

# HeartLogic™

Heart Failure Diagnostic



## Alert Management Guide

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## The 3A Process: Alert, Assessment and Action

This guide explains the 3A Process, a clinical workflow where a HeartLogic™ alert triggers a data review of the Heart Failure Management Report and prompts patient discussions to spur clinical action. When using this guide, practice standard of care<sup>1</sup> for all patients, regardless of their HeartLogic alert status.

The 3A Process suggests steps and information to consider when choosing the course of clinical action.

Once the HeartLogic Diagnostic is enabled on a patient's device, follow the 3A Process of ALERT, ASSESSMENT and ACTION (**Figure 1**):

- Step 1 - The 3A Process starts with **ALERT**, the transmission of the HeartLogic alert and additional heart failure diagnostics, all combined into a Heart Failure Management Report and delivered via the LATITUDE™ NXT Remote Patient Management System.
- 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. In some cases, it may be possible to identify precipitating factors that may lead to worsening heart failure, such as atrial fibrillation or dietary indiscretion, and early signs or symptoms of worsening heart failure.
- Step 3 - Once you've assessed any possible triggers and the patient's status, proceed to **ACTION** based on your standard of care and clinical judgment.
- Continue to monitor the patient and consider repeating the 3A Process per standard of care.

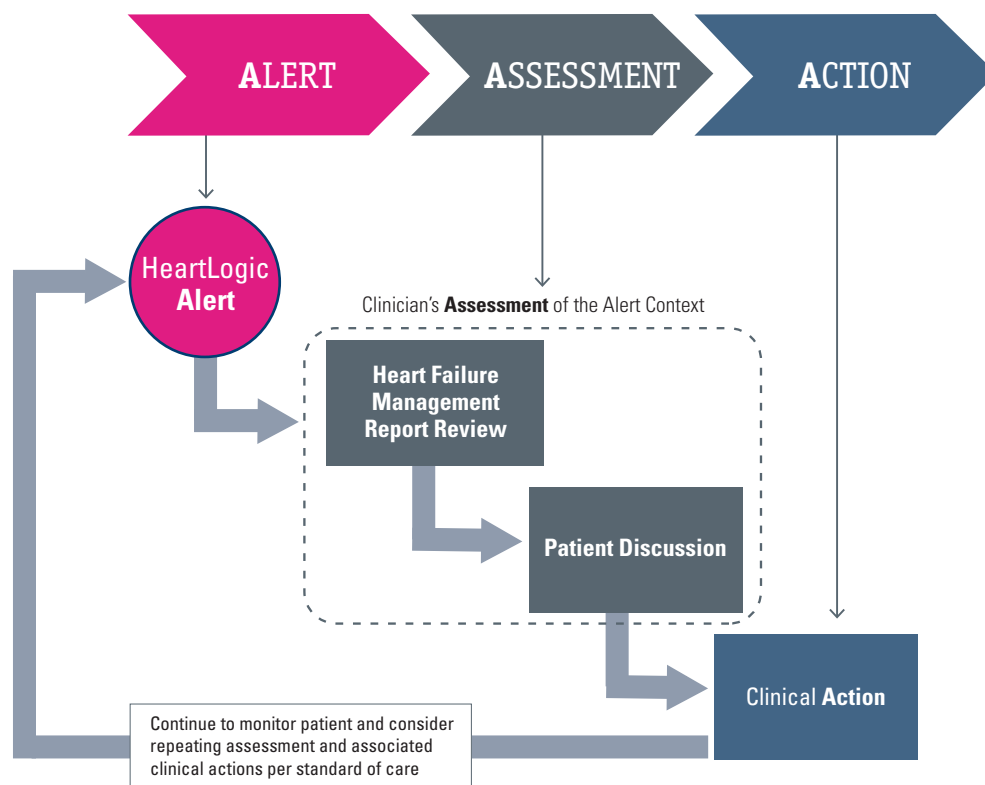


Figure 1: The 3A Process: Alert, Assessment and Action

## 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 LATITUDE™ NXT.

The HeartLogic Index is computed daily and combines measurements from multiple device-based sensors, looking for changes from a historical baseline in a worsening direction and weighting those changes based on a patient's current risk level. Baselines are assessed based on data spanning up to three recent months.

When the HeartLogic Index crosses the threshold, a HeartLogic alert is issued. Additional alerts will be delivered every 7 days as long as the HeartLogic Index remains above the threshold.\*

The key performance attributes of HeartLogic were as follows:†

- At nominal settings, HeartLogic was validated to predict heart failure events with 70% sensitivity and 1.47 unexplained alert rate,<sup>2</sup>
- In 89% of detected heart failure events, HeartLogic alerts would have been issued 2 or more weeks in advance; in 50% of detected heart failure events with 4 or more weeks in advance,<sup>2</sup>
- Heart failure event rate was 10 times higher when HeartLogic was in alert state versus when it was not in alert state<sup>3</sup> and
- HeartLogic augmented the prognosis of a baseline NT-proBNP assessment, stratifying patients with up to 50 times higher rate for heart failure events between the lowest risk and the highest risk patient groups.<sup>4</sup>

\* HeartLogic provides additive, optional information for clinicians to use in context with standard-of-care patient treatment and should not replace standard-of-care treatment. Due to the long-term averaging involved, the Index may not be sensitive to faster changes in sensor data over shorter time frame. As such, sensor changes due to acute interventions may not be immediately reflected in the Index. It is not recommended to use the Index values for day-to-day patient management.

† Using the nominal threshold of 16.

## Step 2: Clinician's Assessment of the Alert Context

Review the Heart Failure Management Report and talk with the patient to assess the context of the alert and identify potential causes. Note that HeartLogic is a sensitive diagnostic that may issue an alert before signs and symptoms.

### The Heart Failure Management Report

The Heart Failure Management Report is a comprehensive summary of diagnostic trends tailored to the management of heart failure. The trends covered in this guide are S3 heart sound, S1 heart sound, thoracic impedance, respiratory rate, night heart rate, sleep incline, activity level, AT/AF burden, V therapy, % LV paced and weight.

The device collects and reports the data daily, and the LATITUDE NXT System delivers the data. Even though not all of the diagnostic trends included in the Heart Failure Management Report are a part of the HeartLogic HF Diagnostic, all the data together can help you understand the context of the HeartLogic alert.

#### S3 HEART SOUND

The S3 heart sound (a HeartLogic trend) uses the accelerometer embedded in the pulse generator to detect cardiac vibrations of the third heart sound during periods of patient inactivity. The vibrations are then used to measure the intensity of the S3 heart sound, reported in milligravities (mG). An S3 heart sound cannot be obtained when the patient's heart rate is too high or the heart rate is too variable.

Auscultated S3 is known as an early sign of heart failure and elevated filling pressure.<sup>5-8</sup> Device-measured S3 occurs during early diastolic filling, consistent with its known physiologic genesis<sup>9</sup>; is correlated with echo parameters consistent with impaired left ventricular functions,<sup>10,11</sup> and correlates with hemodynamic parameters, such as left atrial pressure.<sup>12</sup>

Device-measured S3 includes sub-audible components that were better able to distinguish heart failure patients from non-heart failure patients.<sup>13</sup> A 30-day average S3 of larger than 1 mG predicted the risk of future heart failure events better than the baseline auscultated S3.<sup>14</sup> Worsening heart failure may be associated with an increase in S3.<sup>15-17</sup>

#### S1 HEART SOUND

The S1 heart sound (a HeartLogic trend) uses the accelerometer embedded in the pulse generator to detect cardiac vibrations of the first heart sound during periods of patient inactivity. The vibrations are then used to measure the intensity of the S1 heart sound, reported in milligravities (mG). An S1 heart sound cannot be obtained when the patient's heart rate is too high or the heart rate is too variable.

Auscultated S1, which is related to the closure of the mitral and tricuspid valves, identifies the onset of ventricular systole and the end of mechanical diastole.<sup>18</sup> Acutely, S1 amplitude has been shown to be closely related to cardiac contractility.<sup>12,19,20</sup> A decrease in the intensity of S1 may be associated with myocardial depression, mitral regurgitation, ventricular septal defect and acute aortic regurgitation.<sup>21</sup> Worsening heart failure may be associated with a decrease in S1.<sup>15-17</sup>



## THORACIC IMPEDANCE

Thoracic impedance (a HeartLogic trend) is a measure of thoracic resistance between the coil electrode on the right ventricular lead and the pulse generator. Lower thoracic impedance may be associated with pulmonary congestion,<sup>22,23</sup> pocket infection,<sup>23</sup> pleural/pericardial effusion<sup>24</sup> and respiratory infection.<sup>23</sup> Worsening heart failure may be associated with a decrease in thoracic impedance.<sup>15-17,25</sup>



## RESPIRATORY RATE

Respiratory rate (a HeartLogic trend) is a daily median rate of all valid breaths within 24 hours.

Nearly 90% of patients admitted to hospitals for acute decompensated heart failure had shortness of breath (dyspnea) upon admission according to the ADHERE Registry.<sup>26</sup> When patients experience dyspnea they often have a rapid shallowing breathing pattern with an elevated respiratory rate (tachypnea) and a reduced tidal volume.

Respiratory rate may increase prior to a heart failure event.<sup>15-17,27</sup> A 30-day average respiratory rate above 20 breaths per minute had a 3.5-fold increased risk of heart failure events within the following 30 days.<sup>28</sup> Respiratory rate with a higher day-to-day variation over 30 days had a 4.9-fold increased risk of heart failure events within the following 30 days.<sup>29</sup>



## NIGHT HEART RATE

Night heart rate (a HeartLogic trend) is the average heart rate measured between midnight and 6 am. Night heart rate tends to capture resting heart rate for most patients.

Resting heart rates may have prognostic value in patients with chronic heart failure.<sup>30</sup> An increase in night heart rate may be associated with worsening heart failure<sup>15-17,31</sup> or autonomic dysfunction.<sup>31</sup> An increase in heart rate may also be associated with conducting atrial arrhythmias and may be a sign of an insufficient rate control.



## SLEEP INCLINE

Sleep incline is the angle between the patient's torso and the horizontal plane, measured during a sleep period specified by the patient.

Orthopnea is a symptom where the patient has shortness of breath (dyspnea) when assuming a horizontal posture. Paroxysmal nocturnal dyspnea (PND) is a sudden awakening due to an acute shortness of breath that generally occurs at night. Orthopnea and PND are common posture-related symptoms in heart failure patients, and their importance for heart failure assessment is well supported in current heart failure management guidelines, heart failure clinical assessment scores and clinical research.<sup>1,32-38</sup> Both symptoms are due to fluid redistribution from the periphery to the thoracic region upon lying down. Since these symptoms are unpleasant, patients will often prop themselves up to varying degrees in order to get restful sleep at night.

Elevated sleep incline angle was indicative of orthopnea or PND.<sup>39,40</sup>



## ACTIVITY LEVEL

Activity level shows the number of hours per day a patient is active. Changes in device-measured activity have been correlated with a 6-minute walk test.<sup>41,42</sup> A reduced level of physical activity had a 4-fold increased risk of heart failure hospitalization within the next 30 days.<sup>43</sup> Worsening heart failure may be associated with a decrease in activity.<sup>15-17</sup>



## AT/AF BURDEN

AT/AF burden trend displays the total amount of time spent in an atrial tachy response (ATR) mode switch, in hours per day. The trend is generally representative of the duration of atrial tachycardia (AT) or atrial fibrillation (AF) episodes. AT and AF episodes in heart failure are associated with poor prognosis and mortality<sup>44</sup> and are often asymptomatic.<sup>45</sup> AF can exacerbate heart failure<sup>46-48</sup> and worsening heart failure may result in the new onset or exacerbation of AF.<sup>47,49</sup>



## V THERAPY

V Therapy trend provides an abbreviated summary of antitachycardia pacing (ATP) and shock therapy type delivered each day: ATP (dot) or shock (electrical shock sign). If both types of therapy are delivered on the same day, only the shock sign will be shown. Detailed information on arrhythmia can be found in the Arrhythmia Logbook Report.

Delivery of device therapy may signify an increase in abnormal cardiac rhythms or insufficient rate control.



## % LV PACED

% LV Paced trend is the percent of cardiac beats paced with a left ventricular (LV) lead per day.\* The goal of CRT is to maximize resynchronization through a high rate of biventricular pacing with the preferred percentage of pacing as close to 100% as possible.<sup>50</sup> A high percentage of biventricular pacing in patients with a CRT device is associated with improved prognosis.<sup>50</sup>



## WEIGHT

The weight trend displays daily patient weight data collected by an external weight scale assigned via LATITUDE™ NXT. Guidelines recommend weight monitoring as part of the heart failure management routine.<sup>1</sup> Sudden or steady gain in daily weight may be associated with fluid retention and worsening heart failure.<sup>51, 52</sup>

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

### WORSENING HEART FAILURE MAY BE ASSOCIATED WITH...

...an INCREASE in	...a DECREASE in
S3 Heart Sound	S1 Heart Sound
Respiratory Rate	Thoracic Impedance
Sleep Incline	Activity Level
Night Heart Rate	
AT/AF Burden	
Weight	

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

\* The trend is only available on CRT devices.



## Patient Discussion

Talk with your patient to obtain additional context for the HeartLogic alert and identify a possible course of action. Conduct the patient discussion by phone or in person, following your standard approach to patient assessment or published guidelines.<sup>1</sup> 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.<sup>1</sup>

Depending on the factors you believe may have accompanied the HeartLogic alert (Step 2), 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.<sup>1</sup>

## Acronyms

- AF** – atrial fibrillation  
**AT** – atrial tachycardia  
**ATP** – antitachycardia pacing  
**ATR** – atrial tachy response  
**CRT** – cardiac resynchronization therapy  
**LV** – left ventricular  
**PND** – paroxysmal nocturnal dyspnea  
**V** – ventricular

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#### **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  $\leq$  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 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 over-sensing 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. 92436222 (Rev. A)

**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.

#### **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 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. 92436178 (Rev. B)

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#### **LATITUDE™ NXT Patient Management System**

**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 a compatible Boston Scientific implanted device. 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 View Patient List page on the LATITUDE NXT website. The clinician needs to log onto 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 within 15 minutes of a successful interrogation. However, data uploads may take 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 clinic user that monitoring is not occurring. 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 complete a telemetry session; the Communicator 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 described above by 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 clock; patient environment; cellular data service; telephone system; communicator memory capacity; clinic environment; schedule/configuration changes; or data processing. 92436260 (Rev. A)

**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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#### **Rhythm Management**

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