ESSENTIO™ Pacing System
Models L100, L101

- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System, to improve clinic efficiency and provide a higher level of care for device patients
- 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
- AV Search +, 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 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>L100</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>L101</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>Type</th>
<th>SR</th>
<th>DR</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>RA/RV 2.5V</td>
<td>10.0</td>
<td>8.8</td>
</tr>
<tr>
<td>100%</td>
<td>RA/RV 2.5V</td>
<td>9.2</td>
<td>7.6</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.
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Pacing Therapy

Brady Modes  Normal: DDDR(D)RI(V)DDIR(V)DRII(A)RI(D)-DOO-VOO-AOO-Off
Temporary: DDDR(D)RI(V)DDIR(V)DRII(A)RI(D)-DOO-VOO-AOO-Off

AT/AF Management  ATR Mode Switch, 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 bleeding sensors with sensor trending function

RV Pacing Reduction  AV Search +, AV Delay to 400 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

Patient Diagnostics

Anhythmia Logbook  Event Summary, Stored Electrograms with Annotation
Markers (Intervals and approximately 14 minutes at half-channel EGM, always with 10 seconds Onset and event storage prioritization), implant activation of all available EGMs. On screen measurements of all stored signals, amplitudes and timing. Snapshot Function (up to 12 seconds trace of ECG/EGM display stored)

Histograms & Counters  Ventricular Tachy Counter, Brady Counter, Histograms, Intrusion Promotion (Rate Hysteresis % successful and AVSH+ % successful)

Diagnostics  AT/AF Burden, A & V Arrhythmias

DAILY TREND for last 365 Days  Events, AT/AF Burden, Heart Rate, Lead Impedance and Amplitude, RAAT Trend, RVAC Trend

Implant/In Clinic Follow Up

Implant  Programmable values: Enable use of ZIP™ telemetry (MICS)
Communication Mode (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)

In Clinic Follow Up  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 predetermined time post-implant to help document proper system functionality without requiring manual system testing

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 PacSafe 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 LRL when commanded by the programmer

*The Safety Functions do not have programmable parameters.

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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 bilateral bundle branch block • Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders i.e., sinus bradycardia, sinus arrest, sinoatrial (SA) block • Bradyarrhythmias syndromes, to prevent symptomatic bradycardias or some forms of symptomatic tachyarrhythmias • Ischemic (post-infarct) or hypersensitive cardiac syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for treatment of the following • Conduction disorders that require restoration of AV synchrony • Indications of varying degrees of AV block or AV node rhythm (i.e., pacemaker syndrome) • Low cardiac output or congestive heart failure secondary to bradycardia

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 pacing or use of the RV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy. • Unipolar pacing in patients with both unipolar atrial and ventricular leads. • Single-chamber atrial pacing in patients with impaired AV nodal conduction. • Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. • Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias. • Asynchronous pacing in the presence of bidirectional or incomplete atrioventricular (A-V) block. • Low cardiac output or congestive heart failure secondary to bradycardia

WARNING: Paced the ventricular device is not to be used for the purpose of a lead or endocardial lead. Such damage can result in the patient's injury or death. For single-patient use only. Do not rePROCESS, refurbish or redistribute. Always use external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or lack of therapy delivery. If response is inadequate, consider no-defibrillator lead or lead with defibrillation leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed OFF. Do not confuse atrial tracking modes with the pacemaker's ability to detect atrial fibrillation or flutter. The pacemaker may be more susceptible to electromagnetic interference. Atrial pacing is not intended to provide therapy for a pulse generator system and may experience a lack of atrial function, or re-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 allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/bradycardia), 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 failure may occur. Refer to the product labeling for specific indications, contraindications, warnings/precautions/advise and adverse events. (Rev A)