

INTENDED USE/INDICATIONS FOR USE

The LATITUDE NXT System is intended to remotely communicate with a compatible Boston Scientific implanted device 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 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

WARNINGS

None Known

PRECAUTIONS

The clinician needs to log onto the LATITUDE NXT website in order to receive Alerts. Alerts may appear on the LATITUDE NXT website as often as daily. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NXT website. Although secondary notifications through email and Short Message Service (SMS) text messages are 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 LATITUDE NXT 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 the LATITUDE NXT website 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:

- There may be system limitations. (See "System Limitations" on page 1–3.)
- The Communicator is unplugged.
- The Communicator is not able to connect to the LATITUDE NXT server through the configured method of connection.
- 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.

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 page. (See Figure 2–4 View Patient List Page on page 2-8.)

CAUTION: Ensure that each patient’s alert configuration settings are appropriate when the patient is enrolled and, if applicable, after the implanted device is replaced.

CAUTION: The maximum weighing capacity of the optional weight scale is 200 kg (450 lb). Do not place anything on the scale that is beyond the weighing capacity

POTENTIAL ADVERSE EVENTS

Patients may also experience psychological effects of anxiety related to remote patient monitoring.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

Refer to the product labeling for specific instructions for use. Rx only.
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HEARTLOGIC™

LATITUDE™ NXT

Heart Failure Diagnostic

Checklist



HeartLogic Heart Failure Diagnostic (HeartLogic) information and alerts are available in Boston Scientific's RESONATE™, VIGILANT™, PERCIVA™ and MOMENTUM™ ICDs and CRT-Ds and are viewable in LATITUDE NXT. Please review the following topics before monitoring HeartLogic in LATITUDE NXT.



Understand the HeartLogic Heart Failure Diagnostic

- Utilize self-guided HeartLogic CEU training at <http://heartlogictraining.com>
- Have a process in place to address alerts using the HeartLogic Alert Management Guide



HEART SOUNDS



THORACIC IMPEDANCE



RESPIRATION



HEART RATE



ACTIVITY



Patient Organization

The LATITUDE NXT collaborative care model enables two Patient Groups (in the same clinic or in separate clinics) to remotely monitor the same patient. This enables a variety of configuration options in LATITUDE NXT including the option to monitor for alerts only. For configuration assistance, contact LATITUDE Customer Support at 800.CARDIAC (227.3422).



User Management

Determine which users will be responsible for monitoring HeartLogic and other health trends and ensure these clinicians have appropriate access to LATITUDE NXT.



Heart Failure Reimbursement

Determine if your clinic will seek reimbursement for heart failure monitoring. This may help determine the best workflow and configuration option for your clinic in LATITUDE NXT.



Monitoring Status

To realize the full potential of HeartLogic, patients need to be actively monitored in LATITUDE NXT. Please review the Not Monitored list regularly.