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.

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**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.

<table>
<thead>
<tr>
<th>...an INCREASE in</th>
<th>...a DECREASE in</th>
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<tbody>
<tr>
<td>S3²-⁴ Heart Sound</td>
<td>S1 Heart Sound²-⁴</td>
</tr>
<tr>
<td>Respiratory Rate²-⁴</td>
<td>Thoracic Impedance²-⁴</td>
</tr>
<tr>
<td>Sleep Incline⁵</td>
<td>Activity Level²-⁴</td>
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<tr>
<td>Night Heart Rate²-⁴</td>
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<tr>
<td>AT/AF Burden⁶</td>
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<td>Weight⁷,⁸</td>
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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
INTENDED USE
The LATITUDE™ NXT Patient Management System is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database. The LATITUDE™ NXT System provides patient data that can be used as part of the clinical evaluation of the patient.

CONTRAINdications
The LATITUDE™ NXT Patient Management System is contraindicated for use with any implanted device other than the Boston Scientific implanted device being interrogated.

Not all Boston Scientific implanted devices are compatible with the LATITUDE™ NXT System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

PRECAUTIONS
Alerts may appear on the LATITUDE™ NXT website on a daily basis. Primary notification of alert conditions is through the LATITUDE™ NXT Patient Management System. The LATITUDE™ NXT System provides ongoing notification of alert conditions. For each alert condition, the LATITUDE™ NXT website in order to receive alerts. Although secondary notification through email and SMS text messages is available, these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the website. Implanted device data and alerts are typically available for review on the LATITUDE™ NXT website in 15–24 hours after the implanted device is interrogated. For content that may make significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE™ NXT server to upload data, up to 14 days may elapse before the LATITUDE™ NXT server detects these conditions and informs the clinician, user, or patient. If both of these conditions occur at the same time, this notification could take up to 28 days.

Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following: System limitations; the Communicator is unplugged; the Communicator is not able to connect to the LATITUDE™ NXT server through the configured phone system; the implanted device and the Communicator cannot establish and maintain a connection; the implanted device is damaged or malfunctioning; the patient is not compliant with prescribed use; or is not using the LATITUDE™ NXT System as described in the patient manual; if subscribed to the LATITUDE™ Cellular Data Plan, missing two or more payments discontinues the subscription; the clinic user can identify any patients that are not being monitored as above through using the Not Monitored filter on the View Patient List.

ADVERSE EFFECTS
None known.

SYSTEM LIMITATIONS
The LATITUDE™ NXT System does not provide continuous real-time monitoring. As a remote monitoring system, the LATITUDE™ NXT System provides periodic patient monitoring based on clinician configured settings. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of implanted device, sensor, and patient information as intended by the clinician. These factors include: implanted device location, patient environment, cellular data service; telephone system; communicator memory capacity; clinician environment; schedule/configuration changes; or data processing.

Not all Boston Scientific implanted devices are compatible with the LATITUDE™ NXT System. For contraindications for use related to the implanted device, follow up testing, explant and disposal, supplemental precautionary information. Advise patients to consider 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 re-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 personnel safety, battery management, explantation, explantation and medical environments, follow up testing, explant and disposal, supplemental precautionary information. Advise patients to consider 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 re-apply the magnet.

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ADVERSE EFFECTS
None known.
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 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 or damage. Do not wrap leads for high voltage. Do not use the lead with the leads of other making it so that could cause lead insulation abrasion or 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 a SFA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DR-4 LHLL or DR-4 LLH 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™, and VIGILANT devices with a DF4 ventricular lead 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 MRI 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 MRI conditional. Do not expose patients with non-MR conditional devices to MRI scanning. For potential adverse events applicable when the Conditions of Use are not met or an event 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; Conduct 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 reaction; Hemostatic agent failure; Heart block; Heart failure following chronic RV apical pacing; Heart failure following chronic atrial pacing; Heart failure following chronic AV pacing; Heart failure following chronic RV apical pacing, inappopriate therapy (e.g., shocks and antitachycardia pacing (ATP)) where applicable, pacing; Inc pencial 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 breakdown or abrasion; Lead perforation; Left bundle branch block; Lead failure (leads or connectors); Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential oversensing; Sensing/ 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, Tachybrady, Tachybrady, Tachybrady; 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 disturbances to a pulse generator system and experience the following: Depression; Dependency; Fear of premature battery depletion; Fear of a device malfunction; 92436178 [Rev B]

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.

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References


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