Boston Scientific
Advancing science for life™

# VIGILANT™ EL (Extended Longevity ICD)

## Models D232 and D233


- HeartLogic™ Heart Failure Diagnostic for detecting indications of worsening heart failure status.
- EnduraLife™ Battery Technology provides more power to use more of the device, featuring projected longevity up to 17.5 years for VR devices and 16.0 years for DR devices.*
- ImageReady™ MR Conditional Systems allow patients to safely undergo 1.5T Full Body MRI scans.**

* Assumes: 2.0V RA, 2.0V RV, 0% pacing, 700Ω, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

** When conditions of use are met.

**HeartLogic™** Heart Failure Diagnostic

**EnduraLife™** Battery Technology

**ImageReady™** MR-Conditional Systems

### Mechanical Specifications

| Model | Type | Size (cm) (W x H x D) | Mass (g) | Volume (cc) | Connector Type (RA RV LV) | C-Codes |
|---|---|---|---|---|---|---|
| **D232** | VR | 5.37 x 7.36 x 0.99 | 68.9 | 29.5 | RV: DF4 | C1722 |
| **D233** | DR | 5.37 x 7.68 x 0.99 | 71.4 | 31.0 | RA: IS-1; RV: DF4 | C1721 |

### Pulse Generator 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.com/manuals***, or contact Boston Scientific technical services or your local representative.

| Projected Longevity[a] | Type | Pacing Amplitude | Pacing | 500Ω with LATITUDE™[b] | 700Ω with LATITUDE™[b] | 900Ω with LATITUDE™[b] | 700Ω no LATITUDE™[c] RS, or HFSS |
|---|---|---|---|---|---|---|---|
| **VR** | | | | | | | |
| Typical programmed setting | VR | 2.5 V | 15% | 15.0 | 15.1 | 15.2 | 17.1 |
| Maximum labeled longevity | VR | 2.0 V / Off | 0% | 15.4 | 15.4 | 15.4 | 17.5 |
| **DR** | | | | | | | |
| Typical programmed setting | DR | 2.5 V | 15% | 13.6 | 13.7 | 13.8 | 15.4 |
| Maximum labeled longevity | DR | 2.0 V | 0% | 14.2 | 14.2 | 14.2 | 16.0 |

- Assumes 70 PPM LRL; DDDR mode; 0.4 ms Pulse Width (RA, RV); 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.

### Additional Longevity Information

- Boston Scientific devices have corporate warranties at 10 years (VR) and 8 years (DR) in available geographies. Warranty information available at ***www.bostonscientific.com/warranty***.
- Devices use Li/$MnO_2$ 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™ EL (Extended Longevity ICD)
## Models D232 and D233

### Pacing Therapy

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|---|---|
| **Brady Modes** | Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off<br>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 Right Atrium Automatic Threshold (RAAT) |
| **Rate Adaptive Pacing** | Accelerometer with sensor trending function |
| **RV Pacing Reduction** | AV Search+, RYTHMIQ™, AV Delays to 400 ms, Rate Hysteresis |

### Patient Diagnostics

| | |
|---|---|
| **Daily Trends for Last 365 Days** | Events, Lead impedances and amplitudes, RA Pace Threshold, RV Pace Threshold |
| **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 |
| **AT/AF Diagnostics** | AT/AF Burden, Daily burden, Average V-rate during ATR Mode Switch Episode |
| **Heart Failure Trends and Diagnostics** | Heart Failure Management Report, Weight, Blood Pressure, Events, Activity Level, Respiratory Rate, Heart Rate, Heart Rate Variability (SDANN), HRV Footprint, Thoracic Impedance, Night Heart Rate, Sleep Incline<br>***To note: Weight and Blood Pressure are only available via LATITUDE™*** |

### HeartLogic™ Heart Failure Diagnostic

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

### Device Testing/Induction Methods

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|---|---|
| **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

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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) |

### Remote Follow-Up

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| **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) |

### ImageReady™ MR Conditional System

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| **MRI Lead Selection** | RELIANCE™4-SITE defibrillation leads - active and passive fixation, single and dual coil, 59 cm, 64 cm and 70 cm<br>INGEVITY™ and FINELINE™ II pacing leads – active and passive fixation, straight and J, 45 cm, 52 cm, 58 cm, and 59 cm |
| **MRI Conditions** | 1.5T, SAR 2 W/Kg |
| **MRI Protection Mode** | Asynchronous pacing during scan (DOO, VOO, and AOO)<br>Programmable Time Out: Off, 3, 6, 9, and 12 hours |

### Tachyarrhythmia Therapy

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| **Sensing/Detection** | Zones VF only, or VF and VT or VF, VT, VT-1<br>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<br>VT Zone (160 bpm)–Detection: Rhythm ID or Onset/Stability, Therapy: ATP x 2, 6 high energy shocks |

**References:**


1. Nine independent studies confirm that CRT-Ds powered by EnduraLife Battery Technology offer industry-leading longevity.

2. Haarbo 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, Bitronik = 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 longegity in a community hospital heart failure cohort. Presented at HFSA 2014. 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 cardiacresynchronization therapy in current clinical practice: an analysis according to influencing factors, device generation, and manufacturer. Europace2015; 17:1251-58.doi:10.1093/eurospace/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 repleacements for battery depletion as indicated by ERI.

6. Zanon F, Martignani C, Ammendola E, Menardi E, NarducciML, 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, McEneany D, Roberts M, Large Capacity LiMn02 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, Schaer 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 016;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. Cardiostim Abstract 2016. Total patients = 1489.


**ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, 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 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. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) 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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