LATITUDE™ (NXT) Patient Management System from Boston Scientific
Important Safety Information

LATITUDE™ NXT Patient Management is a remote monitoring system that gives your health care provider access to your implanted device data. The LATITUDE Patient Management system is not intended to assist with medical emergencies. If you are not feeling well, call your physician or 911. The Communicator does not provide continuous monitoring.

The Communicator is designed to operate on standard telephone lines like those found in most homes. The Communicator may work on other telephone systems, such as Digital Subscriber Line (DSL) and Voice Over IP (VoIP) Internet systems, if those systems provide an analog interface for connecting the Communicator.

The Communicator is designed to work only with the implanted device of the patient for whom it was prescribed. It will not work with other patients' implanted devices and should be used only as authorized by the prescribing physician. The Communicator is not for use with any pulse generator other than a Boston Scientific device. Ask your physician if you have questions about any risks with using the Communicator or your implanted device.

It is very important that the Communicator remain plugged into the power outlet. Your communicator should remain connected to a telephone line, ethernet adaptor or cellular adaptor. Some household appliances and other sources of electromagnetic energy could interfere with the communication between your Communicator and your implanted device. You should be at least 36 inches (3 ft.) away from televisions, VCRs, DVD players, personal computers, and other electronic equipment, when you are using the Communicator.

It is recommended that the customer install a surge arrestor in the electrical outlet to which the Communicator is connected.

Rx only (Rev.D)

CRT-D Systems –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; 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)

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 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 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, and 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 B)

References

1. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure. *Circulation.* 2013 Oct 15:128(16):240-327.
2. Gardner RS, et al. Heart failure diagnostic sensor measurements during clinically stable epochs in ambulatory heart failure patients. *Eur J Heart Fail.* 2017;19(1):S277,P1132.
3. Boehmer JP, Sriratanasathavorn C, Fisher J, et al. Heart failure diagnostic sensor measurements change prior to heart failure decompensation events. *J Card Fail.* 2017 Aug;23(8):S65.
4. Sriratanasathavorn C, et al. Heart failure diagnostic sensor measurements change prior to heart failure decompensation events. Presented at APHRS 2017.
5. Hatlestad J, Mehta S, Whelan-Schwartz J, et al. Night-time elevation angles in MultiSENSE study are related to symptoms of orthopnea & paroxysmal nocturnal dyspnea. *J Card Fail.* 2012 Aug;18(8):S8.
6. Capucci A, et al. Atrial arrhythmia burden increases prior to worsening heart failure events. *Heart Rhythm.* 2017;14(5):S216.
7. Gilliam FR, Ewald GA, Sweeney RJ. Feasibility of automated heart failure decompensation detection using remote patient monitoring: Results from the decompensation detection study. *J Innov Card Rhythm Man.* 2012 Apr;3:735-45.
8. Chaudhry SI, Wang Y, Concato J, et al. Patterns of weight change preceding hospitalization for heart failure. *Circulation.* 2007 Oct;116(14):1549-54.

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HeartLogic™
Heart Failure Diagnostic

Alert Management Guide
Quick Reference

The following Quick Reference document is a shortened form of the HeartLogic Alert Management Guide. Please review the HeartLogic Alert Management Guide for complete information and contact your Boston Scientific Sales Representative if you should have any questions.

The 3A Process: Alert, Assessment and Action

This Quick Reference highlights the 3A Process, a suggested 3-step clinical workflow (Figure 1) for managing HeartLogic™ alerts and spurring clinical action. Use this guide in the context of your standard of care for all patients, regardless of their HeartLogic alert status.[1]

Step 1 The 3A Process starts with ALERT, the transmission of the HeartLogic alert and additional heart failure diagnostics.

Step 2 Once an alert is received, perform an ASSESSMENT of the alert context by reviewing the Heart Failure Management Report and talking with your patient.

Step 3 Once you have assessed any possible triggers and the patient's status, proceed to ACTION based on standard of care and clinical judgment.

- Continue to monitor the patient and consider repeating the 3A Process per standard of care.

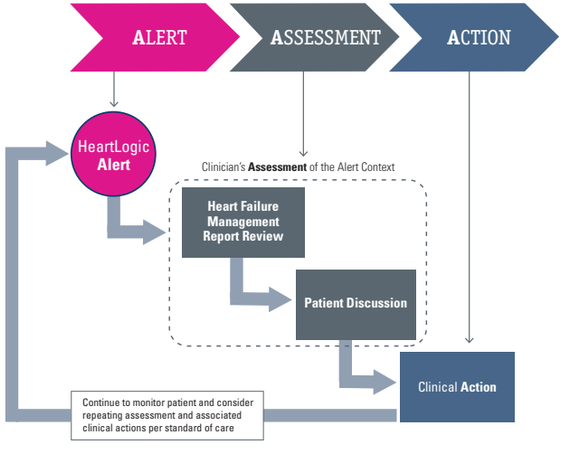

Figure 1: The 3A Process: Alert, Assessment and Action

Step 1: HeartLogic Alert

A HeartLogic alert is a part of the HeartLogic Heart Failure Diagnostic comprised of a composite trend called the HeartLogic Index, a configurable yellow alert and a configurable threshold. These are all delivered via the LATITUDE™ NXT Remote Patient Management System.

Step 2: Clinician's Assessment of the Alert Context

The Heart Failure Management Report

The Heart Failure Management Report is a comprehensive summary of diagnostic trends tailored to the management of heart failure and should be used to understand the context of the HeartLogic alert. Review the HFMR and talk with the patient to assess the context of the alert and identify potential causes. Note: HeartLogic is a sensitive diagnostic that may issue an alert before signs and symptoms occur.

Table 1 provides a brief summary of directional changes in trends from the HFMR that may be associated with worsening heart failure.

WORSENING HEART FAILURE MAY BE ASSOCIATED WITH…	
…an INCREASE in	**…a DECREASE in**
S3[2-4] Heart Sound	S1 Heart Sound[2-4]
Respiratory Rate[2-4]	Thoracic Impedance[2-4]
Sleep Incline[5]	Activity Level[2-4]
Night Heart Rate[2-4]	
AT/AF Burden[6]	
Weight[7,8]	

Table 1: Directional Changes in Trends That May be Associated with Worsening Heart Failure

Patient Discussion

Talk with your patient to obtain additional context for the HeartLogic alert and identify a possible course of action following your standard approach to patient assessment or published guidelines.[1] Seek answers to the following two questions:

1. Are there any specific precipitating factors that can be immediately addressed, such as:

- Medication nonadherence
- Dietary indiscretion
- Use of harmful medications such as NSAIDs
- Arrhythmia and device therapy (ATP, shocks)
- Reduction or loss of CRT (for patients with CRT devices only)
- Recent medication changes
- Recent clinical events especially those requiring infusion of fluids (e.g., a surgery)
- Active ischemia
- Non-optimal medical therapy

2. Are there other signs or symptoms of worsening heart failure, such as:

- Shortness of breath with exertion and/or at rest
- Shortness of breath when lying flat (orthopnea or paroxysmal nocturnal dyspnea)
- Sleeping regularly in a chair or on multiple pillows in bed
- Dry cough or frothy sputum
- Weight gain
- Swelling of abdomen, feet or ankles
- Changes in the frequency of urination
- Fatigue

Step 3: Clinical Action

Upon completing your assessment of the Heart Failure Management Report and patient discussion(s), consider modifying your patient's treatment and monitoring your patient's condition to ensure safety per standard of care.[1]

Depending on the factors you believe may have accompanied the HeartLogic alert, consider one or more of the following actions:

- Reinforce medication compliance
- Repeat patient education on dietary sodium and fluid restriction, remind of daily activity/exercise plan and keeping regular follow-up appointments with his/her healthcare provider
- Address patient therapy related issues, such as worsening atrial burden, loss of CRT pacing, ventricular arrhythmias, etc.
- Treat fluid overload
- Further optimize current ACCF/AHA guideline-directed medical therapies

Continue to monitor your patient by following standard of care guidelines.[1]