RESONATE™ X4 CRT-D
Model G447

- HeartLogic™ Heart Failure Diagnostic for detecting indications of worsening heart failure status.
- SmartCRT™ is Boston Scientific's approach to personalize CRT therapy by providing physicians with smart solutions to optimize where, when, and how to pace.
- EnduraLife™ Battery Technology provides more power to use more of the device, featuring up to 13.3 years projected longevity with MultiSite Pacing turned on.*
- ImageReady™ MR Conditional Systems allow patients to safely undergo 1.5T Full Body MRI scans.**

* Assumes: 2.0V RA, LV-only, 700 Ω, 15% A pacing, 100% LV pacing, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

** When conditions of use are met.

### 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-Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>G447</td>
<td>X4 CRT-D</td>
<td>5.37 x 8.18 x 0.99</td>
<td>73.8</td>
<td>32.5</td>
<td>RA: IS-1; RV: DF4; LV: IS4</td>
<td>C1882</td>
</tr>
</tbody>
</table>

### Pulse Generator Life Expectancy Estimation (Implant to Explant) with EnduraLife Battery (All Models)

EnduraLife Battery Technology provides clinically-proven, industry-leading projected longevity. The following tables represent sample pulse generator life expectancy estimation (implant to explant) with EnduraLife battery as provided in product labeling. For specific programmable parameter ranges, refer to product labeling at [www.bostonscientific-elabeling.com](http://www.bostonscientific-elabeling.com), or contact Boston Scientific technical services or your local representative.

<table>
<thead>
<tr>
<th>Projected longevity</th>
<th>Ventricular Chambers</th>
<th>RA/RV</th>
<th>LV</th>
<th>LVb</th>
<th>500Ω with LATITUDE™</th>
<th>700Ω with LATITUDE™</th>
<th>700Ω no LATITUDE™, RS, or HFSS™</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Typical programmed setting</td>
<td>BiV</td>
<td>2.5 V</td>
<td>3.0 V</td>
<td>Off</td>
<td>9.7</td>
<td>10.5</td>
<td>11.3</td>
</tr>
<tr>
<td>Maximum labeled longevity</td>
<td>LV-Only</td>
<td>2.0 V / Off</td>
<td>2.0 V</td>
<td>Off</td>
<td>12.9</td>
<td>13.2</td>
<td>14.7</td>
</tr>
<tr>
<td>Typical programmed setting</td>
<td>BiV MSP</td>
<td>2.5 V</td>
<td>3.0 V</td>
<td>3.0 V</td>
<td>8.2</td>
<td>9.1</td>
<td>9.7</td>
</tr>
<tr>
<td>Maximum labeled longevity</td>
<td>LV-Only MSP</td>
<td>2.0 V / Off</td>
<td>2.0 V</td>
<td>2.0 V</td>
<td>11.5</td>
<td>12.1</td>
<td>13.3</td>
</tr>
</tbody>
</table>

• Assumes 70 PPM LRL; DDDR mode; 0.4 ms Pulse Width (RA, RV, LV); sensors On, Heart Failure Sensor Suite On.
• Projected longevity is calculated assuming 2 maximum energy charging cycles per year, including automatic capacitor re-forms and therapeutic shocks. These calculations also assume 3-channel EGM Onset is on and that the pulse generator spends 3 months in Storage mode during shipping and storage.

a. Assumes ZIP telemetry use for 2 hours at implant and for 40 minutes annually for in-clinic follow-up checks.
b. Assumes standard use of the LATITUDE™ Communicator as follows: Daily Device Check on, quarterly scheduled remote follow ups, and other typical interrogations.
c. Assumes LATITUDE™ Communicator is not used, Respiratory Sensor is Off, and Heart Failure Sensor Suite is Off.
d. Applies to models with MultiSite Pacing (MSP).

### Additional Longevity Information

- Boston Scientific devices have corporate warranties at 6 years in available geographies.
- Devices use Li/MnO₂ chemistry.
- The Usable Battery Capacity is 1.9 Amp-hours (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by date).
Pacing Therapy

Brady Modes
Normal: DDD(R), DDDR(R), VOO(R), VVIR(R), AAI(R), VVI(R), DOO(R), DDIR, DDD, VDD, VOO, VVI, AAI, AOO, OFF

AT/AF Management
ATR Mode Switch, Ventricular Rate Regulation (VRR) - MIN, MED, MAX, Atrial Flutter Response (AFR), PMT, Termination, Rate Smoothing

Automaticity
PaceSafe Right Ventricular Automatic Threshold (RVAT), PaceSafe Left Ventricular Automatic Threshold (LVAT), PaceSafe Right Atrium Automatic Threshold (RAAT)

Rate Adaptive Pacing
Accelerometer with sensor trending function

Heart Failure Therapy

LV Pacing Lead Configuration
LV VectorGuide streamlines the testing required to determine the optimal LV Pacing Lead Configuration for each individual patient, using four tests: RVS-LVS Delay, LV Pace Threshold, Phrenic Nerve Stimulation (PNS), and LV Lead Impedance. Clinician can quickly evaluate multiple Quadripolar LV pacing vectors and then program the desired configuration

Heart Failure Therapy Optimization
SmartDelay® (AV Optimization), BIV Trigger, LV Offset, LV Sensing, BIV or LV-only pacing modalities

VectorGuide
RVS-LVS sense (automatic), PNS, impedance threshold

LV Lead Options
Quadripolar LV lead

LV Pacing Vector Options
17

LV Sensing Vector Options
8 options plus OFF

Patient Diagnostics

AT/AF Diagnostics
Atrial Arrhythmia Report, AT/AF Burden, RV Rate During AT/AF, Percent Pacing

Arrhythmia Logbook
Events Summary, Stored Electrograms with Annotated Markers, (Intervals and approximately 17 minutes of multi-channel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurement of all stored signal amplitudes and timing

Histograms & Counters
Tachy Events and Brady Counters

Daily Trends For Last 365 Days
Events, Lead impedances and amplitudes, RA Pace Threshold, RV Pace Threshold, LV Pace Threshold

Heart Failure Trends and Diagnostics
Heart Failure Management Report, Weight, Blood Pressure, Events, Activity Level, AT/AF Burden, Respiratory Rate, Heart Rate, Heart Rate Variability (SDANN), HRV/Footprint, Thoracic Impedance, Night Heart Rate, Sleep Incline

To note: Weight and Blood Pressure are only available via LATITUDE™.

HeartLogic™ Heart Failure Diagnostic

HeartLogic™ Heart Failure Diagnostic
The HeartLogic Index and Alert are a validated diagnostic tool to detect gradual worsening of heart failure over days or weeks using multiple physiological measurements. The HeartLogic Index aggregates measurements from multiple device-based sensors (Heart Sounds, Thoracic Impedance, Respiration, and Night Heart Rate) and reflects changes over time in the patient’s sensor trend data from their respective baseline values.

HeartLogic™ Heart Failure Management Report
HeartLogic™ composite index and alert, S3 Heart Sound, S1 Heart Sound, Thoracic Impedance, Respiratory Rate, Night Heart Rate, Sleep Incline, Activity Level, AT/AF Burden, V therapy, RV Rate During AT/AF, Mean Heart Rate, % LV Paced, Heart Rate Variability (SDANN), Weight, Blood Pressure

To note: HeartLogic™ composite index and alert, heart sounds, weight, and blood pressure are only available through LATITUDE™.

Tachyarrhythmia Therapy

Sensing/Detection
Zones VF only, or VF and VT or VF, VT, VT-1

Shock Reduction and Appropriate Therapy
AcuShock™ Advanced Technology including Onset/Stability™, RhythmID™ with RhythmMatch™, Dynamic Noise Algorithm (DNA) for sensing, Automatic Gain Control (AGC) with programmable sensing floor, Narrow Band Pass Filter

Antitachycardia Pacing Therapy (ATP) Termination
Quick Convert™ in VF Zone. Two programmable ATP schemes in both VT and VT-1 zones. Burst, Ramp, Scan, Ramp-Scan

Shock Energy
41 J stored, 35 J delivered. First two shocks in each zone programmable. VT-1 has 5 shocks. VT has 6 shocks and VF has 8 shocks. Reverse Last Shock Polarity in zone. Programmable RV Coil to RA Coil and Can (TRIAD), RV Coil to Can, RV Coil to RA Coil (COLD CAN)

Nominals
VF Zone (200 bpm)—Detection: Rate and Duration, Therapy: Quick Convert, 8 high energy shocks
VT Zone (160 bpm) — Detection: Rhythm ID or Onset/Stability, Therapy: ATP x 2, 6 high energy shocks

MultiSite Pacing

LV Multisite Pacing (MSP)
LV MSP is intended to improve the cardiac resynchronization therapy response by delivering two LV pulses per pacing cycle. 17 vectors with 216 possible MSP configurations

SmartVector
Automatically recommends LV MSP pacing sequence, pacing vectors, and pacing characteristics (amplitude and pulse width) based on RVS-LVS delay and electrode separation distance

SmartOffset
Automatically recommends the programmed delays between the ventricular paces. Timing offsets = 0 – 100 ms

ImageReady™ MR Conditional System

MRI Lead Selection
RELIANCE™-4-SITE defibrillation leads - active and passive fixation, single and dual coil, 59 cm, 64 cm and 70 cm
INGEVITY™ and FINELINE™ II pacing leads – active and passive fixation, straight and J, 45 cm, 52 cm, 58 cm, and 59 cm
ACUTITY™ X4 LV Leads - straight, spiral S and spiral L, 86 cm and 95 cm

MRI Conditions
1.5T, SAR 2 W/Kg

MRI Protection Mode
Asynchronous pacing during scan (DOO, VOO, and AOO) Programmable time out: Off, 3, 6, 9, and 12 hours
Device Testing/Induction Methods

Induction Methods
- V9b Induction, Shock on T Induction, Programmed Electrical Stimulation (PES), 50 Hz/Manual Burst Pacing

Commanded Therapy Methods
- Commanded Shock, Commanded ATP

Implant/In Clinic Follow-Up

Implant

Communication Mode
- Programmable values: Enable use of ZIP™ telemetry (MCIS)
- (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
- Wireless ECG

Remote Follow-Up

Patient Triggered Monitor (PTM)
- Triggers the storage of two minutes onset and one minute post-therapy EGMs, intervals, and annotated marker data during a symptomatic episode—by placing a magnet over the device

Deeper Feature
- (Patient Alerts)
- Beyond diaphragmatic charger, beep when explant is indicated, beep when lead impedance measurement (shock or pace) is out-of-range

Magnet Feature
- Magnet Response (Off, Store EGM, Inhibit Therapy)

Remote Monitoring
- This device is designed to be LATITUDE™ enabled; LATITUDE™ 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 (MCIS)

References:
1. Nine independent studies confirm that CRT-Ds powered by Endurac® battery technology offer industry-leading longevity.
2. Haarbo J, Hjortshøj C, Johansen J, Jorgensen D, Nielsen J, Pedersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. PACE 2017; 40:111-117. http://www.cardioonline.com/common/presentation-detail.aspx?id=15/65/241/800. Boston Scientific = 138 patients, Medtronic = 651 patients, St. Jude Medical = 1,987 patients. Bitnien = 368 patients. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint. The four-year survival rate for devices in the Danish Registry study was 81.1% for Medtronic and 95.7% for Boston Scientific. (P<0.01)
7. Provided by Dr. Ernest Lauer on 04/29/15 in support of Lauer E, Wilson C, Aschfeld K, McNair W, McEneny D, Roberts M. Large Capacity Li-SVO Batteries Extended OTTD Longevity in Clinical Use Compared to Smaller Capacity LiSOV Batteries Over 6 Years. Presented at HRS 2015, Medtronic = 62 patients, Boston Scientific = 27 patients, St. Jude = 66 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
10. Von Gunten S, Schaer BA, Okabe T, Yoo JK, Hjortshøj C, Johansen J, Jorgensen D, Nielsen J, Pedersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. PACE 2017; 40:111-117. http://www.cardioonline.com/common/presentation-detail.aspx?id=15/65/241/800. Boston Scientific = 138 patients, Medtronic = 651 patients, St. Jude Medical = 1,987 patients. Bitnien = 368 patients. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint. The four-year survival rate for devices in the Danish Registry study was 81.1% for Medtronic and 95.7% for Boston Scientific. (P<0.01)
11. VS1 Induction, Shock on T Induction, Programmed Electrical Stimulation (PES), 50 Hz/Manual Burst Pacing

COMMANDS AND CLINICAL USAGE

Indications
- Cardiac resynchronization therapy (CRT) devices with a DF4 right ventricular lead connection are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the implant Cardioverter-defibrillator system with the magnet in place can result in potential adverse events applicable when the Conditions of Use are not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator to the conditions of an MRI when the Conditions of Use are not met.

Potentially adverse events
- Magnetic field (2.0 Tesla) exposure may affect the pulse generator's performance. Potential adverse events include, but are not limited to, the following: electromagnetic interference, disturbance of the programmed function, and inhibition of the device's operation.

Precautions
- 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 to the conditions of an MRI when the Conditions of Use are not met.

References:
- CRM-484005-AA   SEP2017