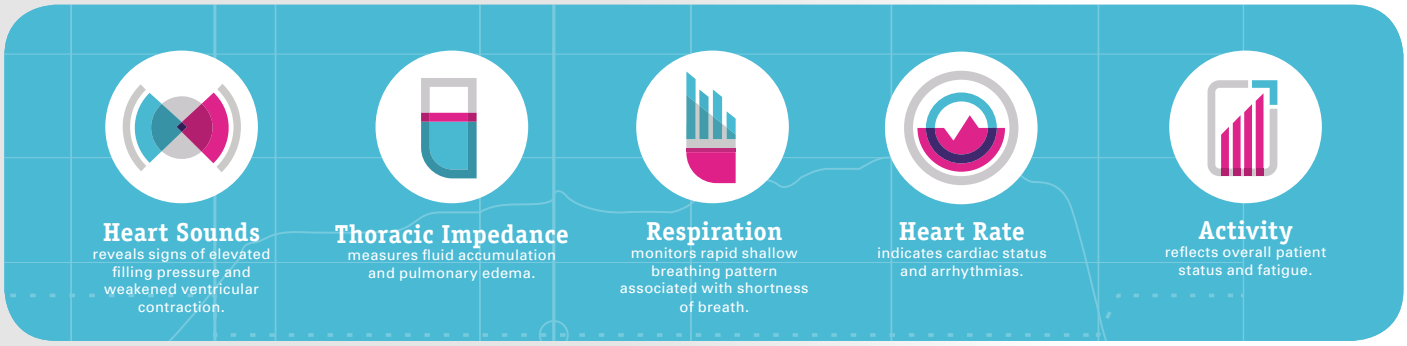
Boston Scientific
Advancing science for life™

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.**[1,2,3] 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:

an observed sensitivity of **70%**

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.[4]

34 days

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[5,6]

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),2 1 6 – 2 56.
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)

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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
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 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 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, 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, home and occupational 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
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)

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 GuideDo 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
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