Threshold settings in a two-stage exercise test

REACTION TIME

When an increase in the level of activity is detected, the pacing rate will increase. How quickly the pacing rate will rise to the new level is determined by the Reaction Time. The value selected for Reaction Time determines the time required for the paced rate to reach the MSR for a maximum level of activity. See Figure 2-14 for a graphic representation of the Reaction Time slopes. Reaction Time affects only the time required for a rate increase to occur. A short Reaction Time will allow the pacing rate to increase rapidly in response to patient activity. A long Reaction Time will result in a slower increase in pacing rate (Figure 2-15). The nominal setting has been shown to be appropriate for the majority of the patients in a previous study we conducted, and therefore is recommended for use in monitoring the rate response prior to programming changes.

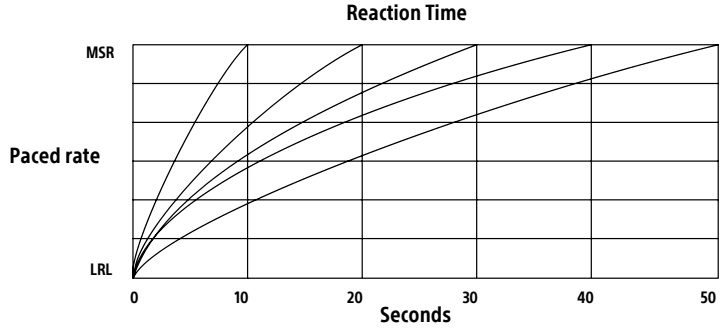


Figure 2-14. The relationship of reaction time and paced rate depending on the programmed Reaction Time setting

A shorter Reaction Time setting results in a more rapid rate increase during a theoretical two-stage exercise test than will a longer Reaction Time (Figure 2-15).

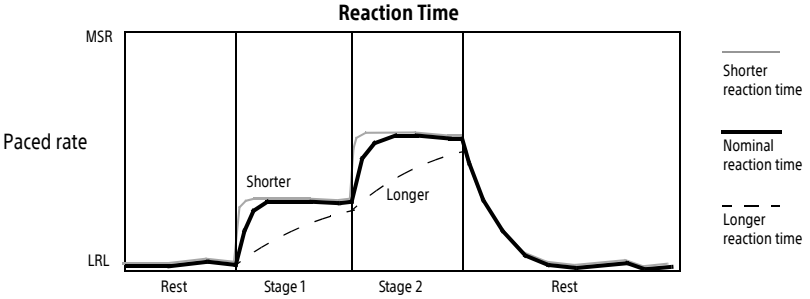


Figure 2-15. Effects of Reaction Time settings in a two-stage exercise test

RECOVERY TIME

The Recovery Time parameter determines the time required for the paced rate to decrease from MSR to LRL in the absence of activity. This feature is intended to prevent an abrupt decrease in pacing rate concurrent with the conclusion of patient activity. See Figure 2-16 for a graphic representation of the recovery times.

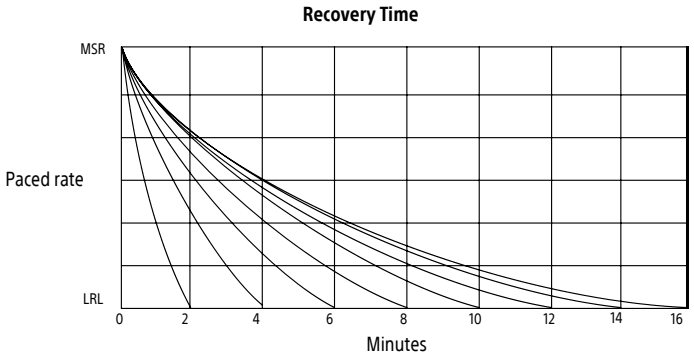


Figure 2-16. The relationship of paced rate to recovery depending on the programmed Recovery Time. Only even numbered settings are shown. There are 15 settings available.

A shorter Recovery Time will allow the pacing rate to decrease more rapidly after cessation or lowered patient activity. A longer Recovery Time will force a slower decrease in pacing rate. Figure 2-17 illustrates the effect of higher and lower settings during a theoretical two stage exercise test.

When using dual sensor blending, program Recovery Time for the Accelerometer to the minimum value of 2 minutes. This allows the physiologic MV signal to control adaptive rate pacing in the exercise recovery phase.

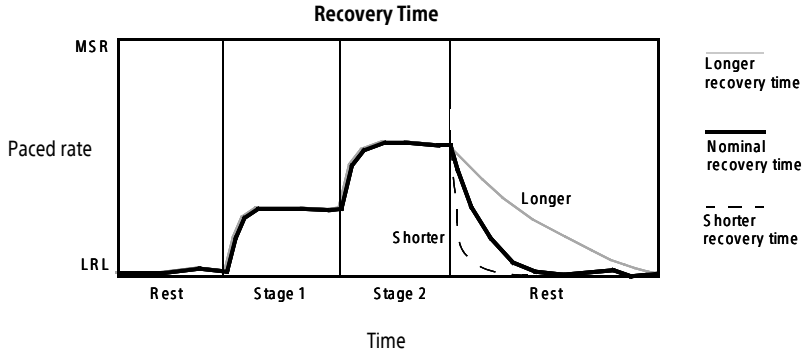


Figure 2-17. Effects of Recovery Time settings in a two-stage exercise test

Recovery Time affects only rate deceleration and is independent of other parameters.

AUTOMATIC RESPONSE FACTOR (ACCELEROMETER)

The Automatic Response feature allows the Accelerometer Response Factor to adapt to changes in the sensor-rate relationship over time.

When the Automatic Response feature is enabled, the pacemaker will record the maximum daily sensor rate excursions for the accelerometer sensor. Each week, the average of the daily maximum will be compared to the programmed Sensor Rate Target. Whenever the weekly average is more than 5 ppm above the Sensor Rate Target, the Response Factor will be reduced. If the weekly average is more than 5 ppm below the Sensor Rate Target, the Response Factor will be increased (Figure 2-18). As a result, the sensor indicated rate will adapt over time. Nonetheless, it is important to verify appropriate response at the time of sensor programming. The adaption algorithm uses 16 nonprogrammable response factor adjustments. Therefore, it may take several weeks before a change will be reported between the Initial Response Factor selection and the Response Factor that the device is currently using. To restore the Initial Response Factor or to select a different Response Factor, select the Reset option.

NOTE: *Automatic Response must be set to Off or Reset to change the Response Factor.*

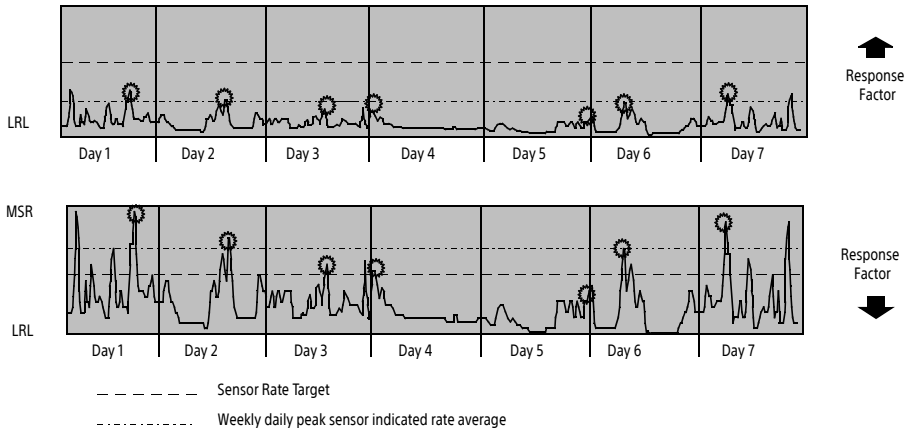


Figure 2-18. Automatic Response Factor examples

If the pacemaker is programmed such that the MSR is reached frequently, the Automatic Response Factor will reduce the sensor indicated paced rate more rapidly. The algorithm reduces the current value

of the Response Factor every 370 consecutive cycles at the programmed MSR (approximately 3 minutes at an MSR of 120 ppm). Take this into consideration when programming the Automatic Response Factor and the MSR.

SENSOR RATE TARGET FOR AUTOMATIC RESPONSE FACTOR

The pacemaker compares the average of the daily maximum sensor rates with the Sensor Rate Target to adjust the rate Response Factor. See discussion above and "Automatic Response Factor (Accelerometer)" on page 2-23 for more information.

ACCELEROMETER (ACC) INITIAL RESPONSE FACTOR

The Accelerometer Initial Response Factor will be used as the starting point for the Automatic Response Factor algorithm. See discussion above.

TEMPORARY BRADY PACING

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

To use this function, follow these steps:

1. From the Tests tab, select the Temp Brady tab to display the temporary parameters.
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.*

CAUTION If the Amplitude is Off during Temporary Brady Mode programming, the pacemaker will not pace. Pacing with the permanently programmed parameters can be restored by breaking the telemetry link or by selecting the Cancel button on the Temporary Parameters Now in Use window.

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 Programmer or if telemetry is lost.

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

MINUTE VENTILATION (MV)

The adaptive rate pacemakers (ALTRUA 40 and 60; INSIGNIA I Plus and Ultra) use transthoracic impedance to measure minute ventilation (MV), which is the product of respiration rate and tidal volume. Based on the MV measurement, the pacemaker calculates the sensor rate. The minute ventilation signal can be measured through either the atrial or the ventricular lead. The selected MV lead must be bipolar but the

Lead Configuration can be programmed Unipolar or Bipolar. See ALTRUA and INSIGNIA I System Guides for a discussion of MV detection.

CAUTION: Electrical signals introduced into the body by some hospital monitoring and/or diagnostic equipment may result in accelerated pacing, possibly up to the maximum sensor-driven rate, when MV is programmed On. Examples of this equipment include, but are not limited to, respiratory monitors, diagnostic echo imaging, surface ECG monitors, and hemodynamic monitors. Deactivate the MV sensor when interaction with this equipment is suspected.

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

WARNING: Inappropriate sustained high-rate pacing occurred in the PULSAR MAX clinical study in 5 out of 130 patients with Minute Ventilation On, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming:

- a reduced Max Sensor Rate (MSR), or
- MV to Passive

MV INITIALIZATION

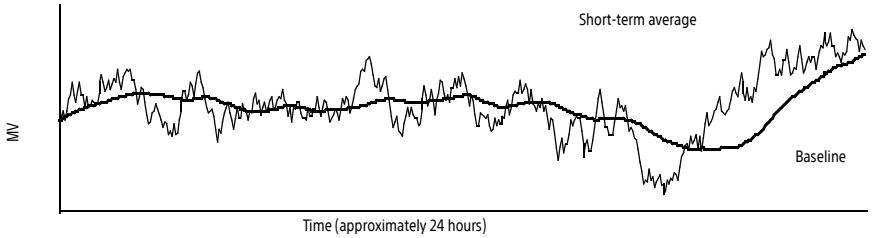
In some patients MV Initialization will need to be repeated by performing the 4→ On-A or 4→ On-V initialization procedure. Factors affecting the MV baseline included lead maturation effects, air entrapment in the pocket, pacemaker motion due to inadequate suturing, and other patient complications (e.g., pneumothorax).

CAUTIONS:

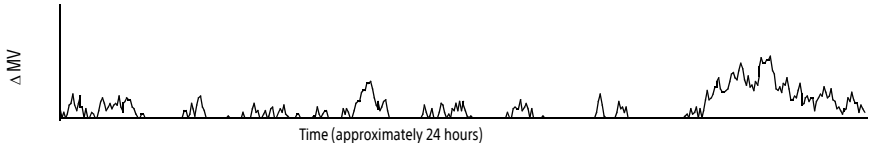
- A 4→ On initialization should be performed if the pacemaker is removed from the pocket following implant, such as during a lead repositioning procedure.
- A 4→ On initialization should be performed to establish a new MV baseline if one of the following conditions is noted during MV sensor evaluation:
  - Failure to achieve a significant sensor-indicated response with the MV Response Factor set to level 1
  - Observed maximum or elevated sensor-indicated rates with the MV Response Factor set to level 2

These programming recommendations are intended to assure that MV calibration is evaluated, and, if necessary, recalibrated (4→ On) when the patient and pacing system have stabilized post-implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred.

To obtain a relative MV measure, a long term (4 hour) average of the measurements (also referred to as the baseline) is compared to a short term (approximately 30 second) average to determine the change in MV due to increased metabolic demand. If the short term average increases above the long term, the difference will be used to increase the sensor rate (Figure 2-19).



TOP: The Baseline (long term average) follows the drift of the short term average with a 4 hour time constant.



BOTTOM: The difference between the short and long term average is used for increasing the pacemaker's rate upon exertion.

Figure 2-19. Long-Term Average and Short-Term Average

To allow 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 (long term average) is fixed for up to 4 hours when the sensor rate is above 50% of the programmed rate range ([LRL + MSR] / 2). For example, if the LRL is 60 ppm and the MSR is 120 ppm, the baseline average will freeze when the heart rate exceeds 90 ppm (180 / 2). After a maximum of 4 hours or when the sensor rate falls below the 50% point, baseline adaptation will be re enabled. This feature is always active when MV is used.

To activate the Minute Ventilation sensor, the system needs a measure of the baseline or resting MV. In dual-chamber devices, the clinician may collect values through the atrial lead (4→ On-A) or the ventricular lead (4→ On-V). (In single-chamber devices, the selection is 4→ On). Selecting one of the 4→ On options instructs the pacemaker to collect resting MV values for 4 minutes and estimate the MV baseline based on this short measurement before automatically activating the MV sensor. The Programmer will display the MV Lead selected.

NOTES:

- *Whenever a magnet is applied and the Magnet Response has been programmed to Async, the pacemaker will pace asynchronously at the magnet rate and will not respond to MV data.*
- *When a 4→ On initialization is selected, AutoLifestyle is automatically enabled.*
- *Maintain the telemetry communication link until the scale indicates that the programming has reached 100% completion and the message window closes.*
- *Performing a 4→ On calibration clears all the MV measurements. This action also resets AutoLifestyle.*

RESPONSE FACTOR (MINUTE VENTILATION)

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

The Response Factor can be automatically optimized to the patient's activity profile using AutoLifestyle. AutoLifestyle must be programmed Off to program a specific Response Factor for MV. Refer to "AUTOLIFESTYLE" on page 2-32 for more information.

The Response Factor parameter determines the pacing rate that will occur above the LRL at various elevated levels of MV. Figure 2-20 shows the relationship of the Response Factor settings. Larger Response Factor values will result in higher sensor rates for a given MV level.

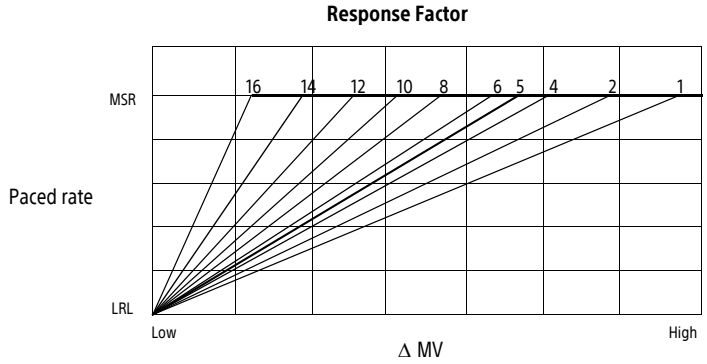


Figure 2-20. Relationship between the programmed Response Factor setting and the rate response

Figure 2-21 illustrates the effect of higher and lower Response Factor settings during a theoretical two-stage exercise test.

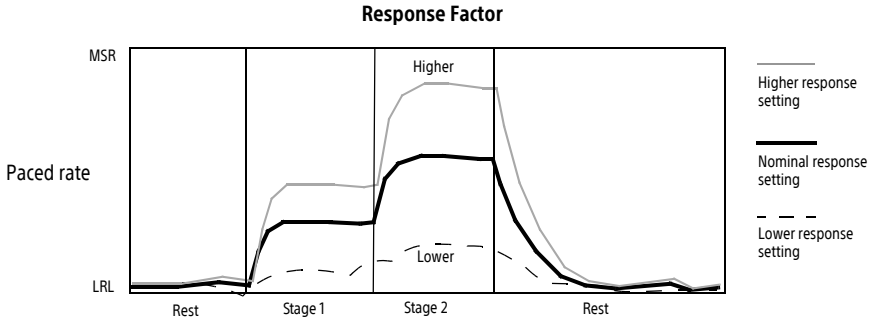


Figure 2-21. Effects of Response Factor settings in a two-stage exercise test

The MV Response Factor[1] may be programmed to Passive to allow for MV trending without a rate response.

NOTE: *Automatic Response must be Off or set to Reset before changing the Response Factor setting.*

ADVANCED MINUTE VENTILATION PARAMETERS

The physiologic relationship between MV and heart rate is approximately bilinear as shown in Figure 2-22. During exercise levels up to the anaerobic threshold, this relationship can be approximated by a linear relationship. At exertion levels above the anaerobic threshold, the slope becomes less pronounced. The relationship between the secondary slope and the primary slope varies from person to person and depends on several factors such as gender, age, and exercise frequency and intensity.

1 Ventilatory Threshold Response term replaces the High Rate Response Factor term used in the System Guides.

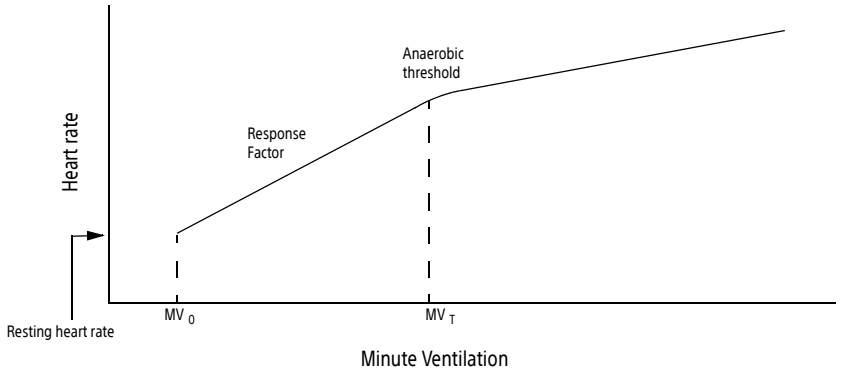


Figure 2-22. Typical physiologic relationship between MV and heart rate (MV0 = resting MV; MVT = MV at the anaerobic threshold)

The pacemakers allow programming of a secondary, less aggressive slope that mimics the physiologic relationship between MV and heart rate. The Ventilatory Threshold Response is programmed as a percentage of the MV Response Factor.

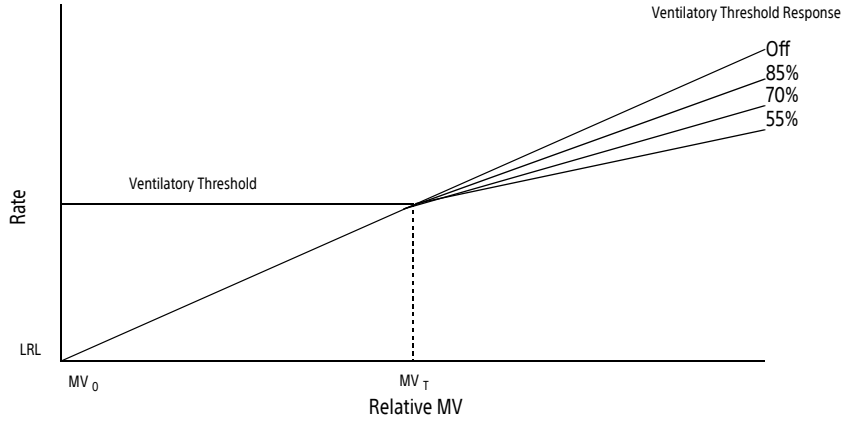


Figure 2-23. The MV Response Factor is linear from the resting state up to the anaerobic threshold predicted heart rate (Ventilatory Threshold) (MV0 = resting MV; MVT = MV at the anaerobic threshold)

The Ventilatory Threshold Response is in effect at rates above the Ventilatory Threshold and will result in a less aggressive response to increased MV at higher rates (Figure 2-23).

VENTILATORY THRESHOLD

The MV 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 between the Ventilatory Threshold and the MSR.

See "Automatic Response Factor (Accelerometer)" on page 2-23 for further information.

MANUAL OPTIMIZATION OF THE MV AND MV BLENDED SENSOR (MV AND ACCELEROMETER)

PROGRAMMING MV BLENDED SENSOR TO PASSIVE (FOR DATA COLLECTION)

Manually optimizing the MV sensor or MV Blended Sensor (a blend of both MV and Accelerometer) allows the clinician to adapt the sensor-driven pacing rate to correspond with the patient's actual observed

activity. Programming the MV and Accelerometer rate sensor(s) to Passive allows for sensor data collection that can be utilized to optimize the sensor(s) without having the sensor(s) drive the rate response. This collected sensor data can be retrieved and displayed on the Trending screen.

To set the MV sensor to Passive, program the device to a rate-responsive mode, calibrate the MV sensor (4→ On), turn AutoLifestyle OFF, and set MV Response Factor to Passive. If desired, optionally program the Accelerometer Response Factor to Passive as well for this optimization. Initiate Trending on the Setup Trending screen by selecting which types of data to be collected by the pacemaker and the resolution at which to acquire the data (see "TRENDS" on page 4-7 for detailed explanation).

NOTE: *The Recording Method must be set to High Resolution or Long Duration in order to gather rate sensor data. Consider changing the Recording Method to High Resolution (which averages the ventricular rate every 16 seconds, records the Accelerometer and MV raw sensor data, and collects up to 6 hours of data) when using trending to manually optimize the sensor(s). The Source must be set to Rate in order to collect rate sensor data. Data Storage can be set as appropriate for the patient's situation.*

RETRIEVING TRENDING DATA AND MANUALLY OPTIMIZING MV BLENDED SENSOR

The Trending screen graphically displays sensor rate information and measured intrinsic events data stored by the pacemaker. Examine the patient's trending data. The black line on the screen indicates the patient's heart rate during activity (intrinsic or paced). The orange line depicts the sensor rate replay; this shows how the sensor(s) will drive the heart rate with the current sensor parameter settings. If no data is available, instruct the patient to perform a 3-5 minute hall walk. Then re-interrogate the pacemaker and go to Trending screen to retrieve the data. If the patient's heart rate is appropriate for the activity performed, no rate sensor optimization is necessary.

If optimization of the MV Sensor, the Accelerometer, or the MV Blended Sensors is necessary (heart rate is too low for the activity level), adjust the MV Response Factor and other sensor parameters (the result is shown by the orange line) so the patient's heart rate is within desired range for the activity performed (this can be accomplished without re-exercising the patient). Under the graph on the Trending screen, select the magnifying glass symbol next to rate sensor to be optimized. This opens the Trending Replay dialog with the parameters for that sensor. Adjust the Response Factor and other sensor parameters, or the MSR and LRL, and observe how the orange line with the sensor rate replay is re-computed on the graph. Adjust the rate sensor parameters until the orange line shows the desired sensor-driven rate appropriate for the patient's level of activity. Select the Copy to Brady button to copy these sensor replay parameters to the Brady Parameters screen, go to the Brady Parameters screen and program these to the pacemaker.

NOTES:

- *For a casual walk a heart rate increase approximately 25 ppm over resting heart rate is normal for this level of exertion by an individual.*
- *The pacemaker will not record rate sensor data while telemetry is active. Remove the wand in order to gather trending data.*

DUAL SENSOR BLENDING

Whenever both adaptive rate sensors are selected for adaptive rate pacing, the ALTRUA 40 and 60 and INSIGNIA I Plus and Ultra pacemakers will blend the two sensor indicated rates to produce a rate dependent weighted average response. As a result, the blended response will always be equal to or between the two individual responses.

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 80%

accelerometer and 20% MV when the blended rate is at LRL, to 40% Accelerometer and 60% MV when the blended rate is at MSR.

The following examples illustrate the blending algorithm operation:

Example 1: *The accelerometer detects motion with a simultaneous MV increase (Figure 2-24). 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 towards 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 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, program Recovery Time for the Accelerometer to a minimum value of 2 minutes. This allows the physiologic Minute Ventilation signal to control adaptive rate pacing in the exercise recovery phase.

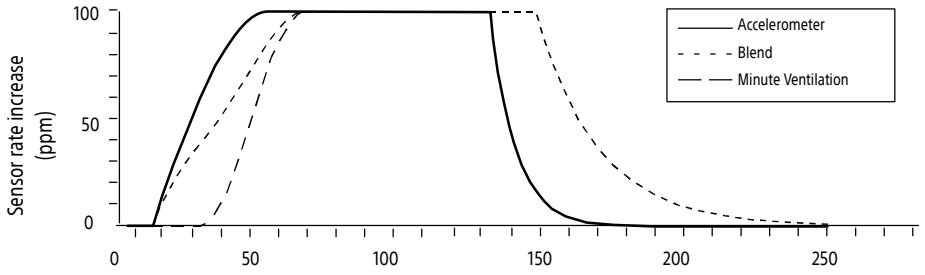


Figure 2-24. Example of blended response using an Accelerometer Reaction Time of 30 seconds (nominal)

The aggressiveness of response at the onset of exercise can be controlled by programming a shorter Accelerometer Reaction Time (Figure 2-25).

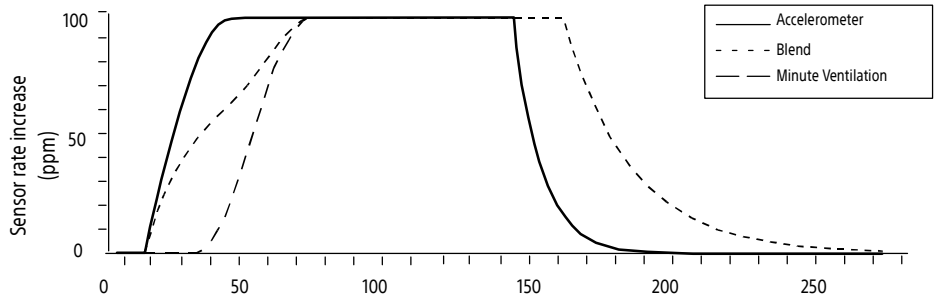


Figure 2-25. Example of blended response using a shorter Accelerometer Reaction Time of 20 seconds. There is a more pronounced rate increase at the onset of exercise.

Example 2: *The accelerometer detects motion with little MV increase (Figure 2-26). 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.*

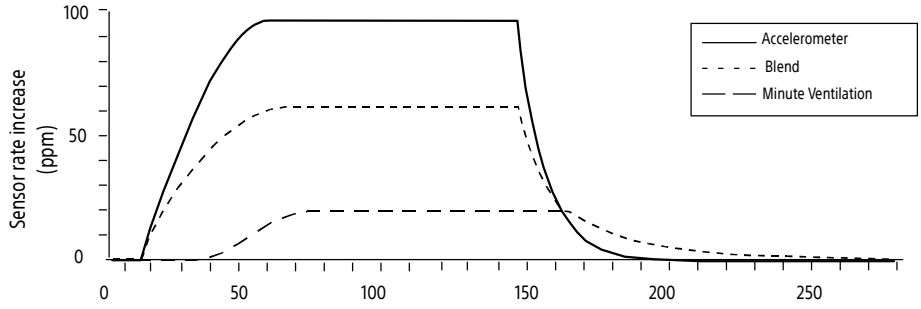


Figure 2-26. The Accelerometer detects motion with little or no increase in Minute Ventilation

Example 3: *MV increases with little accelerometer rate increase (Figure 2-27). 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 an adequate response during increases in metabolic demand, with little or no upper body movement.*

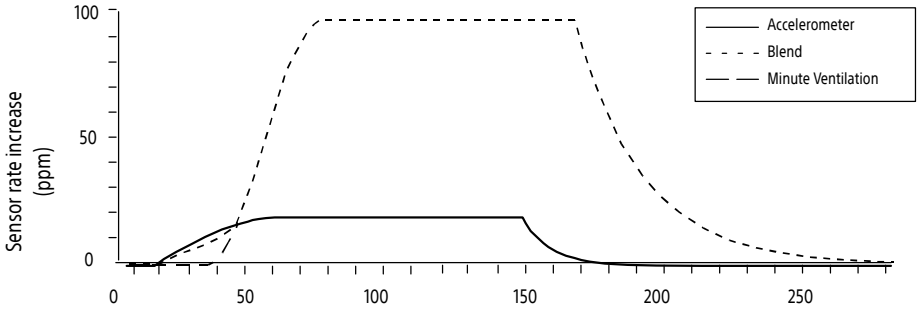


Figure 2-27. Minute Ventilation increases with little or no motion detected

TIME DEPENDENT BLEND

The Time Dependent Blend algorithm will reduce the accelerometer driven sensor response over a period of minutes until either intrinsic activity occurs, LRL/hysteresis limit is reached, or the MV sensor driven pacing rate is reached (Figure 2-28). This algorithm helps ensure the MV sensor governs the sensor driven pacing rate during the recovery phase of exercise.

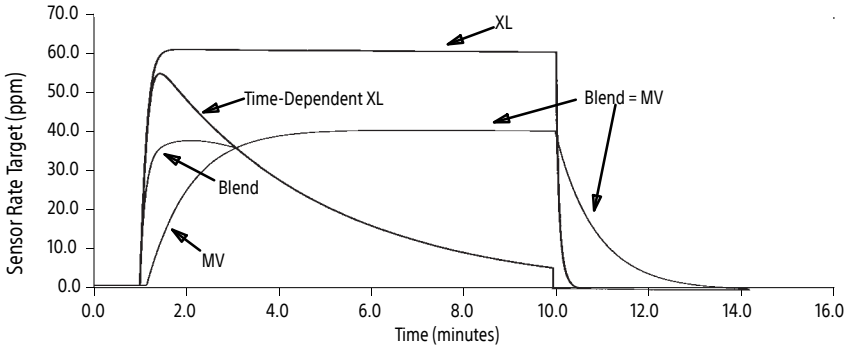


Figure 2-28. Example of time-dependent blend response to exercise with constant motion and minute ventilation. The time-dependent blend algorithm attenuates the detected motion so that MV controls the rate at the end of exercise.

AUTOLIFESTYLE

This feature adjusts the MV Response Factor and Accelerometer Response Factor to adapt the sensor-driven pacing rate to correspond with the patient's actual measured activity. The measurement of exercise intensity and frequency is determined by measuring MV and accelerometer values during patient activity.

RESPONSE FACTOR (MV)

MV Response Factor adaptation is based on the pacemaker's continual measurements of the patient's maximum MV (their functional capacity) and their exercise intensity and frequency.

NOTE: *As a diagnostic, the device measures and stores MV baseline on an hourly basis for the last 24 hours. Performing a 4→On calibration clears all the MV measurements. This action also resets AutoLifestyle.*

The AutoLifestyle feature is designed to adjust MV Response Factor between the 10 nonprogrammable response factor values so that the patient's age-predicted maximum heart rate (220 – patient's age) will be reached when the patient reaches their maximum MV (MV Max). The Max Sensor Rate (MSR) still limits the actual sensor-driven pacing rate, and MSR can be adjusted independently of the patient's age-predicted maximum heart rate. Adjusting the MSR will not affect the AutoLifestyle algorithm. MV must be active in order for AutoLifestyle to operate, although the Accelerometer can be either On or Off. If the Accelerometer is programmed Off, the pacemaker will still use the Accelerometer for exercise measurements, but accelerometer-driven pacing will not occur.

When the algorithm is first activated, it does not have a measured MV Max from the patient. It starts with an MV Max initial value that is typically higher than the patient's true MV Max. This high value will cause the algorithm to under-respond initially. AutoLifestyle continually monitors the patient's MV Max along with the accompanying accelerometer cross-check value. This data is used to update the MV Max Long Term—the MV Max value stored and updated by the device. Whenever this MV Max Long Term is updated, AutoLifestyle recalculates the MV Response Factor so that the age-predicted maximum heart rate will be reached at this new MV Max value. The algorithm determines the patient's true MV Max by increasing or decreasing the MV Max Long Term.

NOTE: *As AutoLifestyle automatically adjusts the Response Factor, the patient may feel a higher heart rate than usual for his/her level of exertion. This is normal because the feature is adjusting the response rates.*

MV MAX LONG TERM

The MV Max Long Term is stored by AutoLifestyle and decreased or increased over time in response to the patient's true MV Max.

DECREASING MV MAX LONG TERM

MV Max Long Term can be decreased based on weekly measurements of MV. The weekly measurements evaluate the greatest measured MV Max during the last seven days and its corresponding accelerometer value. The accelerometer (cross check) value indicates if the MV Max occurred during mild, moderate, or vigorous exercise. Using this information, the patient's true MV Max is estimated by the device. If the estimate is more than 15% lower than the present MV Max Long Term, this value is decreased in 15% increments.

INCREASING MV MAX LONG TERM

MV Max Long Term is increased whenever AutoLifestyle measures an MV Max that is higher than the present MV Max Long Term. If the measured MV Max is higher by more than 10%, then MV Max Long Term is set to the new value. If the measured MV Max is higher but is less than 10% higher, then MV Max Long Term is increased by 10%. Once MV Max Long Term is increased, the weekly evaluations for decreasing MV Max are discontinued.

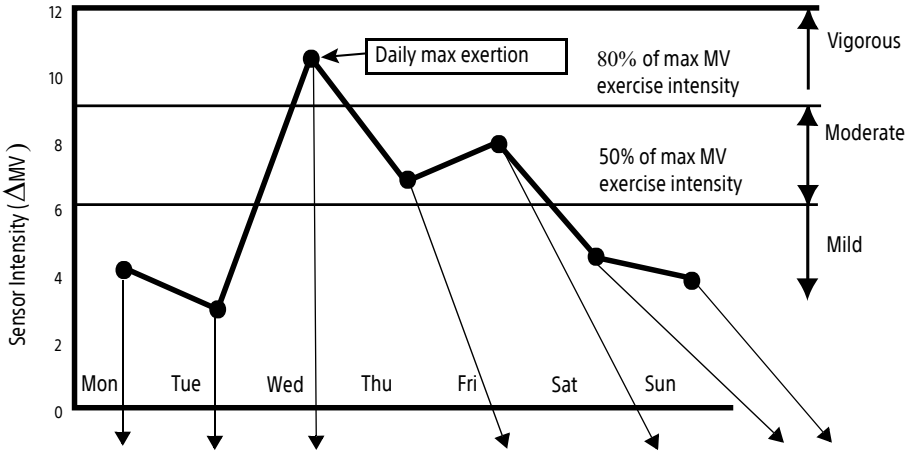
By using these measured MV Max values, the AutoLifestyle algorithm is able to approximate the patient's actual MV Max value and adjust the MV response factor based on this information. AutoLifestyle continues to update the MV Max measurement throughout the patient's lifetime by using the maximum MV measurement that occurred. This allows for continual adjustment to the patient's changing functional capacity.

AutoLifestyle also adjusts the Accelerometer and MV Response Factor using a Sensor Rate Target that is established by device measurements of patient activity. See "Sensor Rate Target for AutoLifestyle" on page 2-33.

The AutoLifestyle algorithm maintains its measured settings for a minimum of 24 hours and a maximum of 48 hours after being programmed Off. If the algorithm is programmed back to On within 24 hours, AutoLifestyle will resume its operation using the previously measured values. AutoLifestyle data such as measured MV Max and Accelerometer values are printed out as a part of the Combined Follow-up report. After each occurrence of 370 consecutive cycles at the programmed MSR, which is approximately 3 minutes at an MSR of 130 ppm, AutoLifestyle decrements the Response Factor for both MV and the Accelerometer.

SENSOR RATE TARGET FOR AUTOLIFESTYLE

Throughout AutoLifestyle, the MV and Accelerometer response factors are adjusted using the Sensor Rate Target. The pacemaker automatically determines the Sensor Rate Target by monitoring the exercise intensity measured each day. This information is gathered weekly and the Sensor Rate Target is then adjusted (Figure 2-29). The maximum effect is approximately 3%.



Sensor Rate Target = (90 ppm + 90 ppm + 90% APMHR + 70% APMHR + 70% APMHR + 90 + 90) / 7

Figure 2-29. Sensor Rate Target weekly calculation (APMHR = Age Predicted Maximum Heart Rate)

ATR MODE SWITCH

The ATR Mode Switch feature provides mode switching from DDD(R) to DDI(R) or VDI(R), and from VDD to VDI(R) in the presence of detected atrial activity that exceeds the ATR Trigger Rate. ATR limits 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.

Rate Smoothing, Dynamic AV Delay, and Dynamic PVARP can be used in combination with the ATR Mode Switch feature. The operation of one feature will not conflict with the operation of the other.

TRIGGER RATE

ATR Trigger Rate is an independently programmable parameter that allows the clinician to determine the rate cutoff at which the pacemaker begins to detect atrial tachycardias (Figure 2-30). The pacemaker monitors atrial events throughout the pacing cycle except during the atrial blanking period and noise interrogation intervals. Events at or above the ATR Trigger Rate will increase the entry counter, and events below the ATR will decrease the entry counter. When the ATR detection counter reaches the programmable Entry Count, the ATR Duration begins and the Exit Count starts ("Figure 2-30. Illustration of ATR behavior" on page 2-36). When the ATR Exit Count reaches zero at any point in time, ATR Duration and/or ATR Fallback will be terminated and the ATR algorithm will be reset. An event marker will be generated whenever the ATR Exit Count or entry counter is incremented or decremented.

ENTRY COUNT

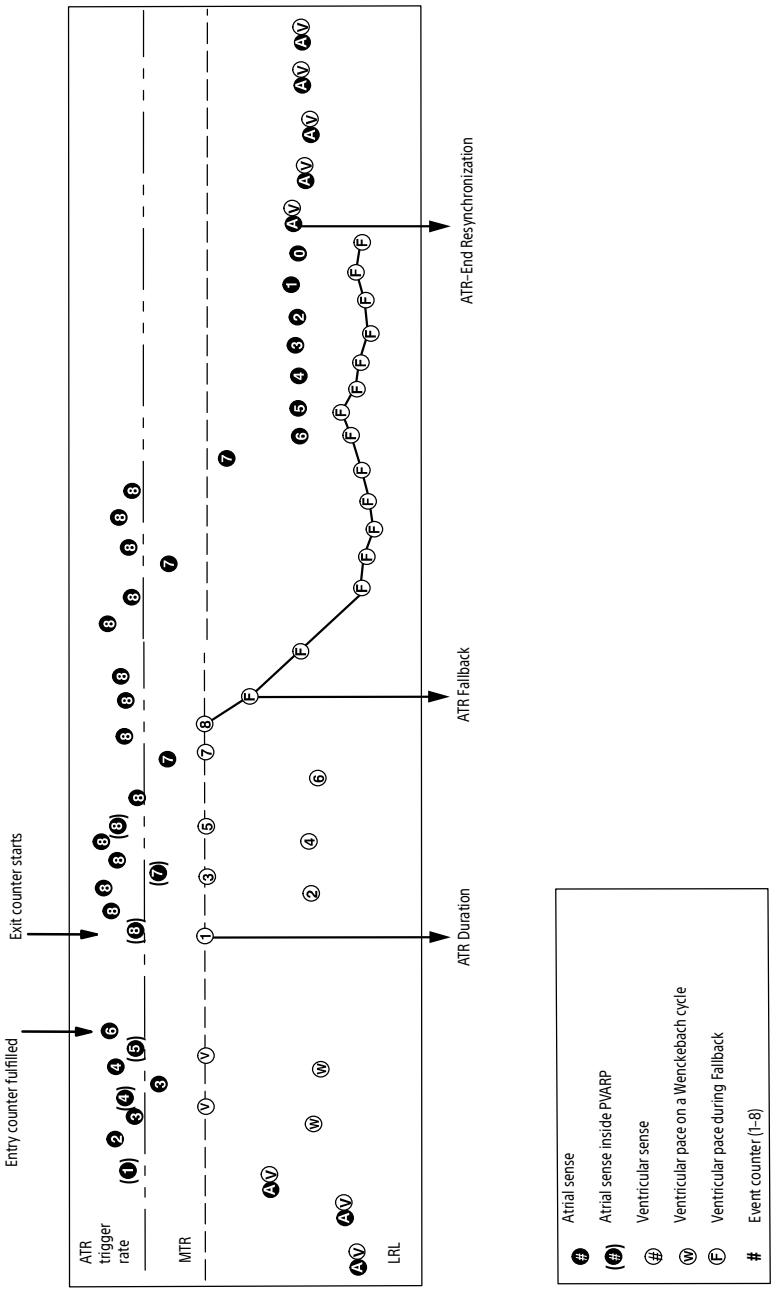
The Entry Count is an independently programmable parameter that allows the clinician to determine how quickly an atrial arrhythmia is initially detected. The lower the programmable value, the fewer fast atrial events are required to fulfill initial detection. Once the number of fast atrial events detected equals the programmable Entry Count, ATR Duration begins and the Exit Count is started.

CAUTION: Exercise care when programming the Entry Count to low values in conjunction with a short Duration. This combination allows mode switching with very few fast atrial beats. If the Entry Count were programmed to 2 and the Duration to 0, for example, ATR mode switching could occur on two 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 is an independently programmable parameter that allows the clinician to determine how quickly the ATR algorithm is terminated once the atrial arrhythmia no longer is detected. The lower the programmable value, the more quickly the pacemaker will return to dual chamber pacing. Once the number of slow atrial events detected equals the programmable Exit Count, ATR Duration and/or ATR Fallback Mode will be terminated and the ATR algorithm will be reset. The exit counter is loaded with the programmable value and begins its count once the Entry Count criteria are fulfilled.

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



(Fallback Mode = VDI, Duration = 8 cycles, Entry Count = 6 cycles, Exit Count = 8 cycles, Fallback Time = 5 sec)

Figure 2-30. Illustration of ATR behavior

DURATION

ATR Duration is a programmable parameter that determines the number of ventricular cycles during which the atrial events continue to be evaluated after initial detection. If the atrial tachycardia persists for the programmed duration, mode switching occurs and the ventricular rate begins to decrease to the sensor rate or the ATR Lower Rate Limit (Figure 2-30). The Duration feature is intended to avoid mode switching due to nonsustained episodes of atrial tachycardia. Whenever the ATR Exit Count reaches 0 during Duration, the A-Tachy Response algorithm will be reset.

FALLBACK MODE

Once Duration has been fulfilled, the pacemaker will automatically switch to the programmed Fallback Mode. After switching modes, the device gradually decreases the ventricular paced rate to the sensor indicated rate or the ATR Lower Rate Limit, depending on the programmed Fallback Mode. The decrease in ventricular paced rate is controlled by the Fallback Time parameter.

FALLBACK TIME

The Fallback Time determines how quickly the rate in fallback will decrease to the ATR Lower Rate Limit or sensor rate. The Fallback Time parameter controls the decrease in the paced rate.

During fallback, the following features will be disabled:

- Rate Smoothing, until fallback reaches ATR Lower Rate Limit or the sensor indicated rate
- Rate Hysteresis and Search Hysteresis
- AV Search Hysteresis

All sensor parameters must be programmed when the adaptive-rate Fallback Mode is selected. When the pacemaker is permanently programmed to an adaptive-rate mode with an adaptive-rate ATR Fallback Mode, the pacemaker will use the sensor and sensor parameters already in effect at the time of the switch.

If the pacemaker is permanently programmed to a nonadaptive rate mode, it is possible to program ATR Fallback Mode to an adaptive rate ATR Fallback Mode using the accelerometer sensor. In this case, on the Sensors screen, the Accelerometer field will display "ATR Only."

ATR LOWER RATE LIMIT

The ATR Lower Rate Limit allows an independently programmed LRL during an ATR mode switch. When the ATR Fallback Mode is programmed to a rate adaptive mode, the response slope is not affected. Consequently, the activity level necessary for rate adaptive pacing to achieve a specific pacing rate remains the same during ATR Fallback as it does during normal dual chamber rate adaptive pacing.

The ATR Lower Rate Limit must be equal to or greater than the permanently programmed brady LRL.

END OF ATR EPISODE

The pacemaker will continue to pace in the Fallback Mode at the sensor indicated rate or the ATR Lower Rate Limit until the atrial arrhythmia terminates. Upon termination of the arrhythmia, the ATR Exit Count decrements from its programmed value until it reaches 0 (Figure 2-30 on page 2-36). The ATR Exit Count is decremented by atrial events slower than the Trigger Rate or paced ventricular events without an intervening atrial event. When the ATR Exit Count reaches 0, the pacing mode automatically resynchronizes to the programmed tracking mode, and P synchronous pacing is restored.

ATR DIAGNOSTIC DATA

A-Tachy Response continuously monitors atrial rates. The onset rate is the rate of the last interval when Duration is met. The maximum rate is the rate of the shortest interval after Duration is met. The number of ATR Fallback events is stored for display in the counter function of the device. Event markers are issued whenever the ATR Count increments or decrements, or whenever the other events outlined in Table 2-5 on page 2-38 occur.

Table 2-5. ATR Event Marker Annotations

Event Marker	Explanation
ATR ↑	ATR Count incremented
ATR ↓	ATR Count decremented
ATR–Dur	ATR Duration started
ATR–FB	ATR Fallback started, pacemaker switched to nontracking mode
ATR–End	ATR Fallback ended, resynchronization occurred

VENTRICULAR RATE REGULATION (VRR)

Ventricular Rate Regulation (VRR) is designed to reduce V—V cycle length variability during conducted atrial arrhythmias. 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 (this is similar to Rate Smoothing, which only uses the most recent V—V interval). 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. This is due to the weighted-sum methodology stated above. The VRR-indicated rate is further bound by the Lower Rate Limit and the VRR Max Pacing Rate.

When programmed On in tracking modes, VRR is active only when an A-Tachy Response mode switch has occurred. Once 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, whenever VRR is active the pacemaker will automatically disable Rate Smoothing and reactivate Rate Smoothing once the atrial arrhythmia has terminated.

When programmed On in single chamber modes, VRR is continually active and updates the smoothed average on each cardiac cycle.

VRR MAX PACING RATE

VRR Max Pacing Rate limits the maximum pacing rate the VRR algorithm can reach.

ATRIAL FLUTTER RESPONSE (AFR)

Atrial Flutter Response (AFR) is designed to prevent pacing into the atrial vulnerable period and to provide immediate fallback for atrial rates higher than the AFR programmable rate. This fallback will be maintained as long as atrial events continually exceed the AFR programmable rate.

AFR may be programmed to On, Off, along with a specified Trigger Rate, depending on the model.

When AFR is programmed to 230 ppm, for example, a detected atrial event inside the PVARP or a previously triggered AFR interval will start an AFR window of 260 ms (230 ppm). Atrial detection inside the AFR will be classified as refractory senses and will not be tracked. The sensing window starts only after both the AFR and the PVARP have expired. Paced atrial events scheduled inside an AFR window will be delayed until the AFR window has expired. If there are fewer than 50 ms remaining before a ventricular pace, the atrial pace is inhibited for the cycle. The ventricular pace is not affected by AFR and will take place as scheduled. The wide programmable range for AFR rates allows for appropriate sensing of slow atrial flutters.

High rate atrial sensing may continuously retrigger the AFR window, effectively resulting in fallback to the VDI(R) mode.

The Atrial Flutter Response feature is available only in DDD(R) and DDI(R) modes. Whenever DDI(R) mode is programmed On, AFR will be set to 230 ppm automatically. The setting should be programmed to Off if the AFR feature is not desired.

When both the Atrial Flutter Response and the ATR Mode Switch are active, mode switches may take longer than when Atrial Flutter Response is not active, as described below.

For atrial arrhythmias that meet the programmed AFR rate criteria, using the Atrial Flutter Response feature will result in slower ventricular pacing rates. If the ATR Mode Switch feature is also programmed On and Duration is programmed to a value > 0, the time to an actual mode switch may be longer with AFR active. This is because the ATR Duration feature counts ventricular cycles for meeting duration and the AFR feature slows the ventricular response to fast atrial arrhythmias.

PMT TERMINATION

In DDD(R) and VDD pacing modes, any pacemaker may detect retrograde conducted P waves that fall outside of PVARP, causing triggered ventricular pacing rates as high as the MTR [i.e., pacemaker mediated tachycardia (PMT)]. When the PMT Termination feature is enabled, a PMT condition will be detected by counting 16 successive ventricular paces at the MTR following atrial sensed events.

Also, the V–A interval will be monitored during the 16 intervals to determine if a PMT is occurring or if the intrinsic atrial rate is simply meeting or exceeding the MTR. The V–A intervals will be compared to the first V–A interval measured during the 16 ventricular paced events. If any of the successive intervals is more than 32 ms shorter or longer than this first interval, the rhythm will be declared a Wenckebach event, the Wenckebach counter will increment, and the algorithm will continue to monitor successive ventricular paces for the presence of a PMT. If the V–A intervals are all within this 32 ms criteria, the rhythm will be declared a PMT.

When a PMT condition at the MTR is detected, the pacemaker will set the PVARP setting to a fixed value of 500 ms for one cardiac cycle, attempting to break the PMT.

Programming the PVARP after PVC/PAC option and/or Rate Smoothing can also be useful in controlling the pacemaker's response to retrograde conduction.

The pacemaker can store PMT episodes in the Arrhythmia Logbook if the PMT EGM trigger is enabled.

RATE ENHANCEMENTS

RATE HYSTERESIS

HYSTERESIS OFFSET

Rate Hysteresis can be used in the DDD(R), DDI(R), VVI(R), and AAI(R) modes. When the pacemaker senses intrinsic activity, the escape rate will be lowered by the programmed Hysteresis Offset value, allowing intrinsic contractions below the LRL or sensor indicated rate.

In nonadaptive rate modes, the escape rate is lowered by the Hysteresis Offset below the LRL. In adaptive rate modes, the escape rate is lowered below the sensor indicated rate. As a result, the patient might benefit from longer periods of sinus rhythm. In addition, due to the reduction of the number of pacing stimuli, Rate Hysteresis can improve pacemaker longevity.

NOTES:

- *When Rate Smoothing Down is enabled, Rate Hysteresis will remain in effect until pacing occurs at the hysteresis rate. This allows Rate Smoothing to control the transition to the hysteresis rate.*
- *During an ATR Mode Switch, Rate Hysteresis is deactivated.*

RATE HYSTERESIS IN NONADAPTIVE RATE MODES

When Rate Hysteresis is enabled in DDD or DDI mode or in single chamber atrial modes, a single nonrefractory sensed atrial event will activate Rate Hysteresis (Figure 2-31 on page 2-40). Rate Hysteresis will be deactivated by a single atrial pace at the hysteresis rate. In DDD and DDI mode, Rate Hysteresis will also be deactivated by a single atrial pace during a cardiac cycle when a ventricular pace is scheduled at the hysteresis LRL, or, in DDD mode, whenever the atrial rate rises above the MTR.

In the VVI mode, a single nonrefractory sensed ventricular event will activate Rate Hysteresis. A single ventricular pace at the hysteresis rate will deactivate it.

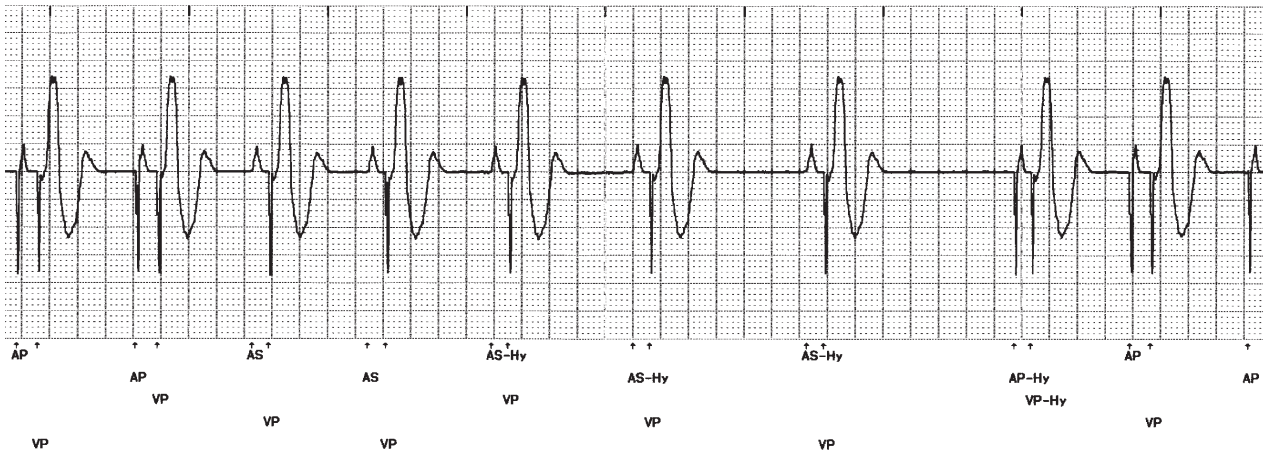


Figure 2-31. Example of Rate Hysteresis in nonadaptive rate modes

RATE HYSTERESIS IN ADAPTIVE RATE MODES

The hysteresis rate in adaptive rate modes is dynamically calculated by lowering the sensor indicated rate by the programmed Hysteresis Offset.

When Rate Hysteresis is enabled in an adaptive rate mode, a single nonrefractory sensed atrial event will activate Rate Hysteresis (Figure 2-32 on page 2-41). In single chamber atrial modes, Rate Hysteresis will be deactivated by a single atrial pace at the sensor hysteresis rate. In DDDR or DDIR mode, Rate Hysteresis will be deactivated by a single atrial pace during a cardiac cycle when a ventricular pace is scheduled at the hysteresis rate, or, in DDDR mode, whenever the atrial rate rises above the MTR.

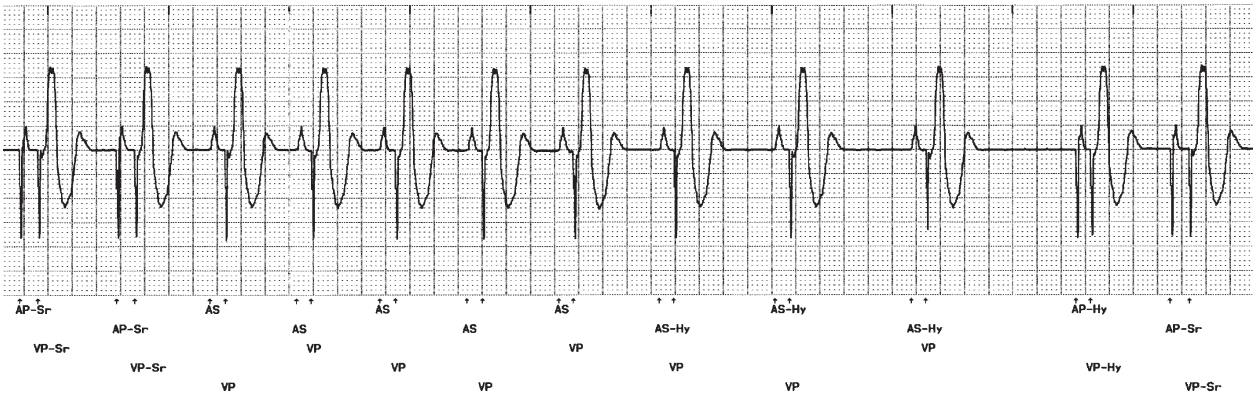


Figure 2-32. Example of Rate Hysteresis in adaptive rate modes

In VVI(R) mode, a single nonrefractory sensed ventricular event will activate Rate Hysteresis. A single ventricular pace at the hysteresis rate will deactivate it.

SEARCH HYSTERESIS

When the Search Hysteresis feature is enabled, the pacemaker will periodically lower the escape rate by the programmed Hysteresis Offset in order to reveal potential intrinsic activity below the LRL or sensor rate (Figure 2-33 on page 2-41).

During Search Hysteresis, the pacing rate is lowered by the Hysteresis Offset for up to 8 cardiac cycles. The search will end and hysteresis will remain active when intrinsic activity is sensed during that period. If there is no intrinsic activity during the 8 cycle search, pacing resumes at the LRL or the sensor indicated rate.

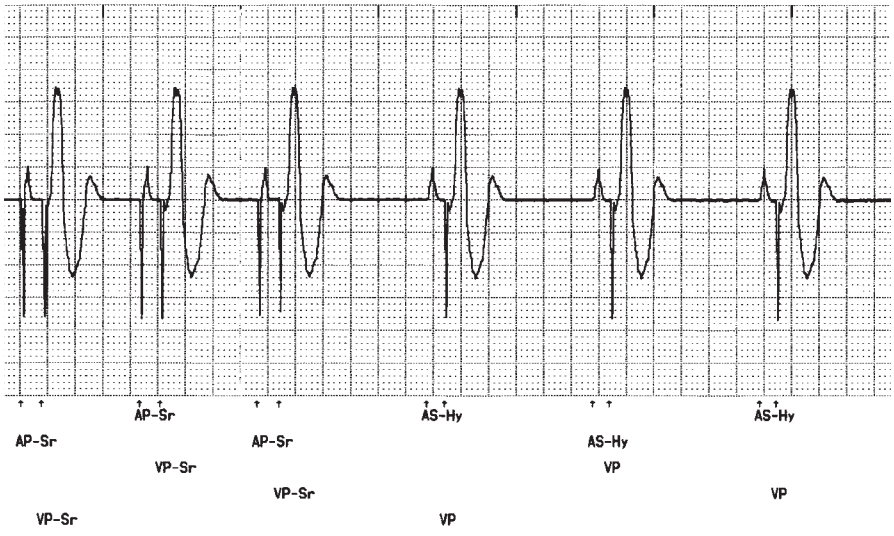


Figure 2-33. Example of Search Hysteresis

Example: At a rate of 70 ppm and a search interval of 256 cycles, a search for intrinsic activity would occur approximately every 3.7 minutes (256 ÷ 70 = 3.7).

Rate Smoothing is disabled during the search cycles. If there is no detected intrinsic activity during the search, the pacing rate is brought up to the LRL or sensor indicated rate, and programmed Rate

Smoothing Up and Rate Smoothing Down are re enabled. See "Rate Smoothing Up" on page 2-43 and "Rate Smoothing Down" on page 2-43 for more information.

RATE SMOOTHING

Rate Smoothing is a programmable feature that controls the pacemaker's response to atrial and/or ventricular rate fluctuations that cause sudden changes in pacing intervals. In a normal conduction system, limited cycle to cycle variation in rate occurs. However, in the presence of any of the following, the paced rate can change dramatically from one beat to the next:

- Sinoatrial disease such as sinus pause or arrest, sinoatrial block, brady–tachy syndrome
- Premature atrial and/or ventricular contractions (PAC/PVC)
- Pacemaker Wenckebach
- Intermittent, brief, self terminating supraventricular tachycardias, atrial flutter/fibrillation
- Retrograde conducted P waves
- Pacemaker sensing of myopotential signals, electromagnetic interference, crosstalk, etc.

Pacemaker 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 their accompanying patient symptoms (such as palpitations, dyspnea, and dizziness).

Rate Smoothing is an important enhancement of the A-Tachy Response (ATR) feature. Rate Smoothing can significantly reduce rate fluctuations associated with the onset and cessation of atrial arrhythmias.

Rate Smoothing operates between the LRL and the MTR or the Max Pacing Rate (SSI and DDI) in nonadaptive rate modes. When the sensor is enabled and MSR is higher than MTR, the operational range is from the LRL to the MSR. Rate Smoothing is also applicable between the hysteresis rate and LRL when hysteresis is active, except during Search Hysteresis.

When programmed On:

- Programmable Rate Smoothing values are a percentage of the R—R interval (3%–24% in 3% increments) and can be independently programmed for increase or decrease.
- The pacemaker stores in memory the most recent R—R interval. R waves may be either intrinsic or paced. Based on this R—R interval and the programmed Rate Smoothing value, the pacemaker sets up two synchronization windows for the next cycle, one for the atrium and one for the ventricle.
- Rate Smoothing is functional except:
  - During the 8 cycles of Search Hysteresis
  - During ATR Fallback, until fallback reaches ATR Lower Rate Limit or the sensor–indicated rate
  - Upon triggering of the PMT Termination algorithm
  - Immediately following programmed increases in the LRL
  - When VRR is active in the dual chamber mode

Also, Rate Smoothing cannot be programmed On when Sudden Brady Response is On.

The clinician should ascertain a given 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.

NOTE: *Without Rate Smoothing, a sudden, large atrial rate increase (e.g., paroxysmal atrial tachycardia) will cause a simultaneous sudden increase in the paced ventricular rate as high as the programmed MTR. With Rate Smoothing, the ventricular paced rate in response to such a change might not reach the programmed MTR.*

RATE SMOOTHING UP

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

RATE SMOOTHING DOWN

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

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

MAX PACING RATE (DDI AND SSI)

When Rate Smoothing is programmed On in DDI, VVI, or AAI, the Rate Smoothing Up parameter is used only between the hysteresis rate and the LRL. The Rate Smoothing Down parameter requires the programming of a Max Pacing Rate. The Rate Smoothing Down parameter will then be used only between the Max Pacing Rate and the LRL or the hysteresis rate.

RATE SMOOTHING EXAMPLE

The pacemaker stores in memory the most recent R—R interval. R waves may be either intrinsic or paced. Based on this R—R interval and the programmed Rate Smoothing value, the pacemaker sets up two synchronization windows for the next cycle, one for the atrium and one for the ventricle. This synchronization window is defined as follows:

Ventricular synchronization window = Previous R—R interval ±Rate Smoothing value

Atrial synchronization window = (Previous R—R interval ±Rate Smoothing value) – AV Delay

An example of how these two synchronization windows are calculated is illustrated below and in Figure 2-34 on page 2-44:

Previous R—R interval = 800 ms

AV Delay = 150 ms

Rate Smoothing Up = 9% Rate Smoothing Down = 6%

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

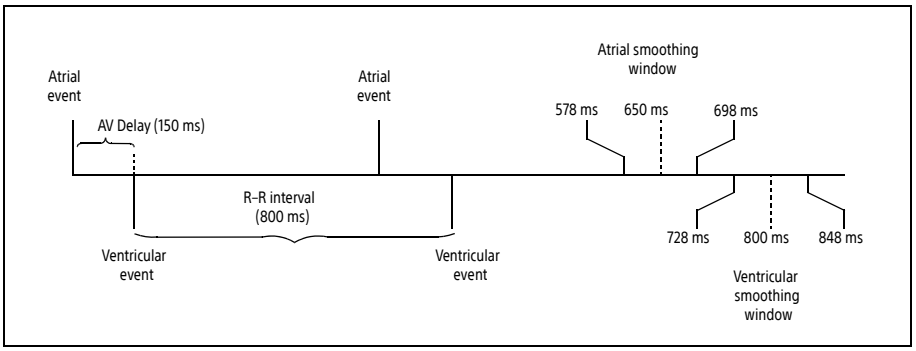


Figure 2-34. An example of the synchronization window

The timing for both windows is initiated at the end of every ventricular event (R–R interval). Paced activity, if it is to occur, must occur within the appropriate synchronization window.

SUDDEN BRADY RESPONSE (SBR)

Sudden Brady Response (SBR) is designed to respond to sudden decreases in intrinsic atrial rates by applying dual chamber pacing at an elevated pacing rate. SBR is available in DDD(R) modes. When SBR is enabled, Rate Smoothing Up and Rate Smoothing Down are not available.

SBR is declared when the atrial chamber has been continuously sensed for a programmable time, 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 ppm.

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 ppm and to determine the rate of SBR therapy.

SBR DETECT TIME

SBR Detect Time is the programmable time interval during which the atrium must be 100% sensed.

SBR NUMBER OF BEATS

The SBR Number of Beats criteria are applied once the decrease in atrial rate has been detected and LRL or sensor indicated rate pacing has occurred. Atrial pacing must occur for the programmable number of consecutive intervals before the SBR criteria are met, with one exception. A "slow" PVC can count as the first SBR Number of Beats. A "slow" PVC is one that yields a ventricular rate that is ≥10 ppm slower than the average atrial rate.

SBR THERAPY RATE OFFSET

SBR Therapy Rate Offset is calculated by using the patient's average atrial rate before the bradycardia and adding a programmable positive offset (Figure 2-35 on page 2-45). Pacing is applied in the DDD(R) mode at the greater of either (1) the previous average atrial rate plus the SBR Therapy Rate Offset, not to exceed the MTR, or (2) the sensor indicated rate (DDDR mode only).

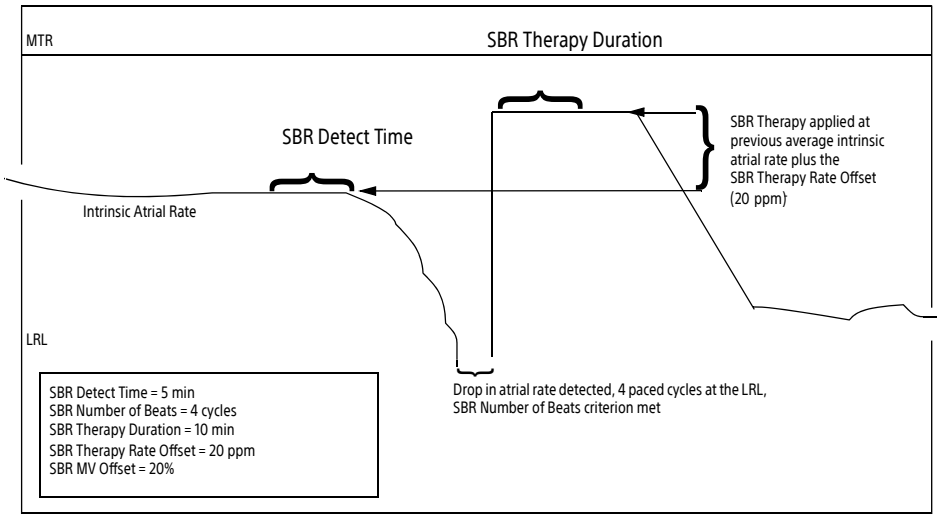


Figure 2-35. Example of a decrease in atrial rate meeting the SBR criteria

SBR THERAPY DURATION

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

SBR MV OFFSET

SBR MV Offset provides the ability to inhibit SBR therapy when the SBR rate and duration criteria are met but the patient's current MV measurement is lower than a programmed value, the MV comparison value.

The Minute Ventilation sensor must be On for the SBR MV Offset to be used. When MV is activated, the pacemaker records the MV baseline value once every hour. The pacemaker then determines the lowest measured MV baseline value over a 1 week period. The SBR MV Offset is a percentage of this lowest weekly MV baseline and is added to the lowest weekly MV baseline to determine the MV comparison value. For example, if the SBR MV Offset is programmed to 20%, the lowest weekly value for MV baseline is increased by 20% to get the MV comparison value for the SBR algorithm. Each week, this MV comparison value is updated so that the algorithm adjusts to long term changes in the patient's MV baseline.

In the event the SBR atrial rate and duration criteria are met, the current MV measurement is compared to the MV comparison value. If the current MV measurement is less than the comparison value, SBR therapy is inhibited (Figure 2-36 on page 2-46). If the present MV measurement is more than the comparison value, SBR therapy is initiated (Figure 2-37 on page 2-46).

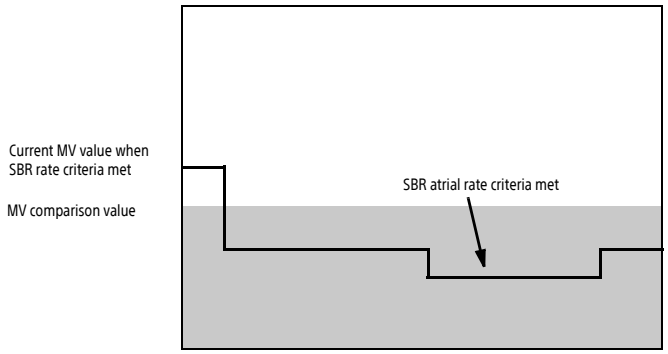


Figure 2-36. Example showing the current MV value is less than the MV comparison value, so when the SBR rate criteria are met, SBR therapy is inhibited.

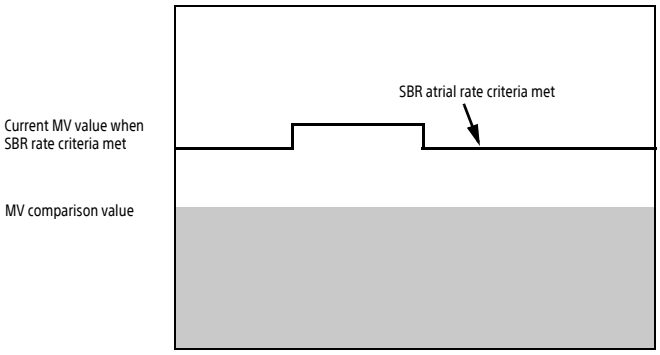


Figure 2-37. Example showing the current MV value is greater than the MV comparison value, so when the SBR rate criteria are met, SBR therapy is delivered

To assist in programming the SBR MV Offset value, the pacemaker records the patient's MV baseline values hourly for the last 24 hours and makes them available for display on the Programmer.

LEAD CONFIGURATION

The ALTRUA and INSIGNIA I pacemakers are programmable to either Unipolar or Bipolar sensing and pacing when bipolar leads are used. Pacing and sensing configurations are individually programmable in both the atrium and ventricle. Lead configuration is programmed on the Settings - Brady screen.

BIPOLAR CONFIGURATION LOCK OUT

The bipolar configuration lock out feature prevents the clinician from inadvertently programming a unipolar lead to bipolar configuration. If the atrial or ventricular lead type is specified as Unipolar on the Patient Data screen, programming to Bipolar configuration for either pacing or sensing is not allowed by the software.

LEAD CONFIGURATION

In dual chamber devices, choosing Bipolar or Unipolar will configure both leads to that configuration.

CAUTION: Do not attempt to program unipolar leads to a Bipolar configuration; no pacing and erratic sensing will occur.

NOTES:

- *If at implant a bipolar pacing configuration is required, ensure that the configuration is programmed to Bipolar before implant.*
- *Unipolar pacing and sensing do not exclude the use of the Minute Ventilation sensor as long as a bipolar lead is used for the MV lead. MV sensor availability is not dependent on the programmed lead configuration setting.*
- *If the clinician selects Unipolar for the atrial or ventricular lead on the Patient Data screen, the application will not allow that lead configuration to be programmed to Bipolar.*

PACING CONFIGURATION

When the unipolar pacing configuration is programmed, the pacing stimulus will be applied between the lead tip and the pacemaker case. In the bipolar pacing configuration, 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.

SENSING CONFIGURATION

When the unipolar sensing configuration is programmed, the 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.

In bipolar configurations, 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.

SAFETY SWITCH (AUTOMATIC LEAD CONFIGURATION)

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

The pacemaker monitors lead integrity daily by measuring lead impedance during paced events. When the Safety Switch feature is programmed On in either the atrium or the ventricle and the measured impedance falls outside the 100–2500 Ω range 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. Select Reset for the Safety Switch to clear the switched indication.

CAUTION: If high impedance leads with measured values approaching 2500 Ω are used, consider programming the Safety Switch Off.

When the lead configuration switches to Unipolar for the lead that is being used for MV, the Minute Ventilation sensor function is automatically disabled. If Minute Ventilation was automatically disabled, select Reset for the Safety Switch to properly re-initialize the Minute Ventilation sensor function in the device, and then rebaseline the MV.

WARNING: In devices with the Safety Switch programmed to On, the lead polarity will revert to Unipolar in the presence of a lead impedance of < 100 Ω or > 2500 Ω. Unipolar pacing is contraindicated for patients with an ICD.

AV DELAY

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

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

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

- Paced AV Delay
- Sensed AV Delay

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

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 Hysteresis to avoid unnecessary RV pacing.*

DYNAMIC AV DELAY

When Dynamic AV Delay is enabled, the pacemaker automatically calculates the AV Delay based on the duration of the previous A–A interval and the programmed parameters for Minimum AV Delay and Maximum AV Delay. The Dynamic AV Delay is not adjusted during a PVC or when the previous cardiac cycle was limited by the MTR or Rate Smoothing Up.

Dynamic AV Delay mimics normal AV nodal function of progressive P–R shortening in response to an increase in rate. When the atrial rate is between the LRL and the higher of the MTR and the MSR, the pacemaker calculates the Dynamic AV Delay based on the previous A–A interval according to the linear relationship shown in Figure 2-38 on page 2-48. This relationship is determined by the programmed values for Minimum AV Delay, Maximum AV Delay, LRL, and the higher of the MTR or MSR. Figure 2-39 on page 2-49 illustrates an ECG strip with Dynamic AV Delay.

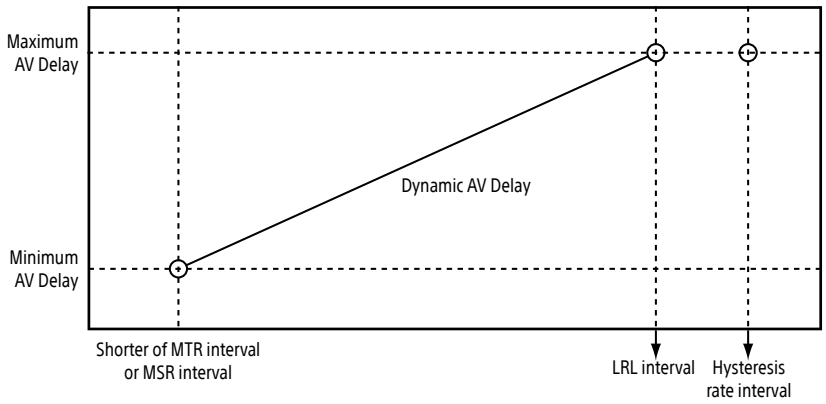


Figure 2-38. Dynamic AV Delay

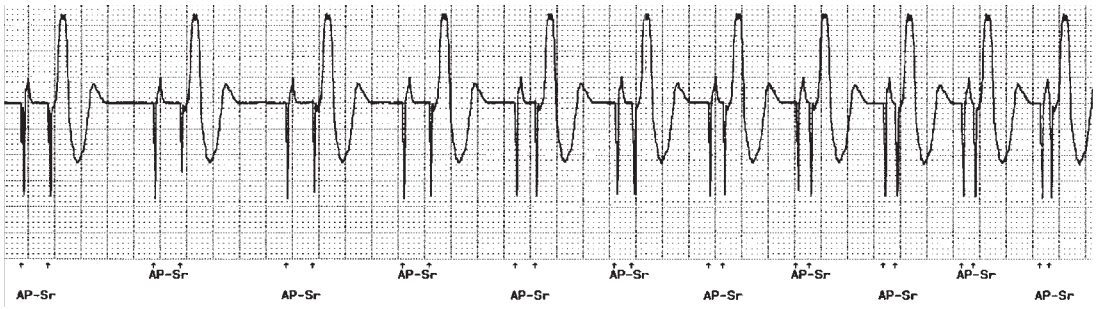


Figure 2-39. Example of ECG strip with Dynamic AV Delay

PACED AV DELAY

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

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

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

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

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

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

When the atrial rate is between the LRL and the higher of the MTR, MSR, and MPR, the pulse generator calculates the linear relationship to determine the Dynamic AV Delay as illustrated in Figure 2-40 on page 2-50.

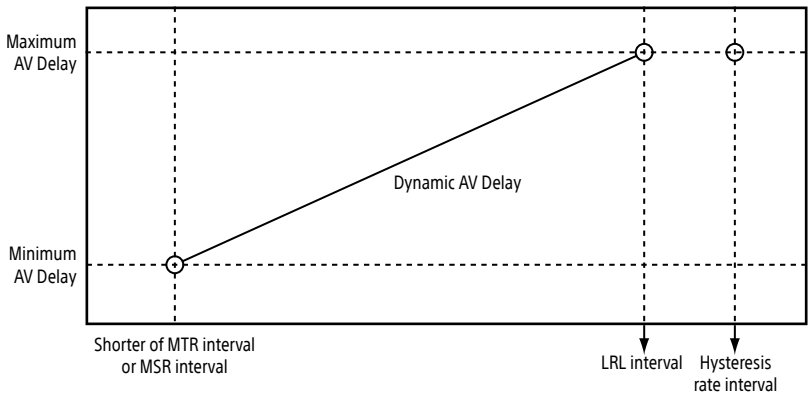


Figure 2-40. Dynamic AV Delay

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

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

SENSED AV DELAY

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

Sensed AV Delay may be programmed to a value shorter than or equal to the Paced AV Delay. A shorter value is intended to compensate for the difference in timing between paced atrial events and sensed atrial events (Figure 2-41 on page 2-50).

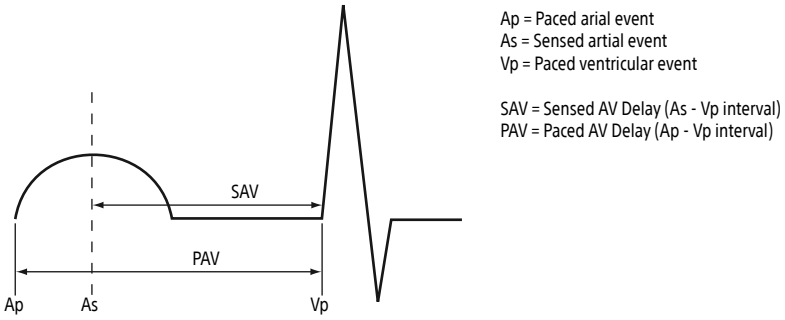


Figure 2-41. Sensed AV Delay

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 2-42 on page 2-51 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 mode.*

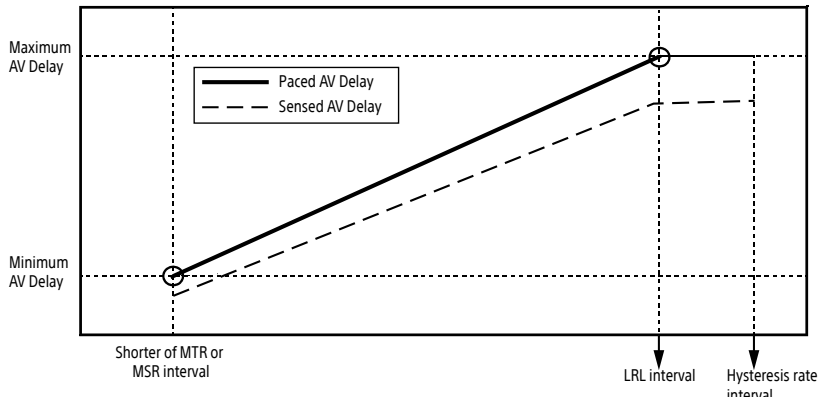


Figure 2-42. Dynamic and Sensed AV Delay as a function of the escape interval

AV SEARCH HYSTERESIS

In patients with exercise dependent or intermittent AV nodal block, the AV Search Hysteresis allows intrinsic AV conduction beyond the programmed AV Delay during episodes of normal AV nodal function. Allowing intrinsic AV conduction via AV hysteresis can improve hemodynamic performance and increase device longevity due to a reduced number of ventricular paces.

When the AV Search Hysteresis feature is enabled, the AV Delay will be lengthened periodically for up to 8 consecutive cardiac cycles. The hysteresis AV Delay will remain active as long as the intrinsic P–R intervals are shorter than the hysteresis AV Delay. The pacemaker will revert to the programmed AV Delay following the first ventricular pace at the hysteresis AV Delay, or when the 8-cycle search expires without sensing intrinsic ventricular activity.

AV SEARCH INTERVAL

The AV Search Interval controls the frequency of the AV Search Hysteresis (Figure 2-43).

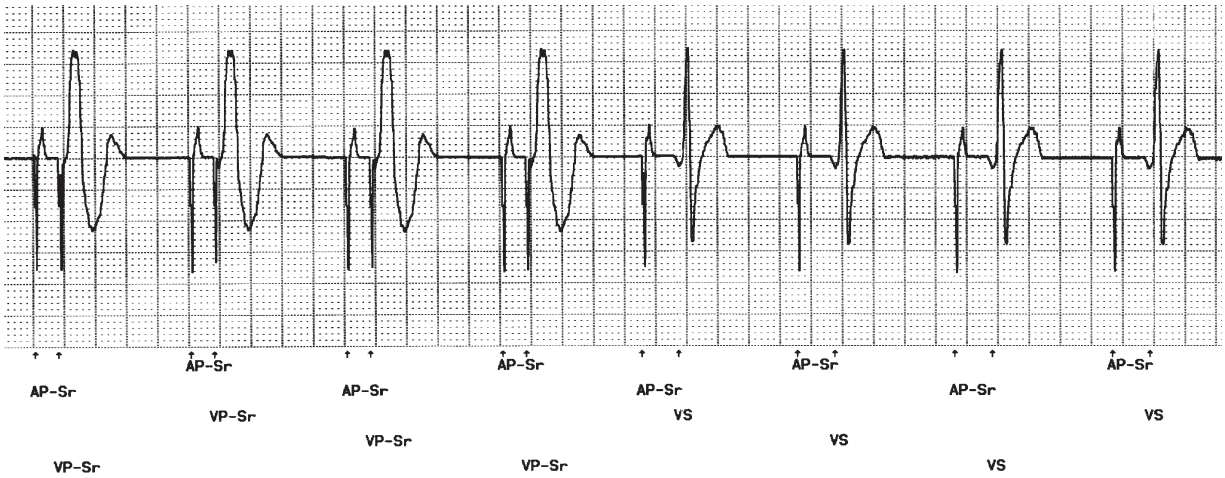


Figure 2-43. Example of ECG strip with a successful AV Search

AV INCREASE

The AV Increase determines how much the AV Delay will lengthen during a search cycle. This percentage is applied to the Fixed AV Delay or the Dynamic AV Delay (depending on which option is programmed) to determine the hysteresis AV Delay. The hysteresis AV Delay will never exceed 300 ms (400 ms for models S602, S603, and S606).

NOTES:

- *During AV Search Hysteresis, the Sensed AV Offset lengthening will be limited to prevent the ventricular pacing rate from dropping below the LRL, sensor indicated rate, or hysteresis rate.*
- *The Automatic Capture feature may add an additional 64 ms AV Hysteresis in order to accommodate a fusion check for a maximum AV Hysteresis delay of 364 ms; for models S602, S603, and S606 the maximum AV Hysteresis delay is 464 ms.*
- *Long programmed AV intervals (≥ 250 ms) should be used with caution. The physician should evaluate the patient and weigh the potential benefit of promoting intrinsic conduction against the potential risk of hemodynamic compromise, such as pacemaker syndrome and diastolic mitral regurgitation.*

REFRACTORY

DYNAMIC PVARP

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 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 2-44 on page 2-53). 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.

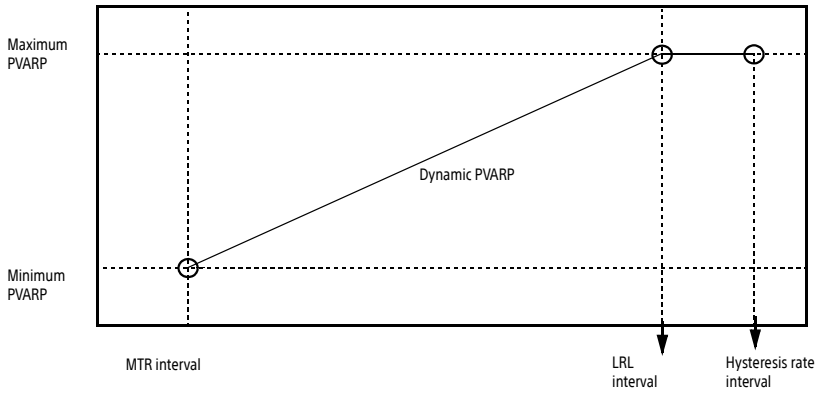


Figure 2-44. Illustration of Dynamic PVARP as a function of the escape interval

MAXIMUM PVARP

If the average rate is equal to or lower than the LRL (i.e., 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/PAC

When the pacemaker is programmed to the DDD(R), DDI(R), or VDD mode, the clinician may choose to program the PVARP after PVC/PAC option. This feature is designed to help prevent pacemaker mediated tachycardia due to loss of A–V synchrony, which may result in retrograde conduction after a premature ventricular contraction (PVC) or a premature atrial contraction (PAC), or atrial oversensing of myopotentials or other EMI which meet the PAC criteria. PVARP is extended for one cycle only and then returns to the originally programmed value. This means that the PVARP will be extended no more frequently than every other cardiac cycle.

The pacemaker automatically extends the PVARP to the programmed value for one cardiac cycle in the following situations:

- Upon detection of a PAC. A PAC is defined as an A–A interval that is equal to or less than 600 ms and more than 25% shorter than the average of the previous four A–A intervals.
- Upon detection of a sensed ventricular event that is preceded by a paced or sensed ventricular event without an intervening atrial event (i.e., a PVC). Atrial senses within PVARP are used.
- 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 mode
- When the pacemaker is programmed from a non-atrial tracking mode to an atrial tracking mode
- When the pacemaker returns from magnet operation to an atrial tracking mode
- When the pacemaker exits fallback mode after A-Tachy Response
- When the pacemaker exits from a temporary non atrial tracking mode to a permanent atrial tracking mode
- When the pacemaker comes out of noise reversion due to an electromagnetically noisy environment

BLANKING AND NOISE REJECTION

Blanking is the first part of the refractory period, where sense amplifiers are completely disabled. It is used to prevent cross chamber sensing and inhibition.

During a blanking interval, the sensing circuit in one chamber ignores sensed electrical activity generated by a pacemaker pulse in the other chamber (cross-talk). Ventricular pacing, if sensed in the atrium, would initiate an inappropriately high ventricular pacing rate in any pacemaker attempting to maintain AV synchrony. Atrial pacing, if sensed in the ventricle, would inhibit ventricular pulses and thereby cause an inappropriate decrease in paced rate. Therefore, a ventricular pace initiates a programmable atrial blanking interval in DDD(R), DDI(R), and VDD modes, and an atrial pace initiates a programmable ventricular blanking interval in the DDD(R) and DDI(R) modes.

V-BLANK AFTER A-PACE (VENTRICULAR BLANKING)

In the ventricle, the atrial pace concurrently starts a retriggerable 60 ms noise rejection interval and a programmable ventricular blanking interval (Figure 2-45 on page 2-54). (Whenever a signal is detected during the retriggerable noise rejection interval, the interval will be restarted at the point where a signal is detected.)

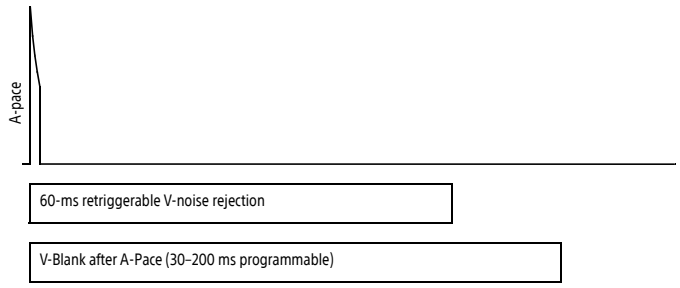


Figure 2-45. Cross-chamber noise rejection after A Pace and V-Blank after A-Pace

A-BLANK AFTER V-PACE (ATRIAL BLANKING)

In the atrium, the ventricular pace concurrently starts a 40 ms retriggerable noise rejection interval and a programmable atrial blanking interval (Figure 2-46 on page 2-54).

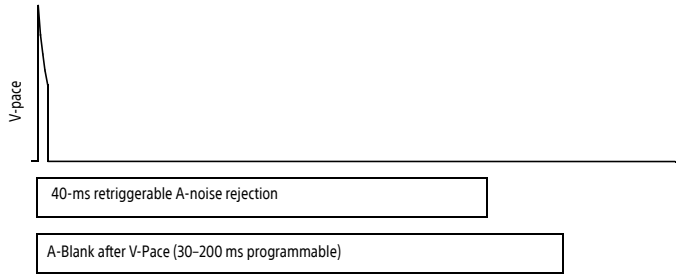


Figure 2-46. Cross-chamber noise rejection after V-Pace and A-Blank after V-Pace

NOISE REJECTION

ATRIAL OR VENTRICULAR PACING

In both the atrium and the ventricle, a pace concurrently starts a fixed 50 ms noise rejection interval followed by a 40 ms retriggerable atrial noise rejection interval and 60 ms retriggerable ventricular noise rejection interval (Figure 2-47 on page 2-55).

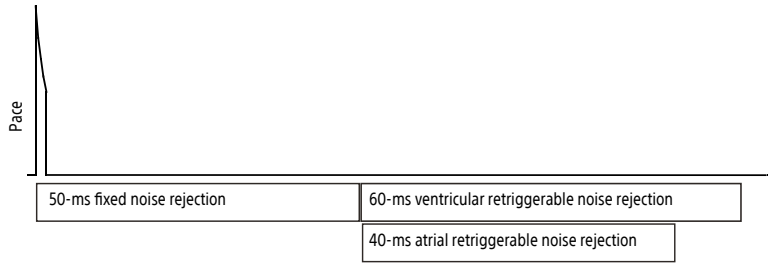


Figure 2-47. Same chamber noise rejection after pace

ATRIAL DEPOLARIZATION SENSING

When an atrial depolarization is sensed, a 40 ms noise rejection interval is started in the atrium only (Figure 2-48 on page 2-55). This interval is retriggered in the continued presence of noise. During noise rejection, intrinsic events will not be detected. Asynchronous operation can result if the noise continues.

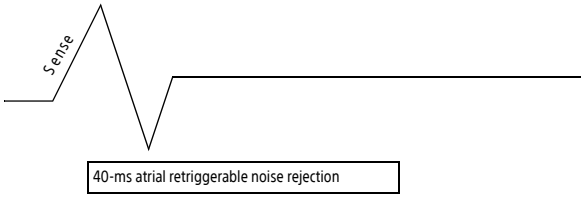


Figure 2-48. Atrial noise rejection after sense

VENTRICULAR DEPOLARIZATION SENSING

When a ventricular depolarization is sensed, a 60 ms noise rejection interval is started in the ventricle and a 40 ms noise rejection interval is started in the atrium (Figure 2-49 on page 2-55). This interval is retriggered in the presence of noise. During noise rejection, intrinsic events will not be detected. Asynchronous operation can result if the noise continues.

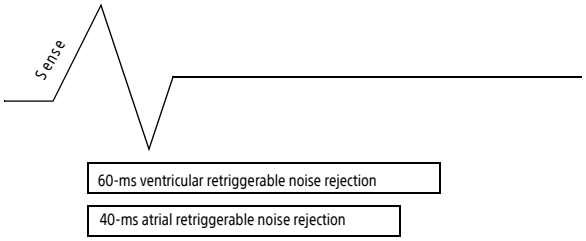


Figure 2-49. Ventricular and atrial noise rejections after ventricular sense

MAGNET SETTINGS

MAGNET RESPONSE

If Magnet Response is programmed to Async, a dual chamber pacemaker will operate in the mode identified in Table 2-6 on page 2-56 when a magnet is applied. A single chamber or VDD mode will operate in SOO mode when a magnet is applied. The actual pacing rate depends on the battery status (see Table 2-7 on page 2-56). If Magnet Response is programmed to Off, the pacemaker will not respond to magnetic fields and/or magnet application.

If Magnet Response is programmed to EGM and the stored EGM diagnostics are enabled, application of the magnet will initiate storage of intracardiac EGMs, and the pacemaker will not perform the normal magnet asynchronous pacing.

Table 2-6. Magnet Modes According to Primary Mode

Primary Modes	Magnet Mode	Magnet Rate/AV Delay (@ BOL)
DDD(R), DDI(R), DOO(R)	DOO	100 ppm/100 ms
VDD, VVI(R), VOO(R), VVT	VOO	100 ppm
AAI(R), AOO(R), AAT	AOO	100 ppm
SSI(R), SOO(R), SST	SOO	100 ppm

Table 2-7. Battery Status Indicators and the Respective Magnet Rates

Magnet Rate [a]	Battery Status	Comments
100 ppm	BOL (Beginning of Life)	Perform normally scheduled follow-ups.
90 ppm	ERN (Elective Replacement Near) [b]	Intensify follow-ups
85 ppm	ERT (Elective Replacement Time) [b]	Schedule replacement. Beat-to-Beat ventricular Automatic Capture is disabled and ventricular output is fixed at twice the last measured threshold but not > 5.0 V and not < 3.5 V. For adaptive-rate modes only: When the pacemaker reaches ERT, the mode will change to nonadaptive rate mode (e.g., DDDR to DDD, VVIR to VVI, etc.).
85 ppm or less	EOL (End of Life)	Three months after ERT, the device will reach EOL. When EOL is reached, dual-chamber pacemakers will change modes to single-chamber operation (DDD and VDD revert to VVI) and the LRL will be lowered to 50 ppm. Schedule replacement immediately.

a. To perform a battery test using the magnet, the magnet operation must be programmed to Async. The AV Delay during a magnet test is 100 ms. When Automatic Capture is programmed Off, the third pulse of the magnet test is at 50% of the programmed Pulse Width to allow evaluation of the pacing safety margin.

b. Intensified follow-up is recommended.

See “Pacemaker Longevity Projections” in the specific ALTRUA and INSIGNIA I System Guides for more information.

SYSTEM DIAGNOSTICS

CHAPTER 3

This chapter contains the following topics:

- "SUMMARY DIALOG" on page 3-1
- "BATTERY STATUS" on page 3-1
- "LEADS STATUS" on page 3-4
- "LEAD TESTS" on page 3-7

SUMMARY DIALOG

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

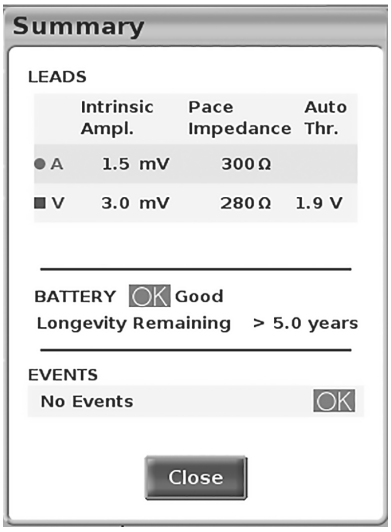


Figure 3-1. Summary dialog

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

- Leads—"LEADS STATUS" on page 3-4
- Battery—"BATTERY STATUS" on page 3-1
- Events—"THERAPY HISTORY" on page 4-1

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.

When a magnet is applied, there is a Magnet option (see "Magnet Feature" on page 4-9).

BATTERY STATUS

The Battery Status screen (Figure 3-2 on page 3-2) displays the date of the last battery test, the previous and present battery status indicators, the current and previous magnet rates of the pace-

maker, and the estimated longevity remaining. Battery status will show 100% until the first 11-hour measurement after lead attachment. After implant battery measurements are performed by the pacemaker every 11 hours and cannot be initiated using the Programmer. The screen also provides a graphical representation of Battery Status.

On initial interrogation, the Programmer retrieves the most recent battery status data and the previous session's stored data from the pacemaker. Figure 3-2 on page 3-2 shows the battery status indicators and their respective magnet rates. The Longevity Remaining estimate is based on measurements indicating the remaining charge in the battery. The time remaining is calculated by using the percentage pacing that occurred in the last 30 days at the programmed device settings and the measured lead impedance. Before implant, the Longevity Remaining calculation assumes a lead impedance of 500 Ω. Time remaining is displayed from > 5.0 years to < 0.5 years in 0.5-year increments. If the pacing percentage increases, the time remaining may be less than the number displayed. If the pacing percentage decreases, the time remaining may be more than the number displayed.

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 3-1).
- 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.

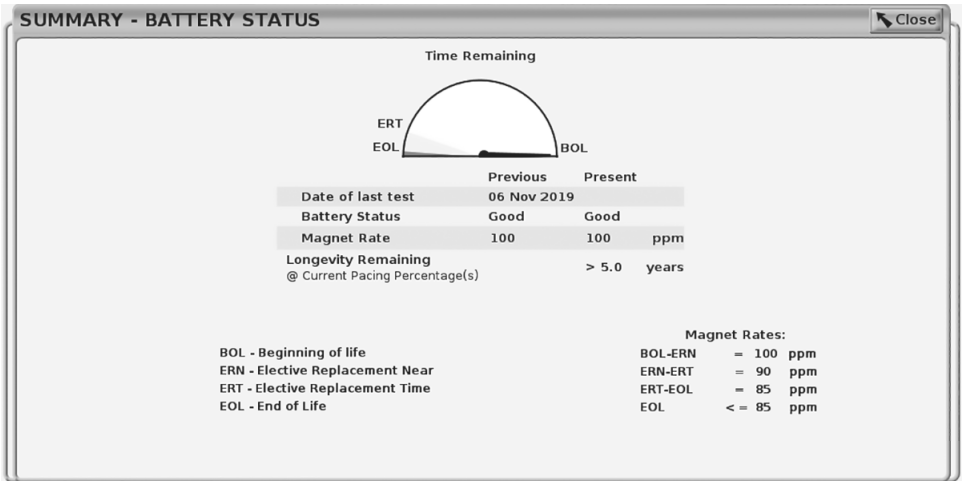


Figure 3-2. Battery Status Summary

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.*

- Longevity Remaining—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, Longevity Remaining 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. Longevity Remaining 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 Longevity Remaining will be forecasted based on the expected changes in power consumption from the reprogrammed features. The next time the pulse generator is interrogated, the Programmer will resume displaying Longevity Remaining based on recent usage history. As new data is collected, Longevity Remaining will likely stabilize near the initial forecast.
- For several days post-implant, the Programmer will display a static Longevity Remaining 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 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:

Table 3-1. Magnet Test and Battery Operation [a]

Battery Status	Magnet Rate
Good / **BOL** (Beginning of Life)	100 ppm
ERN (Elective Replacement Near)	90 ppm
ERT (Elective Replacement Time)	85 ppm
EOL (End of Life)	85 ppm or less

a. To perform a battery test using the magnet, the magnet operation must be programmed to Async. The AV Delay during a magnet test is 100 ms. When Automatic Capture is programmed Off, the third pulse of the magnet test is at 50% of the programmed Pulse Width to allow evaluation of the pacing safety margin.

Additional information about Async and the Magnet Feature is available ("Magnet Feature" on page 4-18).

When the device reaches ERT and EOL, functionality is limited.

Brady Mode will be changed as described below:

Table 3-2. Functionality prior to or at End of Life

Brady Mode prior to EOL	Brady Mode after EOL
SSI(R), SOO(R), SST	SOO
DDD(R), DDI(R), VDD, VVI(R), VVT	VVI
AAI(R)	AAI
DOO(R), VOO(R)	VOO
AAT, AOO(R)	AOO

- Brady Mode can be programmed to Off; no other parameters are programmable
- An LRL of 50 ppm

The following features are not available when the pacemaker reaches ERT:

- Sensors
- Beat-to-Beat Automatic Capture-ventricular output is fixed at twice the last measure threshold (but not > 5.0 V and not < 3.5V)
- Commanded Autothreshold
- Stored EGM
- Sensor Trending
- Real-time EGMs
- Activity Level
- Event Markers
- EP Test
- Rate Trending

Three months after ERT, as the battery continues to deplete, the device will reach EOL. When EOL is reached, the dual-chamber pacemakers will change modes to single-chamber operation (DDD and VDD will revert to VVI) and the LRL will be lowered to 50 ppm. As the battery continues to deplete during EOL, the pacemaker will decrease the pacing amplitude. Telemetry is not guaranteed after EOL.

The following features are not available when the pacemaker reaches EOL:

- Dual-chamber (reverts to single-chamber)
- Temporary Parameters
- Safety Switch—the Lead Configuration remains at its pre-EOL value
- Rate Smoothing
- Search Hysteresis
- Arrhythmia Logbook
- Event Counters
- Histograms
- Lead Impedance measurements—stored and interactive
- P and R-wave measurements—stored and interactive
- Semi-automatic Threshold Tests

The device continues to pace until the battery is depleted.

NOTE: *The device uses the programmed parameters and recent usage history to predict Longevity Remaining. Greater than normal battery usage may result in the subsequent Longevity Remaining to appear less than expected.*

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.
  - The impedances will be reported as <100 Ω, 100 Ω to 2500 Ω in increments of 10 Ω, and >2500 Ω.

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

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 3-6).

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

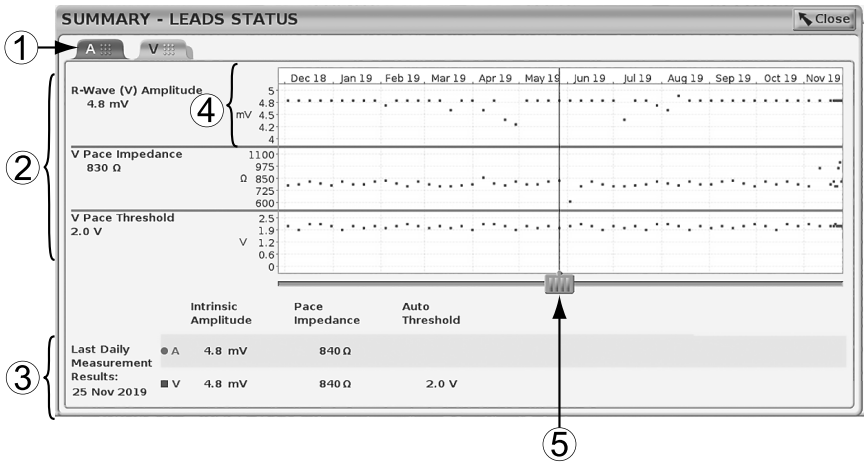
NOTE: *Out-of-range lead impedance measurements may cause the lead configuration to change to Unipolar ("Lead Safety Switch" on page 2-65).*

The Leads Status summary screen provides daily measurement details for applicable leads ("Figure 3-3. Leads Status summary screen" on page 3-6):

- The graph shows daily measurements from the past 52 weeks and the last 7 days.
- 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 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 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 3-3. 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	N/R	Gap
Out-of-range amplitude measurements (mV)	>0.75 mV > 1.5 mV >3.0 mV > 6.0 mV >12.0 mV >20.0 mV	Plotted point at corresponding maximum

Table 3-4. 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	N/R	Gap
Out-of-range impedance measurements (pace leads) (Ω)	> 2500 with attention icon < 100 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.

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
- Magnet is placed on the pulse generator (when Magnet Response set to Async)

LEAD TESTS

The following lead tests are available (Figure 3-4 on page 3-7):

- Pace Impedance
- Intrinsic Amplitude
- Pace Threshold

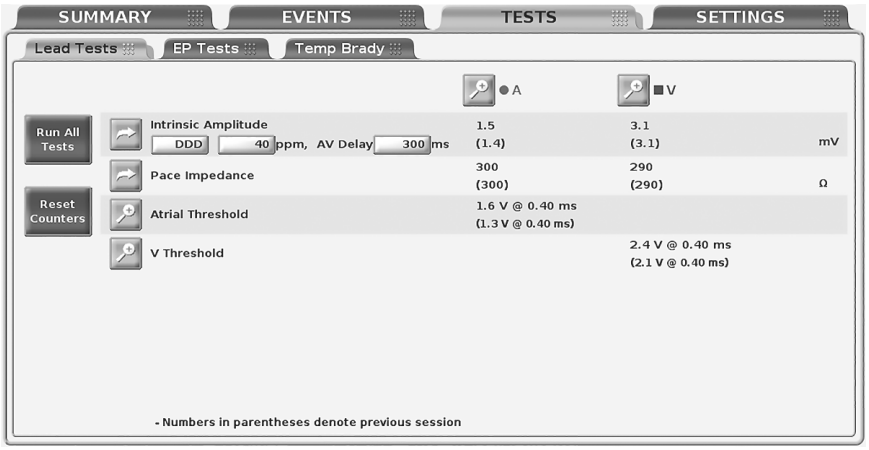


Figure 3-4. Lead Tests screen

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 and displays the intrinsic amplitude for the atrium and/or ventricle. Intrinsic measurement will be available for a given cardiac chamber only if sensing is enabled for that chamber in the current pacing mode.

For intrinsic measurements in single-chamber modes, the clinician can temporarily program a lower LRL value to bring out the patient's underlying rhythm. This parameter change is in effect only during the test.

If the Intrinsic Amplitude Test is desired for both chambers, the atrial and the ventricular measurements must be conducted individually. In this case, the clinician can program the pacemaker to temporarily change the LRL and AV Delay for the duration of the test. The results for each chamber will be gathered in separate but adjacent search periods.

The Intrinsic Amplitude Test is based on the measurement of one complex per chamber. The test is complete and all effects of the parameters programmed for the test are terminated within 10 seconds for each chamber measured, or when either of the following occur:

- The test is terminated via a command from the Programmer (e.g., selecting Cancel or pressing the STAT PACE key)
- The pacemaker exits the temporary state when the telemetry link is broken

The pacemaker stores the results of the last test so that the data from the previous session and the results of the current test can be viewed simultaneously.

Follow these steps to perform an Intrinsic Amplitude Test:

1. Select the LRL and AV Delay values that will allow the intrinsic rhythms to be seen.
2. Select the Intrinsic Amplitude button on the Lead Tests screen.
3. Place the wand over the pacemaker, then select the Start button on the screen. The measurement requires a maximum of 10 seconds of telemetry time per chamber, depending on the presence of intrinsic activity. When the tests are completed, the data will be displayed in the Present column.

If the tests were unsuccessful because the programmed LRL and/or AV Delay did not allow intrinsic rhythms to be seen (i.e., the Measured Amplitude field reports Paced), repeat steps 2 and 3. If the tests are unsuccessful, an N/R message on a pop-up window will indicate that the measurements could not be completed.

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.*

NOTE: *During the Intrinsic amplitude test, the electrogram display is turned off.*

LEAD IMPEDANCE TEST

The Lead Impedance Test will report the lead Impedance at permanently programmed output settings for the leads in the pacemaker system. These energy calculations reflect energy used at programmed settings. To facilitate the measurement, the Amplitude and Pulse Width parameters are temporarily changed to predetermined values based on permanently programmed settings, and the pacemaker switches to a triggered mode. Once the measurements are completed or the measurement period has expired, the permanently programmed pacing parameters are restored.

If the currently programmed pacing Amplitude is 3.5 V or less for the duration of the test, the Amplitude will be set at 3.5 V. If the Amplitude is 4.0, 4.5, or 5.0 V, the Amplitude will be set at 5.0 V. If the Amplitude is 6.5 V, the amplitude will remain at 6.5 V.

If the currently programmed Pulse Width is less than 0.4 ms, the Pulse Width will be set to 0.4 ms; otherwise, the Pulse Width for the test will be set to the currently programmed Pulse Width.

The impedances for the test are based on the measurement of one event and will be reported as <100 Ω, 100 Ω to 2500 Ω in increments of 10 Ω, and >2500 Ω.

If an interactive lead impedance measurement is conducted in DDD mode, the lead impedance for each chamber will be measured separately but in adjacent search periods.

The Lead Impedance Test is complete, and the original parameters are restored within 10 seconds for each chamber measured, or sooner if the test is terminated via the Cancel button, or by breaking the telemetry link.

The pacemaker stores the results of the previous Lead Impedance Test so that the data from the previous session and the results of the current test can be viewed simultaneously. The value may differ from a pacing system analyzer measurement due to the method of calculation. The pacing Lead Impedance Test can be used as a relative measure of lead integrity over time. In addition, lead integrity can be ascertained with pacing measurements.

Energy is calculated using programmed outputs and measured lead impedances.

Follow these steps to perform a Lead Impedance Test:

1. Select the Pace Impedance button on the Lead Tests screen (Figure 3-4).
2. Place the wand over the pacemaker, then select the Start button on the screen. When the test is completed, the lead Impedance will be displayed.

If you are unable to obtain a successful lead impedance measurement, consider the following temporary programming options as appropriate for each patient:

- Increase the Lower Rate Limit above the patient's intrinsic rhythm,
- Decrease the AV Delay to increase the chance that a ventricular pace occurs prior to an intrinsic/conducted ventricular contraction,
- Program the device to an asynchronous mode (e.g. DOO, AOO or VOO), or
- Program the device to a single-chamber mode (e.g. AAI or VVI) or triggered mode (e.g. AAT or VVT)

A report of the displayed test results can be printed using the Data button at the bottom of the screen.

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.*

NOTE: *During the Lead Impedence test, the electrogram display is turned off.*

PACE THRESHOLD TEST

The Pace Threshold Test uses the Smart Start amplitude value, which is 3 voltage steps above the previously measured threshold. If there has not been a previous threshold, the test will start at the programmed voltage and incrementally step that value down as the test progresses. The clinician can also program the starting Amplitude value. The starting value for Pulse Width and the number of cardiac cycles between step changes is programmable by the clinician. The Mode, LRL, AV Delay, and Pacing Lead Configuration to be used during the Threshold Tests are also programmable. These parameters are in effect only during the tests. Testing for a chamber is allowed only when pacing is active for that chamber in the mode specified.

MANUAL PACE THRESHOLD TEST

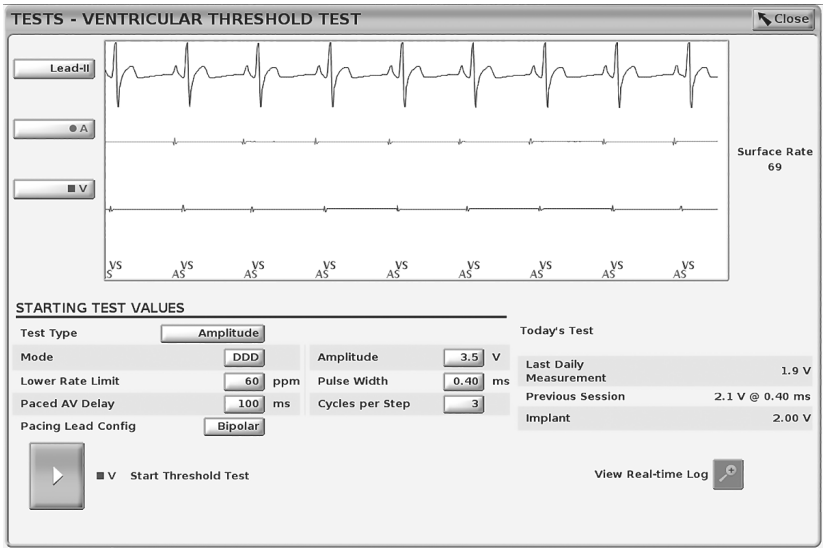


Figure 3-5. Threshold Test screen

Follow these steps to perform Threshold Tests:

1. Select the Pace Threshold button on the Tests screen to display the Threshold Test screen (Figure 3-5).
2. Select the type of test to be performed. Two options are available:
   - Choose Amplitude to decrement the pulse amplitude during the test, or
   - Choose Pulse Width to decrement the pulse width during the test
3. Enter the starting values for each applicable parameter. Parameter applicability is dependent on the Mode selected.
4. Select the Start Threshold Test button on the screen to begin the threshold test. After the programmed number of cycles, the pacemaker automatically decrements the Amplitude or Pulse Width. This will continue until the telemetry link is broken, End Test or STAT PACE is selected, or until the lowest value has been tested.
5. Watch the ECG monitor and break telemetry by removing the wand or selecting the Stop button when loss of capture is observed. The measurement displayed is one step higher than the step at which the test was terminated. If the measurement was unsuccessful, N/R will be displayed.
6. To perform another threshold test, make changes to the test parameter values in the Change column if desired, then begin again with step 5. Results of the tests will be displayed.

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.*

At the end of the test, the previously programmed permanent values are immediately restored.

A report of the displayed test results can be printed using the Data button at the bottom of the screen.

COMMANDED AUTOMATIC PACE THRESHOLD TEST

The following models support Commanded Automatic Pace Threshold Test:

- ALTRUA 60: S601, S602, S603, S604, S605, S606

- INSIGNIA I Ultra: 1190, 1290, 1291

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

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 canceled.
- This feature 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 button ("SNAPSHOT" on page 4-6).
- 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" on page 4-1
- "ARRHYTHMIA LOGBOOK" on page 4-1
- "SNAPSHOT" on page 4-6
- "HISTOGRAMS" on page 4-7
- "COUNTERS" on page 4-7
- "TRENDS" on page 4-7
- "POST-IMPLANT FEATURES" on page 4-8

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 Programmer:

- 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)
- 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 Ventricular Tachycardia (VT), SVT, Atrial Tachycardia (AT), ATR, Nonsustained Ventricular Tachycardia (NSVT), Sudden Brady Response, Pacemaker Mediated Tachycardia (PMT) Episode Stored, Patient Activated EGRAM, Patient Triggered event stored.*

ARRHYTHMIA LOGBOOK

Select the Arrhythmia Logbook button from the Setup tool kit to access the Arrhythmia Logbook Setup screen. The Arrhythmia Logbook Setup screen allows the clinician to enable EGM storage and to choose which events will trigger the EGMs.

Stored electrograms (EGMs) must be enabled by the clinician and can be disabled if desired. When enabled, each triggering event will cause an EGM to be stored in the pacemaker. An EGM is stored for each chamber for which sensing is enabled. The post-trigger portion of the EGM will be stored once the triggering event has occurred. The onset portion of the EGM, which occurred before the event, will also be stored. If all the available storage has been used, the new event will overwrite the oldest event in the pacemaker storage.

NOTE: *Arrhythmia Logbook and EGM data will not be stored for the first 2 hours after the lead is inserted into the header during implant.*

Recording of arrhythmias can be triggered by up to 7 selectable events:

- **Atrial Tachy Detection**—This event is recorded when the pacemaker is operating in an atrial sensing mode and the atrial rate meets or exceeds a programmable Atrial Tachy Detection rate maintained for a programmable Atrial Tachy Detection duration. The Atrial Tachy Detection algorithm does not use any data from the ventricular channel.

  Sensed events falling both outside and inside the atrial refractory period are used to determine the atrial rate.

  The Atrial Tachy Detection trigger is designed to be used when the ATR Mode Switch trigger is Off. The Programmer will prevent both triggers from being turned on simultaneously.

- **ATR Mode Switches**—This event is recorded when ATR Mode Switching fallback is triggered. The ATR Mode Switch feature on the Brady Parameters screen must be programmed On for ATR detection to trigger EGM Storage.

  The ATR Mode Switch trigger is designed to be used when the Atrial Tachy Detection trigger is Off. The Programmer will prevent both triggers from being turned on simultaneously.

- **Ventricular Tachy Detection**—This event is recorded when the pacemaker is operating in a ventricular sensing mode and the ventricular rate meets or exceeds a programmable Ventricular Tachy Detection rate maintained for a programmable Ventricular Tachy Detection duration. The Ventricular Tachy Detection algorithm does not use any data from the atrial channel.

  Sensed events falling both outside and inside the ventricular refractory period are used to determine the ventricular rate.

- **Magnet (Patient Triggered)**—When the pacemaker detects the presence of a magnet, one recording will be triggered. The pacemaker must not have a magnet present for at least one full cardiac cycle following the EGM recording cycle before another magnet-triggered EGM can be recorded. The Magnet Response parameter on the Brady Parameters screen must be programmed to EGM for magnet detection to trigger EGM Storage. This trigger will not be activated if an EGM is being recorded when the magnet is detected.

NOTE: *If patient magnet activation is selected, you may wish to have the patient initiate a stored EGM at the time of feature programming. This may assist with patient education and feature validation.*

- **Nonsustained Ventricular Tachycardia (NSVT)**—This event is recorded when a device is operating in a dual-chamber mode and a run of 3 or more pacemaker-defined PVCs is detected. The pacemaker definition for a PVC is a sensed ventricular event that is preceded by another sensed or paced ventricular event without an intervening atrial event. Atrial senses within PVARP are used.
- **Sudden Brady Response**—This event is recorded when Sudden Brady Response is triggered. The SBR feature on the Brady Parameters screen must be programmed On for SBR detection to trigger EGM Storage.
- **Pacemaker Mediated Tachycardia (PMT)**—This event is recorded when the PMT Termination feature is triggered. The PMT Termination feature on the Brady Parameters screen must be programmed on for a PMT detection to trigger EGM Storage.

When EGM Storage is enabled, the clinician must specify the EGM Storage method. This will determine how many events can be stored in the pacemaker memory.

To select the Trigger Sources, change the selection to On. For the atrial and ventricular detection rates, enter the rate and duration to the right of the parameter name.

For the ventricular and atrial Trigger Sources, sensed events falling both outside and inside the refractory period will be used to determine the rate.

Changes made to the settings on this screen will not be stored automatically. You must select the Initiate Arrhythmia Logbook button before the changes will take effect. If the EGM Storage Method has been changed, selecting the Initiate Arrhythmia Logbook button will initiate the changes and erase existing EGMs.

Changing EGM triggers does not erase data. Navigating to other screens without selecting the Initiate Arrhythmia Logbook button will not delete the changes. If changes to the setup have not been confirmed via the Initiate Arrhythmia Logbook button, they are not used and the pacemaker continues operation using the previous setup information.

EGM SELECTIONS

All EGM selections include event markers and an onset portion that occurs before the EGM trigger is satisfied. Using the EGM feature with its onset EGM increases device current drain by less than 0.5%. Stored EGM and Trending can be active at the same time.

The EGM selections with their Event Markers are as follows:

- Off
- 31 episodes (2 seconds pre-trigger and 2 seconds post-trigger)
- 15 episodes (4 seconds pre-trigger and 4 seconds post-trigger)
- 7 episodes (7 seconds pre-trigger and 7 seconds post-trigger)
- 3 episodes (7 seconds pre-trigger and 28 seconds post-trigger)
- 2 episodes (28 seconds pre-trigger and 14 seconds post-trigger)

CLEARING STORED EGMS

EGMs are cleared by changing the EGM Storage Method.

ARRHYTHMIA LOGBOOK HISTORY

The Arrhythmia Logbook can store up to 40 separate events. As new events are recorded, the oldest events are overwritten. If EGM Storage has been selected, the most recent events also will have EGMs while older episodes would not.

The Arrhythmia Logbook is continuously updated based on the triggers that have been selected and have detected arrhythmias, but the Arrhythmia Logbook cannot be cleared.

The Arrhythmia Logbook stores the information about detected arrhythmias, as described in the table below. All detected arrhythmias also will include date and time.

Table 4-1. Summary of Information Stored in the Arrhythmia Logbook

Trigger	Onset (ppm)	Max (ppm)	Duration
Atrial Tachy Detection	Last measured interval when the detection criteria are first met	Fastest measured interval during the arrhythmia, after criteria are met	Not applicable
Ventricular Tachy Detection	Last measured interval when the detection criteria are first met	Fastest measured interval during the arrhythmia, after criteria are met	Not applicable
Magnet Activated	Not applicable	Not applicable	Duration is equal to the length of EGM stored

Table 4-1. Summary of Information Stored in the Arrhythmia Logbook

Trigger	Onset (ppm)	Max (ppm)	Duration
Nonsustained Ventricular Tachycardia (NSVT)	Last measured interval when the detection criteria are first met	Fastest measured interval during the arrhythmia, after criteria are met	Not applicable
A-Tachy Response	Last measured interval when the detection and duration criteria are first met prior to mode switch	Fastest measured interval during fallback	Duration of mode switch [a]
Sudden Brady Response	Average atrial rate measured before the rate decrease to the LRL or sensor-indicated rate	Not applicable	Duration of therapy [a]
Pacemaker Mediated Tachycardia	Not applicable	Not applicable	Not applicable

a. The minimum Duration value is equal to the length of the EGM stored.

ARRHYTHMIA LOGBOOK RETRIEVAL

When you access the Arrhythmia Logbook screen ("Figure 4-1. The Arrhythmia Logbook screen" on page 4-4), the arrhythmia data interrogated from the pacemaker at initial interrogation are displayed.

Use the following procedure to retrieve the Arrhythmia Logbook data that have been stored since initial interrogation:

1. From the Events tab, select the Arrhythmia Logbook tab, then select the Retrieve Log button.
2. The data displays in chronological order. Use the scroll bar to view more episodes
3. To print out the Arrhythmia Logbook, select the Data button, select the Arrhythmia Logbook report, then select the desired printer and the Print button.[1]

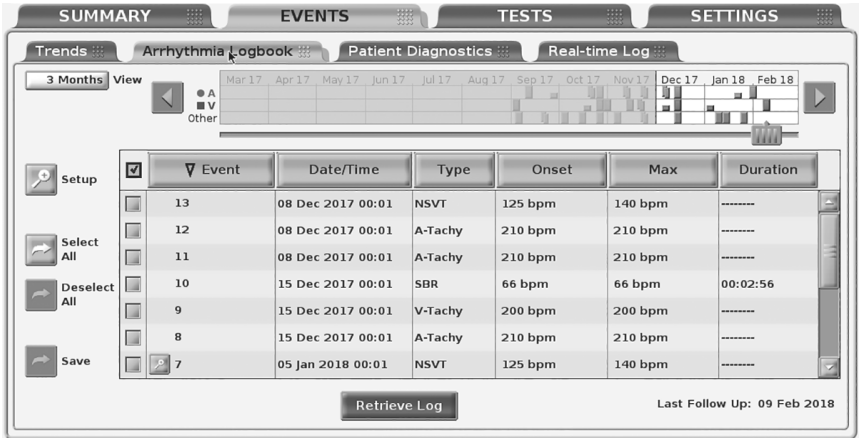


Figure 4-1. The Arrhythmia Logbook screen

EVENTS SUMMARY

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

1 The Logbook can also be transfered to an authorized computing device using Bluetooth®.

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

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

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 Programmer and view the Marker Legend Report.*

2. Use the slider under the upper display window to view different sections of the stored EGM.
3. 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.*

4. 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.
5. 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.
6. Select the Previous Event or Next Event button to display a different event strip.
7. 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 Programmer 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.

SNAPSHOT

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 Real-time Log 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.*

The list of all the recordings is displayed on the screen. A maximum of 100 recordings is listed. 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 100 Snapshots are stored in one Programmer session, the oldest will be overwritten.

Use the following steps to view a stored Snapshot:

1. From the Events tab, select the Real-time Log 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

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

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.

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

COUNTERS

Brady counters are recorded by the pulse generator and displayed on the Patient Diagnostics screen.

VENTRICULAR COUNTERS

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

- Single or Double PVCs
- Three or More PVCs
- Ventricular Tachy Detections

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 ventricle paced
- Intrinsic Promotion—includes Rate Hysteresis % Successful and AV Search Hysteresis % Successful
- ATR Mode Switch—include Mode Switch count, % of Total Time, Maximum Time, Average Time, Total PACs, and Atrial Tachy Detection

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

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—displays a measure of the patient's daily activity represented by the "Percent of Day Active".
- Lead impedance and amplitude—displays trends of the daily intrinsic amplitude and lead impedance measurements ("Leads Status" on page 3-6).
- RV Pace Threshold—displays a trend of the daily right ventricular pacing thresholds.

Follow the steps below to access Trends:

1. From the Events screen, select the Trends Tab.
2. Choose the Select Trends button to specify the trends you want to view. You can choose three trends from the following categories:
   - Events
   - Activity Level
   - P-Wave Amplitude
   - A Pace Impedance
   - R-Wave (V) Amplitude
   - V Pace Impedance
   - V Pace Threshold

The display on the screen can be viewed in the following manner:

1. Select the desired time on the View button to choose the length of visible trend data.
2. 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.
3. 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 Programmer and printed via the Data Management tab.

POST-IMPLANT FEATURES

PATIENT TRIGGERED MONITOR (PTM)

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 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 based on how long the magnet is in contact with the device. 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: When Patient Triggered Monitor is enabled, all other magnet features, including asynchronous pacing, are disabled. The Magnet feature will not indicate magnet position.

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 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 EGM. If the feature is inadvertently left in the Async setting, the patient could potentially cause the device to pace asynchronously by applying the magnet.*

For additional information, contact Boston Scientific using the information on the back cover.

MAGNET FEATURE

The magnet feature allows certain device functions to be triggered when a magnet is placed in close proximity to the pulse generator (Figure 4-2).

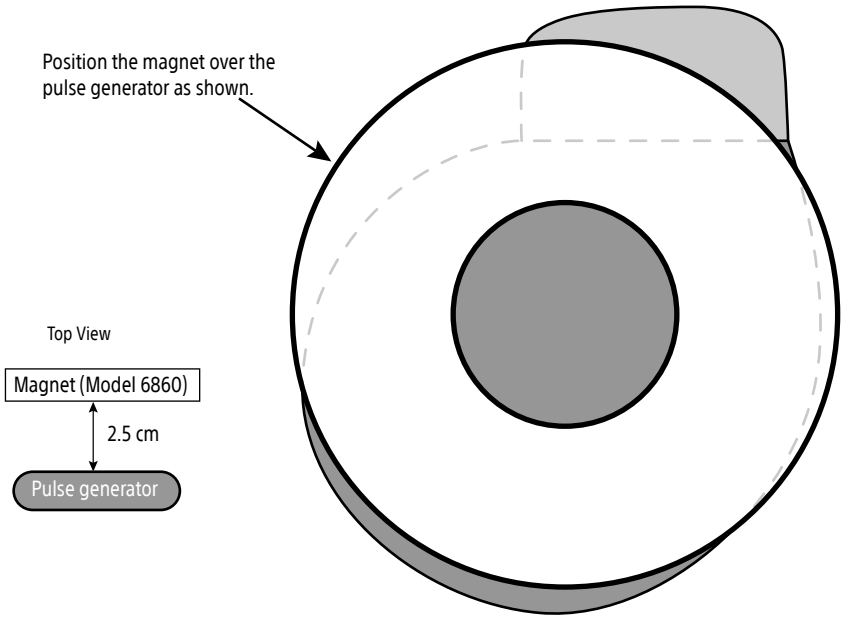


Figure 4-2. Proper position of magnet Model 6860 to activate the pulse generator magnet feature

The pulse generator Magnet Response settings can be programmed to control the behavior of the pulse generator when a magnet is detected. The Magnet Response settings are located in the Timing, Rate Enhancements, Magnet, Noise section of the Brady Settings screen.

The following Magnet Response settings are available:

- Off—no response
- EGM—patient monitoring data will be stored
- 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.

EGM

When the Magnet Response is programmed to EGM, application of the magnet will activate the Patient Triggered Monitor functionality ("Patient Triggered Monitor" on page 4-16).

ASYNC

When the Magnet Response is programmed to 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 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 in "Table 2-6. Magnet Modes According to Primary Mode" on page 2-56.

The third pulse during the 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 Right Ventricular Automatic Capture has been programmed, it is suspended for the duration of magnet application. Output is set to twice the last threshold measurement and there is no beat to beat capture verification for the duration of magnet application.*

ELECTROPHYSIOLOGIC TESTING

CHAPTER 5

This chapter contains the following topics:

- "EP TEST FEATURES" on page 5-1
- "INDUCTION METHODS" on page 5-2

EP TEST FEATURES

Electrophysiologic (EP) Testing features enable you to induce and terminate arrhythmias noninvasively.

WARNING: For dual-chamber devices, the cardiac chamber selection is nominally set to Atrium. Life-threatening ventricular arrhythmias can be induced when the selection is set to Ventricle. Ensure that an external cardiac defibrillator is easily accessible.

The features allowing noninvasive EP testing of arrhythmias include the following:

- Programmed electrical stimulation (PES) induction/termination
- Manual Burst pacing induction/termination

EP TESTS SCREEN

The EP Tests screen displays the real-time status of the episode detection and brady pacing therapy of the pulse generator when telemetry communication is occurring.

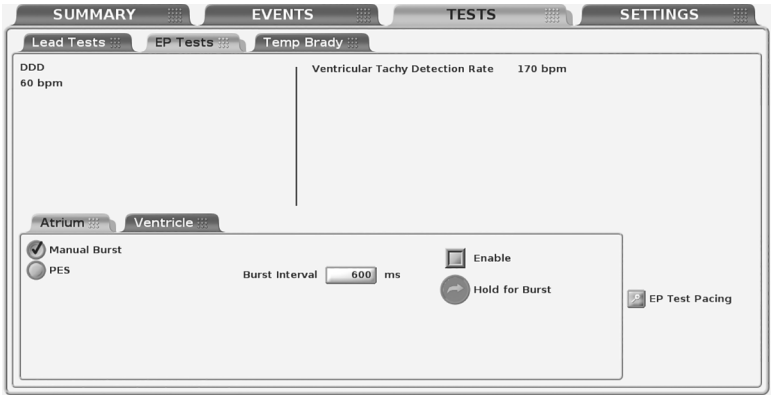


Figure 5-1. EP Tests Screen

Follow the steps below to perform EP Test functions:

1. Select the Tests tab, then select the EP Tests tab.
2. Establish telemetry communication. Telemetry communication between the Programmer and the pulse generator should be maintained throughout all EP test procedures.
3. Set Backup Pacing and EP Test Pacing Outputs as desired.

NOTE: *Backup Pacing during EP testing is not available in single-chamber devices.*

INDUCTION METHODS

Each EP Test method available from the EP Test screen is described below with instructions. During any type of induction/termination, the pulse generator performs no other activity until the test has ceased, at which time the programmed mode will take effect and the pulse generator will respond accordingly.

Consider the following information when using these methods:

- Pacing pulses during induction are delivered at the programmed EP Test pacing parameters

WARNING: For dual-chamber devices, the cardiac chamber selection is nominally set to Atrium. Life-threatening ventricular arrhythmias can be induced when the selection is set to Ventricle. Ensure that an external cardiac defibrillator is easily accessible.

BACKUP VENTRICULAR PACING DURING ATRIAL EP TESTING

Backup ventricular pacing is available during atrial EP testing (PES, Manual Burst) regardless of the programmed Normal Brady Mode.

NOTE: *Backup Pacing is performed in VOO mode.*

NOTE: *Backup Pacing during EP testing is not available in single-chamber devices.*

In dual-chamber devices, program the backup pacing parameters by selecting the EP Test Pacing button. Backup Pacing parameters are independently programmable from the permanent pacing parameters. Backup Pacing can also be disabled by programming the Backup Pacing Mode to Off.

PROGRAMMED ELECTRICAL STIMULATION (PES)

PES induction allows the pulse generator to deliver up to 30 equally timed pacing pulses (S1) followed by up to 4 premature stimuli (S2–S5) to induce or terminate arrhythmias. Drive pulses, or S1 pulses, are intended to capture and drive the heart at a rate slightly faster than the intrinsic rate. This ensures that the timing of the premature extra stimuli will be accurately coupled with the cardiac cycle (“Figure 5-2. 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 devices.*

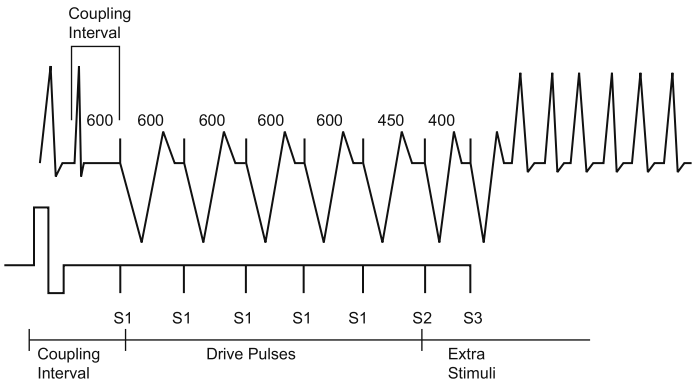


Figure 5-2. PES induction drive train

PERFORMING PES INDUCTION

1. In a dual-chamber device, choose the Atrium or Ventricle tab, depending on which chamber you want to pace.

WARNING: For dual-chamber devices, the cardiac chamber selection is nominally set to Atrium. Life-threatening ventricular arrhythmias can be induced when the selection is set to Ventricle. Ensure that an external cardiac defibrillator is easily accessible.

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 5-3). 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.

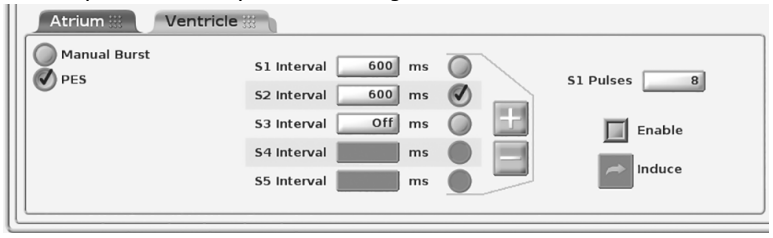


Figure 5-3. PES induction options

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.
6. PES induction is complete when the drive train and extra stimuli are delivered, at which time the pulse generator automatically restarts detection.

NOTE: *Ensure the PES induction is complete before beginning another induction.*

NOTE: *When PES is used to terminate an arrhythmia that has been detected (and an episode declared), the episode is terminated when the PES is commanded regardless of whether it is successful or not. A new episode can be declared after the PES induction is completed. The PES itself is not recorded in therapy history; this may result in several episodes being counted in therapy history.*

NOTE: *Real-time EGMs and annotated event markers will continue to be displayed during the entire test sequence.*

MANUAL BURST PACING

Manual Burst pacing is used to induce or terminate arrhythmias when delivered to the desired chamber. Pacing parameters are programmable for Manual Burst.

Manual Burst pacing pulses are delivered in XOO mode (where X is the chamber) at the programmed EP Test pacing parameters. For Atrial Manual Burst, backup pacing parameters are provided.

NOTE: *Backup Pacing during EP testing is not available in single-chamber devices.*

PERFORMING MANUAL BURST PACING

1. In a dual-chamber device, choose the Atrium or Ventricle tab, depending on which chamber you want to pace.

WARNING: For dual-chamber devices, the cardiac chamber selection is nominally set to Atrium. Life-threatening ventricular arrhythmias can be induced when the selection is set to Ventricle. Ensure that an external cardiac defibrillator is easily accessible.

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 intervals will continue to be decremented until the Minimum interval is reached, then all further pulses will be at the Minimum interval.

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.*

APPENDIX

PROGRAMMABLE OPTIONS AND PARAMETERS

PACING THERAPY PARAMETERS

Table A-1. Pacing therapy parameters (specified into a 750 Ω load)

Parameter	Option, Increments, Ranges	Nominals [a] [b]			
		DDDR	DDD	SR	SSI
Mode - Dual Chamber	DDD(R), DDI(R), DOO(R), VDD, VVT, VVI(R), VOO(R), AAT, AAI(R), AOO(R), ODO, OOO (modes beginning with O available in temporary mode only)	DDD	DDD		
Mode - Single Chamber [c]	SSI(R), SOO(R), SST, OSO, OOO (modes beginning with O available in temporary mode only)			SSI	SSI
Lower Rate Limit (LRL) (ppm) [d] [e]	30, 35, ..., 51, ..., 90, 95, ..., 150, 155, 160, ..., 180, 190..., 300, 320, ..., 380 (in temporary mode only, and only in SSI, SOO, AAI, AOO modes)	60 (1000 ms)			
Maximum Tracking Rate (MTR) (ppm) [d]	80, 85, ..., 185	130 (462 ms)		130 (462 ms) SST only	
Maximum Sensor Rate (MSR) (ppm) [d] [f]	80, 85, ..., 185	130 (462 ms)			
A or V Pulse Width (ms) [g]	0.05, 0.1, 0.2, ..., 1.0	0.4 NOTE: When Automatic Capture is active, the pulse width is fixed at 0.4 ms.			
A or V Amplitude (V)	Atrial–0.1, 0.2, ..., 3.5, 4.0, 4.5, 5.0, 6.5 Ventricle–Auto, 0.1, 0.2, ..., 3.5, 4.0, 4.5, 5.0, 6.5	3.5			
A or V Sensitivity (mV) [h]	Atrial–Auto, 0.15, 0.25, 0.5, 0.75, 1.0, 1.5, ..., 8.0, 9.0, 10.0 Ventricular/Single–Auto, 0.25, 0.5, 0.75, 1.0, 1.5, ..., 8.0, 9.0, 10.0	A–0.75, V–2.5		2.5	
Accelerometer	On, Off, ATR-Only [i]	Off	Off NOTE: If Fallback Mode is rate-adaptive, the Acceler-ometer field displays ATR Only	Off	
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	Passive, 1, 2, ..., 16	8			
Accelerometer Recovery Time (min)	2, 3, ..., 16	5 [q] 2 [r]			
Minute Ventilation [e]	Off, On, 4→ On-A, 4→ On-V (4→ On for single-chamber devices)	Off [r]		Off [r]	

Table A-1. Pacing therapy parameters (specified into a 750 Ω load)

Parameter	Option, Increments, Ranges	Nominals [a] [b]			
		DDDR	DDD	SR	SSI
MV Response Factor	Passive, 1, 2, ..., 16	3 [r]		3 [r]	
Rate Hysteresis Offset (ppm)	Off, -5, -10, ..., -80	Off			
Search Hysteresis (cycles)	Off, 256–4096 cycles in powers of 2	Off			
Rate Smoothing (Up %, Down %)	Off, 3%, 6%, ..., 24%	Off			
Rate Smoothing Maximum Pacing Rate (ppm) [d]	80, 85, ..., 185	130 (462 ms)			
Sudden Brady Response (SBR)	Off, On	Off			
SBR Detect Time (min)	1, 2, ..., 15	5			
SBR Number of Beats (cycles)	1, 2, ..., 8	4			
SBR Therapy Duration (min)	1, 2, ..., 15	10			
SBR Therapy Rate Offset (ppm)	5, 10, ..., 40	5			
SBR MV Offset (%)	Off, 10, 20, ..., 50	Off [r]			
A or V Lead Configuration	Unipolar, Bipolar	Bipolar			
Safety Switch	On, Off, Reset	Off			
Magnet Response	Off, Async, EGM	Async			
Minimum Paced AV Delay (ms) [d] [j]	10, 20, 30, ..., 300 [k] (400 ms for models S602, S603, S606)	80			
Maximum Paced AV Delay (ms) [d] [j]	10, 20, 30, ..., 300 [l] (400 ms for models S602, S603, S606)	150			
Minimum Sensed AV Delay (ms) [d] [j]	10, 20, 30, ..., 300 [k] (400 ms for models S602, S603, S606)	65			
Maximum Sensed AV Delay (ms) [d] [j]	10, 20, 30, ..., 300 [l] (400 ms for models S602, S603, S606)	120			
AV Search Hysteresis	On, Off	Off [r]			
AV Search Interval	32–1024 cycles in powers of 2	32 [r]			
AV Delay Increase (%)	10, 20, ..., 100	30 [r]			
Ventilatory Threshold Response (%)	Off, 55, 70, 85	70 [r]		70 [r]	
Ventilatory Threshold (ppm)	80, 85, ..., 185	110 [r]		110 [r]	
Auto Response	On, Off, Reset	On [t]			
Time Dependent Blended Sensor	On, Off	Off [r]		Off [r]	
AutoLifestyle	On, Off, Reset	On [s]		On [s]	
Sensor Rate Target for Automatic Response Factor (ppm)	70, 75, ..., 175	110 [t]		110 [t]	
ACC Initial Response Factor	1, 2, ..., 16	8			
MV Initial Response Factor	1, 2, ..., 16	3			

Table A-1. Pacing therapy parameters (specified into a 750 Ω load)

Parameter	Option, Increments, Ranges	Nominals [a] [b]			
		DDDR	DDD	SR	SSI
ATR Mode Switch [m]	On, Off	On			
ATR Trigger Rate (ppm) [m] [n]	100, 110, ..., 200	170			
ATR Fallback Mode [o]	VDI(R), DDI(R)	VDI			
ATR Duration (cycles) [m]	0, 8–2048 in powers of 2	8			
ATR Fallback Time (sec) [m]	0, 5, ..., 120	30			
ATR Entry Count (cycles) [m]	1, 2, ..., 8	8			
ATR Exit Count (cycles) [m]	1, 2, ..., 8	8			
ATR Fallback Lower Rate Limit (ppm)	30, 35, ..., 51, ..., 90, 95, ..., 150 ATR Lower Rate Limit must be equal to or greater than the permanent Lower Rate Limit.	70			
ATR Max Pacing Rate MPR (ppm) [m]	50, 55, ..., 185	130			
Atrial Flutter Response [j]	On, Off	Off			
Atrial Flutter Response Trigger Rate (ppm) [n]	130, 140, ..., 230	170 (230 for DDI(R) mode)			
PMT Termination [j]	On, Off	On			
Ventricular Rate Regulation (VRR)	On, Off	On		Off	
VRR Max Pacing Rate MPR (ppm)	60, 65, ..., 150	110			
A-Blank after V-Pace (ms)	30, 40, ..., 200	120			
V-Blank after A-Pace (ms)	30, 40, ..., 200	40			
Refractory Periods: [p]					
V Refractory Period (ms)	200, 210, ..., 500	250			
Maximum PVARP (ms) [j]	150, 160, ..., 500	250			
Minimum PVARP (ms) [j]	150, 160, ..., 500	240			
PVARP after PVC/PAC (ms) [j]	Off, 150, 200, ..., 500	400			

a. Nominal values are for all applicable modes unless otherwise stated.
b. Models with 400 ms AV delay.
c. S refers to a single chamber, either atrium or ventricle. For example, SSI indicates programmability to AAI or VVI.
d. Tolerance is ± 5 ms of programmed interval, independent of load (100–2500 Ω) temperature (20–43 °C), and battery voltage (BOL–EOL).
e. The lower rate limit is the same as basic rate, interference pulse rate, and escape interval.
f. Adaptive-rate modes only.
g. Tolerance is ± 0.02 ms, independent of load (100–2500 Ω), temperature (20–43 °C), and battery voltage (BOL–EOL).
h. Programming sensitivity to a less sensitive setting (i.e., a higher value) always results in the pacemaker becoming less sensitive to intrinsic signals, and conversely, programming to a more sensitive setting always results in the pacemaker becoming more sensitive. Tolerance with a 25-Hz haversine test signal is ± 40% (0.15 mV is ± 50%). Levels using the CENELEC test signal are higher by a factor of 1.2 with the same tolerance (e.g., the 1.5 mV setting will test at 1.2 mV–1.8 mV using a haversine, and 1.44 mV–2.16 mV using the CENELEC test signal. Input impedance is >90 KΩ).
i. ATR Only is not a user-selectable setting. It is set when the primary mode is not rate-responsive and a rate-responsive ATR Fallback Mode is selected.
j. Dual-chamber modes only.
k. For Dynamic AV Delay, the values are 10, 20, ..., 290 ms.
l. The Automatic Capture feature may add an additional 64 ms AV Hysteresis in order to accommodate a fusion check for a maximum AV Hysteresis delay of 364 ms, but for Models S602, S603, S606, the maximum AV Hysteresis delay is 464 ms.
m. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
n. The 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.

o. 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.
p. Tolerance is ± 3 ms of programmed interval, independent of load (100–2500 Ω), temperature (20–43 °C), and battery voltage (BOL–EOL)
q. ALTRUA 20; INSIGNIA I Entra
r. ALTRUA 40 and 60; INSIGNIA I Plus and Ultra
s. ALTRUA 60; INSIGNIA I Ultra
t. ALTRUA 40; INSIGNIA I Plus

STAT, RESET, AND SHIP PARAMETER VALUES

Table A-2. STAT, Reset, and SHIP Parameter Values

Parameter	STAT (VVI/SSI) [a]	Reset (VVI/SSI) [a]	SHIP (DOO or SOO)
Pacing rate (ppm)	65	65	30
Pulse Width (ms)	1.0	1.0	0.4
Amplitude (V)	5.0	5.0	3.5
Sensitivity (mV)	1.5	1.5	NA
Refractory (ms)	320	320	NA
Lead Configuration [c]	Unipolar	Depends on lead [b]	Bipolar
Magnet Response	As Programmed	Off	Off

a. All other parameters normally available in these modes are disabled.
b. Lead Configuration will be Unipolar if a unipolar lead is implanted, and Bipolar if a bipolar lead is implanted.
c. For 5-/6-mm Header devices, the Lead Configuration is Unipolar.

BATTERY INFORMATION

Table A-3. Battery Information [a]

Device Model	Battery Model	Usable Battery Capacity (Ah)	BOL Voltage (V)	Battery Capacity at ERT (Ah)
ALTRUA 20				
S201, S204	WGL 9840 or Litronik 1869	1.04	2.8	0.067
S205, S208	WGL 9841 or Litronik 2269	1.53	2.8	0.087
S203	WGL 9840 or Litronik 1869	1.04	2.8	0.105
ALTRUA 40				
S401	WGL 9840 or Litronik 1869	1.04	2.8	0.067
S402, S404	WGL 9841 or Litronik 2269	1.53	2.8	0.087
S403	WGL 9840 or Litronik 1869	1.04	2.8	0.105
ALTRUA 60				
S602 [b], S604, S606 [b]	WGL 9841 or Litronik 2269	1.53	2.8	0.087
S603 [b], S605 [b]	WGL 9840 or Litronik 1869	1.04	2.8	0.105
S601	WGL 9840 or Litronik 1869	1.04	2.8	0.067
INSIGNIA I Entra				
1195, 1198	WGL 9840 or Litronik 1869	1.04	2.8	0.067
1294, 1295	WGL 9841 or Litronik 2269	1.53	2.8	0.087
1296	WGL 9840 or Litronik 1869	1.04	2.8	0.105
INSIGNIA I Plus				
1194	WGL 9840 or Litronik 1869	1.04	2.8	0.067
1297	WGL 9841 or Litronik 2269	1.53	2.8	0.087
1298	WGL 9840 or Litronik 1869	1.04	2.8	0.105

Table A-3. Battery Information [a]

Device Model	Battery Model	Usable Battery Capacity (Ah)	BOL Voltage (V)	Battery Capacity at ERT (Ah)
INSIGNIA I Ultra				
1291	WGL 9841 or Litronik 2269	1.53	2.8	0.087
1290	WGL 9840 or Litronik 1869	1.04	2.8	0.105
1190	WGL 9840 or Litronik 1869	1.04	2.8	0.067

a. The pacemakers use a single-cell lithium-iodine battery. The cell slowly decreases in output voltage over its lifetime.
b. Models with 400 ms AV delay.

EVENT MARKERS

DDD(R) EVENT MARKERS

Note: *The event markers in bold are included in the subset available when real-time EGMs are selected.*

Table A-4. Event Markers for DDD(R) Models — ALTRUA S203, S205, S208

Marker Description	Annotations	
	Printed	**Screen**
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial pace–rate hysteresis active	AP-Hy	AP
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None

Table A-4. Event Markers for DDD(R) Models — ALTRUA S203, S205, S208

Marker Description	Annotations	
	Printed	Screen
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–sudden brady response	VP-SBR	VP

Table A-5. Event Markers for DDD(R) Models — INSIGNIA I Entra 1296, 1295, 1294

Marker Description	Annotations	
	Printed	Screen
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial pace–rate hysteresis active	AP-Hy	AP
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS

Table A-5. Event Markers for DDD(R) Models — INSIGNIA I Entra 1296, 1295, 1294

Marker Description	Annotations	
	Printed	Screen
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–sudden brady response	VP-SBR	VP

Table A-6. Event Markers for DDD(R) Models — ALTRUA S404, S403

Marker Description	Annotations	
	Printed	Screen
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory/atrial flutter protection	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial sense–in atrial flutter response	AS-FL	AS
Atrial pace–rate hysteresis active	AP-Hy	AP
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–inserted after atrial flutter protection	AP→	AP

Table A-6. Event Markers for DDD(R) Models — ALTRUA S404, S403

Marker Description	Annotations	
	Printed	Screen
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS
Ventricular sense–AV hysteresis active	VS-Hy	VS
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–ventricular rate regulation	VP-VR	VP
Ventricular pace–sudden brady response	VP-SBR	VP

Table A-7. Event Markers for DDD(R) Models — INSIGNIA I Plus 1297, 1298

Marker Description	Annotations	
	Printed	Screen
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory/atrial flutter protection	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial sense–in atrial flutter response	AS-FL	AS
Atrial pace–rate hysteresis active	AP-Hy	AP

Table A-7. Event Markers for DDD(R) Models — INSIGNIA I Plus 1297, 1298

Marker Description	Annotations	
	Printed	Screen
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–inserted after atrial flutter protection	AP→	AP
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS
Ventricular sense–AV hysteresis active	VS-Hy	VS
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–ventricular rate regulation	VP-VR	VP
Ventricular pace–sudden brady response	VP-SBR	VP

Table A-8. Event Markers for DDD(R) Models — ALTRUA S603[a], S602[a], S606[a]

Marker Description	Annotations	
	Printed	Screen
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS

Table A-8. Event Markers for DDD(R) Models — ALTRUA S603[a], S602[a], S606[a]

Marker Description	Annotations	
	Printed	**Screen**
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory/atrial flutter protection	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial sense–in atrial flutter response	AS-FL	AS
Atrial pace–rate hysteresis active	AP-Hy	AP
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–inserted after atrial flutter protection	AP→	AP
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS
Ventricular sense–AV hysteresis active	VS-Hy	VS
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–ventricular rate regulation	VP-VR	VP
Ventricular pace–sudden brady response	VP-SBR	VP

a. Models with 400 ms AV delay.

Table A-9. Event Markers for DDD(R) Models — INSIGNIA I Ultra 1290, 1291

Marker Description	Annotations	
	Printed	Screen
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory/atrial flutter protection	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial sense–in atrial flutter response	AS-FL	AS
Atrial pace–rate hysteresis active	AP-Hy	AP
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–inserted after atrial flutter protection	AP→	AP
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS
Ventricular sense–AV hysteresis active	VS-Hy	VS
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP

Table A-9. Event Markers for DDD(R) Models — INSIGNIA I Ultra 1290, 1291

Marker Description	Annotations	
	Printed	Screen
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–ventricular rate regulation	VP-VR	VP
Ventricular pace–sudden brady response	VP-SBR	VP

SSI(R) EVENT MARKERS

Note: *The event markers in bold are included in the subset available when real-time EGMs are selected.*

Table A-10. Event Markers for SSI(R) Models — ALTRUA S201, S204

Marker Description	Annotations	
	Printed	Screen
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P

Table A-11. Event Markers for SSI(R) Models — INSIGNIA I Entra 1198, 1195

Marker Description	Annotations	
	Printed	Screen
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P

Table A-11. Event Markers for SSI(R) Models — INSIGNIA I Entra 1198, 1195

Marker Description	Annotations	
	Printed	Screen
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P

Table A-12. Event Markers for SSI(R) Model — ALTRUA S401

Marker Description	Annotations	
	Printed	Screen
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P
Pace–ventricular rate regulation	P-R	P

Table A-13. Event Markers for SSI(R) Model — INSIGNIA I Plus 1194

Marker Description	Annotations	
	Printed	Screen
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P
Pace–ventricular rate regulation	P-R	P

Table A-14. Event Markers for SSI(R) Model — ALTRUA S601

Marker Description	Annotations	
	Printed	**Screen**
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P
Pace–ventricular rate regulation	P-R	P

Table A-15. Event Markers for SSI(R) Models — INSIGNIA I Ultra 1190

Marker Description	Annotations	
	Printed	**Screen**
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P
Pace–ventricular rate regulation	P-R	P

SYMBOLS ON PACKAGING

The following symbols may be used on packaging and labeling:

Table A-16. Symbols on packaging

Symbol	Description
	Reference number
	Package contents
	Pulse generator
	Torque wrench
	Literature enclosed
	Serial number
	Use by
	Lot number
	Date of manufacture
	Sterilized using ethylene oxide
	Do not resterilize
	Single use. Do not reuse
	Do not use if package is damaged
	Consult instructions for use on this website: www.bostonscientific-elabeling.com
	Temperature limitation
	Place telemetry wand here
	Open here
	Legal Manufacturer
	MR Conditional

Table A-16. Symbols on packaging

Symbol	Description
	Pacemaker—single-chamber
	Pacemaker—dual-chamber
	Uncoated device
	RF Telemetry
	Double sterile barrier system
	Single sterile barrier system

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