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รายละเอียดคุณลักษณะเฉพาะ

รายการเครื่องช่วยการเต้นของหัวใจถาวรชนิดกระตุ้นหัวใจสองห้อง

ต่อเนื่องกันปรับอัตราการเต้นอัตโนมัติพร้อมสายเครื่องกระตุ้นหัวใจชนิดถาวร

(Dual chamber rate responsive pacemaker)

รุ่น ESSENTIO L111 MRI DR

1.คุณลักษณะเฉพาะ

1.1. เป็นเครื่องช่วยการเต้นของหัวใจชนิดถาวรที่สามารถกระตุ้นหัวใจห้องบนขวา (A) และ ห้องล่างขวา (V) อย่างต่อเนื่องกัน สามารถปรับอัตราการเต้นได้ตามกิจกรรมของคนไข้อัตโนมัติ

1.2. ใช้เป็นเครื่องช่วยการเต้นของหัวใจในผู้ป่วยที่มีภาวะจังหวะการเต้นของหัวใจช้าหรือไม่สม่ำเสมอ

1.3. สามารถเลือกแบบการกระตุ้นได้ดังนี้ คือ VVI(R), VOO, AAI(R), AOO, DDD(R), DDI(R), DOO, VDD(R), OFF

1.4. สามารถใช้การสื่อสารกับ Programmer แบบไร้สายได้

1.5. สามารถปรับความเร็วในการกระตุ้นต่ำสุดได้ตั้งแต่ 30-185 ครั้งต่อวินาที และสามารถปรับอัตราความเร็วสูงสุด ได้ตั้งแต่ 50-185 ครั้งต่อวินาที

1.6. สามารถปรับความสูงของพัลซ์ (Pulse amplitude) ได้ตั้งแต่ 0.1-7.5 Volts (สำหรับ Ventricles) และ 0.1 – 5.0 Volts (สำหรับ Atrium) และแบบอัตโนมัติ

1.7. สามารถปรับระยะเวลาในการส่งกระแสไฟฟ้า (pulse width) ได้ 0.1-2.0 มิลลิวินาที

1.8. สามารถปรับความไวในการรับสัญญาณของหัวใจห้องบนได้ตั้งแต่ 0.15-10.0 มิลลิโวลต์และแบบ AGC

1.9. สามารถปรับความไวในการรับสัญญาณของหัวใจห้องล่างตั้งแต่ 0.25-10.0 มิลลิโวลต์และแบบ AGC

1.10. สามารถปรับค่าระยะเวลาของกระแสที่ผ่านหัวใจห้องบนไปยังหัวใจห้องล่างได้ (A-V interval) ได้ตั้งแต่ 30-400 มิลลิวินาที

1.11. สามารถปรับ Pacing polarity เป็น UNIPOLAR หรือ BIPOLAR ได้

1.12. สามารถปรับ Sensing polarity เป็น UNIPOLAR หรือ BIPOLAR ได้

1.13. สามารถปรับลดการกระตุ้นที่หัวใจเต้นต่ำ ๆ ได้ (Hysteresis mode)

1.14. มีระบบช่วยในการตอบสนองต่อการเกิดหัวใจห้องบนเต้นผิดจังหวะชนิดเร็ว ลดอาการใจสั่นหรือหัวใจเต้นเร็วให้น้อยลง (Automatic mode switch)

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1.15. มีระบบ Autocapture/Automatic capture ทำให้ยืดอายุของแบตเตอรี่ โดยเครื่องจะทำการหาค่า Threshold และปรับกระแสไฟฟ้า (Output) โดยอัตโนมัติ ซึ่งจะทำการตรวจจับอย่างต่อเนื่องทุกๆจังหวะการเต้น (beat to/by beat) พร้อมทั้งมีระบบ Automatic Back-up เพื่อกระตุ้นซ้ำในเวลาอันสั้น ด้วยกระแสไฟฟ้าที่สูงขึ้น

1.16. สามารถปรับค่า Rate responsive ได้ โดยใช้ Accelerometer sensor และ/หรือ Minute Ventilation sensor

1.17. สามารถผ่านเครื่อง MRI ที่ความเข้ม ทั้ง 1.5 และ 3.0 เทสลาได้ทั้งร่างกาย

1.18. ผลิตภัณฑ์มากับ สายเครื่องช่วยกระตุ้นหัวใจชนิดถาวรที่มีขั้วต่อ IS-1 และเป็น ชนิด ที่ปลอดภัยสำหรับ MRI และชุดเข็มแทงเส้นเลือด introducer sheath

1.19. บรรจุอยู่ในกล่องที่ผ่านการฆ่าเชื้อแล้ว 1 กล่องต่อ 1 ชุด สามารถทำการฉีกซองภายในกล่องด้วยวิธี Aseptic technique และใช้ได้ทันที

2. สายเครื่องกระตุ้นหัวใจชนิดถาวร (Pacemaker Lead)

2.1. เป็นสายสำหรับช่วยการกระตุ้นหัวใจที่ออกแบบให้มีขนาดเล็กใช้งานง่าย มีความต้านทานสูงเพื่อลดการไหลของกระแสไฟฟ้า ที่อิเลคโทรดเคลือบด้วยสารที่ทำให้ Acute threshold และ Chronic pacing threshold ต่ำ

2.2. เป็นสายสำหรับใช้งานกับเครื่องช่วยการเต้นของหัวใจ โดยใช้ใส่ไว้ในหัวใจห้องบนขวา และ/หรือ ห้องล่างขวาสำหรับใช้งานกับผู้ป่วยที่มีอัตราการเต้นของหัวใจผิดปกติแบบช้า (Bradycardia)

2.3. เป็นสายช่วยการกระตุ้นหัวใจแบบไบโพลาร์แบบ Active Fixation

2.4. มีขั้วต่อ (Connector) ขนาด IS-1

2.5. มีความยาว 52 เซนติเมตร หรือ 59 เซนติเมตร

2.6. ใช้กับ Lead introducer ขนาด 6 หรือ 7 Fr

2.7. ปลอดภัยสำหรับ MRI 1.5 และ 3 Tesla

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เครื่องช่วยการเต้นของหัวใจถาวรชนิดกระตุ้นหัวใจสองห้องต่อเนื่องกันปรับการเต้นอัตโนมัติ

Boston Scientific
Advancing science for life™

ESSENTIO™ MRI Pacing System

Models L110, L111

1.17

- 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
- RF telemetry for wireless transmission of information and efficiency in the operating room and follow-up setting
- LATITUDE™ NXT Remote Patient Management enabled, offering the opportunity for wireless (RF) remote patient monitoring and follow-up
- PaceSafe™ RV and RA, providing dynamic adjustment of pacing outputs to ensure capture, to maximize efficiency and ease of use
- RightRate™ – MV sensor technology and the only MV sensor clinically proven to restore chronotropic competence[1]
- AVSH+, 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 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

*Please refer to MRI Technical Guide

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)
L110	SR	4.45 x 4.81 x 0.75	23.6	13.2	RA/RV: IS1
L111	DR	4.45 x 5.02 x 0.75	24.8	13.7	RA: IS1 – RV: IS1

1.18

Projected Longevity (Years)

Pacing		SR	DR
50%	RA/RV 2.5V	10.4	9.3
100%	RA/RV 2.5V	9.7	8.2

Additional Longevity Information

- Settings: pacing pulse width 0.4ms, Impedance 750Ω, 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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ESSENTIO™ MRI Pacing System

Models L110, L111

Pacing Therapy

Brady Modes	Normal: DDD(R)-DDI(R)-VDD(R)-VVI(R)-AAI(R)-DOO-VOO-AOO-Off 1.3
	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 1.8, 1.9
	Right Atrial Automatic Threshold (RAAT)
	Right Ventricular Automatic Capture (RVAC) 1.15
Rate Adaptive Pacing	Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function 1.16
RV Pacing Reduction	AV Search +, AV Delay to 400 ms, RateHysteresis 1.13
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 1.11, 1.12

Patient Diagnostics

Arrhythmia 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 AVSH+ % successful)
Diagnostics	AT/AF Burden, A & V Arrhythmias, Weight and Blood Pressure*
DAILY TREND for last 365 Days	Events, AT/AF Burden, Heart Rate, 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 Sterox, FINELINE™II Sterox EZ and INGEVITY™ Pacing Lead Models
MRI Conditions	Full body scan at 1.5T (≤SAR 2W/Kg) for all FINELINE™II models* 1.17
	Full body scan at 3T and 1.5T (≤SAR 4W/Kg) for all INGEVITYTM MRI models*
MRI Mode	Pacing Mode: AOO,VOO,DOO,Off
	Protection Time Out: Off, 12,24,48 hours

*Please refer to the Pacing System MRI Technical Guide as the system is designated as MR Conditional in accordance with specified conditions.

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) 1.4
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

*LATITUDE™ NXT is not available for L100 and L101 models

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. 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).

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REFERENCE GUIDE

ACCOLADE™
ACCOLADE™ MRI
PROPONENT™
PROPONENT™ MRI
ESSENTIO™
ESSENTIO™ MRI
ALTRUA™ 2
FORMIO™
FORMIO™ MRI
VITALIO™
VITALIO™ MRI
INGENIO™
INGENIO™ MRI
ADVANTIO™

PACEMAKER

Model L300, L301, L321, L310, L311, L331, L200, L201, L221, L210, L211, L231, L100, L101, L121, L110, L111, L131, S701, S702, S722, K278, K279, K272, K273, K274, K275, K276, K277, K172, K173, K174, K175, K176, K177, K062, K063, K064

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

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PROGRAMMABLE OPTIONS

APPENDIX A

Table A–1. ZIP Telemetry settings

Parameter	Programmable Values	Nominal[a]
Communication Mode	Enable use of ZIP telemetry (May require limited use of wand); Use wand for all telemetry	Enable use of ZIP telemetry (May require limited use of wand)

a. If the Communication Mode is selected via the Utilities button on the PRM Startup screen, the Nominal setting within the ZOOMVIEW Programmer software application will correspond to the value chosen on the Startup screen.

Table A–2. Device Mode

Parameter	Programmable Values	Nominal
Device Mode	Exit Storage; Enable Electrocautery Protection; Enable MRI Protection[a]	Storage

a. Available in models with the MRI Protection Mode feature.

Table A–3. Pacing therapy parameters (specified into a 750 Ω load)

Parameter	Programmable Values	Nominal
Mode[a c]	DDD(R); DDI(R); DOO; VDD(R); VVI(R); VOO; AAI(R); AOO; Off; Temporary: DDD; DDI; DOO; VDD; VVI; VOO; AAI; AOO; Off	Dual Chamber: DDD; Single Chamber: VVI
Lower Rate Limit (LRL)[a b c] (ppm)	30; 35; ...; 185	60 (Tolerance ± 5 ms)
Maximum Tracking Rate (MTR)[a c] (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Maximum Sensor Rate (MSR)[e] (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Pulse Amplitude[a c d i] (dual chamber, atrium) (V)	Auto; 0.1; 0.2; ...; 3.5; 4.0; ...; 5.0; Temporary: 0.1; 0.2; ...; 3.5; 4.0; ...; 5.0	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude[a c d] (dual chamber, right ventricle) (V)	Auto; 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5; Temporary: 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude[a c d] (single chamber) (V)	Auto; 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5; Temporary: 0.1; 0.2; ...; 3.5; 4.0; ...; 7.5	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude Daily Trend[f] (independently programmable in each chamber that has the Pacesafe feature)	Disabled; Enabled	Enabled (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) Disabled (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)
Pulse Width[a c d g] (atrium, right ventricle) (ms)	0.1; 0.2; ...; 2.0	0.4 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Accelerometer[e]	On; Passive	Passive
Accelerometer Activity Threshold	Very Low; Low; Medium Low; Medium; Medium High; High; Very High	Medium
Accelerometer Reaction Time (sec)	10; 20; ...; 50	30
Accelerometer Response Factor	1; 2; ...; 16	8
Accelerometer Recovery Time (min)	2; 3; ...; 16	2
Minute Ventilation[e]	On; Passive; Off	Passive

Table A–3. Pacing therapy parameters (specified into a 750 Ω load) (continued)

Parameter	Programmable Values	Nominal
Minute Ventilation Response Factor	1; 2; ...; 16	8
Minute Ventilation Fitness Level	Sedentary; Active; Athletic; Endurance Sports	Active
Patient's Age[h]	≤ 5; 6–10; 11–15; ...; 91–95; ≥ 96	56–60
Patient's Gender[h]	Male; Female	Male
Ventilatory Threshold (ppm)	30; 35; ...; 185	120 (Tolerance ± 5 ms)
Ventilatory Threshold Response (%)	Off; 85; 70; 55	70
Rate Hysteresis Hysteresis Offset[e] (ppm)	-80; -75; ...; -5; Off	Off (Tolerance ± 5 ms)
Rate Hysteresis Search Hysteresis[e] (cycles)	Off; 256; 512; 1024; 2048; 4096	Off (Tolerance ± 1 cycle)
Rate Smoothing (Up, Down)[e] (%)	Off; 3; 6; 9; 12; 15; 18; 21; 25	Off (Tolerance ± 1%)
Rate Smoothing Maximum Pacing Rate (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Sudden Brady Response (SBR)[e]	Off; On	Off
SBR Atrial Paces Before Therapy	1; 2; ...; 8	3
SBR Atrial Pacing Rate Increase (ppm)	5; 10; ...; 40	20
SBR Therapy Duration (min)	1; 2; ...; 15	2
SBR Inhibit During Rest	Off; On	On
Atrial Pace/Sense Configuration[a c] (dual chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar; Unipolar/Off; Bipolar/Off	Bipolar 1.11, 1.12
Right Ventricle Pace/Sense Configuration[a c] (dual chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar	Bipolar
Pace/Sense Configuration[a c] (single chamber)	Unipolar; Bipolar; Bipolar/Unipolar; Unipolar/Bipolar	Bipolar
Safety Switch (independently programmable in each chamber)	Off; On	On
Automatic Lead Recognition	Off; On	On
Maximum Paced AV Delay[a c] (ms)	30; 40; ...; 400	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay[a c] (ms)	30; 40; ...; 400	80 (Tolerance ± 5 ms)
Maximum Sensed AV Delay[a c] (ms)	30; 40; ...; 400 1.10	150 (Tolerance ± 5 ms)
Minimum Sensed AV Delay[a c] (ms)	30; 40; ...; 400	65 (Tolerance ± 5 ms)
AV Search +[e]	Off; On	Off
AV Search + Search AV Delay (ms)	30; 40; ...; 400	300 (Tolerance ± 5 ms)
AV Search + Search Interval (cycles)	32; 64; 128; 256; 512; 1024	32 (Tolerance ± 1 cycle)
RYTHMIQ[e]	AAI(R) with VVI Backup; Off	Off
Maximum A-Refractory (PVARP)[a c] (dual chamber) (ms)	150; 160; ...; 500	280 (Tolerance ± 5 ms)
Minimum A-Refractory (PVARP)[a c] (dual chamber) (ms)	150; 160; ...; 500	240 (Tolerance ± 5 ms)
Maximum V-Refractory (VRP)[a c] (dual chamber) (ms)	150; 160; ...; 500	250 (Tolerance ± 5 ms)

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Table A–6. Ventricular Tachy EGM Storage

Parameter	Programmable Values	Nominal
Tachy EGM Storage (single chamber models)	Off; On	On
Ventricular Tachy EGM Storage (dual chamber models)	Off; On	On
Tachy Detection Rate[a] (single chamber models) (bpm)	90; 95; ...; 210; 220	160 (Tolerance ± 5 ms)
VT Detection Rate[b] (dual chamber models) (bpm)	90; 95; ...; 210; 220	160 (Tolerance ± 5 ms)

a. The Tachy Detection Rate must ≥ 5 bpm higher than the Maximum Sensor Rate and the Maximum Pacing Rate, and must be ≥ 15 bpm higher than the Lower Rate Limit.
b. The VT Detection Rate must be ≥ 5 bpm higher than the Maximum Tracking Rate, Maximum Sensor Rate, and the Maximum Pacing Rate, and must be ≥ 15 bpm higher than the Lower Rate Limit.

Table A–7. Atrial Tachy Parameters

Parameter	Programmable Values	Nominal
ATR Mode Switch[a]	Off; On	On
ATR Trigger Rate[a] [c] (bpm)	100; 110; ...; 300	170 (Tolerance ± 5 ms)
ATR Duration[a] (cycles)	0; 8; 16; 32; 64; 128; 256; 512; 1024; 2048	8 (Tolerance ± 1 cardiac cycle)
ATR Entry Count[a] (cycles)	1; 2; ...; 8	8
ATR Exit Count[a] (cycles)	1; 2; ...; 8	8
ATR Fallback Mode [d]	VDI; DDI; VDIR; DDIR	DDI
ATR Fallback Time[a] (min:sec)	00:00; 00:15; 00:30; 00:45; 01:00; 01:15; 01:30; 01:45; 02:00	00:30
ATR Fallback LRL[a] (ppm)	30; 35; ...; 185	70 (Tolerance ± 5 ms)
ATR Ventricular Rate Regulation (VRR)[a]	Off; On	On
ATR Maximum Pacing Rate (MPR)[a] (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)
Atrial Flutter Response[b]	Off; On	On
Atrial Flutter Response Trigger Rate [c] (bpm)	100; 110; ...; 300	170 (Tolerance ± 5 ms)
PMT Termination [b]	Off; On	On
Ventricular Rate Regulation (VRR) [b]	Off; On	Off
VRR Maximum Pacing Rate (MPR) (ppm)	50; 55; ...; 185	130 (Tolerance ± 5 ms)

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
b. This parameter gets disabled during Temporary Brady.
c. ATR Trigger Rate and Atrial Flutter Response Trigger Rate are linked. If either of these rates is reprogrammed, the other will automatically change to the same value.
d. If Normal Brady ATR Fallback Mode is DDIR or DDI, then Temporary Brady ATR Fallback Mode is DDI. If Normal Brady ATR Fallback Mode is VDIR or VDI, then Temporary Brady ATR Fallback Mode is VDI.

Table A–8. Sensitivity

Parameter[a] [b] [c]	Programmable Values	Nominal
Sensing Method[d]	AGC; Fixed	Fixed
Atrial Sensitivity (AGC) (mV)	AGC 0.15; AGC 0.2; AGC 0.25; AGC 0.3; AGC 0.4; ...; AGC 1.0; AGC 1.5 1.8	AGC 0.25

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Table A–8. Sensitivity (continued)

Parameter[a] [b] [c]	Programmable Values	Nominal
Right Ventricular Sensitivity (AGC) (mV)	AGC 0.15; AGC 0.2; AGC 0.25; AGC 0.3; AGC 0.4; ...; AGC 1.0; AGC 1.5 1.9	AGC 0.6
Atrial Sensitivity (Fixed) (mV)	Fixed 0.15; Fixed 0.25; Fixed 0.5; Fixed 0.75; Fixed 1.0; Fixed 1.5; ...; Fixed 8.0; Fixed 9.0; Fixed 10.0 1.8	Fixed 0.75
Right Ventricular Sensitivity (Fixed) (mV)	Fixed 0.25; Fixed 0.5; Fixed 0.75; Fixed 1.0; Fixed 1.5; ...; Fixed 8.0; Fixed 9.0; Fixed 10.0	Fixed 2.5 1.9

a. Separately programmable for Temporary Brady.
b. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
c. In single-chamber models, the chamber chosen determines the nominal value.
d. The programmed value for Sensing Method determines the applicable values (AGC or Fixed) in each chamber.

Table A–9. Daily Lead Measurements

Parameter	Programmable Values	Nominal
Atrial Intrinsic Amplitude	On; Off	On
Ventricular Intrinsic Amplitude	On; Off	On
Intrinsic Amplitude (single-chamber models)	On; Off	On
Atrial Pace Impedance	On; Off	On
Ventricular Pace Impedance	On; Off	On
Pace Impedance (single-chamber models)	On; Off	On
Atrial Low Impedance Limit (Ω)	200; 250; ...; 500	200
Atrial High Impedance Limit (Ω)	2000; 2250;...; 3000 (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) 2000; 2250; 2500 (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)	2000
Ventricular Low Impedance Limit (Ω)	200; 250; ...; 500	200
Ventricular High Impedance Limit (Ω)	2000; 2250;...; 3000 (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) 2000; 2250; 2500 (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)	2000
Low Impedance Limit (Ω) (single-chamber models)	200; 250; ...; 500	200
High Impedance Limit (Ω) (single-chamber models)	2000; 2250;...; 3000 (ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 devices) 2000; 2250; 2500 (FORMIO, VITALIO, INGENIO, and ADVANTIO devices)	2000
Post-Operative System Test (POST) (hours)	Off; 2; 3; ...; 24	4

PACING THERAPIES

WARNING: During MRI Protection Mode, if Brady Mode is programmed to Off, Bradycardia therapy is suspended. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only program Brady Mode to Off during MRI Protection Mode if the patient is judged to be clinically capable of tolerating no Bradycardia therapy (including pacing-dependence or need for overdrive pacing) for the entire duration in which the pulse generator is in MRI Protection Mode.

The bradycardia pacing function is independent of the tachycardia detection function of the device, with the exception of interval-to-interval sensing.

Single and dual-chamber pacemakers provide atrial and/or ventricular sensing and pacing, including adaptive-rate modes. 1.1

The pulse generator provides the following types of therapies:

Normal Bradycardia Pacing

- If the intrinsic heart rate falls below the programmed pacing rate (i.e., LRL), the device delivers pacing pulses at the programmed settings. 1.2
- Adaptive-rate pacing allows the pulse generator to adapt the pacing rate to the patient's changing activity levels and/or physiologic needs. 1.1

Additional Options

- Temporary Bradycardia Pacing—allows the clinician to examine alternate therapies while maintaining the previously programmed normal pacing settings in the pulse generator memory ("Temporary Brady Pacing" on page 2-26).
- STAT PACE—initiates emergency ventricular pacing at high output settings when commanded via the PRM using telemetry communication ("STAT PACE" on page 1-17).
- Electrocautery Protection—provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer ("Electrocautery Protection Mode" on page 2-3).
- MRI Protection—modifies certain pulse generator functions in order to mitigate risks associated with exposing the pacing system to the MRI environment ("MRI Protection Mode" on page 2-3).

DEVICE MODES

Once the pulse generator has been programmed out of Storage Mode, the following device modes are available:

- Brady Therapy Enabled—indicates that the pulse generator is providing normal pacing therapy. This mode is not selectable; it is set automatically so long as Brady Mode is programmed to anything except Off.
- Brady Therapy Off—indicates that the pulse generator is not providing any therapy. This mode is not selectable; it is set automatically when the Brady Mode is programmed to Off.
- Electrocautery Protection Mode—provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer. This mode is enabled via the Device Mode button.

The following scenarios will trigger the Check Atrial Lead alert:

- Threshold > Programmed Amplitude will be displayed if RAAT is in Daily Trend mode and the ambulatory test results of the last 4 consecutive days exceed the manually programmed fixed output.
- Automatic Threshold Suspension will be displayed if no successful tests are performed for 4 consecutive days in Auto or Daily Trend mode.

Table 2–1. Threshold Test Codes

Code	Reason
N/R: device telem.	Telemetry started during an ambulatory test
N/R: comm. lost	Telemetry was lost during a commanded test
N/R: no capture	Capture was not obtained at the starting amplitude for a commanded test or capture is > 4.0 V for an ambulatory test
N/R: mode switch	ATR mode switch either started or stopped
N/R: fusion events	Too many consecutive or too many total fusion events occurred
No data collected	Minimum pacing amplitude was reached without losing capture for an ambulatory test, or neither Auto nor Daily Trend is turned on to obtain an ambulatory result
N/R: battery low	Test was skipped due to Battery Capacity Depleted
N/R: noise	Too many consecutive sense channel noise or Evoked Response noise cycles occurred
N/R: incompat. mode	Incompatible Brady mode was present (e.g. VDI Fallback Mode, Magnet Mode) or a Lead Safety Switch occurred
N/R: rate too high	Rate was too high at the start of the test, a rate increase would raise the rate too high or more than 2 rate increases were required
N/R: user cancelled	Commanded test was stopped by the user
N/R: intrinsic beats	Too many cardiac cycles occurred during the test
N/R: test delayed	Test was delayed due to telemetry being active, VT episode already in progress, Electrocautery mode, MRI Protection Mode, or RAAT was turned on while the device remained in Storage mode
N/R: respiration	Respiratory artifact was too high
N/R: low ER	The Evoked Response signal could not be assessed adequately
Auto N/R	Minimum pacing amplitude was reached without losing capture for a commanded test, or telemetry is manually cancelled during a commanded test
Invalid Failure Code	Unexpected Failure

PaceSafe Right Ventricular Automatic Capture (RVAC)

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

1.15

PaceSafe RVAC is designed to dynamically adjust the right ventricular pacing output to ensure capture of the ventricle by optimizing the output voltage to 0.5 V above the capture threshold. RVAC maintains this output while confirming capture on a beat-to-beat basis. RVAC will measure pacing thresholds between 0.2 V and 3.0 V at 0.4 ms, and the output will be a minimum of 0.7 V and a maximum of 3.5 V with a fixed pulse width of 0.4 ms.

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NOTE: *RVAC is intended for ventricular use only. It is not intended to be used with Amplitude programmed to Auto for single-chamber devices implanted in the atrium.*

NOTE: *RVAC is available in DDD(R), DDI(R), VDD(R), and VVI(R) modes, as well as during VDI(R) and DDI(R) Fallback Modes.*

RVAC can be programmed on by selecting Auto from the Ventricular Amplitude parameter options. If starting from a fixed amplitude greater than 3.5 V, program a fixed amplitude of 3.5 V prior to selecting Auto. Programming the ventricular output to Auto will automatically adjust the Pulse Width to 0.4 ms and set the ventricular voltage output to an initial value of 5.0 V unless there is a successful test result within the last 24 hours.

RVAC must first successfully measure the ventricular threshold before it will enter its beat-to-beat capture verification mode. This measurement can be made through a commanded test, or it will be performed automatically within one hour after the programming session is completed. Both methods are described below.

NOTE: *Prior to programming RVAC on, consider performing a Commanded Ventricular Automatic Capture Measurement to verify that the feature functions as expected.*

RVAC is designed to work with typical lead implant criteria and a ventricular threshold between 0.2 V and 3.0 V at 0.4 ms.

The RVAC algorithm then measures the ventricular pacing threshold each day and adjusts the voltage output. During testing and on a beat-to-beat basis, RVAC uses an evoked response signal to confirm that each ventricular pacing output captures the ventricle.

If any loss of capture occurs during beat-to-beat operation, then the pulse generator will deliver a backup pacing output within approximately 70 ms of the primary pulse. The backup safety pulse amplitude will be a minimum of 3.5 V and a maximum of 5.0 V. If there is a Confirmed Loss of Capture (C-LOC; 2 out of 4 cardiac cycles do not capture the ventricle), RVAC will enter Suspension and a test re-attempt will occur at the next hourly interval. 1.15

When Daily Trend is selected along with a fixed Amplitude, ambulatory ventricular automatic capture measurements will occur every 21 hours with no change to programmed output.

The RVAC feature is designed to operate with a large range of pacing leads (high impedance, low impedance, tined fixation, or positive fixation). Also, RVAC is independent of pacing and sensing lead polarity; the Ventricular Pace and Sense Lead Configurations can be programmed to Unipolar or Bipolar.

For information about resumption of RVAC after exit from MRI Protection Mode, refer to the MRI Technical Guide.

Ambulatory Ventricular Automatic Capture Measurement 1.15

When RVAC is set to Auto or Daily Trend, ambulatory ventricular automatic capture measurements are conducted every 21 hours, or when loss of capture is detected while in beat-to-beat mode, up to hourly until the next daily measurement.

In atrial tracking modes, the automatic capture measurement adjusts the following parameters to help ensure a valid measurement is obtained:

- Paced AV Delay is fixed at 60 ms.

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5. When a patient's heart rate is within the desired range for the activity performed, select Program.

NOTE: *Sensor Trending results may be printed via the Reports tab. Both the Present (currently programmed) and Replay (clinician adjusted) parameters are provided in addition to the current graph as represented on the programmer screen.*

NOTE: *Sensor adjustments should not be based on data which is collected during the MV calibration time period.*

ATRIAL TACHY RESPONSE

ATR Mode Switch

This feature is available in ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO devices.

ATR is designed to limit the amount of time that the ventricular paced rate is at the MTR or exhibits upper-rate behavior (2:1 block or Wenckebach) in response to a pathological atrial arrhythmia.

In the presence of detected atrial activity that exceeds the ATR Trigger Rate, the pulse generator switches the pacing mode from a tracking mode to a nontracking mode as follows:

- From DDD(R) to DDI(R) or VDI(R)
- From VDD(R) to VDI(R)

An example of ATR behavior is shown (Figure 2–36 ATR behavior on page 2-52).

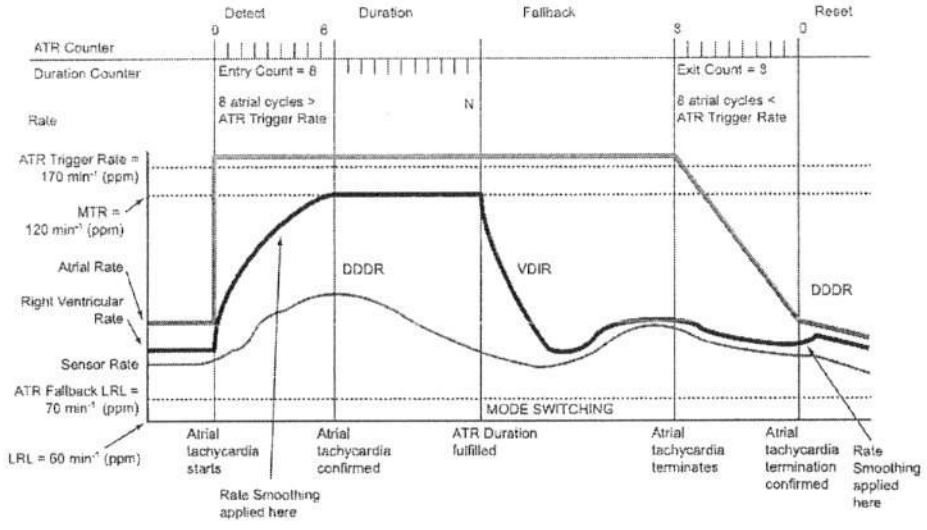


Figure 2–36. ATR behavior

NOTE: *Parameter settings that reduce the atrial sensing window may inhibit ATR therapy.*

Fallback Mode

Fallback Mode is the nontracking pacing mode that the pulse generator automatically switches to when ATR Duration is fulfilled.

1.14

After switching modes, the pulse generator gradually decreases the ventricular paced rate. This decrease is controlled by the Fallback Time parameter.

NOTE: *Dual-chamber pacing fallback mode values are only available when the Normal pacing mode is also set to dual-chamber.*

NOTE: *ATR Fallback mode may be programmed rate responsive even if the permanent brady mode is non-rate responsive. In this scenario, the sensor parameters will indicate "ATR Only".*

Fallback Time

Fallback Time controls how quickly the paced rate will decrease from the MTR to the ATR Fallback LRL during fallback. The paced rate will decrease to the highest of the sensor-indicated rate, VRR rate, or the ATR Fallback LRL.

During fallback, the following features are disabled:

- Rate Smoothing—disabled until fallback reaches the ATR Fallback LRL or the sensor-indicated rate. If VRR is enabled, then Rate Smoothing is disabled throughout the mode switch
- Rate Hysteresis
- AV Search +
- PVARP Extension

Fallback LRL

The ATR Fallback LRL is the programmed lower rate to which the rate decreases during mode switching. The ATR Fallback LRL may be programmed higher or lower than the permanent brady LRL.

The rate will decrease to the highest among the sensor-indicated rate (when applicable), the VRR rate (if enabled), and the ATR Fallback LRL.

End of ATR Episode

The End of ATR Episode identifies the point when the pulse generator reverts to AV-synchronous operation because the atrial arrhythmia is no longer detected.

With the termination of the arrhythmia, the ATR Exit Count decrements from its programmed value until it reaches 0. When the ATR Exit Count reaches 0, the pacing mode automatically switches to the programmed tracking mode, and AV-synchronous operation is restored.

NOTE: *If RYTHMIQ is enabled, the pacing mode automatically switches back to the mode that was present prior to the ATR mode switch [AAI(R) or DDD(R) mode].*

Ventricular Rate Regulation (VRR)

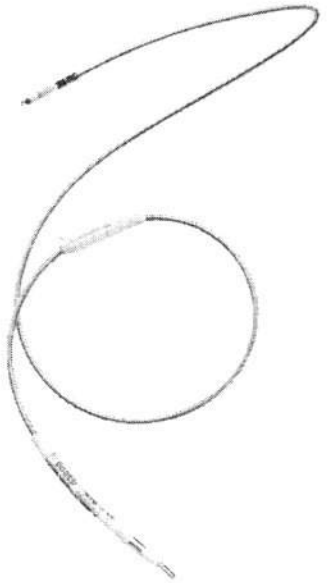
This feature is available in ACCOLADE, PROPONENT, FORMIO, VITALIO, and INGENIO devices.

สายกระตุ้นหัวใจชนิดถาวร (Pacemaker lead)

Boston Scientific
Advancing science for life™

INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842



The INGEVITY+ pacing leads are 6F (2.0 mm) steroid-eluting, endocardial pace/sense leads designed for permanent implantation for either atrial or ventricular applications.

INGEVITY+ is built on the proven INGEVITY platform, with nearly 700,000 INGEVITY leads sold worldwide with a 99.2% reliability at 7 years.[1]

INGEVITY+ is specifically designed with three layers of insulation between conductors and a polyurethane lead body. The tri-filar inner coil design provides consistent, low, and repeatable turn counts when extending and retracting the helix[2].

These leads utilize an IS-1 bipolar connector. The tip features a flexible neck design and incorporates an IROX™ (iridium oxide) coating on the tip electrode.

Lead Specifications and Reimbursement Information

Product	INGEVITY+ Pacing Lead
Model/Length	7840 / 45 cm 7841 / 52 cm 7842 / 59 cm } 2.5
Type	Bipolar Atrial / Ventricular Straight
Connector	IS-1 BI 2.4, 2.3
Compatibility	Pulse generators with an IS-1 port, which accepts an IS-1 terminal
MRI Conditions of Use*	ImageReady™ MR-Conditional System when used with an MR-Conditional pulse generator - Full body scan 1.5T and 3T 2.7
Introducer without guide wire	6F (2.0 mm) 2.6
Introducer with guide wire	9F (3.0 mm)
Fixation	Extendable/retractable helix
Expected number of rotations to fully extend/retract the helix**	6 ± 2 turns with straight stylet 7 ± 3 turns with J stylet
Recommended maximum number of turns to extend/retract the helix**	30
Nominal fixation helix penetration depth	1.8 mm

[1] Q3 2019 Boston Scientific Corporation Product Performance Report
Internal data on file
* Refer to the MRI Technical Guide for a complete list of cardiology and radiology conditions of use
** Use fluoroscopy markers for verification of full extension/retraction of the helix. The number of turns to extend or retract the helix may vary based on patient anatomy and implant conditions

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INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

Lead Specifications and Reimbursement Information *(continued)*

Product	INGEVITY+ Pacing Lead
Nominal Electrode:	
Fixation helix surface area	4.5 mm^2
Distance between electrodes	10.7 mm
Anode electrode surface area	20 mm^2
Nominal Diameter:	
Insertion	2.0 mm (6 F)
Anode electrode	2.0 mm
Lead body	1.9 mm
Fixation helix	1.2 mm
Material:	
External insulation	Polyurethane (55 D)
Internal insulation	Silicone rubber
Terminal ring contact	316 L stainless steel
IS-1 terminal pin contact	316L stainless steel
Tip electrode	IROX™ (iridium oxide) coated Pt-Ir
Anode electrode	IROX (iridium oxide) coated Pt-Ir
Conductor Type	Tri-filar inner coil of MP35N™ and single-filar outer coil of MP35N with a silver core.[1]
Steroid	0.91 mg dexamethasone acetate 2.1
Radiopaque Markers	Pt-Ir
Suture Sleeve	Radiopaque white silicone rubber
C-code	1898

[1]MP35N is a trademark of SPS Technologies, Inc.

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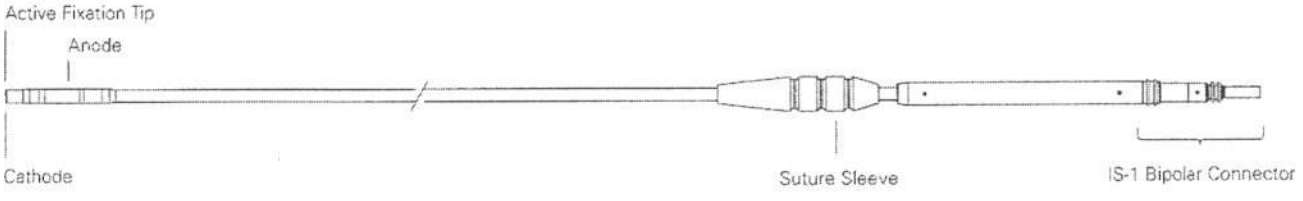
INGEVITY™+ Pacing Lead

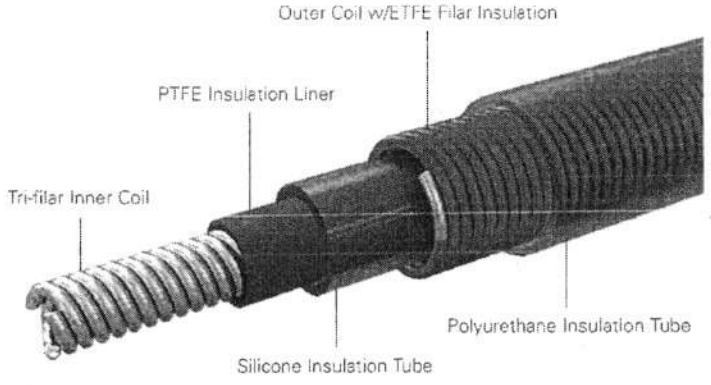
Active Fixation Models: 7840, 7841, 7842

Features

Lifetime Warranty: The INGEVITY+ pacing lead family is backed with a lifetime warranty.*

Lead Body Design: The isodiametric lead body consists of a coaxial design that includes a tri-filar inner coil and a single-filar outer coil. Both the inner and outer coils are designed for MR Conditional use in the MRI environment and provide robust flexural fatigue performance. In addition, the tri-filar inner coil provides consistent helix deployment performance. The conductors are separated by both a silicone rubber and Polytetrafluoroethylene (PTFE) lining. The outer coil is covered in Ethylene tetrafluoroethylene (ETFE) for extra insulation protection. The entire lead body is encompassed in a polyurethane outer insulation.





IROX™-coated Electrodes: The electrodes are coated with IROX to increase the microscopic surface area.

Steroid-eluting: Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at the distal electrode. The steroid suppresses the inflammatory response believed to cause threshold rises typically associated with implanted pacing electrodes.

Radiopaque Suture Sleeve: The radiopaque suture sleeve is visible under fluoroscopy and is used to secure, immobilize, and protect the lead at the venous entry site after lead placement. The window feature is designed to aid compression of the sleeve onto the lead during suturing.

*Limited lifetime warranty. For a full and complete description of the INGEVITY™+ warranty, please review the warranty card included with the product labeling.

2.1

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INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

Active Fixation Features 2.3

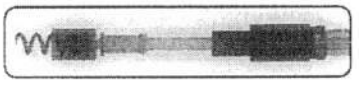
Extendable / Retractable Fixation: The extendable/retractable helix design anchors the distal tip electrode to the endocardial surface without support of trabecular structures, offering various lead placement possibilities for the tip electrode in the right atrium and/or right ventricle. The helix serves as the cathode for endocardial pacing and sensing. The lead is designed with a tri-filar inner coil for consistent and repeatable turn counts when extending and retracting the helix. The helix is extended and retracted using the fixation tool. 2.2

Mapping: The lead helix is electrically conductive to allow mapping (measuring pacing and sensing thresholds) of potential electrode positions without extending the helix into the tissue. Mapping prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

Fluoroscopic Markers: radiopaque markers near the distal tip can be seen under fluoroscopy. These markers show when the helix is fully retracted or fully extended.

Fully Retracted

Fully Extended



Packaged Accessories

- Vein Pick
- Fixation Tool
- Stylet Guide
- Stylets:

	Pre-loaded	Packaged
7840	45cm soft, long tapered	45cm soft, long tapered 45cm extra soft, tapered 45cm soft, atrial J 45cm soft, wide atrial J
7841	52cm soft, long tapered	52cm soft, long tapered 52cm extra soft, tapered 52cm soft, atrial J 52cm soft, wide atrial J
7842	59cm soft, long tapered	59cm soft, long tapered 59cm extra soft, tapered

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INGEVITY™ + and INGEVITY™ MRI Extendable/Retractable Fixation and Tined Fixation Pacing Leads

INDICATIONS

2.9

This Boston Scientific lead is indicated for use as follows:

- Intended for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator (INGEVITY+ and INGEVITY MRI extendable/retractable fixation)
- Intended for chronic pacing and sensing in the right atrium (Preformed Atrial J) or right ventricle (Straight) when used with a compatible pulse generator (INGEVITY MRI tined fixation)

CONTRAINDICATIONS

Use of these leads are contraindicated for the following patients:

- Patients with a hypersensitivity to a nominal single dose of 0.91mg dexamethasone acetate (for INGEVITY+ and INGEVITY MRI extendable retractable fixation)
- Patients with a hypersensitivity to a nominal single dose of 0.61mg dexamethasone (for INGEVITY MRI tined fixation)
- Patients with mechanical tricuspid heart valves

WARNINGS

Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads. Implant of the system cannot be performed in an MRI site Zone (III and higher). Take care to obtain appropriate electrode position. Failure to do so may result in suboptimal lead measurements. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements of the implanted system. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as a complete list of MRI related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.
For INGEVITY+ and INGEVITY MRI extendable/retractable fixation: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow-up testing.

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 products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; 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; Hemorrhage; Hemothorax; Inability to pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Pulse generator and/or lead migration; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboembolic; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion)

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady™ MR Conditional Pacing System or Defibrillation System MRI Technical Guide.
92436283 (Rev B)

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.

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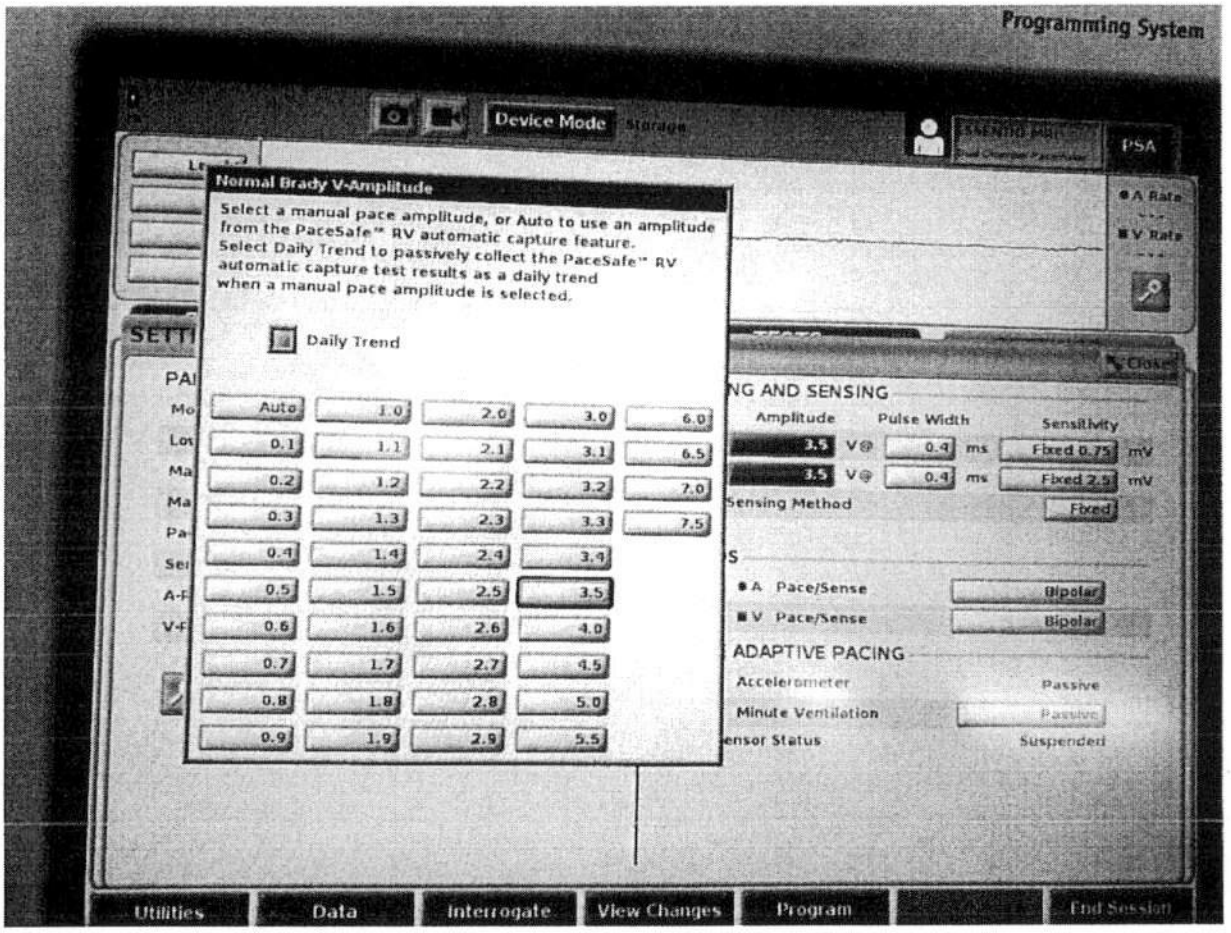

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