

LATITUDE™ NXT Communicator Quick Reference Guide

Model 6498, 6280 and 6290



(For any other home monitor models, call Patient Services during normal business hours)




This guide is meant to assist with basic troubleshooting, lights, and common questions for the LATITUDE NXT Communicator. If further help is needed see Additional LATITUDE Resources below, call Patient Services during normal business hours (M-F 8am-5pm CST), or contact the patient’s health care provider. For setup assistance, see the LATITUDE Communicator manual or Quick Setup Guide available on the Boston Scientific website.







NOTE: The LATITUDE System is not meant to assist with health emergencies. If the patient is not feeling well or urgent health care is needed, call a health care provider, or dial 911. The LATITUDE monitor does not provide continuous monitoring and does not affect the operation of the patient’s implanted device.




Additional LATITUDE Resources:

MyLATITUDE™ Patient App: Download on the App Store (for iOS) or Google Play Store (For Android) - Search for "MyLATITUDE".

Boston Scientific Website: www.bostonscientific.com/patients

| Scenarios/Lights | Guidance | |
|--|---|---|
| <p>Red Call Doctor light (flashing or solid)</p>  | <p>Potential change with implanted device was detected. The home monitor cannot send any information from the implanted device to the LATITUDE system. Your immediate response is required. Call your health care provider.</p> <p>To attempt to resolve, follow the steps below:</p> | |
| | <p>1. Unplug power supply, wait for one full minute, and plug monitor back in. The Red Call Doctor may reappear.</p> | |
| | <p>2. If using Boston Scientific-provided Cellular or Ethernet adapters, wait until a light is visible on adapter, then briefly press and release Heart Button.</p> |  |
| | <p>3. Data has been sent when a blue figure and solid green waves appear on both sides of the heart. Inform the patient’s health care provider of potential change with implanted device.</p> |  |
| <p>4. If results differ from described, see Yellow Collecting Wave or Yellow Sending Wave troubleshooting sections below and call the patient’s health care provider if not previously contacted before troubleshooting.</p> | | |

| Scenarios/Lights | Guidance | |
|--|--|---|
| <p>Yellow Call Doctor light (flashing or solid)</p>  | <p>The home monitor is currently unable to read the patient’s implanted device OR monitoring of the patient’s implanted device through the LATITUDE system may be suspended.</p> <ol style="list-style-type: none"> 1. Unplug the power supply from both the wall outlet and the monitor, wait for one full minute. After one minute, plug the monitor back in. The Yellow Call Doctor may reappear. 2. Locate small, white Status Button on back of monitor (near cords). Press and hold until flashing green lights appear on right side of heart. If no lights change, the monitor will need to be replaced. Please call Patient Services during normal business hours. 3. If waves on right of heart light are solid green and the doctor icon lights blue, the Yellow Call Doctor light should turn off. If results differ from described, see Yellow Sending Wave troubleshooting section below or call Patient Services during normal business hours. |   |
| <p>Send a reading OR Heart Button is flashing</p>  | <p>The heart button is flashing because the Communicator needs help completing a previously scheduled device check. NOTE: This does not indicate a problem with the implanted device.</p> <ol style="list-style-type: none"> 1. Ensure all cords are connected properly. Briefly press and release Heart Button. Stay within arm’s reach of monitor while the interrogation completes. 2. Data has been sent when a blue figure and solid green waves appear on both sides of the heart. 3. If results differ from described, see Yellow Collecting Wave or Yellow Sending Wave troubleshooting sections below or call Patient Services during normal business hours. |   |

| <p>Yellow Collecting Waves (unable to collect data from implanted device)</p>  | |
|--|---|
| <p>Refer to “Where to place your Communicator” section of the LATITUDE Communicator Patient Manual</p> | |
| <p>1. Move wireless electronics at least 3 feet away from monitor (examples-cordless or cellular phones, baby monitors, cable boxes, other medical equipment, iPads/tablets, computer routers)</p> | |
| <p>2. Briefly press and release Heart Button, stay within arm’s reach of monitor while the interrogation completes.</p> |  |
| <p>3. Data has been sent when a blue figure and solid green waves appear on both sides of the heart.</p> |  |
| <p>4. If results differ from described, call Patient Services during normal business hours.</p> | |

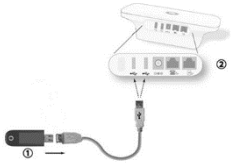
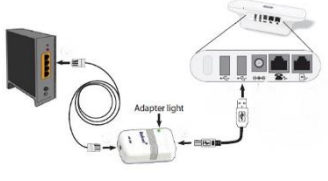
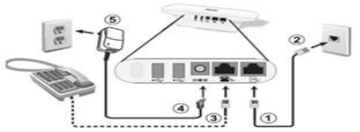


Yellow Sending Waves (unable to send data to LATITUDE system)



Refer to “Where to place your Communicator” section of the LATITUDE Communicator Patient Manual

Home monitors are designed to work with a Boston Scientific-provided cellular or ethernet adapter, or a landline.

Note: Only ONE connection method should be used at a time.

| CELLULAR ADAPTER | ETHERNET ADAPTER | LANDLINE |
|---|---|---|
| <p>1. Ensure the black USB extender cord attaches securely to back of monitor and USB drive. *Adapter light may flash, stay solid, change color, or turn off briefly. This is normal operation.</p>  | <p>1. Ensure one end of the provided ethernet adapter cord attaches securely to the USB port on the back of the monitor. Connect the other end of the ethernet adapter cord to the active ethernet/LAN port on the WIFI router. (Adapter will light)</p>  | <p>1. Ensure one end of the phone cord attaches securely to back of monitor in far-right port. Connect the other end of the phone cord to a working wall jack or modem depending on phone service. Verify a steady dial tone in the phone wall jack and all phones are hung up.</p>  |
| <p>2. For all connection methods, all switches on the bottom of the monitor should be positioned closest to the numbers.</p> <p>Note: Landline users that require a prefix/dial out number, or landline users travelling outside U.S. refer to LATITUDE Communicator manual for switch settings.</p>  | | |
| <p>3. Unplug the power for one minute, then plug the monitor back in. Locate the small, white Status Button on back of monitor (near cords). Press and hold until flashing green lights appear on right of heart. Data has been sent when a blue figure and solid green waves appear on right of heart.</p>  | | |
| <p>4. If unsuccessful, move monitor to new location and repeat steps above. If still unsuccessful, call Patient Services during normal business hours.</p> | | |

Common Questions and Answers

| | |
|---|--|
| Implant device related symptoms; shocks; battery life; monitor schedule, data or reports | Inform the patients' health care provider. Boston Scientific does not have access to medical information. |
| Travel questions such as: Should patients take monitor while traveling; who should be informed; airport security | Inform the patients' health care provider, they will provide guidance on taking monitor. All monitor equipment is X-ray safe, pack in carry-on luggage, and ensure correct connection method is taken for travel (example: cell adapter). Implanted device is designed to function normally without the use of the monitor. |
| What happens if the power goes out/monitor is unplugged | Data is stored in monitor's memory. When power is restored/plugged back in, the monitor will resume normal operation. The monitor will briefly flash yellow then the LATITUDE light will turn green. If a green LATITUDE light does not come on, call Patient Services during normal business hours. |
| How do I make sure monitor is working? | Press and release the small, white Status Button on back of monitor (near cords) for one second. If the lights are green on both sides of Heart, the monitor is working correctly. If yellow lights appear, see Yellow Collecting Wave or Yellow Sending Wave troubleshooting sections above. |
| What does the flashing yellow LATITUDE indicator light mean? | The LATITUDE indicator light flashes yellow briefly during the startup process and flashes yellow longer during a software upgrade. The LATITUDE indicator light turns green after startup process or software upgrade is complete. |

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.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (Rev A) 92436260



Rhythm Management

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