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HEARTLOGIC™
Heart Failure Diagnostic

Alert Management Guide

TABLE OF CONTENTS

HeartLogic Summary 1

The 3A Process: Alert, Assessment and Action 2

Step 1: HeartLogic™ Alert 3

Step 2: Clinician's Assessment of the Alert Context 4

- Heart Failure Management Report 4
- HeartLogic and Heart Failure Physiologic Sensors 4-5
- Patient Discussion 6

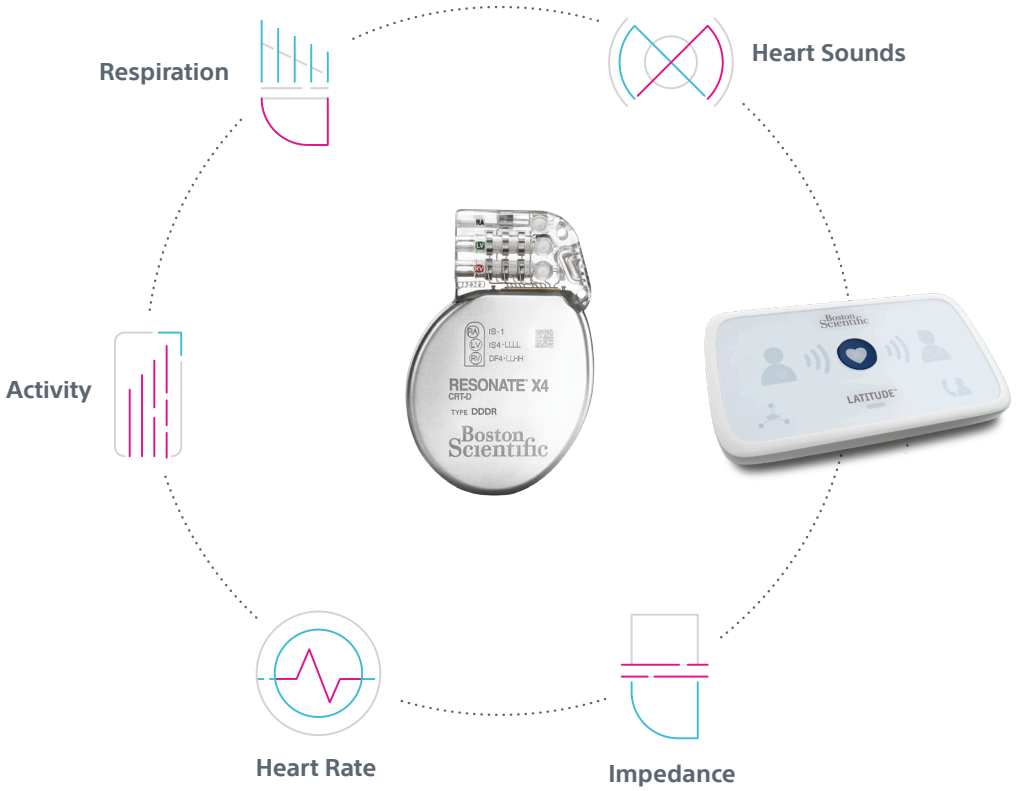
Step 3: Clinical Action 7

References 7

Appendix: MANAGE-HF Alert Management Guide 8-9

HeartLogic Summary

HeartLogic™ is the first FDA approved Heart Failure Diagnostic available in an implantable cardiac therapy device that uses multiple sensors to track physiologic trends and combines them into one composite index.[1] When the index crosses over a configurable threshold, HeartLogic provides a proactive alert via the LATITUDE™ NXT Remote Patient Management System. HeartLogic is available in the RESONATE™ family devices and will alert clinicians when patients are at risk of worsening heart failure to facilitate early clinical intervention.[1]



The MultiSENSE Study validated that HeartLogic:

Had **high sensitivity** of 70% in detecting heart failure events[1]

Had a **very low alert burden** of less than 2 alerts per patient per year[1]

Would have provided **weeks of advance notice** of a potential heart failure event[1]

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 for all patients, regardless of their HeartLogic alert status.[2]
The 3A Process suggests steps and information to consider when choosing the course of clinical action.

Once HeartLogic 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 physiologic data, 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.

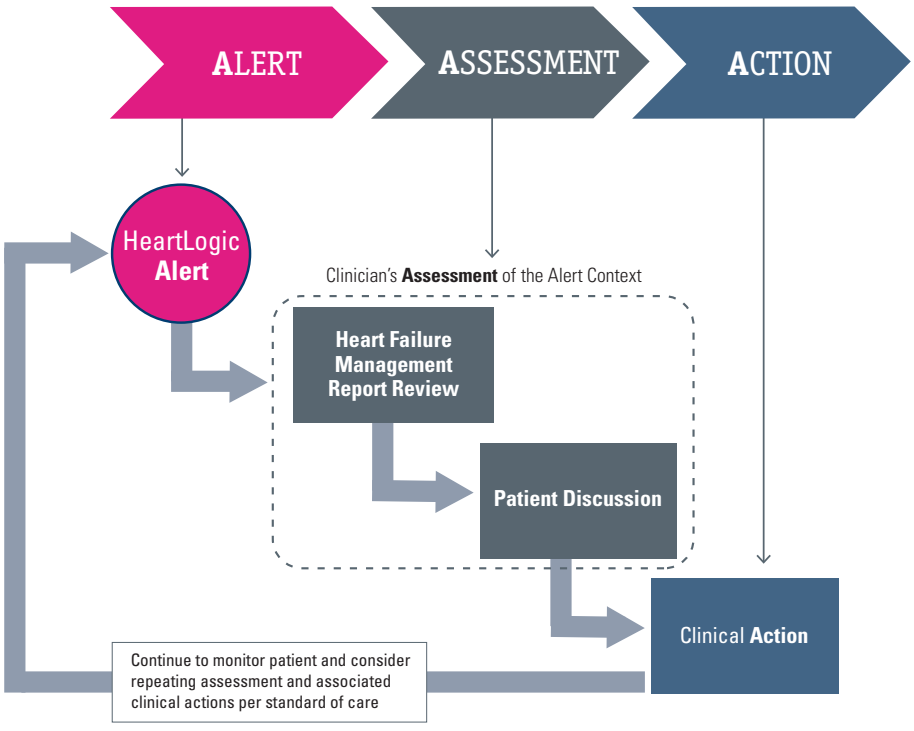


Figure 1: The 3A Process: Alert, Assessment and Action

Step 1: HeartLogic™ Alert

A HeartLogic alert is comprised of a composite trend called the HeartLogic Index, a configurable yellow alert and a configurable alert threshold (see Heart Failure Management Report below). 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, an initial HeartLogic alert is issued and denotes that a patient is IN-ALERT state and at risk for a HF event. Additional re-alerts will be delivered every 7 days as long as the HeartLogic Index remains above the recovery threshold.* A patient will remain IN-ALERT state until the HeartLogic Index falls below the recovery threshold and then is considered OUT-of-ALERT state **(see Figure 2 below).**

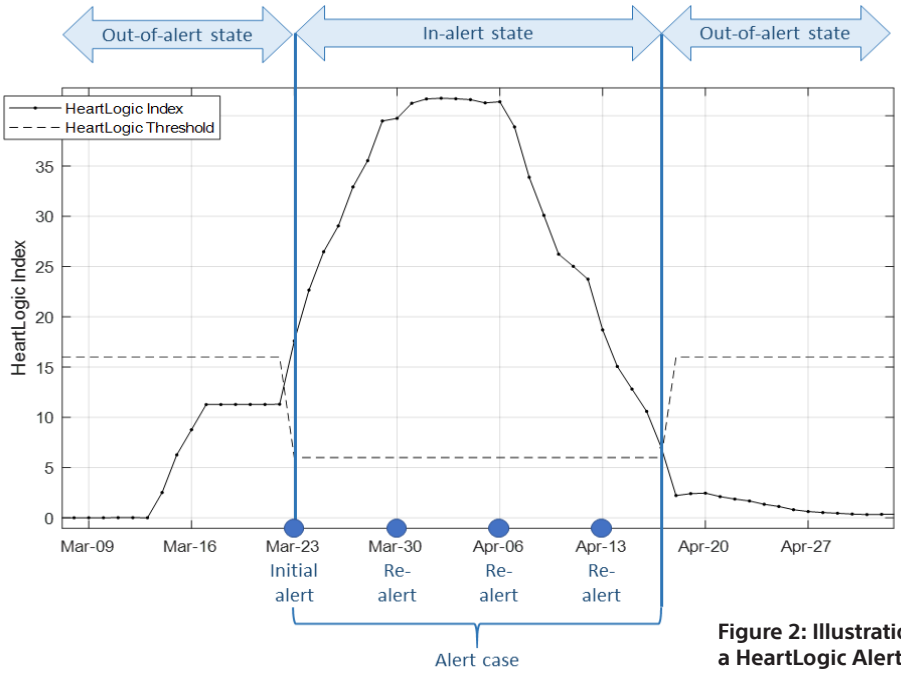


Figure 2: Illustration of a HeartLogic Alert Case[3]

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,[1]
- In 89% of detected heart failure events, HeartLogic alerts would have been issued 2 or more weeks in advance; in 63% of detected heart failure events with 4 or more weeks in advance,[1]
- Heart failure event rate was 10 times higher when HeartLogic was in alert state versus when it was not in alert state[4] 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.[4]

* 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 a 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. This report includes the 5 HeartLogic sensors (S3 & S1 heart sounds, thoracic impedance, respiration, night heart rate, activity level) and additional physiologic and device-based sensor data that comprise our overall Heart Failure Sensor Suite.

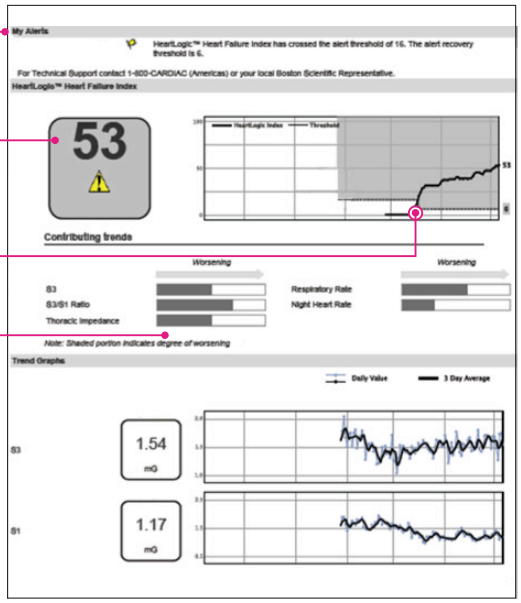
The device collects and reports the data daily, and the LATITUDE™ NXT System delivers the data. Even though not all of the diagnostic trends included in the Heart Failure Management Report are a part of the HeartLogic Heart Failure Diagnostic, all the data together can help you understand the context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

HeartLogic™ Alert Notification
The system generates a yellow alert when the index crosses over the threshold.

HeartLogic™ Composite Index
Our algorithm compiles data from multiple sensors into one composite score.

HeartLogic™ Configurable Threshold
See the threshold from 10 to 40 in steps of 2.

HeartLogic™ Contributing Trends
At-a-glance trends, including Heart Sounds (S3 and S1), Thoracic Impedance, Respiration, Heart Rate, and Activity.



HeartLogic and Heart Failure Physiologic Sensors

Below highlights the physiologic sensors available on the Heart Failure Management Report:

HeartLogic™ Heart Failure Diagnostic Sensors	
Heart Sounds (S3 & S1)	Measured from the accelerometer and reveals signs of elevated filling pressure and weakened ventricular contraction via S3 and S1 heart sounds, respectively.[5-7] Heart sounds are measured every 20 minutes at rest and aggregated throughout the day.
Thoracic Impedance	Measures impedance between electrodes on the RV lead and the pulse generator, which is indicative of fluid accumulation and pulmonary edema.[8] Thoracic impedance is measured every 2 minutes and aggregated throughout the day.
Respiration	Monitors respiratory patterns associated with shortness of breath including respiratory rate and rapid shallow breathing via RSBI (rapid shallow breathing index), which is a ratio of respiratory rate (RR) to tidal volume.[9-10] Worsening HF may be associated with with an elevated respiratory rate, worsening Rapid Shallow Breathing pattern, or an increase in day-to-day Respiratory Rate variability.[9]
Night Heart Rate	Night HR is measured beat by beat then aggregated between midnight and 6 am, which for most patients is indicative of the RESTING heart rate.[11]
Activity	Monitors a patient's activity in hours per day reflecting overall global patient status and fatigue. Low level of activity or declining activity level may be associated with worsening heart failure.[12]

Additional Heart Failure and Device-Based Physiologic Sensors	
Sleep Incline 	Measures angle between the patient's torso and the horizontal plane, measured during a sleep period specified by the patient. Elevated sleep incline angle was indicative of orthopnea or paroxysmal nocturnal dyspnea.[13] *Requires Calibration at least 7-10 days after implant.
AT/AF Burden 	Displays the total amount of time spent in an atrial tachy response (ATR) mode switch, in hours per day. AF can exacerbate heart failure[14-16] and worsening heart failure may result in the new onset or exacerbation of AF.[14,15]
Ventricular Therapy 	Provides an abbreviated summary of antitachycardia pacing (ATP) and shock therapy type delivered each day. Delivery of device therapy may signify an increase in abnormal cardiac rhythms or insufficient rate control.
Mean Heart Rate	Displays mean heart rate.
Heart Rate Variability (SDANN) 	Measures Standard Deviation of Averages of Normal Sinus to Normal Sinus intervals.
RV Rate During AT/AF 	Shows maximum and mean RV rate during AT/AF. Only in Health Tab or HF Management Report in RESONATE™ and MOMENTUM™ devices.
% LV Paced 	Trend is percent of cardiac beats paced with a left ventricular (LV) lead per day. *Only available on Health Tab or HF Management Report in RESONATE and MOMENTUM devices.

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[7]	S1 Heart Sound[7]
Respiratory Rate[7]	Thoracic Impedance[7]
Sleep Incline[13]	Activity Level[7]
Night Heart Rate[7]	% LV Pacing[17]
AT/AF Burden[14]	
Ventricular Arrhythmias[18]	
% RV Pacing[19]	

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.[2] 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
- Recent heart failure or other medication changes
- Use of harmful medications such as NSAIDs
- Onset or worsening of atrial or ventricular arrhythmias
- Recent device therapy (ATP, shocks) or changes in device programming (e.g., pacing mode, lower rate limit, etc)
- Reduction or loss of CRT (for patients with CRT devices only)
- Excessive right ventricular pacing
- 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.[2]

Importantly, the MANAGE-HF Study evaluated the implementation of HeartLogic into clinical practice. Key results of the study included:

1) Treating in response to HeartLogic alerts was safe with very few serious adverse events related to alert-prompted medication changes.[3]
2) Early HF treatment augmentation was associated with faster recovery of the HeartLogic Index and shorter alert case duration.[3]
3) 67% reduction in HF hospitalization rate compared to pre-study 12-month rate.[20]
4) Development of an Alert Management Guide that was used as a reference for clinicians to respond to HeartLogic alerts during the trial.[3] (See Appendix)

Depending on the factors you believe may have accompanied the HeartLogic alert (Step 2), consider one or more of the following actions:

- Reinforce medication adherence
- 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 AHA/ACC/HFSA guideline-directed medical therapies[2]

Continue to monitor your patient by following standard of care guidelines.[2]

References

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Appendix: MANAGE-HF Alert Management Guide[3]

The MANAGE-HF HeartLogic™ Alert Management Guide was developed and adapted by the Steering Committee throughout the study considering response to initial and re-alerts. Below you will find the final study version including the following content: 1) How to choose a response to a HeartLogic Alert, 2) Example figure of how the HeartLogic Index may behave in response to treatment escalation, and 3) How to escalate treatment.

***Note:** this reference is provided as an example of a published clinical protocol from MANAGE-HF and has not yet been shown to improve clinical outcomes. Patient management is at the discretion of the clinician.

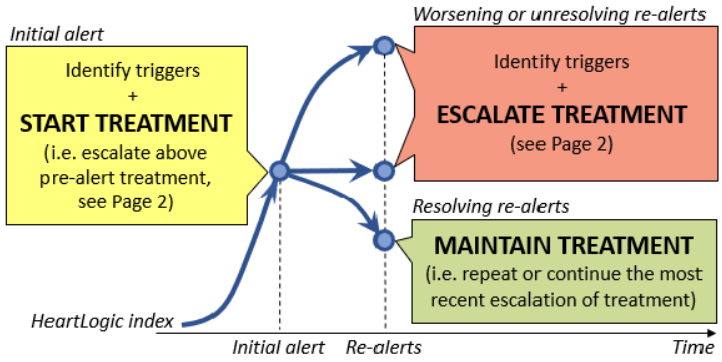
MANAGE-HF HEARTLOGIC ALERT MANAGEMENT GUIDE REV. C

This HeartLogic Alert Management Guide has been developed by the MANAGE-HF steering committee.

Use as a reference to manage participants in response to HeartLogic alerts in the trial. The Guide suggests clinical decision steps and potential heart failure treatments defined in the MANAGE-HF protocol [1].

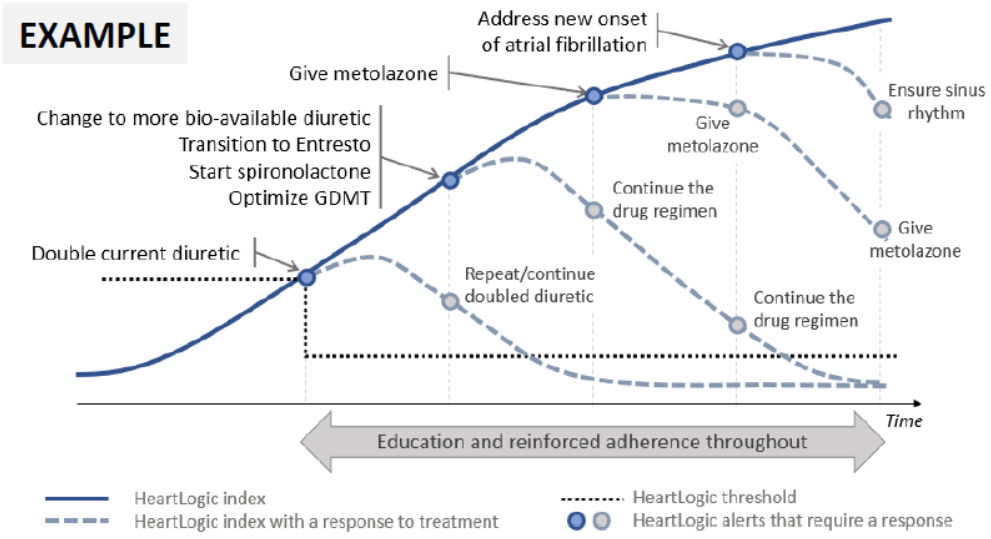
HOW TO CHOOSE A RESPONSE TO A HEARTLOGIC ALERT:

The goal of each weekly HeartLogic alert review is to implement an adjustment to participant's treatment plan within 6 calendar days to drive a reduction of the HeartLogic index, ultimately to the out-of-alert state as soon as possible. The following figure shows how to choose a response to a HeartLogic alert.



At initial alert start a new treatment which is an escalation from the pre-alert treatment. At re-alerts and if the HeartLogic index is **below** the value from a week prior, maintain treatment by repeating or continuing your most recent treatment escalation. If the HeartLogic index is **at or above** the value from a week prior, escalate treatment further. You may wait until the next re-alert if an escalation of treatment has been started in the 6 calendar days prior to the alert post date. Monitor for adverse effects at all alerts.

The figure below shows an example of treatment escalation depending on the HeartLogic index behavior.

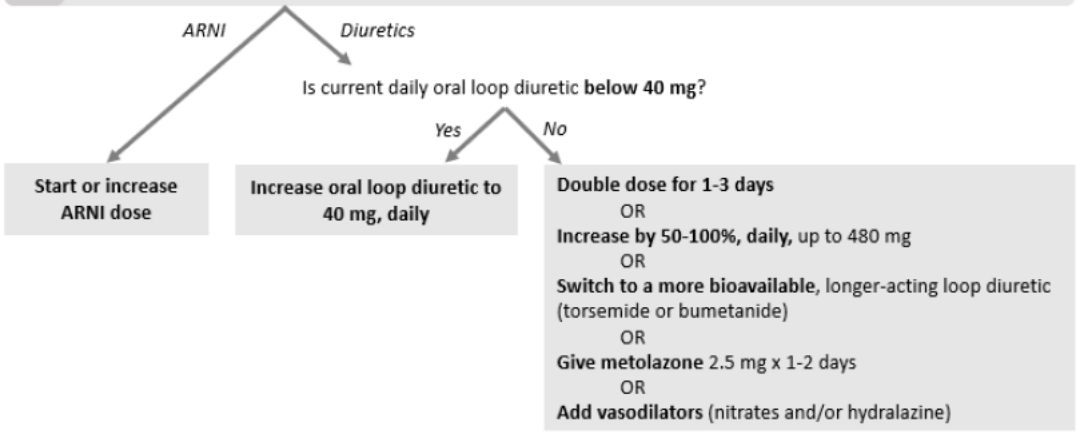


Appendix: MANAGE-HF Alert Management Guide[3] *continued*

How to escalate treatment:

To escalate treatment, choose one or more of the options below. If all the options are contraindicated (e.g. pneumonia, dehydration, infection, or high fever), choose a different treatment and provide supporting documentation with justification. Absence of signs and symptoms of worsening heart failure does not justify an exception from escalation.

1 Augment a decongestive treatment



It is recommended to check renal function and electrolytes at the time of a diuretic change, 3 to 7 days after, then as clinically indicated at the discretion of the provider. If the diuretic change lasts more than two weeks or is considered an ongoing change to baseline diuretics, additional monitoring of electrolytes and renal function may be warranted. Other pharmacologic changes may be appropriate as well.

2 Address a precipitating factor of the alert

Some alerts may be associated with one or more precipitating factors, such as

- Onset or worsening of atrial or ventricular arrhythmia
- Suboptimal CRT configuration
- Worsening of PVC burden
- Excessive right ventricular pacing
- Recent changes in the device programming (e.g. pacing mode, lower rate limit, AV delay)
- Recent reduction of a heart failure medication
- Recent addition of a heart failure-exacerbating medication
- Recent clinical intervention (e.g. administration of intravenous fluids)
- Iron deficiency/anemia
- Active ischemia

Reminders of adherence to the decongestive treatment is recommended in addition to the escalation of treatment.

3 Optimize guideline-directed medical therapy for heart failure

Start or augment current ACCF/AHA guideline-directed medical therapies for ACE/ARB/ARNI, BB, MRA, or hydralazine/nitrates [2].

Abbreviations:

ACCF	American College of Cardiology Foundation	**AV**	atrioventricular
ACE	angiotensin-converting-enzyme inhibitor	**BB**	beta blocker
AHA	American Heart Association	**CRT**	cardiac resynchronization therapy
ARB	angiotensin receptor blocker	**MRA**	mineralocorticoid receptor antagonist
ARNI	angiotensin receptor blocker neprilysin inhibitor	**PVC**	premature ventricular contraction

References:

1. Multiple cArdiac seNsors for mAnaGEment of Heart Failure (MANAGE-HF) Protocol, NCT03237858.

2. Yancy CW, et al. 2013 ACCF/AHA guideline for the management of heart failure. Circ 2013:128:240-327.

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; 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 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 evets 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, 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 evets 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 malfunctions; 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.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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