ACCOLADE™ EL MRI Pacing System

ImageReady™ MR Conditional Pacing System

Model L331

- 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
- Extended Longevity device projected to last up to 16.7 years**
- Advanced AF and HF diagnostic reports provide a comprehensive and proactive approach for comorbidity management
- RF telemetry for wireless transmission of information and efficiency in the operating room and follow-up setting
- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System
- Automatity with PaceSafe™ RV and RA, providing dynamic adjustment of pacing outputs to ensure capture and Automatic Gain Control to dynamically adjust the sensitivity in both the atrium and the ventricle, to maximize efficiency and ease of use
- RightRate™ MV sensor is the only sensor clinically proven to restore chronotropic competence1
- RYTHMIQ™, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development
- Enhanced features and diagnostics, including AP Scan™ and Respiratory Rate Trend, designed to provide you with greater insight into your patient’s disease progression based on the patient’s own respiration
- 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

*When conditions of use are met, please refer to MRI Technical Guide.
**Assumes LRL 60bpm, ventricular and atrial settings of 0.4 ms pacing pulse width; no MV sensor; EGM Onset On; RA/RV 50% pacing; RA/RV 1000 Ω.

### Mechanical Specifications

<table>
<thead>
<tr>
<th>Model</th>
<th>Type</th>
<th>Size (cm) (W x H x D)</th>
<th>Mass (g)</th>
<th>Volume (cc)</th>
<th>Connector Type (RA RV LV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L331</td>
<td>DR</td>
<td>4.45 x 5.88 x 0.75</td>
<td>29.2</td>
<td>14.2</td>
<td>RA: IS1 – RV: IS1</td>
</tr>
</tbody>
</table>

### Longevity

<table>
<thead>
<tr>
<th>Projected Longevity</th>
<th>Pacing Amplitude</th>
<th>Pacing</th>
<th>MV Sensor</th>
<th>500Ω</th>
<th>750Ω</th>
<th>1000Ω</th>
</tr>
</thead>
<tbody>
<tr>
<td>DR EL</td>
<td>Typical programmed setting</td>
<td>2.5</td>
<td>100%</td>
<td>On</td>
<td>12.1</td>
<td>13.2</td>
</tr>
<tr>
<td>Maximum labeled longevity**</td>
<td>2.0</td>
<td>50%</td>
<td>Off</td>
<td>15.8</td>
<td>16.4</td>
<td>16.7</td>
</tr>
</tbody>
</table>

### Additional Longevity Information

- Settings: LRL 60bpm, ventricular and atrial settings of 0.4 ms pacing pulse width; sensors 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 48 minutes annually for in-clinic follow-up checks.
- Power Supply: lithium-carbon monofluoride cell; Boston Scientific; 402294.

**No MV Sensor.
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### Pacing Therapy

**Brady Modes**
- Normal:DDDR(DI/Iri-VDDR(VI)/AAIR-DOO-DOO-AOO-Off
  - Temporary: DDD-DDD-VDD-VI/AAI-DOO-DOO-AOO-Off

**AT/AF Management**
- ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AAR), Atrial Pacing Preference (APP), ProACI, Rate Smoothing

**Automaticity**
- Automatic Gain Control (AGC) for sensitivity
- Right Atrial Automatic Threshold (RAAT)
- Right Ventricular Automatic Capture (RVAC)

**Rate Adaptive Pacing**
- Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function

**RV Pacing Reduction**
- AV Search, RYTHMIQ™, AV Delay to 40 ms, Rate Hysteresis

**Rate Management**
- Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP

**Pace/Sense Configuration**
- Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/OFF, Bipolar/OFF, Lead Safety Switch, Automatic Lead Recognition

### Patient Diagnostics

**Arhythmia Logbook**
- 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)

**Histograms & Counters**
- Ventricular Tachy Counter, Brady Counter, Histograms, Intrinsic Promotion (Rate Hysteresis % successful and AVH% % successful)

**HF Therapy / Diagnostics**
- Heart Rate Variability (HRV) with SDANN and AVM, Respiratory Rate Trend, AP Scan, ATAF Burden, Activity Level, A & V Arrhythmias, Weight and Blood Pressure*

**Atrial Arrhythmia Report**
- ATAF Burden and Total Time in ATAF, ATAF Burden Trend, RV Rate during ATAF Trend, Pacing Percent Trend, Heart Rate Trend, Activity Level and Respiratory Rate Trends, RV Rate during ATAF Histogram, Timeline
- History of interrogations, programming, and counter resets for one year: Longest ATAF, Fastest RV rate in ATAF, and most recent episode.

**DAILY TREND for last 365 Days**
- Events, Activity Level, ATAF Burden, Pacing Percent, Respiratory Rate, AP Scan, Heart Rate, SDANN, HRR, Footprint, AVM, Lead Impedance and Amplitude, RAAT, Trend, RVAC Trend

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

### ImageReady™

**MRI Lead Selection**
- Pulse Generator MR-conditional with all FINELINE™ II Stroxx, FINELINE™ II Stroxx EZ and INGEVITY™ MRI Pacing Lead Models

**MRI Conditions**
- Full body scan at 3T and 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**

**MRI Mode**
- Pacing Mode: AOO, VOO, DOO-Off
- Protection Time Out: Off, 12,24,48 hours

**Implant/In Clinic Follow Up**

**Implant Communication Mode**
- Programmable values: Enable use of ZIP™ telemetry (MICS)
  - Requires initial use of wand for device (ID)
  - Use wand for all telemetry

**In Clinic Follow Up**
- Snapshot Function: 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

**Indications-Based Programming (IBP)**
- Tool that provides specific programming recommendations based on the patient’s clinical needs and primary indications

### Remote Follow Up

**Remote Monitoring**
- This device is designed to be LATITUDE™ NXT enabled; LATITUDE NXT availability varies by region

**Thresholds**
- Automatic storage of last successful daily PaceSafe threshold test for all active chambers

**Wireless**
- Remote follow-up for all devices (MICS)

**Patient Triggered Monitor (PTM)**
- 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

### Safety Functions**

**Safety Core**
- 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

**Electrocautery Protection Mode**
- Provides asynchronous pacing at the programmed outputs and URL when commanded by the programmer

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