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 ต่อเนื่องกันปรับการเต้นอัตโนมัติ

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## ESSENTIO™ MRI Pacing System

Models L110, L111

- Provides an ImageReady™ MR Conditional pacing system\* at 3T and 1.5T, full body, with no time limitations, with automatic MRI timeout feature to optimize workflow in the MR environment
- RF telemetry for wireless transmission of information and efficiency in the operating room and follow-up setting
- LATITUDE™ NXT Remote Patient Management enabled, offering the opportunity for wireless (RF) remote patient monitoring and follow-up
- PaceSafe™ RV and RA, providing dynamic adjustment of pacing outputs to ensure capture, to maximize efficiency and ease of use
- RightRate™ – MV sensor technology and the only MV sensor clinically proven to restore chronotropic competence<sup>1</sup>
- AVSH+, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development
- Enhanced features and diagnostics designed to provide you with greater insight into your patient's disease progression
- POST function to facilitate patient follow up with a fully automatic device and lead check
- EASYVIEW™ header with port identifiers designed to make the implant experience more efficient

\*Please refer to MRI Technical Guide.



### Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)
L110	SR	4.45 x 4.81 x 0.75	23.6	13.2	RA/RV, IS1
L111	DR	4.45 x 5.02 x 0.75	24.8	13.7	RA, IS1 – RV, IS1

### Projected Longevity (Years)

Pacing		SR	DR
50%	RA/RV 2.5V	10.4	9.3
100%	RA/RV 2.5V	9.7	8.2

### Additional Longevity Information

- Settings: pacing pulse width 0.4ms, Impedance 750Ω, LRL 60bpm, Sensor On, EGM Onset On. These calculations also assume that the pulse generator spends 6 months in Storage mode during shipping and storage, the ZIP™ telemetry use for 1 hour at implant time and for 40 minutes annually for in-clinic follow-up checks. For longevity calculations based on different settings please contact Boston Scientific technical services or your local representative.
- Power Supply SR and DR models: lithium-carbon monofluoride cell; Boston Scientific; 402290.

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# ESSENTIO™ MRI Pacing System

Models L110, L111

## Pacing Therapy

<b>Brady Modes</b>	Normal: DDD(R)-DDI(R)-VDD(B)-VVI(R)-AAI(R)-DOO-VOO- AOO-Off Temporary: DDD-DDI-VDD-VVI-AAI-DOO-VOO- AOO-Off	3 ✓
<b>AT/AF Management</b>	ATR Mode Switch, Rate Smoothing	
<b>Automaticity</b>	Automatic Gain Control (AGC) for sensitivity Right Atrial Automatic Threshold (RAAT) Right Ventricular Automatic Capture (RVAC)	8, 9 ✓ 15 ✓
<b>Rate Adaptive Pacing</b>	Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function	16 ✓
<b>RV Pacing Reduction</b>	AV Search +, AV Delay to 400 ms, RateHysteresis	13 ✓
<b>Rate Management</b>	Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP	14 ✓
<b>Pace/Sense Configuration</b>	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off, Lead Safety Switch	11, 12 ✓

## Patient Diagnostics

<b>Arrhythmia Logbook</b>	Event Summary, Stored Electrograms with Annotation Markers (Intervals and approximately 14 minutes all multi- channel EGM, always with 10 seconds Onset and event storage prioritization), Implant activation of all available EGMs, On screen measurements of all stored signal, amplitudes and timing, Snapshot Function up to 12 seconds trace of ECG/EGM display stored)
<b>Histograms &amp; Counters</b>	Ventricular Tachy Counter, Brady Counter, Histograms, Intrinsic Promotion (Rate Hysteresis % successful and AVSH+ % successful)
<b>Diagnostics</b>	AT/AF Burden, A & V Arrhythmias, Weight and Blood Pressure*
<b>DAILY TREND for last 365 Days</b>	Events, AT/AF Burden, Heart Rate, Lead Impedance and Amplitude, RAAT Trend, RVAC Trend

\*Weight and Blood Pressure are only available via LATITUDE NXT.

## ImageReady™

<b>MRI Lead Selection</b>	Pulse Generator MR-conditional with all FINELINE™ II Sterox, FINELINE™ II Sterox EZ and INGEVITY™ Pacing Lead Models
<b>MRI Conditions</b>	Full body scan at 1.5T (≤SAR 2W/Kg) for all FINELINE™ II models* Full body scan at 3T and 1.5T (≤SAR 4W/Kg) for all INGEVITY™ MRI models*
<b>MRI Mode</b>	Pacing Mode: AOO, VOO, DOO, Off Protection Time Out: Off, 12, 24, 48 hours

\*Please refer to the Pacing System MRI Technical Guide as the system is designated as MR Conditional in accordance with specified conditions.

## Implant/In Clinic Follow Up

<b>Implant Communication Mode</b>	Programmable values: Enable use of ZIP™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry Nominal: Enable use of ZIP™ telemetry (Requires initial use of wand for device ID)
<b>In Clinic Follow Up</b>	Snapshot Function up to 12 seconds trace of ECG/EGM display stored POST (Post-Operative System Test) provides an automatic device/lead check at a pre-determined time post-implant to help document proper system functionality without requiring manual system testing

## Remote Follow Up

<b>Remote Monitoring</b>	This device is designed to be LATITUDE™ NXT enabled, LATITUDE NXT availability varies by region*
<b>Thresholds</b>	Automatic storage of last successful daily PaceSafe threshold test for all active chambers
<b>Wireless</b>	Remote follow-up for all devices (MICS) 4 ✓
<b>Patient Triggered Monitor (PTM)</b>	Triggers the storage of two minutes onset and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device

\*LATITUDE™ NXT is not available for L100 and L101 models.

## Safety Functions\*

<b>Safety Core</b>	Is intended to provide life-sustaining therapy if certain non-recoverable or repeat fault conditions occur. Safety Core operates independently and acts as a backup to these components
<b>Electrocautery Protection Mode</b>	Provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer

\*The Safety Functions do not have programmable parameters.

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1. Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise, Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology, 1989; 3: 176-180. Refer to the Physician's System Guide for more information on adaptive-rate therapy. Additional clinical performance was assessed using INSIGNIA™ ultra clinical data with the Autolifestyle™ feature programmed On. Boston Scientific, Data on file. ALTRUA™ Pacemaker System Guide, 2008, 1 20-25, monthly Full Interrogations (scheduled remote follow ups, and quarterly patient-interrogations).

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REFERENCE GUIDE

**ACCOLADE™**

**ACCOLADE™ MRI**

**PROPONENT™**

**PROPONENT™ MRI**

**ESSENTIO™**

**ESSENTIO™ MRI**

**ALTRUA™ 2**

**FORMIO™**

**FORMIO™ MRI**

**VITALIO™**

**VITALIO™ MRI**

**INGENIO™**

**INGENIO™ MRI**

**ADVANTIO™**

PACEMAKER

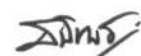
Model L300, L301, L321, L310, L311, L331, L200, L201, L221, L210,  
L211, L231, L100, L101, L121, L110, L111, L131, S701, S702, S722,  
K278, K279, K272, K273, K274, K275, K276, K277, K172, K173, K174,  
K175, K176, K177, K062, K063, K064

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

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## PROGRAMMABLE OPTIONS

### APPENDIX A

Table A-1. ZIP Telemetry settings

Parameter	Programmable Values	Nominal <sup>a</sup>
Communication Mode	Enable use of ZIP telemetry (May require limited use of wand); Use wand for all telemetry	Enable use of ZIP telemetry (May require limited use of wand)

a. If the Communication Mode is selected via the Utilities button on the PRM Startup screen, the Nominal setting within the ZOOMVIEW Programmer software application will correspond to the value chosen on the Startup screen.

Table A-2. Device Mode

Parameter	Programmable Values	Nominal
Device Mode	Exit Storage; Enable Electrocautery Protection; Enable MRI Protection <sup>a</sup>	Storage

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


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

Parameter	Programmable Values	Nominal
Mode <sup>a c</sup>	DDD(R); DDI(R); DOO; VDD(R); VVI(R); VOO; AAI(R); AOO; Off; Temporary: DDD; DD; DOO; VDD; VVI; VOO; AAI; AOO; Off	Dual Chamber: DDD; Single Chamber: VVI
Lower Rate Limit (LRL) <sup>a b c</sup> (ppm)	30; 35; ...; 185	60 (Tolerance ± 5 ms)
Maximum Tracking Rate (MTR) <sup>a c</sup> (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Maximum Sensor Rate (MSR) <sup>a</sup> (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Pulse Amplitude <sup>a c d</sup> (dual chamber, atrium) (V)	Auto; 0.1; 0.2; ...; 3.5; 4.0; ...; 5.0; Temporary: 0.1; 0.2; ...; 3.5; 4.0; ...; 5.0	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude <sup>a c d</sup> (dual chamber, right ventricle) (V)	Auto; 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5; Temporary: 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude <sup>a c d</sup> (single chamber) (V)	Auto; 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5; Temporary: 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude Daily Trend <sup>f</sup> (independently programmable in each chamber that has the Pacesafe feature)	Disabled; Enabled	Enabled (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices)  Disabled (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)
Pulse Width <sup>a c d g</sup> (atrium, right ventricle) (ms)	0.1; 0.2; ...; 2.0	0.4 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Accelerometer <sup>h</sup>	On; Passive	Passive
Accelerometer Activity Threshold	Very Low; Low; Medium Low; Medium; Medium High; High; Very High	Medium
Accelerometer Reaction Time (sec)	10; 20; ...; 50	30
Accelerometer Response Factor	1; 2; ...; 16	8
Accelerometer Recovery Time (min)	2; 3; ...; 16	2
Minute Ventilation <sup>h</sup>	On; Passive; Off	Passive

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

Parameter	Programmable Values	Nominal
Minute Ventilation Response Factor	1; 2; ...; 16	8
Minute Ventilation Fitness Level	Sedentary; Active; Athletic; Endurance Sports	Active
Patient's Age <sup>h</sup>	≤ 5; 6-10; 11-15; ...; 91-95; ≥ 96	56-60
Patient's Gender <sup>h</sup>	Male; Female	Male
Ventilatory Threshold (ppm)	30; 35; ...; 185	120 (Tolerance ± 5 ms)
Ventilatory Threshold Response (%)	Off; 85; 70; 55	70
Rate Hysteresis Hysteresis Offset <sup>g</sup> (ppm)	-80; -75; ...; -5; Off	Off (Tolerance ± 5 ms)
Rate Hysteresis Search Hysteresis <sup>g</sup> (cycles)	Off; 256; 512; 1024; 2048; 4096	Off (Tolerance ± 1 cycle)
Rate Smoothing (Up, Down) <sup>g</sup> (%)	Off; 3; 6; 9; 12; 15; 18; 21; 25	Off (Tolerance ± 1%)
Rate Smoothing Maximum Pacing Rate (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Sudden Brady Response (SBR) <sup>g</sup>	Off; On	Off
SBR Atrial Paces Before Therapy	1; 2; ...; 8	3
SBR Atrial Pacing Rate Increase (ppm)	5; 10; ...; 40	20
SBR Therapy Duration (min)	1; 2; ...; 15	2
SBR Inhibit During Rest	Off; On	On
Atrial Pace/Sense Configuration <sup>a, c</sup> (dual chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar; Unipolar/Off; Bipolar/Off	Bipolar ⑪, ⑫ ✓
Right Ventricle Pace/Sense Configuration <sup>a, c</sup> (dual chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar	Bipolar
Pace/Sense Configuration <sup>a, c</sup> (single chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar	Bipolar
Safety Switch (independently programmable in each chamber)	Off; On	On
Automatic Lead Recognition	Off; On	On
Maximum Paced AV Delay <sup>a, c</sup> (ms)	30; 40; ...; 400	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay <sup>a, c</sup> (ms)	30; 40; ...; 400	80 (Tolerance ± 5 ms)
Maximum Sensed AV Delay <sup>a, c</sup> (ms)	30; 40; ...; 400	150 (Tolerance ± 5 ms)
Minimum Sensed AV Delay <sup>a, c</sup> (ms)	30; 40; ...; 400	65 (Tolerance ± 5 ms)
AV Search + <sup>e</sup>	Off; On	Off
AV Search + Search AV Delay (ms)	30; 40; ...; 400	300 (Tolerance ± 5 ms)
AV Search + Search Interval (cycles)	32; 64; 128; 256; 512; 1024	32 (Tolerance ± 1 cycle)
RYTHMIQ <sup>e</sup>	AAI(R) with VVI Backup; Off	Off
Maximum A-Refractory (PVARP) <sup>a, c</sup> (dual chamber) (ms)	150; 160; ...; 500	280 (Tolerance ± 5 ms)
Minimum A-Refractory (PVARP) <sup>a, c</sup> (dual chamber) (ms)	150; 160; ...; 500	240 (Tolerance ± 5 ms)
Maximum V-Refractory (VRP) <sup>a, c</sup> (dual chamber) (ms)	150; 160; ...; 500	250 (Tolerance ± 5 ms)

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สมัคร



Table A-6. Ventricular Tachy EGM Storage

Parameter	Programmable Values	Nominal
Tachy EGM Storage (single chamber models)	Off; On	On
Ventricular Tachy EGM Storage (dual chamber models)	Off; On	On
Tachy Detection Rate <sup>a</sup> (single chamber models) ( bpm)	90; 95; ...; 210; 220	160 (Tolerance ± 5 ms)
VT Detection Rate <sup>b</sup> (dual chamber models) ( bpm)	90; 95; ...; 210; 220	160 (Tolerance ± 5 ms)

- a. The Tachy Detection Rate must ≥ 5 bpm higher than the Maximum Sensor Rate and the Maximum Pacing Rate, and must be ≥ 15 bpm higher than the Lower Rate Limit.  
 b. The VT Detection Rate must be ≥ 5 bpm higher than the Maximum Tracking Rate, Maximum Sensor Rate, and the Maximum Pacing Rate, and must be ≥ 15 bpm higher than the Lower Rate Limit.

Table A-7. Atrial Tachy Parameters

Parameter	Programmable Values	Nominal
ATR Mode Switch <sup>a</sup>	Off; On	On
ATR Trigger Rate <sup>a c</sup> ( bpm)	100; 110; ...; 300	170 (Tolerance ± 5 ms)
ATR Duration <sup>a</sup> (cycles)	0; 8; 16; 32; 64; 128; 256; 512; 1024; 2048	8 (Tolerance ± 1 cardiac cycle)
ATR Entry Count <sup>a</sup> (cycles)	1; 2; ...; 8	8
ATR Exit Count <sup>a</sup> (cycles)	1; 2; ...; 8	8
ATR Fallback Mode <sup>d</sup>	VDI; DDI; VDIR; DDIR	DDI
ATR Fallback Time <sup>a</sup> (min:sec)	00:00; 00:15; 00:30; 00:45; 01:00; 01:15; 01:30; 01:45; 02:00	00:30
ATR Fallback LRL <sup>a</sup> ( ppm)	30; 35; ...; 185	70 (Tolerance ± 5 ms)
ATR Ventricular Rate Regulation (VRR) <sup>a</sup>	Off; On	On
ATR Maximum Pacing Rate (MPR) <sup>a</sup> ( ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Atrial Flutter Response <sup>b</sup>	Off; On	On
Atrial Flutter Response Trigger Rate <sup>c</sup> ( bpm)	100; 110; ...; 300	170 (Tolerance ± 5 ms)
PMT Termination <sup>b</sup>	Off; On	On
Ventricular Rate Regulation (VRR) <sup>b</sup>	Off; On	Off
VRR Maximum Pacing Rate (MPR) ( ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)

- a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.  
 b. This parameter gets disabled during Temporary Brady.  
 c. ATR Trigger Rate and Atrial Flutter Response Trigger Rate are linked. If either of these rates is reprogrammed, the other will automatically change to the same value.  
 d. If Normal Brady ATR Fallback Mode is DDIR or DDI, then Temporary Brady ATR Fallback Mode is DDI. If Normal Brady ATR Fallback Mode is VDIR or VDI, then Temporary Brady ATR Fallback Mode is VDI.

Table A-8. Sensitivity

Parameter <sup>a b c</sup>	Programmable Values	Nominal
Sensing Method <sup>d</sup>	AGC; Fixed	Fixed
Atrial Sensitivity (AGC) (mV)	AGC 0.15; AGC 0.2; AGC 0.25; AGC 0.3; AGC 0.4; ...; AGC 1.0; AGC 1.5	AGC 0.25

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Table A-8. Sensitivity (continued)

Parameter <sup>a b c</sup>	Programmable Values	Nominal
Right Ventricular Sensitivity (AGC) (mV)	AGC 0.15; AGC 0.2; AGC 0.25; AGC 0.3; AGC 0.4; ...; AGC 1.0; AGC 1.5 (9)	AGC 0.6
Atrial Sensitivity (Fixed) (mV)	Fixed 0.15; Fixed 0.25; Fixed 0.5; Fixed 0.75; Fixed 1.0; Fixed 1.5; ...; Fixed 8.0; Fixed 9.0; Fixed 10.0 (8) ✓	Fixed 0.75
Right Ventricular Sensitivity (Fixed) (mV)	Fixed 0.25; Fixed 0.5; Fixed 0.75; Fixed 1.0; Fixed 1.5; ...; Fixed 8.0; Fixed 9.0; Fixed 10.0 (9)	Fixed 2.5

- a. Separately programmable for Temporary Brady.
- b. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
- c. In single-chamber models, the chamber chosen determines the nominal value.
- d. The programmed value for Sensing Method determines the applicable values (AGC or Fixed) in each chamber.

Table A-9. Daily Lead Measurements

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

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## PACING THERAPIES

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

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

Single and dual-chamber pacemakers provide atrial and/or ventricular sensing and pacing, including adaptive-rate modes. ① ✓

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. ② ✓
- Adaptive-rate pacing allows the pulse generator to adapt the pacing rate to the patient's changing activity levels and/or physiologic needs. ① ✓

### 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 2-26).
- STAT PACE—initiates emergency ventricular pacing at high output settings when commanded via the PRM using telemetry communication ("STAT PACE" on page 1-17).
- Electrocautery Protection—provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer ("Electrocautery Protection Mode" on page 2-3).
- MRI Protection—modifies certain pulse generator functions in order to mitigate risks associated with exposing the pacing system to the MRI environment ("MRI Protection Mode" on page 2-3).

## DEVICE MODES

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

- Brady Therapy Enabled—indicates that the pulse generator is providing normal pacing therapy. This mode is not selectable; it is set automatically so long as Brady Mode is programmed to anything except Off.
- Brady Therapy Off—indicates that the pulse generator is not providing any therapy. This mode is not selectable; it is set automatically when the Brady Mode is programmed to Off.
- Electrocautery Protection Mode—provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer. This mode is enabled via the Device Mode button.

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The following scenarios will trigger the Check Atrial Lead alert:

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

Table 2-1. Threshold Test Codes

Code	Reason
N/R: device telem.	Telemetry started during an ambulatory test
N/R: comm. lost	Telemetry was lost during a commanded test
N/R: no capture	Capture was not obtained at the starting amplitude for a commanded test or capture is > 4.0 V for an ambulatory test
N/R: mode switch	ATR mode switch either started or stopped
N/R: fusion events	Too many consecutive or too many total fusion events occurred
No data collected	Minimum pacing amplitude was reached without losing capture for an ambulatory test, or neither Auto nor Daily Trend is turned on to obtain an ambulatory result
N/R: battery low	Test was skipped due to Battery Capacity Depleted
N/R: noise	Too many consecutive sense channel noise or Evoked Response noise cycles occurred
N/R: incompat. mode	Incompatible Brady mode was present (e.g. VDI Fallback Mode, Magnet Mode) or a Lead Safety Switch occurred
N/R: rate too high	Rate was too high at the start of the test, a rate increase would raise the rate too high or more than 2 rate increases were required
N/R: user cancelled	Commanded test was stopped by the user
N/R: intrinsic beats	Too many cardiac cycles occurred during the test
N/R: test delayed	Test was delayed due to telemetry being active, VT episode already in progress, Electrocautery mode, MRI Protection Mode, or RAAT was turned on while the device remained in Storage mode
N/R: respiration	Respiratory artifact was too high
N/R: low ER	The Evoked Response signal could not be assessed adequately
Auto N/R	Minimum pacing amplitude was reached without losing capture for a commanded test, or telemetry is manually cancelled during a commanded test
Invalid Failure Code	Unexpected Failure

### PaceSafe Right Ventricular Automatic Capture (RVAC)

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

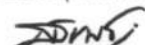


PaceSafe RVAC is designed to dynamically adjust the right ventricular pacing output to ensure capture of the ventricle by optimizing the output voltage to 0.5 V above the capture threshold. RVAC maintains this output while confirming capture on a beat-to-beat basis. RVAC will measure pacing thresholds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

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

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

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

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

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

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

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

If any loss of capture occurs during beat-to-beat operation, then the pulse generator will deliver a backup pacing output within approximately 70 ms of the primary pulse. The backup safety pulse amplitude will be a minimum of 3.5 V and a maximum of 5.0 V. If there is a Confirmed Loss of Capture (C-LOC; 2 out of 4 cardiac cycles do not capture the ventricle), RVAC will enter Suspension and a test re-attempt will occur at the next hourly interval. (15) ✓

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

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

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

#### Ambulatory Ventricular Automatic Capture Measurement (15) ✓

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

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

- Paced AV Delay is fixed at 60 ms.

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

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

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

## ATRIAL TACHY RESPONSE

### ATR Mode Switch

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

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

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

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

An example of ATR behavior is shown (Figure 2-36 ATR behavior on page 2-52).

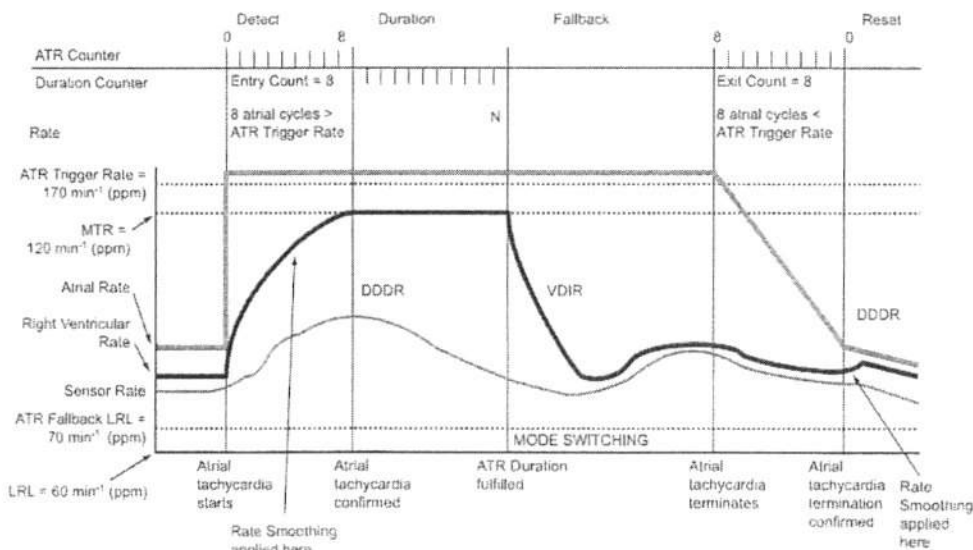


Figure 2-36. ATR behavior

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

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**Fallback Mode**

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

After switching modes, the pulse generator gradually decreases the ventricular paced rate. This decrease is controlled by the Fallback Time parameter. (14) ✓

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

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

**Fallback Time**

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

During fallback, the following features are disabled:

- Rate Smoothing—disabled until fallback reaches the ATR Fallback LRL or the sensor-indicated rate. If VRR is enabled, then Rate Smoothing is disabled throughout the mode switch
- Rate Hysteresis
- AV Search +
- PVARP Extension

**Fallback LRL**

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

The rate will decrease to the highest among the sensor-indicated rate (when applicable), the VRR rate (if enabled), and the ATR Fallback LRL.

**End of ATR Episode**

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

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

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

**Ventricular Rate Regulation (VRR)**

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

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