Boston Scientific
Advancing science for life™

# ESSENTIO™ Pacing System

## Models L100 and L100

- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System
- RightRate™ MV sensor is the only sensor clinically proven to restore chronotropic competence[1]
- Post-Operative System Test (POST) function to facilitate patient follow-up with a fully automatic device and lead check


### Mechanical Specifications

| Model | Type | Size (cm) (W x H x D) | Mass (g) | Volume (cc) | Connector Type (RA RV LV) | C-Code |
|---|---|---|---|---|---|---|
| **L100** | SR | 4.45 x 4.81 x 0.75 | 23.6 | 11.7 | RA/RV: IS1 | C1786 |
| **L101** | DR | 4.45 x 5.02 x 0.75 | 24.8 | 12.2 | RA: IS1 – RV: IS1 | C1785 |

| Projected Longevity | Pacing Amplitude | Pacing | MV Sensor | 500Ω | 750Ω | 1000Ω |
|---|---|---|---|---|---|---|
| | | | **SR** | | | |
| **Typical programmed setting** | 2.5 | 100% | On | 9.2 | 9.7 | 10.0 |
| **Maximum labeled longevity** | 2.0 | 50% | Off | 11.1 | 11.3 | 11.5 |
| | | | **DR** | | | |
| **Typical programmed setting** | 2.5 | 100% | On | 7.6 | 8.2 | 8.7 |
| **Maximum labeled longevity** | 2.0 | 50% | Off | 10.0 | 10.3 | 10.5 |

### 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.
- The following LATITUDE usage will decrease longevity by approximately 10 months: Daily device check on, monthly full interrogations (scheduled remote follow-ups, and quarterly patient-initiated interrogations). Daily device checks and quarterly full interrogations will decrease longevity by approximately 9 months.
- Power Supply VR and DR models: lithium-carbon monofluoride cell; Boston Scientific; 402290.

# ESSENTIO™ Pacing System

Models L100, L101

## Pacing Therapy

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|---|---|
| **Brady Modes** | Normal:DDD(R)-DDI(R)-VDD(R)-VVI(R)-AAI(R)-DOO-VOO-AOO-Off<br>Temporary: DDD-DDI-VDD-VVI-AAI-DOO-VOO-AOO-Off |
| **AT/AF Management** | ATR Mode Switch, Rate Smoothing |
| **Automaticity** | Automatic Gain Control (AGC) for sensitivity<br>Right Atrial Automatic Threshold (RAAT)<br>Right Ventricular Automatic Capture (RVAC) |
| **Rate Adaptive Pacing** | Accelerometer, RightRate™ (Minute Ventilation) or blended 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

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| **Arrhythmia Logbook** | Event Summary, Stored Electrograms with Annotation Markers (Intervals and approximately 14 minutes all multichannel 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 AVSH+ % successful) |
| **Diagnostics** | AT/AF Burden, A & V Arrhythmias, Signal Artifact Monitor |
| **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

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| **Implant Communication Mode** | Programmable values: Enable use of Zip™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry<br>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<br>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

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| **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*

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|---|---|
| **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.



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.

**ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™MRI, INGENIO™, INGENIO™MRI, ADVANTIO™ PACEMAKER**

**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) • Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias • Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus 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, including varying degrees of AV block • VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm • 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 MV 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 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 (or likelihood) of competition between paced and intrinsic rhythms

**Warnings** Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. 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 electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack 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 tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Automatic Lead Recognition should be programmed to Off before implant for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and 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 a 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. ACCOLADE MRI, PROPONENT MRI, ESSENTIO MRI, FORMIO MRI, VITALIO MRI and INGENIO MRI devices are considered MRI Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. All other devices covered by this statement are not MR conditional. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to 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, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.

**Potential Adverse Events** Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to pace; Inappropriate pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT) (applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation; dissection, erosion); Worsening heart failure.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of device malfunction.

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***Caution:*** *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

Boston Scientific

*Advancing science for life™*

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