

LATITUDE™ NXT 5.0 Frequently Asked Questions


1. When does the LATITUDE 5.0 release launch in the U.S.? Do I need to do anything to get this new version?

LATITUDE 5.0 launches on May 22, 2017. When you log into LATITUDE NXT on or after this date, the update will be available for you. No additional action is required from you.

2. How do I learn about the new features in LATITUDE NXT 5.0

- Go to www.bostonscientific.com/latitudeupdates
- Speak with your Boston Scientific sales rep
- Call LATITUDE Customer Support at 1.800.CARDIAC (227-3422)

3. How do I enter a note in the Patient Notes field?

After clicking on the patient's name, simply type your comments in the Patient Note field and click *Save*. Once a note is saved it can be updated by clicking on the Patient Note icon  from any filtered list.

4. Will I see anything new on the website with this release for my existing patients?

Health and Lead Trend improvements were added to enhance the user experience and facilitate the review of health and leads data including:

- Measurement boxes have been added to the left of each trend
- A 3 day average trend is also available for trends with a single line on the Health Tab
- Trend graphs will now auto-scale based on the values within that graph
- Interactive display and hover boxes have been added to the trend graphs

Many of these improvements are available on the Combined Follow-up and Heart Failure Management Reports.

5. How will the EMR changes help my workflow?

Event Detail Reports will automatically transfer to EMR, once LATITUDE NXT 5.0 launches. This change is available for customers using IDCO format to transfer data to the EMR. The number of episodes may be limited if a large amount of data is being transferred.

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.