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

LATITUDE™ NOT Patient Management is a remote monitoring system that provides your health care provider access to your implanted device data. The LATITUDE Patient Management System is not intended to assist with medical emergencies or to provide continuous monitoring.

The Communication system is designed to operate on standard telephone lines as found in most homes. The Communication system 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 Communication system.

The Communication system 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 Communication system is not compatible with other than a Boston Scientific device.

Risk Management

Ask your physician if you have questions about any risks with using the Communication or your implanted device.

Inosure System – RESONATE™ X4, VIGILANT™ X4, LATITUDE™ NXT Patient Management is a remote monitoring system that gives your health care provider access to your implanted device data.

The system is indicated for use in patients with an implanted pulse generator system for pulse generator therapy, atrial tracking, antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. It is contraindicated for the following conditions: (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage or damage, lead or accessory infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a non-implanted lead or device may result in patient decompensation. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a non-implanted lead or device may result in patient decompensation.

POTENTIAL ADVERSE EVENTS

The following adverse events are potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not use this pulse generator without an MRI shield. Mistransfer of data may occur if the patient has an implanted pulse generator system while in the magnetic field, use MRI scanning of the patient does not restrict MRI Conditional requirements for the implanted system, and significant harm or death of the patient 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 use this pulse generator without an MRI shield. Mistransfer of data may occur if the patient has an implanted pulse generator system while in the magnetic field, use MRI scanning of the patient does not restrict MRI Conditional requirements for the implanted system, and significant harm or death of the patient or damage to the implanted system may result.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following: allergic reactions/irritation, drug toxicity, dislodgement, lead or system damage, hematoma formation, infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of dying, fear of device failure, or imagined shocks. In rare cases severe complications or device failures can occur.

Rhythm Management

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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.

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<th>…an INCREASE in</th>
<th>…a DECREASE in</th>
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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 exercise/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