Boston Scientific
Advancing science for life™

ESSENTIO™ EL Pacing System

Model L121

- Industry-leading longevity projected to last over 12 years[1-3]
- 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[4]
- 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 designed to make the implant experience more efficient

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)	C-Codes
L121	DR	4.45 x 5.88 x 0.75	29.1	15.8	RA: IS1 – RV: IS1	C1785

Projected Longevity

Pacing		Years
50%	RA/RV 2.5V	14.0
100%	RA/RV 2.5V	12.1

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: lithium-carbon monofluoride cell; Boston Scientific; 402294.

ESSENTIO™ EL Pacing System

Model L121

Pacing Therapy

Brady Modes	Normal:DDD(R)-DDI(R)-VDD(R)-VVI(R)-AAI(R)-DOO-VOO-AOO-Off 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 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 +, 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

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
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 Communication Mode	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)
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 pre-determined 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 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 LRL when commanded by the programmer

*The Safety Functions do not have programmable parameters.

1. Boston Scientific ACCOLADE Pacemaker Physician's Technical Manual 359246-001 EN US 2014-05.
2. Medtronic Advisa DR MRI SureScan A2DR01 Clinician Manual. M950432A001E 2013-11-15.
3. St. Jude Medical Accent MRI Pacemaker Rep to Clinician PPT. httpprofessional-intl.sjm.com~mediaproproductscrma-faccent-mri-pacemakermrireptoclinician_ppt_final_1020.ashx. Accessed 1/10/14.
4. 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).

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) • 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. 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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead 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; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary 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: 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/sensing), 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.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
(Rev A)

Boston Scientific
Advancing science for life™

Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-287006-AB FEB2015