LATITUDE™ NXT 6.1 Frequently Asked Questions

1. **When does LATITUDE NXT 6.1 launch in the U.S.?**
   LATITUDE 6.1 launches on July 22, 2019. 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 6.1?**
   - 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 Signal Artifact Monitor (SAM) yellow alert work?**
   LATITUDE NXT 6.1 enables a yellow alert if Signal Artifact Monitor (SAM) disables the Minute Ventilation (MV) sensor in the Ingenio and Accolade family of pacemakers and cardiac resynchronization therapy pacemakers (pacemakers). SAM is an interval-based algorithm designed to quickly eliminate pacing inhibition due to MV sensor signal oversensing by switching the vector MV operates on or disabling the MV sensor. By design, diagnostic data (EGMs) for certain SAM yellow alerts prior to the 6.1 upgrade may only be accessible through in-clinic programmer interrogation of the pacemaker.

   The SAM yellow alert will be 'Off' for existing patients when LATITUDE NXT 6.1 launches. Prior to enabling the SAM yellow alert, it is recommended that you talk to your rep. As with other Yellow alerts in LATITUDE NXT, this can be configured at the Patient Group and individual patient level.

4. **Why do some SAM alerts not have associated diagnostic episode data?**
   A SAM alert may be generated for past episodes where MV was disabled by SAM. If the episode occurred before the LATITUDE NXT v6.1 update and the device has completed a full transmission, diagnostic episode data may not be available. After these alerts are uploaded, only new alerts complete with diagnostic episode data will be sent.

5. **Other than SAM what recent Brady firmware upgrades will LATITUDE NXT 6.1 support?**
   Auto Lead Recognition (ALR), MRI Protection Mode for VALITUDE X4 and VISIONIST X4, and RightRate (MV as a Rate Driver) Pacing to VISIONIST models

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) 046774 AH

CRM-641902-AA