ACCOLADE™ Pacing System
Models L300, L301

- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System, to improve clinic efficiency and provide a higher level of care for device patients
- Advanced 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
- PaceSafe™ RV and RA, providing dynamic adjustment of pacing outputs to ensure capture and maximize efficiency
- RightRate™ with the MV sensor, the only MV sensor clinically proven to restore chronotropic competence
- RYTHMIQ™, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development
- Enhanced features and diagnostics, including Respiratory Rate Trend, designed to provide you with greater insight into your patient’s disease progression based on the patient’s own respiration
- Post Operative System Test (POST) to facilitate patient follow-up with a fully automatic device and lead check
- EASYVIEW™ header with port labels (on DR device) designed to make the implant experience more efficient

### 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>
<th>C-Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>L300</td>
<td>SR</td>
<td>4.45 x 4.81 x 0.75</td>
<td>23.6</td>
<td>13.2</td>
<td>RA/RV: IS1</td>
<td>C1786</td>
</tr>
<tr>
<td>L301</td>
<td>DR</td>
<td>4.45 x 5.02 x 0.75</td>
<td>24.8</td>
<td>13.7</td>
<td>RA: IS1 – RV: IS1</td>
<td>C1785</td>
</tr>
</tbody>
</table>

### Projected Longevity (Years)

<table>
<thead>
<tr>
<th>Pacing</th>
<th>SR</th>
<th>DR</th>
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</thead>
<tbody>
<tr>
<td>50%</td>
<td>RA/RV 2.5V</td>
<td>10.0</td>
</tr>
<tr>
<td>100%</td>
<td>RA/RV 2.5V</td>
<td>9.2</td>
</tr>
</tbody>
</table>

### Additional Longevity Information

- Settings: pacing pulse width 0.4ms, Impedance 500Ω, 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.
Pacing Therapy

| Brady Modes | Normal:DDD(R)-DDIR(R)-VDD(R)-VVI(R)-VVI(R)-DOO-VOO-AOO-Off
| AT/AF Management | ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), Rate Smoothing
| Automaticity | Automatic Gain Control (AGC) for sensitivity, Right Atrial Automatic Threshold (RAAT), Right Ventricular Automatic Capture (RVAC)
| Rate Adaptive Pacing | Accelerometer, RhythmManager (Minute Ventilation) or blended sensors with sensor trending function
| RV Pacing Reduction | AV Search +, RHYTHMIQ™, AV Delay to 400 ms, RhythmManager (AVSD) and Rate Hysteresis
| Rate Management | Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP
| Pace/Sense Configuration | Unipolar, Bipolar, Unipolar/Bipolar, Unipolar/Bipolar, Unipolar/Bipolar, Unipolar/Bipolar, Unipolar/Bipolar

Implant/In Clinic Follow Up

- Programmable values: Enable use of ZIP™ telemetry (IMCS)
- Nominal: Enable use of ZIP™ telemetry (IMCS)

In Clinic Follow Up

- Snapshot function up to 12 seconds trace of ECG/EGM

Remote Follow Up

- Remote Monitoring: This device is designed to be LATITUDE™ NXT enabled
- Thresholds: Automatic storage of last successful paceSafe threshold test for all active chambers
- Wireless: Remote follow-up for all devices (IMCS)
- Patient Triggered Protection (PTM): Triggers the storage of two minutes on set and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device

Patient Diagnostics

- Arhythmia Logbook: Event Summary, Stored Electrophagrams with Annotation Markers (intervals and approximately 14 minutes out multi channel EGM, always with 10 seconds Onset and event storage prioritization).
- Histograms & Counters: Ventricular Tachy Count, Brady Count, Histograms, Intrinsin Promotion (Rate Hysteresis % successful and AVSH % successful)
- Therapy/Diagnostics: Heart Rate Variability (HRV) with SDANN and ABM, Respiratory Rate, Brakecore Bundle, Atrioventricular (AV) Nerve Function
- Atrial Arrhythmia Report: AT/AF % and Total Time in AT/AF, Atrioventricular Rate, Activity Level and Respiratory Rate Trends, RV Rate during AT/AF Rate, Heart Rate Activity Level and Respiratory Rate Trends, RV Rate during AT/AF Histogram, Timeline history of interrogations programming, and counter resets for one year. Longest ATIAE Fastest RVs rate in AT/AF, and most recent episode.
- DAILY TREND for last 365 Days: Events, Activity Level, Atrioventricular (AV) Brakecore Bundle, Atrioventricular Pacing Percent, Respiratory Rate, Heart Rate, SDANN, HRV Footprint, ABM, Lead Impedance and Amplitude, RAA Trends, RVV TREND

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
- Electrocardiography Protection Mode: Provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer

*The Safety Functions do not have programmable parameters.


Pacing Systems from Boston Scientific – ACCOLADE and ESSENTIO

INDICATIONS AND USAGE: Boston Scientific pacemakers are indicated for treatment of the following conditions: • Symptomatic paroxysmal or permanent second or third-degree AV block • Symptomatic biventricular bundle branch block • Symptomatic paroxysmal or permanent sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, bradycardia atrioventricular syndrome, to prevent symptomatic bradycardia or some forms of symptomatic lathyromias) • Neuromuscular-lathyromial syndromes or hyperensive cardiac sinus syndrome

CONTRAINDICATIONS: These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads. Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed: • Unipolar to or use of the AV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy. • Minute Ventilation in patients with both unipolar atrial and ventricular leads • Single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias • Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms

WARNINGS: Read this manual thoroughly before therapy to avoid damage to the pulse generator and lead(s). Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiology testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a loss of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial lathyromial syndromes. Lead Safety Switch should be programmed OFF for patients with an ICD. Unipolar pacing due to RhythmManager is contraindicated for patients with an ICD. Unipolar pacing due to RhythmManager should be programmed OFF for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Do not expose a patient to RFI scanning. Do not subject a patient with an implanted pulse generator and/or lead(s) to diathermy since diathermy

PRECAUTIONS: For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; patient information; device troubleshooting; implant and deposit; supplemental prescriptive information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration

POTENTIAL ADVERSE EVENTS: Potential adverse events include, but are not limited to, the following: allergypedrugs/medicalsurgery/reaction, death, erosion/resection, lysis or other lathyromias, lead or accessory bundle atrioventricular heart lead/tip, remodeling/strut fracture, malposition or inability to provide therapy (backing/winging, infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

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See relevant sections of the PACES™ User Manual and Product Information Guide. Refer to the labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev A)