

LATITUDE™ NXT 6.0 Frequently Asked Questions

1. When does LATITUDE NXT 6.0 launch in the U.S.?

LATITUDE 6.0 launches on May 21st, 2018. When you log into LATITUDE NXT on or after this date, the update will be available for you. No action is required from you.

2. How do I learn about the new features in LATITUDE NXT 6.0?

- 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 will the new Antitachycardia pacing (ATP) therapy delivered to convert arrhythmia alert work?

This alert is nominally ON in LATITUDE NXT and is available for all tachy devices except EMBLEM S-ICD. If both ATP and a shock occur, two alerts will be generated. One alert is generated for each episode since the last counter reset. You may be notified of multiple ATP alerts soon after the launch of LATITUDE NXT 6.0 if counters for specific patients have not been reset recently. As with other Yellow alerts in LATITUDE NXT, this can be configured at the Patient Group and individual patient level.

4. How will the new Nonsustained ventricular arrhythmia (NSVT) episode(s) alert work?

This alert is nominally OFF in LATITUDE NXT and is available for all brady and tachy devices except EMBLEM S-ICD. One alert is generated per communicator interrogation. If multiple NSVT episodes are detected during an interrogation, only one alert is generated. As with other Yellow alerts in LATITUDE NXT, this can be configured at the Patient Group and individual patient level.

5. Why is the Voltage too low for projected remaining capacity alert changing from a Yellow alert to a Red alert?

6476 Communicators check for Yellow alerts once per week and Red alerts daily. The change ensures that all Communicators (6476, 6290, 6280 and 6498) check for this alert daily.

6. What is changing with LATITUDE NXT EMR Integration?

For clinics using this software, Boston Scientific is updating the Infor Cloverleaf® Secure Courier client that enables LATITUDE™ NXT EMR Integration. This application is installed at your site to manage the export of data from the LATITUDE NXT website to your EMR or device management system. We recommend that you work with your IT department to complete the migration as soon as possible to take advantages of the latest security updates available in this release. Please note that the current Cloverleaf Secure Courier version will continue to work until **November 1, 2018**. However, on that date, the version will be retired and data from the LATITUDE NXT system will no longer transfer unless your clinic has completed the migration. LATITUDE Customer Support can be reached at 888.283.8713 or LATITUDEITdatamgmt@bsci.com to assist with the migration or any questions you may have about this update.

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.

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

Rhythm Management

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www.bostonscientific.com

Medical Professionals:

1.800.CARDIAC (227.3422)

Patients and Families:

1.866.484.3268

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