

## SUMMARY

Boston Scientific's LATITUDE™ NXT Patient Management System enables clinicians to periodically monitor patient and implanted device information remotely via a Communicator placed in the patient's home.

This article describes how the Communicator can make use of a personal Wi-Fi hotspot to send information over an internet connection.

### Products Referenced

LATITUDE NXT Patient Management System

Products referenced are unregistered or registered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are the property of their respective owners.

For comprehensive information on device operation, reference the full instructions for use or found at: [www.bostonscientific-elabeling.com](http://www.bostonscientific-elabeling.com).

**CAUTION:** The law restricts this device to sale by or on the order of a physician.

Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

### Contact Information

[www.bostonscientific.com](http://www.bostonscientific.com)

#### Americas

##### Technical Services

##### LATITUDE™ Customer Support

1.800.CARDIAC (227.3422)

+1.651.582.4000

##### Patient Services

1.866.484.3268

#### Europe, Middle East, Africa

##### Technical Services

+32 2 416 7222

[intltechservice@bsci.com](mailto:intltechservice@bsci.com)

##### LATITUDE Customer Support

[latitude.europe@bsci.com](mailto:latitude.europe@bsci.com)

#### Japan

##### Technical Services

[japantechservice@bsci.com](mailto:japantechservice@bsci.com)

##### LATITUDE Customer Support

[japan.latitude@bsci.com](mailto:japan.latitude@bsci.com)

#### Asia Pacific

##### Technical Services

+61 2 8063 8299

[aptechservice@bsci.com](mailto:aptechservice@bsci.com)

##### LATITUDE Customer Support

[latitudeasiapacific@bsci.com](mailto:latitudeasiapacific@bsci.com)

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## How to Use a Personal Hotspot Feature with a LATITUDE™ NXT Communicator

The LATITUDE System gives health care providers access to implanted device data between scheduled office visits. At scheduled intervals, the Communicator sends your implanted device data to the LATITUDE system using one of several methods, dependent on setup. Some setup methods may require additional equipment. Data may be sent over the following types of connections:

- Standard telephone line (landline)
- Cellular data network (using a USB Cellular Adapter)
- Hard-wired internet (using a LATITUDE USB Ethernet Adapter)
- Wireless internet (using a LATITUDE Wireless Internet Adapter)
- Personal hotspot (using a LATITUDE USB Accessory Adapter)

A hotspot is a physical location, usually a cellular phone or other mobile device (e.g., cellphone, smartphone, or tablet), that offers wireless internet access—typically using Wi-Fi technology.

If supported by your mobile device and service plan, a hotspot can be enabled and paired with your Communicator. This allows the Communicator to wirelessly access the Internet to send encrypted data to your LATITUDE clinic.

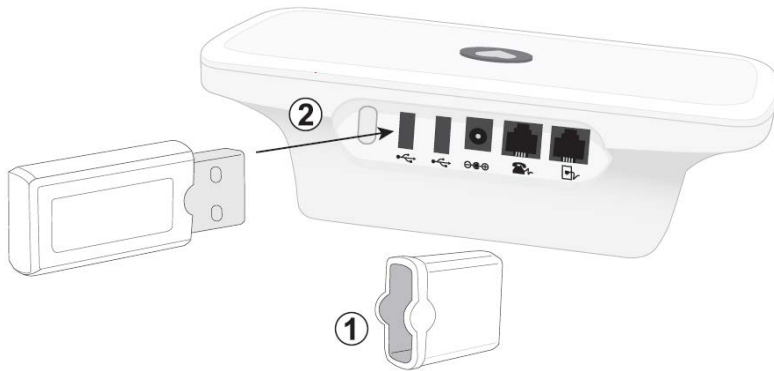
Enable Personal Hotspot, Bluetooth®, and Bluetooth tethering (if applicable) on your mobile device while near your Communicator for at least one hour each day and for manual device interrogations. This should allow enough time for the Communicator to connect to the hotspot and contact the LATITUDE system.

Hotspots, and any fees associated with them, are administered through your mobile service provider. Be sure that you understand the internet data allowance for your service plan as your plan may charge overage fees if you exceed your data allowance. Additionally, please be aware that using Bluetooth and the hotspot on your mobile device may reduce the battery life of your mobile device.

### What You Will Need

- A Communicator that is connected to an electrical outlet
- A mobile device, with hotspot capability, that supports Bluetooth connectivity (and Bluetooth tethering, if applicable)
- A service plan with an internet data allowance and hotspot capability
- A LATITUDE USB Accessory Adapter connected to the Communicator (Figure 1)

To obtain a LATITUDE USB Accessory Adapter, contact the appropriate Boston Scientific office (see sidebar). In the Americas, please use the Patient Services number.



**Figure 1. Connecting the LATITUDE USB Accessory Adapter.** Remove cap (1) and insert LATITUDE USB Accessory Adapter (2) into either of the two USB slots on the back panel of the Communicator.

### Pairing Your Hotspot and Communicator

- 1) *Configure your mobile device by turning on:*
  - the hotspot functionality
  - Bluetooth tethering (if applicable)
  - Bluetooth
  - Bluetooth pairing/discoverable mode

These options are likely found on the 'Settings' screen of your mobile device. For additional assistance configuring your mobile device, please contact your mobile service provider.

- 2) *Check to make sure the Communicator:*
  - is plugged into a working power outlet
  - has a LATITUDE USB Accessory Adapter connected to either one of the USB ports on the back panel (Figure 1)
- 3) *Pair the Communicator with your mobile device*
  - Press and hold the 'Status' button on the back panel of the Communicator for three seconds. This will allow the Communicator to find your mobile device and begin the pairing process.
  - Select the Communicator when it appears in the list of available connections on your mobile device. It will appear in the list of options as 'MISC' or 'LATITUDE NXT'.
  - When you are prompted to enter a PIN on your mobile device, enter "123456".
  - Once the Communicator has paired successfully, the blinking green sending waves will turn solid and the blue doctor icon will appear. This will complete the pairing process. The Communicator and mobile device will remain paired and do not need to repeat the pairing process again.

If the pairing is not successful, yellow sending waves will be displayed on the Communicator. For additional assistance with pairing your mobile device, please contact your mobile device service provider.

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## **LATITUDE™ NXT Patient Management System from Boston Scientific CRM**

### **Indications for 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. C)*