





HeartLogic[™] SmartCRT[™] EnduraLife[™] ImageReady[™]











This can give you and your team more time to proactively intervene, adjust treatment and potentially improve

patient outcomes.

HeartLogic[™]

Heart Failure Diagnostic

HeartLogic™ uses multiple sensors to track physiological trends and combines them into one composite index that provides insight into a patient's condition. When a patient's numbers change from his or her baseline and exceed your chosen threshold, you'll get an actionable yellow alert through the LATITUDE™ NXT Patient Management System.

HOW SUCCESSFUL IS IT?

The MultiSENSE* study assessed more than 900 patients and validated the alert to have:



EDUCARE

For more information, training resources and CEU credits, visit heartlogictraining.com.

^{*}The HeartLogic Index and Alert were validated using data from the MultiSENSE study; however, HeartLogic's impact on clinical outcome has not been established. Establishment of the impact will require a post market trial designed specifically to study clinical outcomes directly related to the use of this feature.





SmartCRT[™]

Technology

SmartCRT™ is a systematic, step-by-step approach for maximizing patient response. Customize therapy by using all the features—including MultiSite Pacing—without compromising longevity. Only from Boston Scientific.

OPTIMIZE WHERE, WHEN AND HOW TO PACE.

Where: Each device has 17 vectors, giving you the flexibility to choose the most therapeutic vector for each patient. You'll also have data on RV-LV delay to help you choose the best cathode. And with ACUITY™ X4 leads, you'll be able to pace exactly where you need to.

When: The SmartDelay[™] algorithm recommends personalized sensed and paced AV delays to maximize the hemodynamic response. Patients with long RV-LV delay and SmartDelay achieved a six-fold increase in response rate.³

How: Customize treatment using either singlesite or multisite pacing, with pacing from two independent LV vectors. SmartVector™ provides simple, automated programming recommendations in less than 5 seconds. 13.3
YEARS PROJECTED LONGEVITY

even with MultiSite Pacing turned on

(Assumes: 2.0V RA, LV-only, 2.0V LV, 700Ω, 15% A pacing, 100% LV pacing, No LATITUDE, No Respiratory Rate

216

MULTI-SITE PACING VECTOR COMBINATIONS

ELECTRODE "E1" S

ELECTRODE "E2" S

ELECTRODE "E3" S

ELECTRODE "E4" S

OF PATIENTS
with a spiral lead were paced

with a spiral lead were paced from a proximal electrode in the NAVIGATE X4 STUDY⁴ ELECTRODE "

ELECTRODE "E3"

CTRODE "E4"

CTRODE "E4"







OUTLAST THE OTHERS.





EnduraLife[™]

Battery Technology

Fully leverage all the device capabilities and maintain industry-leading longevity.

longevity. Resonate[™] family of ICDs and CRT-Ds is powered by EnduraLife, the longest-lasting battery on the market. that Boston Scientific CRT-Ds offer industry-leading longevity, Even with Multisite Pacing turned on, an EnduraLife battery is projected to last over 13 years. So you have the clinical freedom to make programming decisions that optimize therapy for the

Projected longevities for RESONATE and VIGILANT devices:

VR ICD	Up to 17.5 years*	
DR ICD	Up to 16.0 years*	
CRT-D	Up to 14.7 years**	

NICE

CARE WITH COMPATIBILITY.





50-75%

ESTIMATED NUMBER OF PATIENTS

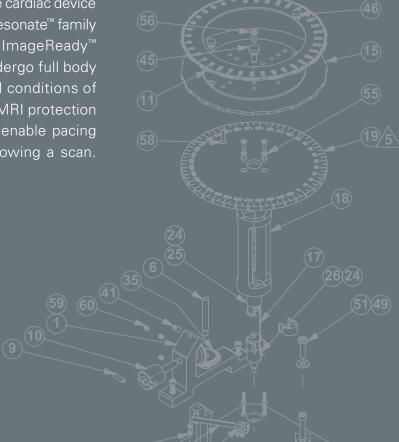
with implantable cardiac devices who will need an MRI scan over the lifetime of their device.¹³

ImageReady[™]

MR-Conditional Systems

When patients need access to MRI scans, they're ready.

Chances are, your patients with an implantable cardiac device will need an MRI. Now some models of the Resonate™ family of ICDs and CRT-Ds have the advantage of ImageReady™ MR-Conditional capability.* Patients can undergo full body scans in 1.5T MRI environments when MRI conditions of use are met. For increased confidence, the MRI protection mode features an automatic time-out to reenable pacing and defibrillation therapy programming following a scan.





WHAT WAS ONCE OUT OF REACH IS NOW IN YOUR HANDS.

You now hold the latest, most advanced technology in your expert hands. With your leadership, we can help slow heart failure progression, reduce decompensation and rehospitalizations, and extend the life expectancy and quality of life for heart failure patients.



FAMILY OF ICDs AND CRT-Ds



SmartCRT™ Technology [NEW]

MultiSite Pacing [NEW]

ImageReady™ MR-Conditional* [NEW]

EnduraLife™ Battery Technology

PaceSafe™ Auto Thresholds [NEW]

LV VectorGuide™

SmartDelay™ with LV-only Pacing [NEW]

HeartFailure Managment Report [NEW]

Impedance Trend [NEW]

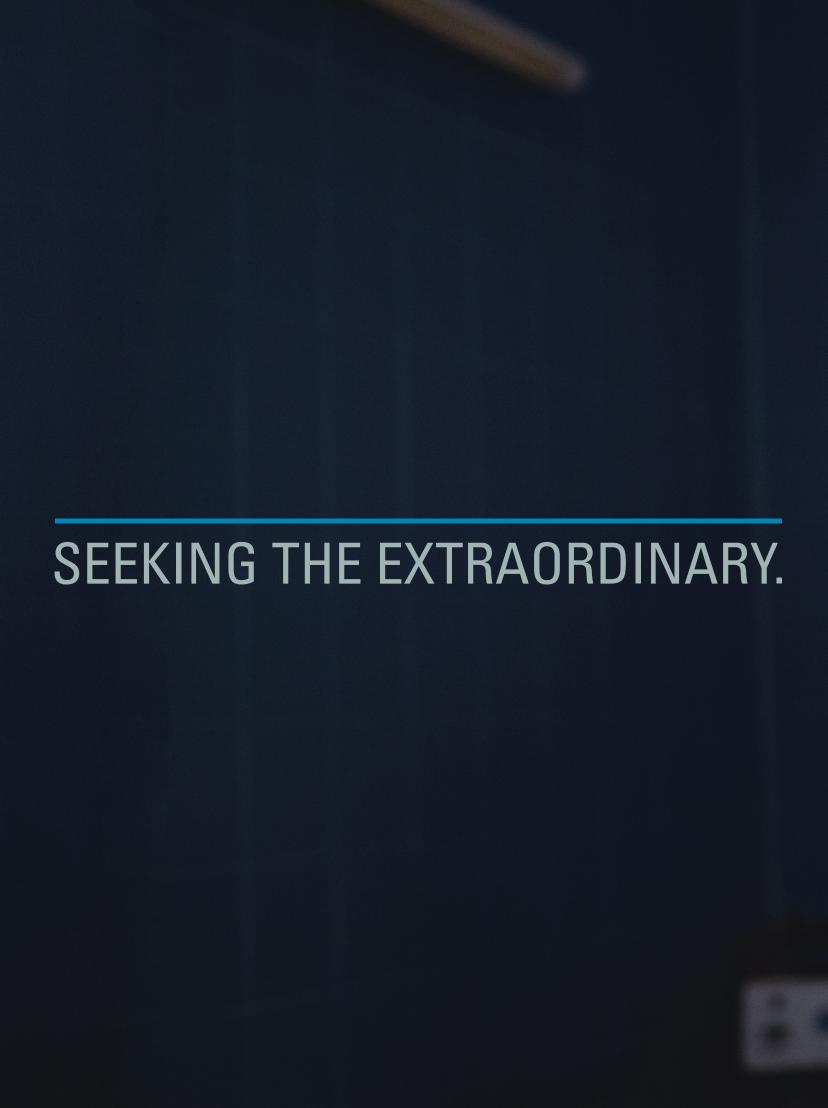
Sleep Incline Trend [NEW]

Atrial Arrhythmia Report [NEW]

*In certain models, when conditions of use are met

Available in RESONATE X4 and EL, MOMENTUM, and PERCIVA devices.







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- Mittal et al. J Cardiovasc Electrophysiol 2016; doi:10.1111/jce.13044
- Mittal et al. J Cardiovasc Electrophysiol 2016; doi:10.1111/jce.13044
 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/presentationdetail.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).

 Williams R. Stevenson Contemporary cardiac resynchronization
- Registry study was 81.1% for Medtronic and 95.7% for Boston Scientific (P-Q.01).

 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/full text. 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. Ellis CR, Dickerman DI, Orton JM, Hassan S, Good EG, Okabe T, Andruilli JA, Quan KJ, Greenspon 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.
- replacements for battery depletion as indicated by ERI.
 Landolina M, Curnis A, Morani G, Vado A, Ammendola E, D'onofrio
 A, Stabile G, Crosato M, Petracci B, Ceriotti C, Bontempi L, Morosato
 M, Ballari GP, Gasparini M. Longevity of implant Cardioverterdefibrillators for cardiac resynchronization therapy in current
 clinical practice: an analysis according to influencing factors,
 device generation, and manufacturer. Europace 2015;17:1251-58.
 doi:10.1038/jeurospace/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 to 2010)
 calculated using device replacements for battery depletion as
 indicated by ERI.

 Zanon F Martignani C. Ammendola F. Menardi F. Narducci MI.
- Indicated by ERI.

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 De Filippo P, Santamaria M, Campana A, Stabile G, Potenza DR,
 Pastore G, Iori M, La Rosa C, and Biff M. Device Longevity in a
 Contemporary Cohort of ICD/CRT-D Patients Undergoing Device
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 CRT-D systems extracted between March 2013 and May 2015.
 Medtronic = 195 patients, Boston Scientific = 157 patients, St. Jude
 = 72, Biotronik = 9.6.
- = 72, Biotronik = 9.6.

 10. 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 LiSV0 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. 11. 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.
- Europace. 2015 Nov 25; Epub 2015 Nov 25. Total patients = 3436.

 12. 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.
- 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.
- 14. BSC data on file. Data current through February 2016. 3,000 patients
- per device group. http://news.bostonscientific.com/2017-03-16-NICE-Recomn Boston-Scientific-CRT-D-Devices-Powered-By-EnduraLife-Battery-Technology-For-Treatment-Of-Heart-Failure.

CRT-D Systems - RESONATE" HF, RESONATE," RESONATE X4, VIGILANT," VIGILANT" X4, MOMENTUM, MOMENTUM X4

INDICATIONS AND USAGE

These Boston Scientific Cardiac Resynchronization Therapy Defibrillator (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (DPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (INYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class II) ischemic heart failure.

CONTRAINDICATIONS

here are no contraindications for this device.

WARNINGS

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 defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Models) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. 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 contact any other portion of the IS4-LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4-LLHH or DF4-LLHO and IS4-LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-nohly modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. 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, and VIGILANT devices with an IS-1/DF4/IS4 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,

PRECAUTIONS

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, follow up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

POTENTIAL ADVERSE EVENTS

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Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse evets associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; 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); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomens; Formation of hematomas or seromas; Heart block; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; Lead dislodgement; Lead fracture; Lead insulation breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MII); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/ undersensing, Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous scclusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. D) 046774 AH

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

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

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 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 damag

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 warming 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. All other devices covered by this manual are not MR conditional. Do not expose patients with non-MR conditional devices to MRI scanning. For protential 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 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

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POTENTIAL ADVERSE EVENTS

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Refer to the product labeling for specific indications, contraindications warnings/precautions and adverse events. Rx only. (Rev. D) 046774 AH

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Rhythm Management www.bostonscientific.com

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