

LATITUDE™ NXT Patient Management System from Boston Scientific CRM

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 two weeks 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.

Refer to the product labeling for specific instructions for use. Rx only.
(Rev. D) 046774 AH



Rhythm Management
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www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
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CRM-544001-AB



HeartLogic™

Heart Failure Diagnostic

LATITUDE™ NXT

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.