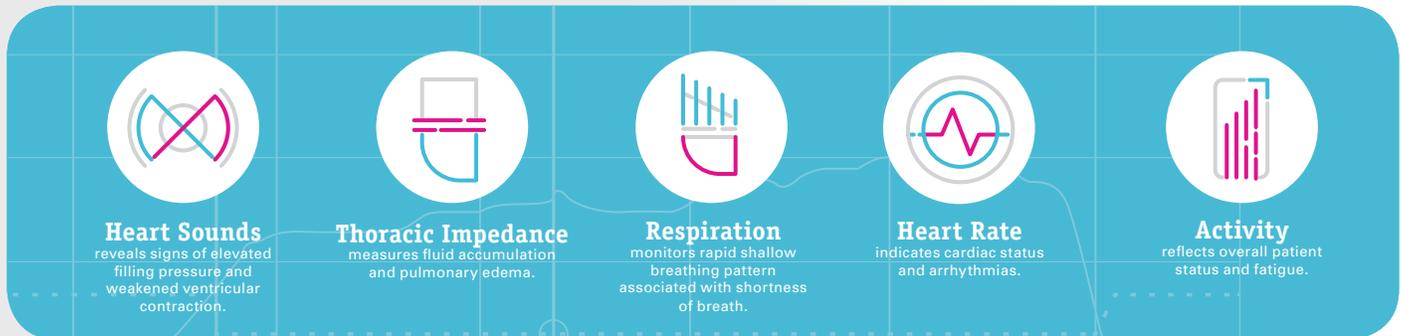


# HeartLogic™

## Heart Failure Diagnostic

**Multisensor Chronic Evaluation in Ambulatory Heart Failure Patients (MultiSENSE Study) Demonstrated High Sensitivity, Low Alert Burden and Weeks of Advance Notice of a Heart Failure Event**

Heart failure (HF) involves costly hospitalizations with 25% of HF patients requiring readmission within 30 days.<sup>1,2,3</sup> The MultiSENSE study validated the performance of the HeartLogic™ Heart Failure Diagnostic to proactively predict worsening heart failure using a proprietary algorithm. The algorithm combines data from sensors in an implantable device evaluating heart sounds, thoracic impedance, respiration rate and volume, heart rate and activity over time.



The study assessed more than 900 patients who had enhanced sensor data collection enabled in their cardiac resynchronization therapy defibrillator (CRT-D) systems. The data validated the alert to have:



The ability to provide weeks of advance notice – a median of 34-days ahead of an impending HF event – and low burden for detecting indications of worsening HF.<sup>4</sup>



### The following were observed in the MultiSENSE Study:



#### THE HEARTLOGIC DIAGNOSTIC PERFORMANCE\*

- Observed sensitivity to detect a hospitalization or unplanned intravenous therapy primarily for heart failure of **70%**
- Low burden of **less than two total alerts per patient per year**
- Success in alerting clinicians of an associated HF event with weeks of advance notice
- **34 day median alert window**
- **89%** of events had alert occur **at least 2 weeks before event**



#### HF EVENT RATE DURING AN ALERT\*

- **10 times higher HF event rate** when in vs. out of alert (0.80 vs. 0.08 events per patient per year)
- **5.9 times higher HF event rate** when in vs. out of alert after adjusted for baseline characteristics: N-terminal pro b-type natriuretic peptide (NT-proBNP), history of atrial fibrillation, renal disease, New York Heart Association (NYHA) functional classification, diabetes, left ventricular ejection fraction, plasma total protein and sodium
- **83%** of patient-days out of alert



#### SLEEP INCLINE TREND

- Available only in the Boston Scientific Resonate™ family of implantable cardioverter defibrillator (ICD) and CRT-D devices in addition to the HeartLogic Diagnostic
- **Elevated sleep incline angle** was indicative of Orthopnea or Paroxysmal nocturnal dyspnea<sup>5,6</sup>

**The HeartLogic Heart Failure Diagnostic and sleep incline trend have CE Mark and U.S. Food and Drug Administration approval within the Resonate™ family of ICD and CRT-D systems.**

\*Calculated at the nominal HeartLogic alert threshold of 16.

1. Fonarow GC, Abraham WT, Albert NM, et al. Association between performance measures and clinical outcomes for patients hospitalized with heart failure. JAMA. 2007;297(1):61-70. <https://www.ncbi.nlm.nih.gov/pubmed/17200476>  
 2. Fonarow GC, Abraham WT, Albert NM, et al. Factors identified as precipitating hospital admissions for heart failure and clinical outcomes: findings from OPTIMIZE-HF. Arch Intern Med. 2008;168:847. <https://www.ncbi.nlm.nih.gov/pubmed/18443260>  
 3. O'Connor CM, Abraham WT, Albert NM, et al. Predictors of mortality after discharge in patients hospitalized with heart failure: an analysis from the Organized Program to Initiate Lifesaving treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF). Am Heart J. 2008  
 4. Boehmer J et al., JACC-HF; 2017;5(3);216-256.  
 5. Hatlestad J, Mehta S, Whelan-Schwartz J, Shankar R, Boehmer JP. Night-time Elevation Angles In MultiSENSE Study Are Related To Symptoms of Orthopnea & Paroxysmal Nocturnal Dyspnea. Journal of Cardiac Failure, Vol. 18 No. 8S, Aug 2012, pp. S8  
 6. Rials SJ, Hatlestad JD, Smith A, Pubbi D, Slotwiner D, Boehmer JP. Night-time elevation angle in heart failure patients indicates orthopnea and paroxysmal nocturnal dyspnea. Eur J of Heart Failure 2017;19(Suppl. S1):109(P454)

## RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4 CRT-D

**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  $\leq$  35% and QRS duration  $\geq$  120 ms; or left bundle branch block (LBBB) with QRS duration  $\geq$  130 ms, EF  $\leq$  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** 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 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. 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-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. 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 MOMENTUM devices except for those with an RA: IS-1; RV: IS-1/DF-1; LV: LV-1 lead connection are considered MR Conditional. VIGILANT 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. 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 PTM feature has been triggered and the magnet response set to inhibit therapy the patient should not reapply 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, 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** Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events 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 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 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. 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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. 92436222 (Rev A)

## 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 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 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 EL, 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 events 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.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. 92436178 (Rev B)

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