Boston Scientific
Advancing science for life™

EL ICD

Extended Longevity

LONGEVITY. Amplified.

Powered by ENDURALIFE™ Battery Technology

Truth in Longevity

Boston Scientific ICDs and CRT-Ds have the longest projected longevities on the market – with up to 80% more battery capacity than Medtronic devices.[1]

The EL ICD is projected to last up to 11.7 years.[2]

Cut the risk.

Better ICD longevity could lead to reduced risk of exposure to infections and complications for your patients.[3-5]

Visit **thebeat.bostonscientific.com/longevity** to learn more.

ENDURALIFE Battery Technology

Capacity + Chemistry + Efficiency

Capacity

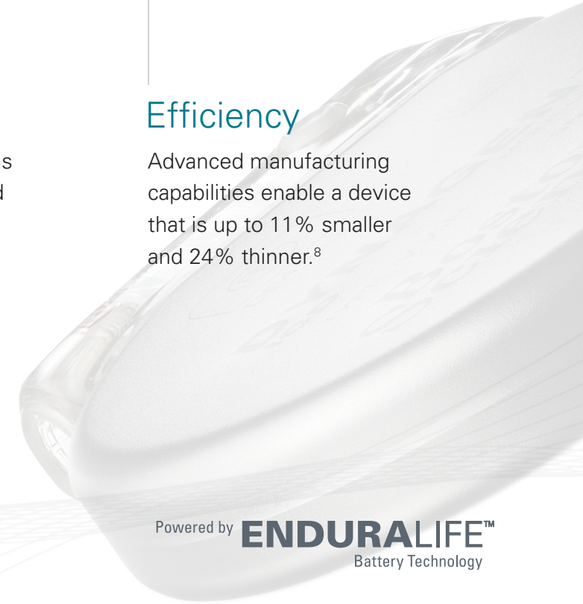
High battery capacity is nearly 2x the standard capacity of Medtronic ICDs.[6]

Chemistry

Li/MnO_2 chemistry maintains stable operating voltage and internal resistance for effective battery utilization.[7]

Efficiency

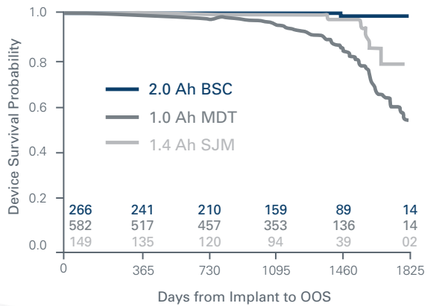
Advanced manufacturing capabilities enable a device that is up to 11% smaller and 24% thinner.[8]



Powered by ENDURALIFE™ Battery Technology

Longevity Performance

Multiple clinical studies confirm Boston Scientific CRT-Ds outperformed Medtronic CRT-Ds[9-12*]

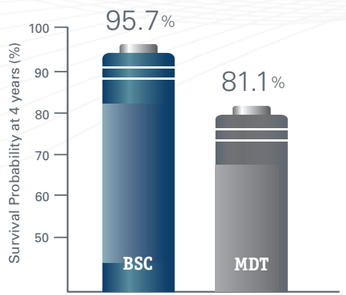


2014 Ellis Study

Ampere Hour (Ah) as a Predictor of CRT-ICD Pulse Generator Battery Longevity was a multi-center, retrospective, observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from August 1, 2008, to December 31, 2010, at 5 major institutions.[9]

Boston Scientific = 273 patients Medtronic = 587 patients St. Jude Medical = 153

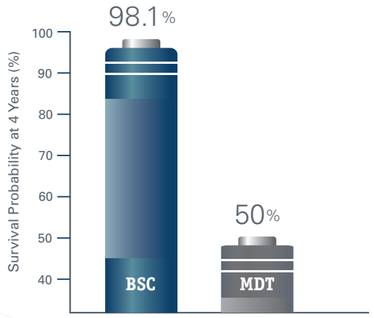
Log-rank P-values (Comparing Survival Curves)
Any Difference <0.001 2.0 Ah vs 1.0 Ah <0.001 2.0 Ah vs 1.4 Ah 0.0013 1.0 Ah vs 1.4 Ah 0.0036



2014 Johansen Study

Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry was the second independent, retrospective study inclusive of devices with contemporary battery technology.[11]

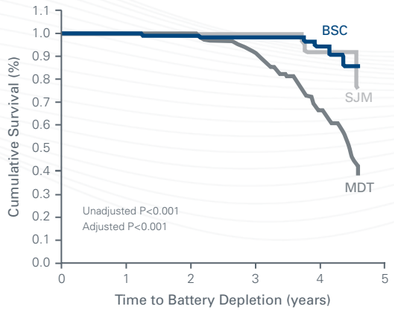
Boston Scientific = 136 patients Medtronic = 651 patients



2014 Williams Study

Contemporary Cardiac Resynchronization Implantable Cardioverter Defibrillator Battery Longevity in a Community Hospital Heart Failure Cohort was the third independent, retrospective study inclusive of devices with contemporary battery technology.[10]

Boston Scientific = 53 patients Medtronic = 28 patients



2013 Saba Study

Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators was an independent, single-center, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2008, to December 31, 2010, at University of Pittsburgh Medical Center hospitals.[12]

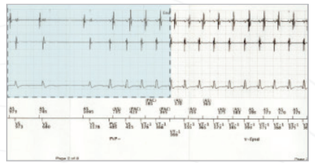
Boston Scientific = 173 patients Medtronic = 416 patients St. Jude Medical = 57

*Boston Scientific CRT-Ds in these studies were powered by **ENDURA**LIFE™ Battery Technology.*

*DYNAGEN™ EL and INOGEN™ EL devices were not included in these studies.

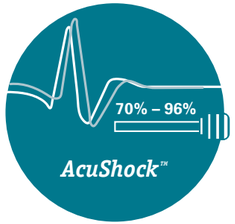
Uncompromised Set of Features

Contemporary Boston Scientific devices achieve a 30% energy consumption reduction while also offering increased features and functionality.[13]



Onset EGM

Unlike other manufacturers, Boston Scientific's 3-channel EGM Onset is turned On permanently and does not impact battery longevity.[14]

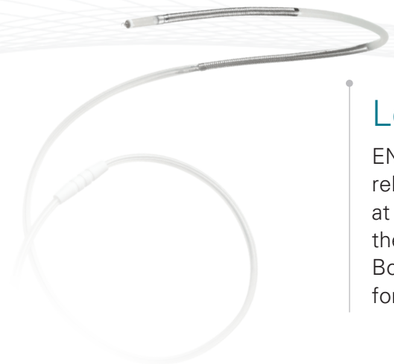


Appropriate Therapy

AcuShock™ Advanced allows physicians to customize the Rhythm ID™ algorithm to reduce inappropriate therapy.

LATITUDE™ NXT Patient Management System

Interrogations are all initiated by the Communicator. Daily checks for alerts are included in the published longevity estimates. With other manufacturers, longevity projections do not account for daily alert communications.[14]



Lead Reliability

ENDOTAK RELIANCE™ is the industry's most reliable lead with a survival probability of 98.4% at ten years.[15,16] This family of leads maintains the same core design elements that have made Boston Scientific the leader in ICD lead reliability for the past 20 years.

ICD Systems from Boston Scientific – DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD

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. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. 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. Patients should 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. Do not expose a patient to MRI scanning. 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. 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 this pulse generator with another pulse generator. This combination could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.)

PRECAUTIONS: For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information.

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 A)

Sources

[1]Boston Scientific CRT-Ds with contemporary battery technology have 1.8 Ah. Medtronic CRT-Ds have 1.0 Ah.

[2]Physician's Technical Manual DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD 2014 page 27-29.

[3]de Bie, MK. et al. Cardiac Device Infections are Associated with a Significant Mortality Risk. Heart Rhythm 2012; 9:494-498.

[4]Pfenninger Khan D. The Advisory Board Company. Re-focusing technology investments on cost effectiveness, long-term outcomes. Nov 2011. http://www.advisory.com/research/cardiovascular-roundtable/cardiovascular-rounds/2011/11/refocusing-technology-investments-on-cost-effectiveness-long-term-outcomes

[5]Ramachandra. Impact of ICD Battery Longevity on Need for Device Replacements. PACE 2010; 33:314–319

[6]Boston Scientific ICDs and CRT-Ds with contemporary battery technology have 1.8 Ah. Medtronic ICDs and CRT-Ds have 1.0 Ah.

[7]Data on file at Boston Scientific Corporation.

[8]Physician's Technical Manual DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD 2014 page 27-29. PROTECTA™ XT VR D314VRM 2013 page 330. EVERA™ XT VR DVBB1D4 2013 page 24. AnalyST™, AnalyST Accel™, Current™, Current Accel™, Fortify™, Fortify™ ST, Promote™, Promote Accel™, Promote™ Q, Unify™ Devices User's Manual 2013 page 29. St. Jude Medical™ High-Voltage Devices User's Manual 2013 page 16.

[9]Ellis C, Markus T, Dickerman D, Orton J, Hassan S, Good E, Okabe T, Greenspon A. Ampere Hour as a Predictor of CRT ICD Pulse Generator Longevity: A Multi-Center Study. Presented at HFSA 2014. http://www.onlinejcf.com/article/S1071-9164(14)00337-6/fulltext. Ampere Hour (Ah) as a Predictor of CRT ICD Pulse Generator Battery Longevity Study. The five major institutions performing the study include, at Vanderbilt University, Eastside Cardiovascular Medicine, University of Michigan, Thomas Jefferson University, Robert Wood Johnson University Hospital, Cooper Health System and North Ohio Research. Boston Scientific = 173 patients, Medtronic = 587 patients, St. Jude Medical = 153 patients. Survival rate calculated using device replacements for battery depletion as indicated by ERI.

[10]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. Boston Scientific = 53 patients, Medtronic = 28 patients, St. Jude Medical = 10 patients. Survival rate calculated using device replacements for battery depletion as indicated by ERI.

[11]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.

[12]Alam M, Munir B, Rattan R, Flanigan S, Adelstein E, Jan S, Saba S. Battery Longevity in Cardiac Resynchronization Therapy Defibrillators. 2013; Europace (2013) doi: 10.1093/europace/eut301. First published online: October 6, 2013. 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. Survival rate calculated using device replacements for battery depletion as indicated by ERI.

[13]Compared to Boston Scientific ICDs prior to TELIGEN™ ICD. Data on file at Boston Scientific Corporation.

[14]Medtronic Evera XT VR manual, pages 28-29.

[15]Based on lead survival probability rates from Returned Product Analysis, reported complications and post-market surveillance registries included in the manufacturers' Product Performance Reports: Boston Scientific Q3 2013; Biotronik July 2013; Medtronic 2013 1st Edition; Sorin May 2013; St. Jude 2013 1st Edition.

[16]See also the following independent studies: 1) Borleffs CJ, van Erven L, van Bommel RJ, et al. Risk of failure of transvenous implantable cardioverter-defibrillation leads. Circulation: Arrhythmia and Electrophysiology. 2009; 2:411-416. 2) Faulknier B, Traub D, Aktas M, et al. Time-Dependent Risk of Fidelis Lead Failure, The American Journal of Cardiology. 2010; Volume 105, Issue 1, 95-99. 3) Hauser R, Maron B, Marine J, et al. Safety and efficacy of transvenous high-voltage implantable cardioverter-defibrillator leads in high-risk hypertrophic cardiomyopathy patients. Heart Rhythm. 2008; Volume 5, Issue 11, 1517-1522. 4) Hauser R, Hayes D. Increasing hazard of Sprint Fidelis implantable cardioverter-defibrillator lead failure. Heart Rhythm. 2009; Volume 6, Issue 5, 605-610.

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