HEARTLOGIC™
Heart Failure Diagnostic

Boston Scientific
Advancing science for life™

Better insights, consistent outcomes

HeartLogic empowers you to change your patient's clinical trajectory by proactively predicting worsening heart failure (HF) in your patients early, often prior to symptoms, allowing weeks of advanced notice for intervention and giving you time to possibly prevent a HF event. Available for your patients with a RESONATE™ family ICD or CRT-D, HeartLogic combines data from five HF-focused physiologic sensors into a simple composite index. When the HeartLogic index crosses a programmable threshold, you'll be notified via an FDA-approved alert in LATITUDE NXT™ to focus your attention to patients at risk.[1]

HEART SOUNDS
reveals signs of elevated filling pressure and weakened ventricular contraction

THORACIC IMPEDANCE
measures fluid accumulation and pulmonary edema

RESPIRATION
monitors rapid shallow breath pattern associated with shortness of breath

HEART RATE
indicates cardiac status and arrhythmias

ACTIVITY
reflects overall patient status and fatigue

HeartLogic was validated in the MultiSENSE study, which assessed more than 900 patients with Boston Scientific CRT-D systems, to have[1]:

an observed sensitivity of **70%**

34 days — the ability to provide weeks of advance notice - a median of 34 days ahead of an impending HF event

low alert burden - less than 2 alerts per patient per year

Calculated at the nominal HeartLogic alert threshold of 16.

MANAGE-HF Results: HeartLogic was integrated into clinical care safely. Early treatment was associated with more rapid recovery of the HeartLogic index and shorter alert case duration. More consistent treatment in response to HeartLogic alerts was associated with fewer HF events.[2-4]

0.015 SAEs*
Per Patient-Year

MORE RAPID RECOVERY
of HeartLogic Index

67% REDUCTION
In HF Hospitalizations Associated with HeartLogic**

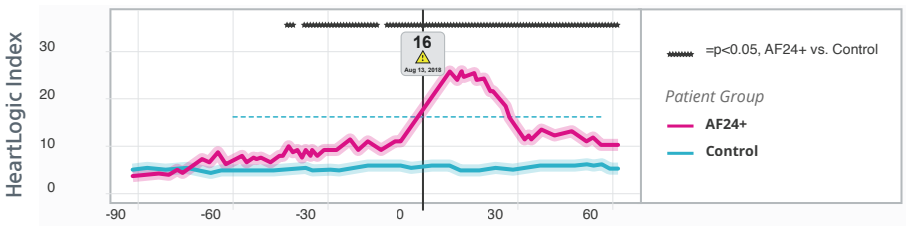
SCAN ME

HeartLogic Alert Management Guide from MANAGE-HF:
The MANAGE-HF Alert Management Guide was developed throughout the study and provided as a suggestion to consider in managing HeartLogic alerts.[2] Scan the QR code to watch how this was developed and an example approach to consider when treating patients with HeartLogic alerts.

EP Insights: HeartLogic provides the insight to understand patients physiologic response to arrhythima or device based changes.

Bidirectional interaction between HF and atrial fibrillation (AF) was documented by HeartLogic demonstrating worsening HF status prior to an AF event and subsequent worsening HF status after AF.[5]

Relationship Between Atrial Fibrillation and HeartLogic Index[7]



RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4

INDICATIONS AND USAGE: These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: • Moderate to severe heart failure (NYHA 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 I) ischemic heart failure.

CONTRAINDICATIONS: There are no contraindications for this device.

WARNINGS: • 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 Mode(s) to Off during implant, explant, or postmortem procedures. • 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 contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal, possibly compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a short within the header. • 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 implanting 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. Inserting a lead into an incorrect port will result in unanticipated device behavior (potentially leaving the patient without effective therapy). • Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. • Do not use atrial-only 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. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zone. • 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. • All devices except for those with an LV: LV-1 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. Significant harm to or death of the patient and/or damage to the implanted system may result. Do not expose patients with non-MR Conditional devices to MRI scanning. Strong magnetic fields may damage the pulse generator and/or lead system, possibly resulting in injury to or death of the patient. • 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 (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. • 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 Magnet Response programming automatically will be set to Inhibit Therapy. When this happens, the patient should not apply the magnet because tachyarrhythmia therapy could be inhibited.

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. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.

POTENTIAL ADVERSE EVENTS: • 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 phenomena • 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 dislodgment • Lead fracture • Lead insulation breakage or abrasion • Lead perforation • Lead tip deformation and/or breakage • Local tissue reaction • Loss of capture • Myocardial infarction (MI) • 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 occlusion • Venous trauma (e.g., perforation, dissection, erosion) • Worsening heart failure

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following: • Dependency • Depression • Fear of shocking while conscious • Fear that shocking capability may be lost • Imagined shocking • Fear of premature battery depletion • Fear of 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 coronary veins

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use/MRI Technical Guide" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. Rx only. 92436222 (Rev. B.6)

RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL 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. 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, VIGILANT and MOMENTUM devices 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. Do not expose patients with non-MR conditional devices to MRI scanning. 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, supplemental precautionary information.

POTENTIAL ADVERSE EVENTS: 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; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; 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 or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); 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 occlusion; 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.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. Rx only. 92436178 (Rev. B.3)

**SAE = These Serious Adverse Events were classified as abnormal lab values, renal insufficiency/failure, dizziness, or syncope events. These events are not uncommon with augmenting HF medications.*

***Compared with pre-study hospitalization rate (12 months).*

1. Boehmer JP, Hariharan R, Devecchi FG, et al. A multisensor algorithm predicts heart failure events in patients with implanted devices: results from the MultiSENSE study. *JACC Heart Fail*. 2017 Mar;5(3):216-225. https://doi.org/10.1016/j.jchf.2016.12.011
2. Hernandez AF et al. JCF, 2022;28(8):1245-1254. https://doi.org/10.1016/j.*cardfail*.2022.03.349
3. Hernandez AF et al. MANAGE-HF Phase I results. Abstract presented at: ESC-HF 2021. June 29-July 1, 2021. Virtual. https://onlinelibrary.wiley.com/doi/epdf/10.1002/ejhf.2297 (Page 159)
4. Allen LA et al. Variation in treatment responses to HeartLogic heart failure alerts in the Multiple Cardiac Sensors for Management of Heart Failure (MANAGE-HF) Study. Abstract and Oral Presentation at HFSA 2021 Annual Scientific Meeting. Sept 2021; Denver, CO
5. Capucci A, Wong J, Gold M, et al. Temporal Association of Atrial Fibrillation With Cardiac Implanted Electronic Device Detected Heart Failure Status. *J Am Coll Cardiol* EP. 2022 Feb, 8 (2) 182–193. https://doi.org/10.1016/j.jacep.2021.09.015

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