

VIGILANT™ X4 CRT-D

Model G247

- 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, 2.0V LV, 700, 15% A pacing, 100% LV pacing, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

** When conditions of use are met.



HeartLogic™
Heart Failure Diagnostic

SmartCRT™
Technology

ImageReady™
MR-Conditional Systems

EnduraLife™
Battery Technology

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)	C-Code
G247	X4 CRT-D	5.37 x 8.18 x 0.99	73.8	32.5	RA: IS-1; RV: DF4; LV: IS4	C1882

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

EnduraLife Battery Technology provides clinically-proven, industry-leading projected longevity.¹⁻¹⁰ 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, or contact Boston Scientific technical services or your local representative.

Projected longevity ^a	Ventricular Chambers	RA/RV	LV	LVb ^d	500Ω with LATITUDE™ ^b	700Ω with LATITUDE™ ^b	700Ω no LATITUDE™, RS, or HFSS ^c
MultiSite Pacing Off							
Typical programmed setting	BiV	2.5 V	3.0 V	Off	9.7	10.5	11.3
Maximum labeled longevity	LV-Only	2.0 V / Off	2.0 V	Off	12.9	13.2	14.7
MultiSite Pacing On							
Typical programmed setting	BiV MSP	2.5 V	3.0 V	3.0 V	8.2	9.1	9.7
Maximum labeled longevity	LV-Only MSP	2.0 V / Off	2.0 V	2.0 V	11.5	12.1	13.3

- 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.

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

Additional Longevity Information

- Boston Scientific devices have corporate warranties at 6 years in available geographies. Warranty information available at www.bostonscientific.com/warranty.
- 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).

VIGILANT™ X4 CRT-D

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Pacing Therapy

Brady Modes	Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off Temporary: DDD, DDI, DOO, VDD, VVI, VOO, 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	AT/AF Burden, Daily burden, Average V-rate during ATR Mode Switch Episode
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 <i>To note: Weight and Blood Pressure are only available via LATITUDE™.</i>

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, Mean Heart Rate, % LV Paced, Heart Rate Variability (SDANN), Weight, Blood Pressure <i>To note: HeartLogic™ composite index and alert, heart sounds, weight, and blood pressure are only available through LATITUDE™.</i>

Tachyarrhythmia Therapy

Sensing/Detection	Zones VF only, or VF and VT or VF, VT, VT-1 Lowest Zone can be Monitor Only
Shock Reduction and Appropriate Therapy	AcuShock™ Advanced Technology including Onset/Stability™, RhythmID™, 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	Vfib 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 (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)
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Remote Follow-Up

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
Beeper Feature (Patient Alerts)	Beep during capacitor charge, 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 (MICS)

References:

1. Nine independent studies confirm that CRT-Ds powered by EnduraLife Battery Technology offer industry-leading longevity.
2. Haarlo J, Hjortshoj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. Presented at HRS 2014. <http://ondemand.hrsonline.org/common/presentation-detail.aspx/15/35/1241/9000>. Boston Scientific = 136 patients, Medtronic = 651 patients, St. Jude Medical = 1,587 patients, Biotronik = 369 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).
3. J. Williams, R. Stevenson. Contemporary cardiac resynchronization implantable cardioverter defibrillator battery longevity in a community hospital heart failure cohort. Presented at HFSA 2014. [http://www.onlinejcf.com/article/S1071-9164\(14\)00389-3/fulltext](http://www.onlinejcf.com/article/S1071-9164(14)00389-3/fulltext). Boston Scientific = 53 patients, Medtronic = 28 patients, St. Jude Medical = 10 patients. Four-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
4. Ellis CR, Dickerman DI, Orton JM, Hassan S, Good EG, Okabe T, Andruilli JA, Quan KJ, Greenspoon AJ. Ampere Hour as a Predictor of Cardiac Resynchronization Defibrillator Pulse Generator Battery Longevity: A Multicenter Study. PACE 2016 doi: 10.1111/pace.12831 first published online 11-MAR-2016. The five major institutions performing the study include, at Vanderbilt University, Henry Ford Hospital, University of Michigan, Thomas Jefferson University, Cooper Health System, North Ohio Heart Center. Boston Scientific = 322 patients, Medtronic = 794 patients, St. Jude Medical = 186 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
5. Landolina M, Curnis A, Morani G, Vado A, Ammendola E, D'onofrio A, Stabile G, Crostao M, Petracci B, Ceriotti C, Bontempi L, Morosato M, Ballari GP, Gasparini M. Longevity of implant Cardioverter-defibrillators for cardiac resynchronization therapy in current clinical practice: an analysis according to influencing factors, device generation, and manufacturer. Europace 2015; 17:1251-58 doi:10.1093/europace/euv109. First published online: May 14, 2015. Medtronic = 532 patients, Boston Scientific = 291 patients, St. Jude Medical = 106 patients, Biotronik = 20 patients, Sorin = 69. Five-year survival rate of latest marketed devices (between 2006 and 2010) calculated using device replacements for battery depletion as indicated by ERI.
6. Zanon F, Martignani C, Ammendola E, Menardi E, Narducci ML, De Filippo P, Santamaria M, Campana A, Stabile G, Potenza DR, Pastore G, Iori M, La Rosa C, and Biffi M. Device Longevity in a Contemporary Cohort of ICD/CRT-D Patients Undergoing Device Replacement. Doi:10.1111/jce.12990, First published online 20-APR-2016. Comparison of device longevity by Kaplan-Meier curves of CRT-D systems extracted between March 2013 and May 2015. Medtronic = 195 patients, Boston Scientific = 157 patients, St. Jude = 72, Biotronik = 9.
7. Provided by Dr. Ernest Lau on 04/29/15 in support of Lau E, Wilson C, Ashfield K, McNair W, McEneaney D, Roberts M, Large Capacity LiMnO2 Batteries Extended CRTD Longevity in Clinical Use Compared to Smaller Capacity LiSVO 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.
8. Von Gunten S, Schaefer BA, Yap SC, Szili-Torok T, Kühne M, Sticherling C, Osswald S, Theuns DA. Longevity of implantable cardioverter defibrillators: a comparison among manufacturers and over time. Europace. 2015 Nov 25. Epub 2015 Nov 25. Total patients = 3436.
9. Alam MB, Munir MB, Rattan R, Adelstein E, Jain S, Saba S. Battery longevity from cardiac resynchronization therapy defibrillators: differences between manufacturers and discrepancies with published product performance reports. Europace 2016;doi:10.1093/europace/euw044. First published online: 22-MAR-2016. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude Medical = 57 patients. Previously evaluated these patients at a four-year survival rate calculated using device replacements for battery depletion as indicated by ERI. 2014; Europace (2014) 16,246-51.
10. Shabanna Din, Shabanna, Mcgee, Rao, Archana, Wright, Jay D. Longevity of implantable cardioverter defibrillators: The impact of device manufacturer and device type on device longevity were assessed. Europace. 2015 Nov 25; Epub 2015 Nov 25. Total patients = 3436. Cardiac Abstract 2016. Total patients = 1489.

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™ EL, VIGILANT™ EL, MOMENTUM™ EL

INDICATIONS AND USAGE Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning, or patients who have a unipolar pacemaker.

WARNINGS Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or sterilize. 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. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Modes to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, and VIGILANT 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 patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. 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. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

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, and supplemental precautionary information.

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 (shocks/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 B)

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Boston Scientific
Advancing science for life™

Rhythm Management

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