

CLINICIAN MANUAL

LATITUDE™ NXT

LATITUDE™ NXT PATIENT MANAGEMENT
SYSTEM

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ABOUT THIS MANUAL

This manual contains information about the LATITUDE NXT Patient Management System (“LATITUDE NXT System”), which includes two distinct types of Communicators. Much of the Communicator information in this manual applies to both types. In that case, the reference is simply to Communicator or LATITUDE Communicator. However, when there are differences in how the two Communicators relate to the LATITUDE NXT System, distinction between the two will appear as follows:



WAVE WIRELESS COMMUNICATOR (Models 6288/6290)
Differences between these models will be noted as appropriate.
(Model 6288 may not be available in all geographies.)



TOUCH-SCREEN WIRELESS COMMUNICATOR (Model 6468)
(Model 6468 may not be available in all geographies.)

This literature is intended for use by authorized health care providers of the LATITUDE NXT Patient Management System.

The screen illustrations used in this manual are intended to familiarize you with the general screen layout. The actual screens you see when using the LATITUDE NXT System will vary based on model, location, and language.

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TABLE OF CONTENTS

THE LATITUDE NXT PATIENT MANAGEMENT SYSTEM	1-1
CHAPTER 1	
INTRODUCTION: LATITUDE NXT PATIENT MANAGEMENT SYSTEM	1-2
Intended Use	1-2
Contraindications	1-2
Precautions	1-2
Adverse Effects.....	1-3
System Limitations	1-3
LATITUDE NXT Secure Server	1-4
LATITUDE Communicator Overview.....	1-4
LATITUDE Customer Support	1-7
Optional Home Health Monitoring Equipment.....	1-7
BASIC CONCEPTS	1-8
Access to Patient Data	1-8
Registered Users	1-8
Patient, Clinician, and Clinic Relationships.....	1-8
Patient Groups.....	1-9
Clinic User Privileges.....	1-9
Alerts	1-10
Red Alerts	1-10
Yellow Alerts	1-11
Implanted Device Interrogation.....	1-13
Patient Initiated Interrogations.....	1-13
USING THE LATITUDE NXT PATIENT MANAGEMENT SYSTEM.....	2-1
CHAPTER 2	
GETTING STARTED	2-2
Requirements	2-2
Logging In and Out.....	2-2
Navigating the Site	2-5
CLINIC AND PATIENT CONFIGURATION.....	2-5
Configuration Details	2-6
THE VIEW PATIENT LIST PAGE.....	2-7
Generating and Printing Patient Reports	2-11
SEARCH PATIENTS TOOL.....	2-11
PATIENT ENROLLMENT.....	2-12
Online Patient Enrollment	2-12
Enrolling Existing Patients	2-13
Equipment Distribution	2-13
PATIENT INITIALIZATION	2-14
MANAGING PATIENTS	2-14
Changing Patient Demographic and Equipment Information	2-14
Changing Patient Groups.....	2-14
Transferring Patients	2-15
Unenrolling Patients.....	2-15
MANAGING PATIENT GROUPS.....	2-15
Adding Patient Groups	2-15
Deleting Patient Groups.....	2-15

Other Patient Group Management Functions.....	2-16
MANAGING USER ACCOUNTS	2-16
Adding User Accounts	2-16
Deleting User Accounts	2-16
Other User Account Management Functions	2-16
User Account Self-Management.....	2-17
PASSWORDS	2-17
Temporary Passwords	2-17
Security Questions	2-17
Changing Your Password	2-17
Resetting Your Forgotten Password.....	2-18
EMR SYSTEM INTEGRATION.....	2-18
Configuring the EMR Feature.....	2-20
View EMR Log.....	2-22
EDUCATING PATIENTS ABOUT THE LATITUDE COMMUNICATOR	3-1
CHAPTER 3	
LATITUDE COMMUNICATOR OVERVIEW.....	3-2
WAVE WIRELESS COMMUNICATOR.....	3-2
Communicator Placement.....	3-2
Identifying Buttons, Connectors, and Indicators	3-2
Indicator Descriptions.....	3-4
The Status Button	3-5
Explaining the WAVE WIRELESS COMMUNICATOR Setup	3-6
Setting the WAVE WIRELESS COMMUNICATOR Switches.....	3-8
Heart Button Interrogation Sequence.....	3-11
Connecting the USB Accessory Adapter	3-11
TOUCH-SCREEN WIRELESS COMMUNICATOR	3-12
Identifying Buttons, Connectors, and Indicator.....	3-12
Button and Indicator Light Descriptions.....	3-13
Touch-Screen Display	3-13
Explaining the TOUCH-SCREEN WIRELESS COMMUNICATOR Setup	3-14
TROUBLESHOOTING GUIDE.....	A-1
APPENDIX A	
Troubleshoot Yellow Collecting Waves.....	A-1
Troubleshoot Yellow Sending Waves	A-3
Red/Yellow Call Doctor Icon.....	A-5
Weight Scale or BPM Readings not Received	A-7
Blood Pressure Monitor Error	A-7
Incorrect Language Displayed.....	A-8
“No dial tone”	A-8
“LATITUDE is temporarily unavailable”	A-9
“Interrogation could not be completed”	A-10
Monitoring Suspended.....	A-11
Blank Screen and the Action Button is Yellow	A-11
The Action Button on the Communicator is Red.....	A-11
Weight Scale or BPM Readings not Received	A-12
Blood Pressure Monitor Error.....	A-12
SYMBOLS	B-1
APPENDIX B	

THE LATITUDE NXT PATIENT MANAGEMENT SYSTEM

CHAPTER 1

This chapter contains the following topics:

- “INTRODUCTION: LATITUDE NXT PATIENT MANAGEMENT SYSTEM” on page 1-2
- “BASIC CONCEPTS” on page 1-8

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INTRODUCTION: LATITUDE NXT PATIENT MANAGEMENT SYSTEM

The LATITUDE NXT Patient Management System ("LATITUDE NXT System") enables authorized members of a clinic to periodically monitor patient and device status remotely. (See "Alerts" on page 1-10 for device and patient conditions that are monitored.)

Data collected from the implanted device are combined with data from an optional weight scale or blood pressure monitor. By combining these internal and external measurements with historical information, clinicians can use the LATITUDE NXT System to develop an informed understanding of the patient's implanted device and cardiac health status. Clinic users can periodically monitor devices and bring patients into the office according to implanted device labeling and also when clinically appropriate.

Intended Use

The LATITUDE NXT System is intended to remotely communicate with a compatible Boston Scientific implanted device 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 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

The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Alerts may appear on the LATITUDE NXT website as often as daily. Primary notification of alert conditions is through the **View Patient List** page on the LATITUDE NXT website. Although secondary notification through email and Short Message Service (SMS) text messages are 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 LATITUDE NXT website. (SMS text messages may not be available in all geographies.)

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 the LATITUDE NXT website 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:

- There may be system limitations. (See "System Limitations" on page 1-3.)
- The Communicator is unplugged.
- The Communicator is not able to connect to the LATITUDE NXT server through the configured method of connection.
- 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.

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** page. (See Figure 2–4 View Patient List Page on page 2-8.)

Adverse Effects

There are no known adverse effects.

System Limitations

The LATITUDE NXT System is not intended to assist with medical emergencies. Patients who are not feeling well should call their physician or emergency services number.

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** — Proper reporting of implanted device data and alert notifications by the LATITUDE NXT System depends on the implanted device clock being programmed accurately with a Programmer/Recorder/Monitor (PRM). Proper reporting may continue to be impacted for some period of time after the implanted device clock is programmed correctly, depending on the amount of data received with inaccurate time information and the time difference of the implanted device clock error.
- **Patient environment** — To transmit data, the Communicator must be plugged into an electrical outlet. The Communicator must also maintain regular connection with the LATITUDE NXT server. Patients must be within range of the Communicator at the appropriate times. Radio-frequency (RF) interference from wireless electronic products may interfere with communication between the implanted device and the Communicator.
- **Telephone system** — Variations in infrastructure compatibility among telephone service providers, as well as variations in the quality of the telephone line from inside the patient's home to telephone company equipment and switching stations can affect LATITUDE NXT System data delivery. Other equipment attached to the telephone line inside the patient's home can also affect data delivery.
- **Cellular data service** — Use of the cellular data network does not guarantee coverage. A cellular adapter may need to be connected, as applicable. Actual coverage may be affected by such things as terrain, weather, foliage, buildings and other construction, signal strength, timely payment (as applicable), and other factors.
- **Internet connectivity** — For patients using Internet connectivity, performance of the Communicator depends on an active Internet service. If using a USB Ethernet Adapter for connection, the adapter must remain connected to a functioning router/modem.

If using the hotspot feature on their mobile device for wireless Internet connectivity (not available in all geographies), the patient must enable hotspot and *Bluetooth*® wireless technology on their mobile device while near their Communicator for at least one hour each day and for manual device interrogations.

- **Communicator memory capacity** — Communicator memory used to store implanted device data may reach its capacity if the Communicator cannot connect to the LATITUDE NXT server for an extended period.

- If this occurs in a WAVE WIRELESS COMMUNICATOR, the Communicator will delete the oldest collected implanted device data that does not contain any red alerts from its memory in order to store newly collected implanted device data. If all implanted device data contains red alerts, the oldest data is deleted.
- If this occurs in a TOUCH-SCREEN WIRELESS COMMUNICATOR, the oldest collected implanted device data will be deleted from memory in order to store the newly collected implanted device data.
- **Clinic environment** — Delays in contacting clinicians may occur for a variety of reasons, including computer equipment that may be down or offline, cell phones that may not be able to receive alert text messages, and the unavailability of clinical staff.
- **Schedule/configuration changes** — Under normal conditions, the patient's Communicator should be plugged in continuously and operating properly as described in the patient manual. Under these normal conditions, changes in schedule and configuration settings can take up to eight days to be sent to the patient's Communicator and become effective.
- **Data processing** — Data acquisition and delivery can be delayed or prevented due to:
 - Temporary, scheduled, and unscheduled downtime of computer servers.
 - Variations in server loads and processing times.
 - Other data processing issues.

LATITUDE NXT Secure Server

The LATITUDE NXT secure server is a centralized computer database that stores patient data, implanted device data, and sensor data sent from LATITUDE NXT Communicators. The LATITUDE NXT secure server also stores clinic and clinic user configuration information. The LATITUDE NXT secure server provides the data presented on the LATITUDE NXT website, which is available over the Internet to authorized users. The data provided to the LATITUDE NXT website includes the most recently received implanted device and sensor data as well as historical data related to previous remote follow-ups for the clinic associated with the currently implanted device.

LATITUDE Communicator Overview

A key component of the LATITUDE NXT System is the LATITUDE Communicator, an in-home monitoring device for patients. The Communicator reads implanted device information based on the schedule configured by the clinic. It then sends the data to the LATITUDE NXT server through a standard telephone line. Other options for connection to the LATITUDE NXT server are through a cellular data network or over the Internet (availability per model shown below).

For purposes of this manual, the two types of Communicators sending data to the LATITUDE NXT server are:

WAVE WIRELESS COMMUNICATOR (Models 6288/6290)



- For cellular connection:
 - Model 6288 has built-in capability for cellular communication.
 - Model 6290 uses the LATITUDE USB 3G Cellular Adapter for cellular communication.
- For Internet connection, both models may use:
 - The LATITUDE USB Ethernet Adapter or
 - The hotspot feature on a mobile device (requires USB Accessory Adapter) (not available in all geographies).
- For standard telephone connection:
 - Both models support only tone analog dialing mode.

TOUCH-SCREEN WIRELESS COMMUNICATOR (Model 6468)



- For cellular connection:
 - Model 6468 uses an external cellular adapter for cellular communication.
- For Internet connection:
 - Model 6468 does not support an Internet connection.
- For standard telephone connection:
 - Model 6468 supports both tone and pulse analog dialing mode.

For setup and general operating information, refer to "Wave Wireless Communicator" on page 3-2 or "Touch-Screen Wireless Communicator" on page 3-12.

NOTES:

- *The LATITUDE Communicator can only read data from an implanted device and cannot reprogram, command lead tests, or change any functions of the implanted device. The implanted device can only be reprogrammed with a Programmer/Recorder/Monitor (PRM).*
- *The LATITUDE Communicator does not provide continuous real-time monitoring. It reads implanted device information at times scheduled by the clinic user.*
- *When the LATITUDE Communicator connects to the LATITUDE NXT server, it receives any schedule and configuration updates entered by a clinic user on the LATITUDE NXT website.*
- *The patient receives a LATITUDE Communicator from the clinic after the patient is enrolled in the LATITUDE NXT System. After the patient activates the Communicator according to the instructions in the patient manual, the Communicator is able to interrogate the patient's implanted device. (See "Implanted Device Interrogation" on page 1-13.) When the patient is enrolled, the Communicator is configured to communicate with a single implanted device.*
- *The Communicator uses a wireless (radio frequency) communication system to communicate with the patient's implanted device, as well as the optional weight scale and blood pressure monitor. This communication can be disrupted by electromagnetic interference. Patients should avoid placing a Communicator next to or in the immediate vicinity of other wireless products and sources of electromagnetic energy (such as microwaves or computer monitors). For patients with an S-ICD supported on LATITUDE, the wireless communication between the Communicator and an S-ICD is orientation and distance sensitive. In some positions, the Communicator may need to be closer to the S-ICD to complete an interrogation. Contact LATITUDE Customer Support if the patient needs help finding a suitable location for their Communicator or if there are questions about possible sources of interference.*
- *The LATITUDE Communicator is designed for use by a single patient. Once a Communicator has been used by a patient, it cannot be reconfigured or distributed to a different patient.*
- *The LATITUDE Communicator, designated per model as shown below, is designed to work in the following countries.*

Country	Model 6468	Model 6288	Model 6290
Austria	x	x	x
Belgium	x	x	x
Czech Republic	x	x	x
Denmark	x	x	x
Finland	x	x	x
France	x	x	x
Germany	x	x	x
Greece		x	x
Hong Kong			x
Hungary		x	x
Ireland (Republic)	x	x	x
Italy	x	x	x
Netherlands	x	x	x
Norway	x	x	x
Poland	x	x	x
Portugal	x	x	x
Slovak Republic		x	x
Spain	x	x	x
Sweden	x	x	x
Switzerland	x	x	x
United Kingdom	x	x	x

Depending on the model and the method of connection, the LATITUDE Communicator may or may not be able to be used in other European Economic Area (EEA) countries or outside the EEA. Refer to the following table for details. Please contact LATITUDE Customer Support for more information.

Method of Connection	Model 6468	Model 6288	Model 6290
Communicator use in EEA countries other than those listed in the above table:			
Standard telephone line	Not supported		
Cellular data network	Allowed		
Internet	Not supported	Allowed	
Communicator use in countries outside the EEA: ^a			
Standard telephone line	Not supported		Supported in countries that have switch settings
Cellular data network	May be restricted due to radio-frequency (RF) laws		Allowed
Internet	Not supported	May be restricted due to RF laws	

- a. When traveling to a country outside of the EEA, the data transmitted from the Communicator will be subject to laws of that country, which may provide less privacy protection for your data than the laws of your home country. Please contact your health care provider for specific information about data privacy.

LATITUDE Customer Support

LATITUDE Customer Support provides technical and general maintenance support to customers using the LATITUDE NXT System.

LATITUDE Customer Support telephone numbers are listed in the following table.

Table 1–1. LATITUDE Customer Support Telephone Numbers

Country	Number
Austria	0800 202289
Belgium	0800 80697
Czech Republic	239 016 657
Denmark	70 10 01 82
Finland	010 80 48 19
France	0805 5404 22
Germany	069 51709 481
Greece	442 035 647 788
Hong Kong	852 8105 5433
Hungary	06 80 981 579
Ireland (Republic)	1890 812005
Italy	848 781164
Netherlands	0800 0292077
Norway	81 00 00 47
Poland	22 306 07 33
Portugal	800844729
Slovak Republic	02 686 223 89
Spain	901 010840
Sweden	020 160 57 07
Switzerland	0844 000110
United Kingdom	0845 602 9283

Boston Scientific may contact the clinic regarding the LATITUDE NXT System and/or patients managed in the system.

Optional Home Health Monitoring Equipment

The LATITUDE Weight Scale and LATITUDE Blood Pressure Monitor are optional components of the LATITUDE NXT System. These components are referred to as *sensors*. They transmit measurements over a wireless connection to the patient's Communicator. For the WAVE WIRELESS COMMUNICATOR, a provided USB Accessory Adapter must be plugged into the Communicator to communicate with the patient's sensors.

NOTE: *Sensors may not be available in all geographies.*

The Communicator automatically sends these measurements to the LATITUDE NXT server where they are made available for clinician review. Weight alerts are sent to the LATITUDE NXT server when detected. For the WAVE WIRELESS COMMUNICATOR, unless an alert is detected, received readings can be transmitted with the next scheduled connection to the LATITUDE NXT server (up to seven days). For the TOUCH-SCREEN COMMUNICATOR, received readings can be transmitted every day.

The weight scale and blood pressure monitor are designed for use by a single patient. A patient's weight scale and blood pressure monitor cannot be reconfigured or distributed to another patient.

Although the patient may use the scale and blood pressure monitor at any time, only one daily measurement is reported on the LATITUDE NXT website. The measurement displayed is the last measurement within a 20-minute interval that starts with the first measurement of the day. The purpose of the interval is to allow patients to retake their measurement if necessary.

Weight measurements that differ by more than 9.1 kg (20 lb) from the previous day are considered invalid. If a measurement is not available for the previous day, then measurements that differ by more than 13.6 kg (30 lb) from the most recent measurement (up to seven days) are considered invalid. Invalidating widely varying values is not done with blood pressure measurements.

NOTE: *If a patient receives a replacement sensor, their Communicator must connect to the LATITUDE NXT server before measurements from the new sensor will be accepted.*

CAUTION: The maximum weighing capacity of the scale is 200 kg when using the WAVE WIRELESS COMMUNICATOR and 150 kg when using the TOUCH-SCREEN WIRELESS COMMUNICATOR. Do not place anything on the scale that is beyond the weighing capacity.

BASIC CONCEPTS

The following sections explain the basic concepts of the LATITUDE NXT Patient Management System.

Access to Patient Data

The LATITUDE NXT System collects patient data that are protected health information. Access to patient data is provided only to clinic users authorized by the clinic that enrolled the patient. Clinic users must be assigned to a Patient Group of which the patient is a member. Designated Boston Scientific personnel also have access to patient data. All user access of LATITUDE patient data is logged.

Registered Users

Boston Scientific reserves the right to deactivate any user or account that uses or accesses the LATITUDE NXT System contrary to the LATITUDE Licensing Agreement, any policies related to LATITUDE, or any relevant privacy and data protection laws or regulations.

Users who have not logged in for an extended period of time are considered inactive and may be deleted.

Patient, Clinician, and Clinic Relationships

Patient monitoring on the LATITUDE NXT System is based on the relationship of patients to clinics. Each LATITUDE NXT System clinic user has a user account that is associated with a specific clinic.

Each LATITUDE NXT System patient can be associated with up to two different clinics or two different Patient Groups in one clinic:

- **Primary clinic (or Patient Group)** (typically includes an electrophysiologist) — This clinic is typically responsible for monitoring a patient's device, including regularly scheduled device follow ups. This clinic is also responsible for managing any red alerts detected any time the patient's implanted device is interrogated. The primary clinic is also responsible for managing yellow alerts if notification has been configured. All LATITUDE NXT System patients must have an assigned primary clinic in order to be monitored.

- **Secondary clinic (or Patient Group)** (typically includes a cardiologist or heart failure specialist) — A patient may also be assigned a secondary clinic. This clinic is not notified of red alerts, but can monitor for yellow alert conditions as guided by the type of care they are providing for that patient. Specifically, for a patient with heart failure, this clinic may include the specialist who monitors the patient’s condition through the use of weight, blood pressure, and relevant device measured trends.

Patient Groups

A clinic is organized into one or more Patient Groups. Clinic users can be assigned to any number of Patient Groups. Clinic users assigned to a Patient Group have access to all patients enrolled in that Patient Group. Clinic Account Managers have access to all patients in all Patient Groups.

Patient Groups provide default alert and schedule configuration settings for their associated patients. A patient can have customized settings that differ from the Patient Group default settings.

CAUTION: Ensure that each patient’s alert configuration settings are appropriate when the patient is enrolled and after the implanted device is replaced.

Clinics that organize patients into Patient Groups have the option of associating a patient with two Patient Groups. One Patient Group is primary and manages the patient’s device; the other Patient Group is secondary and also monitors the patient’s condition.

Clinic User Privileges

Three types of privileges for clinic users control access to patient data as described below. The functions that each can perform are shown in the following table.

- **Read-Only Access** – Intended for users who need to work with patient data but are not responsible for managing the patients within the system. Access is limited to patients in assigned Patient Groups.
- **Limited Access** – Intended for users who are responsible for managing patients. These users have full capability to manage patients, but access is limited to patients in assigned Patient Groups.
- **Complete Access (Clinic Account Managers)** – Intended for the user who is responsible for managing the clinic and the clinic’s users and patients. Access is open to all patients in all Patient Groups. User accounts can be created by the Clinic Account Manager.

Table 1–2. Functions Permitted for Clinic Users by Privilege

Function	Complete Access (Clinic Account Manager)	Limited Access	Read-Only Access
	All Patient Groups	Assigned Patient Groups	Assigned Patient Groups
Add/Manage Clinic Users	✓		
Add/Manage Patient Groups	✓		
Manage schedule and alert configurations	✓	✓	
Enroll/Manage patients	✓	✓	
Dismiss patients on the View Patient List page	✓	✓	

Table 1–2. Functions Permitted for Clinic Users by Privilege (continued)

Function	Complete Access (Clinic Account Manager)	Limited Access	Read-Only Access
	All Patient Groups	Assigned Patient Groups	Assigned Patient Groups
View patients on the View Patient List page	✓	✓	✓
View patient data and reports ^a	✓	✓	✓

a. Viewing patient data or reports will record the action and may update **Review Status** from **New Data** to **Viewed**, even if using **Read-Only Access**.

Alerts

The LATITUDE NXT System generates alert notifications for a number of conditions that vary depending on the implanted device model.

There are two levels of alert conditions: red alerts and yellow alerts. The alerts are designed to notify clinic users of potential health conditions or device clinical events. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care. Alerts can be verified by viewing information on the LATITUDE NXT website and by using a Programmer/Recorder/Monitor (PRM) to review additional supporting diagnostic information stored in the implanted device.

Alert conditions can be detected during daily alert checks as determined by the configured schedule, weekly monitor interrogations, scheduled follow-up interrogations, and **Patient Initiated Interrogations**. The LATITUDE NXT System notifies the patient's clinicians of any detected alert conditions.

Alert notification is provided through the **View Patient List** page on the LATITUDE NXT website (Figure 2–4 View Patient List Page on page 2-8). The LATITUDE NXT System sends one notification for an alert condition detected by the system. For most alerts, it does not issue alert notifications for the same condition unless the condition is no longer detected and then reoccurs during a following data collection activity.

Designated Boston Scientific personnel may provide notification of alert conditions in place of the notifications provided by the LATITUDE NXT website. If the LATITUDE NXT System is unable to provide implanted device data, the LATITUDE NXT website or Boston Scientific personnel may provide alert notification. The clinic may be contacted regarding data that is currently not available on the LATITUDE NXT website. For example, if there is an alert condition that cannot be retrieved and displayed automatically by the LATITUDE NXT website, Boston Scientific personnel may contact you to inform you of that alert.

NOTE: *Most Daily Measurements are nominally On within the implanted device. However, if these features are ever programmed Off within the implanted device, the LATITUDE NXT System will not generate an alert for an event even if the LATITUDE alert is configured On. The implanted device must first measure, record, and detect data as out of range before the LATITUDE NXT System will detect and generate a red or yellow alert.*

Red Alerts

Implanted device conditions that could potentially leave the patient without available device therapy result in the declaration of a red alert.

The LATITUDE NXT website is designed to notify clinic users assigned to the primary Patient Group if the Communicator reports a red alert to the LATITUDE NXT server. Red alert notification cannot be disabled (except for the right ventricular nonphysiologic signal detected and right ventricular pacing lead impedance abrupt change alerts). If the Communicator is not able to

connect and transfer the red alert data within 24 hours, an indicator on the Communicator is illuminated indicating the patient should call his or her clinic.

Red alert notifications occur for the following conditions, depending on device model:

- Remote monitoring disabled due to limited battery capacity
- Shock lead impedance out of range
- Low shock lead impedance detected when attempting to deliver a shock
- High shock lead impedance detected when attempting to deliver a shock
- Right ventricular or single chamber pacing lead impedance out of range
- Right ventricular pacing lead impedance abrupt change

NOTE: *If more than 14 days elapse between alert checks, some data may not be assessed for the alert condition.*

- Right ventricular non-physiologic signal detected
- V-Tachy mode set to value other than Monitor + Therapy
- Possible device malfunction
- High voltage detected on shock lead during charge
- Device in Safety Mode
- Device in Electrocautery Protection Mode
- S-ICD devices:
 - Device battery has reached End of Life (EOL)
 - Therapy off
 - High electrode impedance
 - Possible device malfunction

Yellow Alerts

Notification of yellow alerts is configurable and may be selected by either of a patient's LATITUDE NXT System Patient Groups. A Patient Group may be configured to receive some, all, or none of the yellow alerts.

Yellow alert notifications can be configured for the following conditions, depending on device model:

- Explant indicator reached
- Voltage too low for projected remaining capacity
- Right ventricular or single chamber intrinsic amplitude out of range

- Right ventricular automatic threshold detected as greater than programmed amplitude or suspended¹
- Left ventricular intrinsic amplitude out of range
- Left ventricular pacing lead impedance out of range
- Left ventricular automatic threshold detected as greater than programmed amplitude or suspended¹
- Atrial intrinsic amplitude out of range
- Atrial pacing lead impedance out of range
- Atrial automatic threshold detected as greater than programmed amplitude or suspended¹
- Ventricular shock therapy delivered to convert arrhythmia
- Accelerated ventricular arrhythmia episode
- VT Episodes (V>A)
- Atrial Arrhythmia burden within a 24-hour period (exceeding a user-selectable limit)

NOTE: *If more than 14 days elapse between alert checks, some data may not be assessed for the alert condition.*

- Patient triggered event stored
- Cardiac Resynchronization Therapy pacing percentage (less than a user-selectable percentage)

NOTE: *This condition will not generate an alert if the implanted device's Pacing Chamber parameter is programmed to right ventricular (RV) only.*

- Right ventricular pacing percentage (exceeds a user-selectable percentage)
- Device Brady Mode Off
- Therapy history corruption detected
- Weight gain (exceeding a user-selectable limit in a user-selectable number of days)
- S-ICD devices:
 - Device battery has reached Elective Replacement Indicator (ERI)
 - Shock therapy delivered to convert arrhythmia
 - Untreated episode
 - Sensing not fully optimized

1. While the device has an automatic capture feature through PaceSafe, the LATITUDE NXT System does not assess capture or loss of capture and will only alert if certain criteria are met in the device and the alert is detected from the device.

Implanted Device Interrogation

The Communicator can perform several types of implanted device interrogations. Each interrogation type varies in the amount and type of data that are collected, as shown in the following table.

Table 1–3. Data Collection and Configuration Details for Each Interrogation Type

Interrogation Type	Full Interrogation (with Presenting EGM)	Full Interrogation (with no Presenting EGM)	Red Alert Check	Yellow Alert Check	Configuration Details
Remote Scheduled Follow-ups	✓		✓	✓	<ul style="list-style-type: none"> Off/Manual 1 week 2 weeks Monthly intervals from 1 to 12 months Automatic except for S-ICD patients, for whom it is prompted
Alert Check ^a (not available for S-ICD patients)	If red or yellow alert is detected ^a		✓	✓ WAVE WIRELESS COMMUNICATOR only	<ul style="list-style-type: none"> Daily Not configurable
Data Updated Interrogation^a WAVE WIRELESS COMMUNICATOR only	✓		✓	✓	<ul style="list-style-type: none"> A recent PRM interrogation has occurred^a or Sensors assigned and no full interrogation in 7 days^a
Weekly Implanted Device Alert Monitoring^a WAVE WIRELESS COMMUNICATOR, Model 6290, S-ICD patients only	If red or yellow alert is detected ^a		✓	✓	<ul style="list-style-type: none"> Weekly Configurable Prompted
Weekly Implanted Device Alert Monitoring TOUCH-SCREEN WIRELESS COMMUNICATOR only	If red alert is detected ^a	✓	✓	✓	<ul style="list-style-type: none"> Weekly Configurable
Patient Initiated Interrogations (See "Patient Initiated Interrogation" on page 1-13.)	✓		✓	✓	As directed by clinician

a. WAVE WIRELESS COMMUNICATOR only: If any of the following are detected during an alert check (or during **Weekly Implanted Device Alert Monitoring** for an S-ICD), the Communicator will attempt to collect a full interrogation with presenting electrogram (EGM):

1. A red or yellow alert, or
2. A recent PRM (Programmer/Recorder/Monitor) interrogation, or
3. No full interrogation has occurred within the past seven days (for patients with assigned sensors).

TOUCH-SCREEN WIRELESS COMMUNICATOR only: If a red alert is detected, the Communicator will also attempt to collect a full interrogation with presenting EGM.

NOTE: Boston Scientific personnel may contact the clinic if an implanted device uses too much RF telemetry to perform remote interrogations.

Patient Initiated Interrogations

The Communicator supports non-scheduled, **Patient Initiated Interrogations** (PIIs), which provide the same data as a scheduled follow-up interrogation including a presenting EGM.

The Communicator limits the number of **Patient Initiated Interrogations** to one of the following limits as specified by the LATITUDE NXT website:

- Five per week (if enabled)
- Zero (when feature is disabled)

Clinic users who are assigned to the patient's group(s) and have complete or limited access can enable or disable PII's. PII's are configured for all patients in a Patient Group or for an individual patient through their **Edit/View Schedule and Alert Configuration** page. If PII's are disabled or the weekly limit is reached, a clinic user can allow one PII by selecting the **Allow one Patient Initiated Interrogation** button within the patient's **Edit/View Schedule and Alert Configuration** page.

Patients initiate an interrogation by pressing the Heart button on the WAVE WIRELESS COMMUNICATOR (see Figure 3–1 WAVE WIRELESS COMMUNICATOR Buttons, Connectors, and Indicator on page 3-3) or by pressing the blue button on the TOUCH-SCREEN WIRELESS COMMUNICATOR (see Figure 3–10 TOUCH-SCREEN WIRELESS COMMUNICATOR Buttons, Connectors, and Indicator on page 3-13). The Communicator will not perform an interrogation if this feature is not enabled or the limit has been reached.

If the PII configuration setting is changed, the LATITUDE NXT server will send a notification to the patient's Communicator the next time the Communicator calls the LATITUDE NXT server. It could take up to eight days for the Communicator to call the LATITUDE NXT server. If PII's are disabled in the Communicator and the patient attempts to interrogate, the Communicator will call the LATITUDE NXT server to check for updated information. Before recommending a PII, clinicians may want to verify that the patient is stable, not symptomatic, and able to perform the PII. Refer to "Precautions" on page 1-2 and "System Limitations" on page 1-3.

USING THE LATITUDE NXT PATIENT MANAGEMENT SYSTEM

CHAPTER 2

This chapter contains the following topics:

- “GETTING STARTED” on page 2-2
- “CLINIC AND PATIENT CONFIGURATION” on page 2-5
- “THE VIEW PATIENT LIST PAGE” on page 2-7
- “SEARCH PATIENTS TOOL” on page 2-11
- “PATIENT ENROLLMENT” on page 2-12
- “PATIENT INITIALIZATION” on page 2-14
- “MANAGING PATIENTS” on page 2-14
- “MANAGING PATIENT GROUPS” on page 2-15
- “MANAGING USER ACCOUNTS” on page 2-16
- “PASSWORDS” on page 2-17
- “EMR SYSTEM INTEGRATION” on page 2-18

GETTING STARTED

The LATITUDE NXT website provides clinicians a convenient and secure way to review the data they scheduled the Communicator to collect from a patient's implanted device. It also provides analysis and trending tools.

The LATITUDE NXT website is available to clinic personnel who are authorized by their clinic to use the LATITUDE NXT website. These personnel are called clinic users in the LATITUDE NXT website.

Clinicians authorized to use the LATITUDE NXT website also have the option of using the LATITUDE NXT Mobile Application accessible on an Apple™ iPhone™ mobile digital device. Clinicians may use this English-only mobile application to access patient information on a read-only basis and generate Portable Document Format (PDF) reports, which are viewable either through the browser or Adobe™ Reader™ software. An Internet connection is required.

For more information, from your iPhone navigate to:

- <http://www.bostonscientific.com/latitudenxt-mobile-europe>

Requirements

The LATITUDE NXT website was developed to support the following Internet browsers¹:

- Internet Explorer™ Internet browser
- Mozilla Firefox™ Internet browser
- Apple™ Safari™ on the Mac™, iPad™, and iPhone™ Internet browsers

Adobe™ Reader™ software or compatible PDF viewer is required to view reports that are in PDF format.

Use of a current anti-virus program is recommended.

Logging In and Out

Log in to the LATITUDE NXT website by doing the following:

1. Launch your web browser and enter the LATITUDE NXT System web address:

<http://www.latitude.bostonscientific.com>

The initial access page will display, as represented by the following figure.

1. The LATITUDE NXT website was developed with browsers that were current at that time. The LATITUDE NXT website may not function properly when using browser versions that were subsequently released. Call LATITUDE Customer Support for a list of supported Internet browsers.



Figure 2-1. LATITUDE NXT Initial Access Page

2. The first time you access the LATITUDE NXT website or the first time you access the website from a different computer, select your country and language, as applicable.
 - During subsequent logins, country and language can be changed by clicking **Change Country/Language** on the login page, as shown in the following figure. This will bring you back to the initial access page.
 - Language can also be changed at any time by selecting the **Language** menu at the top of all pages. Language and country can also both be changed by selecting **My Profile** at the top of all pages.
3. Click the **LATITUDE NXT** button to display the login page shown in the following figure.



(1) Click this link to change your country or language.

Figure 2–2. Login Page

4. Enter your **User ID** and **Password** and click the **Login** button.

Users accessing the LATITUDE NXT website for the first time are prompted to change their temporary password and complete a set of personal security questions. The security questions can be used at a later time by the user to reset a forgotten password. (See "Resetting Your Forgotten Password" on page 2-18.)

An announcement or broadcast message may be displayed when you login.

Login Session Time Out — An individual session is started each time a user logs on to the LATITUDE NXT website. If a user remains logged in but is inactive for more than 60 minutes, the session is automatically closed, effectively logging the user out. The user is redirected to the login page.

5. If two factor authentication (TFA) is required, the first time you click the **Login** button, select the method for receiving the TFA verification code (SMS text message or email), then enter either your phone number (mobile phone only) or email address. When you receive the verification code, enter it on the Two Factor Authentication page. At subsequent logins, you will automatically receive the verification code to enter on the Two Factor Authentication page.

NOTE: Both options of TFA verification code notifications, SMS text message and email, may not be available in all locations.

To change how verification codes are sent, on the **Update Clinic User** page, scroll down to **Login Information** and **Security**, and click **View/Edit Two Factor Authentication**.

The Clinic Account Manager or LATITUDE Customer Support may create a one-time verification code for a clinic user to use at their next login. See "Other Patient Group Management Functions" on page 2-16.

Log out of the LATITUDE NXT website by clicking the **Logout** link in the upper-right corner of the screen. Users are advised to close their web browsers to complete the log-out process.

Navigating the Site

The following figure shows the top banner and navigation buttons that appear on the LATITUDE NXT website. Descriptions are listed below.

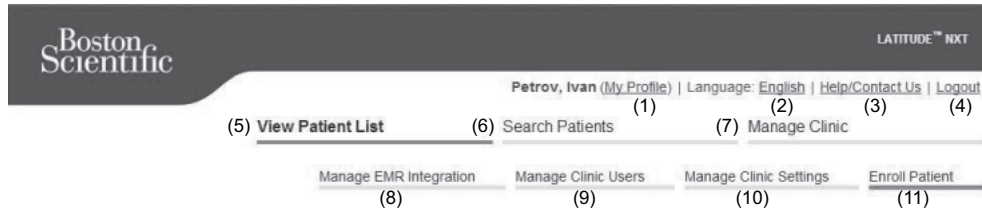


Figure 2–3. LATITUDE NXT System Banner

Table 2–1. Navigating the Site

(1)	My Profile	Links to the Update Clinic User page for the current user
(2)	Language	Displays selected language; links to the Update Clinic User page for the current user where the selected language can be changed
(3)	Help/ Contact Us	Links to contact information, troubleshooting guides, and other resources
(4)	Logout	Ends the user's session
(5)	View Patient List	Links to a page that provides a list of patients to which the current user has access (See Figure 2–4 View Patient List Page on page 2-8.)
(6)	Search Patients	Links to the Search Patients page
(7)	Manage Clinic	Displays clinic-related action links 8–11
(8)	Manage EMR Integration	Links to a page that enables clinicians to configure integration with their clinic's electronic medical record (EMR) system and view the export status of their EMR files (See "EMR SYSTEM INTEGRATION" on page 2-18.)
(9)	Manage Clinic Users	Links to a list of clinic users and associated configuration information
(10)	Manage Clinic Settings	Links to clinic and Patient Group demographics and membership and associated configuration information
(11)	Enroll Patient	Links to enrollment form that enables clinicians to enroll new patients

CLINIC AND PATIENT CONFIGURATION

The following table shows the LATITUDE NXT website locations and types of information that can be configured for Patient Groups and individual patients. The information in "Configuration Details" on page 2-6 provides important details about configuration settings.

Table 2–2. Patient Groups Configuration

Patient Groups	Manage Clinic → Manage Clinic Settings
	Edit/View Schedule and Alert Defaults <ul style="list-style-type: none"> • Remote Scheduled Follow-ups • Weekly Implanted Device Alert Monitoring • Patient Initiated Interrogations • Alert Configuration • Additional Alert Notification (SMS text and email messages)

Table 2–3. Individual Patient Configuration

Individual Patient	View Patient List ⇒ Patient Summary Page (click patient's name)
	Edit/View Schedule and Alert Configuration <ul style="list-style-type: none"> • Next Scheduled Remote Follow-up • Remote Scheduled Follow-ups • Weekly Implanted Device Alert Monitoring (availability dependent on type of implanted device and model of Communicator) • Patient Initiated Interrogations • Alert Configuration
	Edit/View Patient and Equipment Information <ul style="list-style-type: none"> • General Information • Implanted Device • Patient Group Membership • Equipment

Configuration Details

Saving Settings

Remember to select the **Save and Close** button to ensure any changes you make to configuration settings are stored in the LATITUDE NXT System. You can select the **Close Without Saving** button to discard any changes and revert to the settings from the previously saved version. Changes to settings will be updated on the Communicator of the affected patient the next time the Communicator connects to the LATITUDE NXT server. **It could take up to eight days for the Communicator to call the LATITUDE NXT server. Until then, the Communicator will continue to operate using the previous configuration.**

Remote Scheduled Follow-ups

Remote follow-ups can be scheduled manually or set automatically. For manual scheduling, you may pick a new follow-up date each time the previous one has been completed. For automatic scheduling, the next follow-up is automatically scheduled by using the configured interval and day of the week. The scheduled date is calculated by taking the date the remote scheduled interrogation was received and adding the configured interval and the number of days of the configured day of the week (scheduled date = interrogation date + interval + configured week days).

If a patient's follow-up schedule (interval or day of the week) is changed, the date of the next follow-up does not change, unless you specifically change that date. Even with automatic scheduling, you can always manually select a new follow-up date by using the scheduling calendar.

NOTE: The number of days used for a monthly interval is 30 times the number of months selected except for 1 month and 3 months, which are 31 and 91 days respectively. The number of days for 1 through 12 months equals 31, 60, 91, 120, 150, 180, 210, 240, 270, 300, 330, and 360.

While **Remote Scheduled Follow-ups** are configured by the clinician, the occurrence of interrogations depends on the type of implanted device:

- Except for a patient with an S-ICD implanted device, interrogations occur automatically on the scheduled dates. The patient does not need to perform any action. These interrogations often occur without the patient's knowledge.
- For a patient with an S-ICD implanted device, interrogations do not occur automatically; instead, the patient must respond as prompted by the Communicator for the interrogation to occur.

Weekly Implanted Device Alert Monitoring (WAVE WIRELESS COMMUNICATOR, Model 6290, S-ICD patients only)

Weekly alert monitoring can be enabled or disabled. When enabled, the patient will be prompted on a weekly basis to interrogate the implanted device. If a red or yellow alert is detected, a recent PRM interrogation has occurred, or no full interrogation has occurred within the past seven days (for patients with assigned sensors), the Communicator will attempt to collect a full interrogation with presenting EGM and upload the data.

Weekly Implanted Device Alert Monitoring (TOUCH-SCREEN WIRELESS COMMUNICATOR only)

Weekly alert monitoring can be enabled or disabled. When enabled, an implanted device is interrogated weekly, the data is uploaded, and any configured alerts detected are reported. If a red alert is detected, the Communicator will also attempt to collect a full interrogation with presenting EGM.

Patient Initiated Interrogations

Patient initiated interrogations (PIIs) can be enabled (five per week) or disabled. You can also configure one additional PII at any time. This additional PII can be configured from the **Edit/View Schedule and Alert Configuration** page. See "Patient Initiated Interrogation" on page 1-13.

Additional Alert Notifications

Additional alert notification is available through text (SMS) and email messages. These reminders can only be configured at the Patient Group level. They can be configured for red alerts only, for yellow alerts only, or for both red and yellow alerts. The primary means of alert notification is through the **View Patient List** page on the LATITUDE NXT website (Figure 2-4 View Patient List Page on page 2-8).

You can select to have messages sent 24 hours, 7 days a week or between 8 AM and 5 PM, Monday-Friday. Messages will be sent at the selected time even if a patient's alert has already been dismissed. Delivery of SMS and email is not guaranteed as described in "Precautions" on page 1-2.

Up to three SMS numbers and three email addresses can be configured for each Patient Group. When an alert is detected, a notification will be sent to each SMS number and each email address configured. The notifications do not include patient-identifying information. The user needs to check the **View Patient List** page on the LATITUDE NXT website. The LATITUDE NXT System allows a test message to be sent to each SMS number and email address entered.

If a patient has multiple alerts at the same time, a separate SMS or email is sent for each one.

Individual Patients

To change configuration settings for an individual patient, deselect the **Use Patient Group Defaults** checkbox under the respective section. This allows you to change settings for the patient. A patient's specific remote scheduled follow-up date can be changed by clicking on the date. This displays the scheduling calendar where you can select a new scheduled remote follow-up. A new date can be selected even if the patient's follow-ups are automatically scheduled using a Patient Group setting.

THE VIEW PATIENT LIST PAGE

The **View Patient List** page (shown below) is the first page displayed after logging on to the LATITUDE NXT website. By default, the page uses the **For Review** filter to display patients for all assigned Patient Groups. Reports for one or more patients can be generated from this page.

Two tools are provided to select and filter patient lists (shown below):

1. **Viewing Patient Group** pull-down menu – Provides a list of Patient Groups for which the user is assigned.
2. **Filters** – Used to further filter patients that are in the selected group.

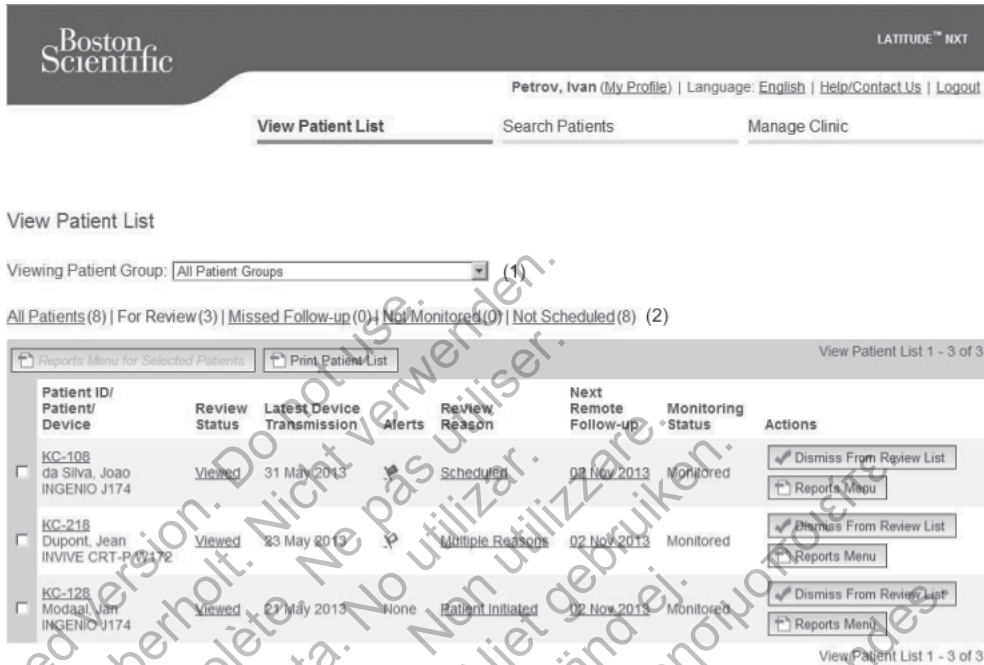


Figure 2-4. View Patient List Page

The following list provides a description of the filters, other tools, and each column of the **View Patient List**:

Reports Menu for Selected Patients

Reports can be generated by selecting the checkbox next to one or more patient names and clicking the **Reports Menu for Selected Patients** button. A separate window is opened where you can generate one or more reports. When generating reports, a single PDF file is created for each report request. The user can print and save the reports.

Print Patient List

This button creates a report that includes all the patients listed using the selected filter.

All Patients | For Review | Missed Follow-up | Not Monitored | Not Scheduled

Each of these filters can further restrict patients within specific Patient Group(s).

- **All Patients** – Lists all patients in the selected Patient Group(s).
- **For Review** – Lists patients with reviewable data that have not been dismissed. Reviewable data includes data associated with alerts, **Remote Scheduled Follow-ups**, or patient initiated interrogations. Patients are listed in order of alert severity, followed by order of patient last name. The **For Review** list is the default filter when the user logs in and anytime **View Patient List** is selected.

- **Missed Follow-up** – Lists patients that had a remote scheduled follow-up but a remote interrogation has not yet been completed successfully. Patients are filtered by remote scheduled date with the most recent listed first.
- **Not Monitored** – Lists patients that currently are not being monitored. See "Monitoring Status" on page 2-10.
- **Not Scheduled** – Lists patients that currently do not have a scheduled remote follow-up.

NOTE: A patient may appear more than once in a filtered list. This can happen if a clinician is a member of two different Patient Groups which are both following the patient. In this case, each entry for that patient will include the associated Patient Group name.

Checkbox

You can select the checkbox for one or more patients. The **Reports Menu for Selected Patients** function at the top of the patient list is performed for all patients selected with the checkbox.

Patient ID/Patient/Device

Click on the patient's ID to see detailed information for that patient.

Review Status

Provides information on the status of the patient's review such as **New Data**, **Viewed**, or **Dismissed**. Click on the status to see additional detail on actions taken by users of the patient record.

Latest Device Transmission

This date is the last time a full interrogation was collected from the patient's implanted device.

Alerts

Indicates the patient has one or more alerts that have not been dismissed. Alerts persist from the time the patient is added to the **For Review** list until they are dismissed from the review list. The flag displayed indicates the current highest severity alert for that patient. Click on the flag to see a detailed list of alerts.



A red flag indicates a patient has one or more red alerts or red and yellow alerts and has not been dismissed.



A yellow flag indicates a patient has one or more yellow alerts and has not been dismissed.

None No alert was detected.

Review Reason

Indicates the reason the patient was added to the **For Review** patient list. Review reasons include:

- **Scheduled**
- **Patient Initiated**
- **Weight Change**
- **Implanted Device Alert**

- **Multiple Reasons**

Click on the reason to see more detailed information related to the review, including transmission dates, post dates, and summary information related to the reviewable data.

Next Remote Follow-up

Indicates the date of the patient's next scheduled remote follow-up. Click on this date to display the scheduling calendar and set a new date for a patient's next scheduled remote follow-up.

Monitoring Status

Indicates the current monitoring status of the patient. A patient is considered monitored once their Communicator has been activated, has communicated with their implanted device, and is able to check for alerts and provide device data as configured by the clinic user.

When the LATITUDE NXT System identifies that monitoring is not occurring as intended, the patient is considered not monitored and one of the following status indications is displayed. A patient may have more than one **Not Monitored** status at a given time. In this case, the status that should be resolved first is displayed on the **View Patient List** page. Any other statuses are displayed on the patient detail pages.

After notification, the clinician is responsible for resolving the status condition. This may include referring the patient to LATITUDE Customer Support in the event the clinician is unable to resolve the condition. Alert identification and notification will not occur until the status condition is resolved.

- **Patient Transferred** – Applicable only for the clinic from which the patient transferred.
- **No Primary Clinic** – Primary clinic is required for a patient to be remotely monitored.
- **No Communicator Assigned** – Patient does not have a Communicator currently assigned.
- **Implanted Device Replaced** – Remains until the Communicator has successfully collected data from the new implanted device and sent it to the LATITUDE NXT server.
- **Communicator Not Set Up** – Remains until the Communicator has successfully collected data from the implanted device and sent it to the LATITUDE NXT server.
- **Remote Monitoring Disabled** – Occurs because the implanted device has limited battery capacity.
- **Implanted Device Not Found** – Communicator has been unable to successfully communicate with the implanted device for 14 days or more from the date an interrogation was scheduled.
- **Software Mismatch** – Communicator does not support the implanted device's current software.
- **Communicator Not Connecting** – Communicator has not connected to the LATITUDE NXT server in 14 days or more.

Clicking on the status opens a window that displays the related section of the Troubleshooting Guide. Refer to "TROUBLESHOOTING GUIDE" on page A-1 for a description and troubleshooting recommendations for each status.

Actions

These buttons are links to dismiss the patient from the review list or generate reports for the patient.

Generating and Printing Patient Reports

One or more reports, using data from the latest device transmission, can be generated for individual patients or for several patients at a time. When printing reports, report information is retrieved, and a single PDF file is generated for each report request. Once the selected report(s) are generated, the user can print and save the reports.

You may print up to 10 individual reports at a time. If you attempt to print more than 10 reports, a message appears asking you to modify your selection to print 10 or fewer reports.

The following reports are available:

- Quick Notes Report/S-ICD Summary Report
- Most Recent Presenting EGM/S-ECG Report
- Combined Follow-up Report
- HF PERSPECTIV Report
- Atrial Arrhythmia Report (available only for applicable implanted devices)
- Arrhythmia Logbook Report
- Event Detail Report
- Device Settings Report

The Quick Notes/S-ICD Summary, Combined Follow-up, Presenting EGM/S-ECG, and Atrial Arrhythmia reports are available for previous interrogations from a patient's **Follow-up History** page. The **Follow-up History** page lists remote interrogations that result in the patient being added to the **For Review** patient list.

The date, time, and user that generated the report is logged and is displayed in the **Review Status** pop-up window. The **Reports Menu** button is available on all webpages listing patients or patient data.

SEARCH PATIENTS TOOL

A link to the **Search Patients** tool is located in the navigation bar on all webpages. The **Search Patients** tool (shown in the following figure) enables a user to search for patient records from all those that the user is authorized to access. One or more fields can be used to search for patient records. Searches using multiple fields are performed using all the words entered into each field.

Clicking the **Search** button displays the matching patient records below the search criteria in a table similar to the **View Patient List** page. From the table, you can print the search results list, access details of a patient appearing in the list, print reports for one or more selected patients, or dismiss a patient that is for review.



Figure 2-5. Search Patients Tool

PATIENT ENROLLMENT

This section describes the steps the clinic needs to complete for a patient to be enrolled and appear on the LATITUDE NXT website:

- Online Patient Enrollment
 - **Patient enrollment through the LATITUDE NXT System cannot be completed without the Communicator model and serial numbers.** You should record these numbers before you give a Communicator to the patient.
- Equipment Distribution to Patients
 - Clinics can order Communicators, weight scales, and blood pressure monitors by contacting Customer Service.

Online Patient Enrollment

Clinic users enroll new patients using the **Enroll Patient** link under the **Manage Clinic** menu option as shown in the following figure. A patient is identified by their implanted device's model and serial number and by their date of birth.

Boston Scientific LATITUDE™ NXT

Petrov, Ivan (My Profile) | Language: English | Help/Contact Us | Logout

View Patient List Search Patients Manage Clinic

Manage EMR Integration Manage Clinic Users Manage Clinic Settings **Enroll Patient**

Enroll Patient Step 1 of 4: Enter implanted device and patient's date of birth.

*Indicates Required Field

Implanted Device

Note: If this is a replacement implanted device for an existing patient, please go to the patient's "Patient and Equipment Information" page and edit the implanted device information.

*Model:
-Select Model-

*Serial Number:

Date of Birth

*Date of Birth:
 (e.g.: 24 Jan 1990)

Continue

Figure 2-6. Enroll Patient Page

Patient enrollment through the LATITUDE NXT System cannot be completed without the Communicator model and serial number. During patient enrollment, the clinic user enters the model and serial number of the patient's Communicator.

If the patient will use a weight scale or blood pressure monitor, those model and serial numbers may be entered at enrollment or later through the **Edit/View Patient and Equipment Information** pages. The clinic user also enters the patient's time zone, as applicable.

The clinic user must assign a Patient Group from a selectable list before submitting the multiple webpage form. A confirmation of enrollment is displayed and can be printed.

Enrolling Existing Patients

If a patient has been previously enrolled in the LATITUDE NXT System, their existing data will be available to the new clinic after enrollment is complete. Users in the new clinic will see the last patient data sent but will not see any follow-up or alert history. If a patient has been previously enrolled, their date of birth entered during enrollment must match the date recorded in the system to complete the enrollment. Contact LATITUDE Customer Support if you need assistance.

Equipment Distribution

Patients should receive a Communicator in the clinician's office. To improve patient acceptance and satisfaction, we recommend that clinics provide the following basic education, as applicable, to patients during distribution of the Communicators:

- "LATITUDE Communicator Overview" on page 1-4
- Setup and general operating information about the "Wave Wireless Communicator" on page 3-2
- Setup and general operating information about the "Touch-Screen Wireless Communicator" on page 3-12

PATIENT INITIALIZATION

After a patient is assigned a Communicator, they appear on the **Not Monitored** list, with a status of **Communicator Not Set Up**. To appear with a status of **Monitored**, the patient should complete the setup of their Communicator:

WAVE WIRELESS COMMUNICATOR: The patient presses the flashing Heart button to start Communicator setup. During the initial setup process, the Communicator performs a patient initiated interrogation (PII). Once the patient has completed setup of their Communicator, they appear with a status of **Monitored**.

TOUCH-SCREEN WIRELESS COMMUNICATOR: The patient follows the instructions on the Communicator screen to perform setup. During the initial setup process, the Communicator confirms the identity of the implanted device but does not perform an interrogation. The patient will appear with a status of **Monitored** once the Communicator notifies the LATITUDE NXT server it has completed an interrogation (up to eight days) or when the patient performs a patient initiated interrogation (PII).

If the patient has difficulties completing setup, clinic users may access troubleshooting recommendations by clicking on the **Communicator Not Set Up** link.

MANAGING PATIENTS

The following information is provided to help clinic users manage their LATITUDE patients.

Changing Patient Demographic and Equipment Information

Users can view and edit patient demographic, implanted device, and LATITUDE equipment information from the **Edit/View Patient and Equipment Information** page. Update of some data is restricted to users in the primary clinic. A button linking to the **Edit/View Patient and Equipment Information** page appears on the detailed summary pages of all patients.

NOTE: *When the patient's implanted device is replaced, all uploaded data, follow-up history, and alert history for the previous implanted device are no longer viewable. We recommend printing any desired reports before updating the implanted device.*

The Communicator performs several time-sensitive functions. If a patient moves or travels to a different time zone, the new time zone where the Communicator is being used needs to be selected on the **Edit/View Patient and Equipment Information** page. Patients with a **TOUCH-SCREEN WIRELESS COMMUNICATOR** are able to select their time zone on their Communicator screen.

If patients need replacement LATITUDE equipment, their patient configuration information needs to be updated with new model and serial numbers.

The Communicator, weight scale, and blood pressure monitor are intended to be used by a single patient. A Communicator, weight scale, and blood pressure monitor received by a patient may not be reconfigured and/or distributed to a different patient.

Changing Patient Groups

Clinics that organize patients into Patient Groups can change that organization on the **Edit/View Patient and Equipment Information** page:

- The patient can be moved from one Patient Group to a new Patient Group. Only clinic users associated with the new Patient Group will have access to the patient. This change does not affect the patient's data or status on the **View Patient List** page.
- The patient can be associated with a second Patient Group. The user must specify which Patient Group is primary (manages the patient's device) and which is secondary. Users in

both the original Patient Group and the second Patient Group will have access to the patient. Users in the secondary Patient Group will see the patient's current data but will not be notified of red alerts and will not see any follow-up or alert history associated with the primary Patient Group.

Transferring Patients

Patients can be transferred from an existing clinic to a new clinic, based on patient consent. When a clinic enrolls a patient, the user will see an indication that the patient is being followed by a different clinic. Once the user indicates that the patient has authorized the transfer, the enrollment can be completed and the patient is immediately transferred to the new clinic.

Users in the new clinic will see the patient's current data and will also see any undismissed alerts from the old clinic. They will not see any follow-up or alert history from the old clinic.

Users in the old clinic will see the patient's status is **Patient Transferred**. The existing follow-up and alert history information is available to print any desired reports. No new data will be visible to users in the old clinic. The old clinic can unenroll the patient from the **Edit/View Patient and Equipment Information** page.

Unenrolling Patients

Patients can be unenrolled by a clinic user selecting the **Unenroll Patient** button on the **Edit/View Patient and Equipment Information** page. Unenrolling the patient immediately removes access to the patient records.

If the patient is unenrolled from the primary clinic, LATITUDE NXT System monitoring and data collection will be suspended. If the patient is still enrolled in a secondary clinic, that clinic will see the patient's status as **No Primary Clinic**. The patient's existing data will still be visible to the secondary clinic, but no new data will be sent until the patient has a primary clinic.

NOTES:

- *Once a patient account is unenrolled, patient data is no longer accessible by that clinic in the LATITUDE NXT System.*
- *Clinics are responsible for unenrolling patients if a clinic is no longer in practice. If a clinic dissolves, Boston Scientific personnel may contact LATITUDE NXT patients enrolled in the clinic.*

MANAGING PATIENT GROUPS

The list of existing Patient Groups can be viewed through the **Manage Clinic Settings** link under the **Manage Clinic** menu. Clinic users only see the Patient Groups to which they are assigned.

Adding Patient Groups

A Clinic Account Manager can add Patient Groups by selecting the **Add Patient Group** link on the **Manage Clinic Settings** page. Adding a Patient Group automatically assigns all Clinic Account Managers to that Patient Group. A second screen is displayed that allows assigning additional clinic users to the Patient Group.

Deleting Patient Groups

Patient Groups can be removed by Clinic Account Managers, but only if there are no patients enrolled in the Patient Group. To delete a Patient Group, click on the **Edit/View Demographics and User Membership** button associated with a Patient Group on the **Manage Clinic Settings** page. Then click on the **Remove Patient Group** button.

Other Patient Group Management Functions

Other Patient Group management functions are available from the **Manage Clinic Settings** page:

- Schedule and Alert Defaults – selecting the **Edit/View Schedule and Alert Defaults** button associated with a Patient Group allows clinic users to manage the schedule and alert defaults.
- Demographic and User Membership – selecting the **Edit/View Demographics and User Membership** button associated with a Patient Group allows clinic users to update the Patient Group's name and description and to see the other users assigned to the Patient Group. Clinic Account Managers can assign clinic users to, or remove clinic users from, the Patient Group. Note that Clinic Account Managers are assigned to all Patient Groups and cannot be removed from a Patient Group.

MANAGING USER ACCOUNTS

A user with complete privileges (Clinic Account Manager) can create user accounts for other users in the same clinic.

Clinic Account Managers can also perform certain user account management functions for all users within their clinic, including resetting passwords. Any user can also reset their own password by correctly responding to security questions.

A Clinic Account Manager clicks on the **Manage Clinic Users** link from the **Manage Clinic** menu option to access all account management functions. This displays the list of clinic users.

Adding User Accounts

Clinic user accounts can be added by selecting the **Add Clinic User** button on the **Manage Clinic Users** page. The **Add Clinic User** page provides a set of required and optional data entry fields. Adding an account includes selecting the user's privileges and assigning them to the desired Patient Groups.

Deleting User Accounts

Clinic user accounts can be removed by Clinic Account Managers. To delete a user, click on the **Edit/View Demographics and Access Settings** button associated with that user on the **Manage Clinic Users** page, then click on the **Remove Clinician** button. Removing an account removes that user from all access to patients and deletes that user's account.

It is the responsibility of the clinic to ensure that accounts are deleted for users who are no longer employed by the clinic or who should no longer have access to patient data in the LATITUDE NXT System.

Users who have not logged in for an extended period of time are considered inactive and may be deleted.

Other User Account Management Functions

Other account management functions are available by selecting the **Edit/View Demographics and Access Settings** button associated with a user on the **Manage Clinic Users** page. The following functions are supported on the **Update Clinic User** page:

- The Clinic Account Manager may edit the demographic data for any user and save it into the LATITUDE NXT System. Values that can be modified include user information, **User ID**, user privileges, and assigned Patient Groups.

- **Reset Password** – If a user forgets their password, this function can be used to assign a temporary password. Clicking the **Reset Password** link assigns a temporary password and displays it in a pop-up window. The user must change this temporary password at the next login attempt.
- **Get Two Factor Verification Code** – If two factor authentication is required, the Clinic Account Manager may create a one-time verification code for a clinic user to use at their next login, which must be within 10 minutes. The link to create the verification code is in the **Login Information** and **Security** section.

User Account Self-Management

Users can update their own information by clicking on the **My Profile** link at the top of the page. A user can change their password or modify their **User ID**, security questions, and demographic information. A user who has forgotten their password can reset it by answering one of their security questions.

PASSWORDS

Passwords cannot be retrieved, not even by an administrator. Password rules and suggestions for creating a good password are provided on the LATITUDE NXT website.

Passwords expire three months after being issued. A user's account is locked after six consecutive login attempts with an incorrect password or verification code. If their account is locked, a user can unlock it by providing their answer to a security question, or a Clinic Account Manager can reset the user's password. See "Resetting Your Forgotten Password" on page 2-18.

Temporary Passwords

When a Clinic Account Manager creates an account or resets the password for a clinic user, a temporary one-time password is assigned. The Clinic Account Manager needs to give this password to the clinic user. The clinic user must change this password when logging in for the first time. Temporary passwords expire three months after being issued.

Security Questions

A clinic user is prompted to change their password the first time they log in with their temporary password. The clinic user is then prompted to enter answers to three security questions. The user can select from a list of questions.

A clinic user is prompted for their answer to one of these security questions if they forget their password and need to reset it. Clinic users can also ask their Clinic Account Manager to reset their passwords. Refer to "Resetting Your Forgotten Password" on page 2-18.

Changing Your Password

Your password can be changed by clicking the **My Profile** link next to your name at the top of every page on the LATITUDE NXT website, and then by clicking the **Change Password** link in the **Login Information** section. Enter your old and new password as shown in the following figure. Click the **Save and Close** button. Your new password will take effect the next time you log in.

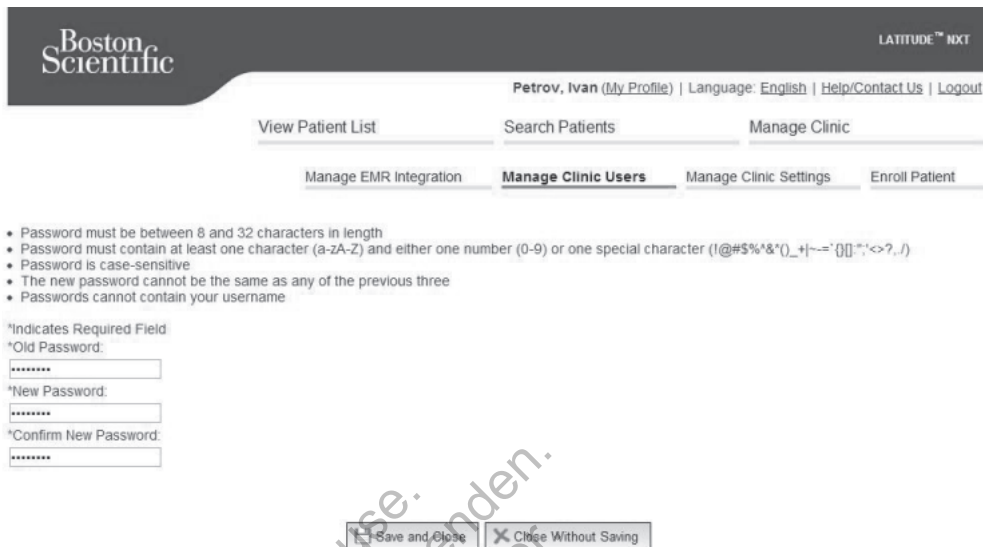


Figure 2-7. Change Password

Resetting Your Forgotten Password

If you forget your password or your login account is locked, you can reset your password at any time using the **Forgot Password?** link (shown in the following figure). You will need to provide an answer to one of your security questions in order to reset your password. You can also ask your Clinic Account Manager to reset your password.

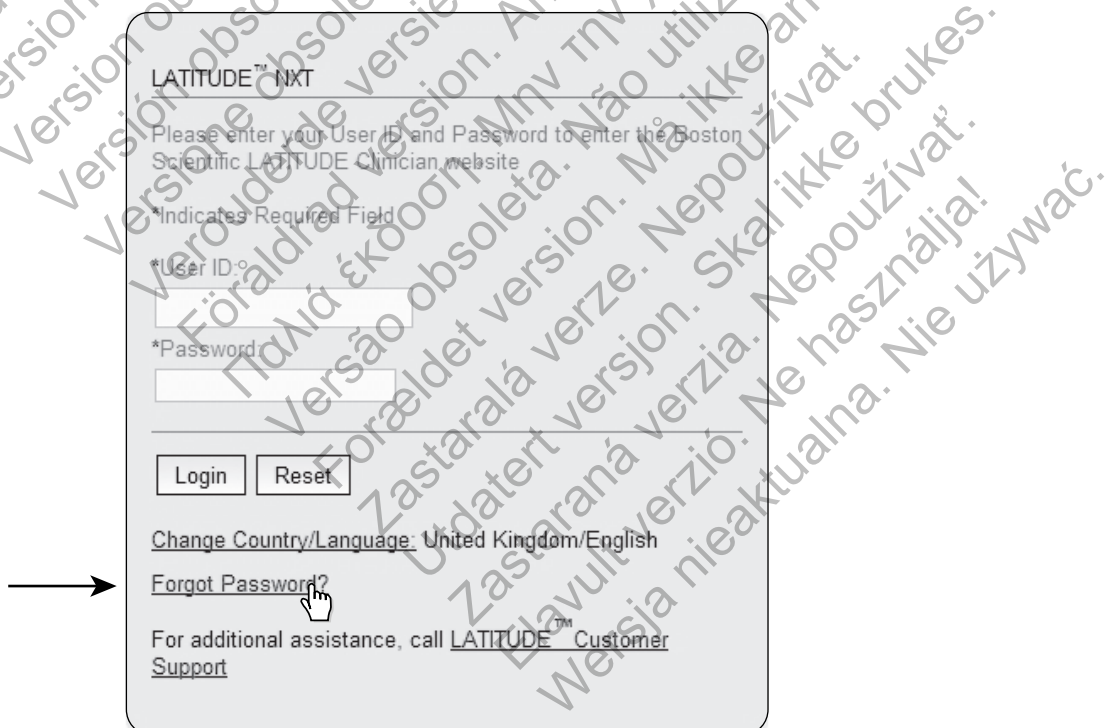


Figure 2-8. Forgot Password? Link

EMR SYSTEM INTEGRATION

The optional LATITUDE NXT Electronic Medical Record (EMR) system integration feature provides an automated way to export patient implanted device data to a clinic's internal EMR

application. Sensor data, sensor alerts, and monitoring status are not included in data exported to an EMR application. Clinicians may want to refer to the Implantable Device Cardiac Observation (IDCO) integration specification of Boston Scientific for details on how its implanted device data is converted into IDCO messages, which are used to deliver patient data to the EMR application.

The data exported are based on the Quick Notes Report/S-ICD Summary Report and include implanted device alerts. The data may also include PDFs of the Presenting EGM/S-ECG Report, Combined Follow-Up Report, HF PERSPECTIV Report, and Arrhythmia Logbook Report, if available. Not all EMR applications accept these types of data. When enabled, EMR integration exports data for all patients in all Patient Groups within your clinic.

The EMR integration feature provides the following functions:

- Enables and disables EMR integration as needed (default is disabled).
- Automatically exports patient data to your EMR application each time a patient appears on the **For Review** list, except for a weight change. The data provided is associated with implanted device alerts, **Remote Scheduled Follow-ups**, and **Patient Initiated Interrogations**.
- Selects the data format for your EMR application.
- Displays details of each data export including time stamps and export status.
- Allows you to resend EMR data.

NOTES:

- *The LATITUDE NXT System only exports EMR files when the **Enable EMR Integration** checkbox on the LATITUDE NXT website is selected. The system does not create or export EMR files for patient interrogation data received while EMR is not enabled. Refer to "Configuring the EMR Feature" on page 2-20.*
- *Connection difficulties may delay or prevent EMR file delivery to the EMR application. The LATITUDE NXT System is the system of record for remote patient management. Clinicians should not rely on the presence of data in the EMR application to determine if a remote follow-up or **Implanted Device Alert** has occurred.*
- *An EMR data export is not performed for a weight alert. Sensor measurements are not exported.*
- *Any changes to data from within the EMR application will not change data in the LATITUDE NXT System.*
- *Some EMR applications may not directly import LATITUDE NXT data. You or your EMR vendor may have to provide additional software to import LATITUDE NXT data into your EMR application. Technical information is located separately in the Boston Scientific IDCO and HL7 integration specification documents.*
- *If an attempt to export an EMR file fails, the LATITUDE NXT System continues to attempt to export the file to your EMR application for up to 30 days. The LATITUDE NXT System will then discontinue the attempt to export the EMR file and report a **Failed** status. If this occurs, you may resend the data using the **Resend** button.*

Configuring the EMR Feature

The LATITUDE NXT EMR feature must be configured and enabled before LATITUDE NXT EMR files can be created and exported. Configuration includes downloading, installing, configuring, and registering the EMR integration software on a computer within your clinic.

The EMR integration software will typically be installed on the clinic's EMR application server or another clinic server rather than an individual's workstation. In order to install the EMR integration software, you may need administrative access on the target system. If you are unfamiliar with the setup of your target system or EMR application, please consult the information technology (IT) professional responsible for administering your systems.

Complete the following steps to install the software and configure the EMR integration feature:

1. Navigate to the **Manage EMR Integration** page.
2. Click the **Edit/View EMR Configuration** button (as shown below).

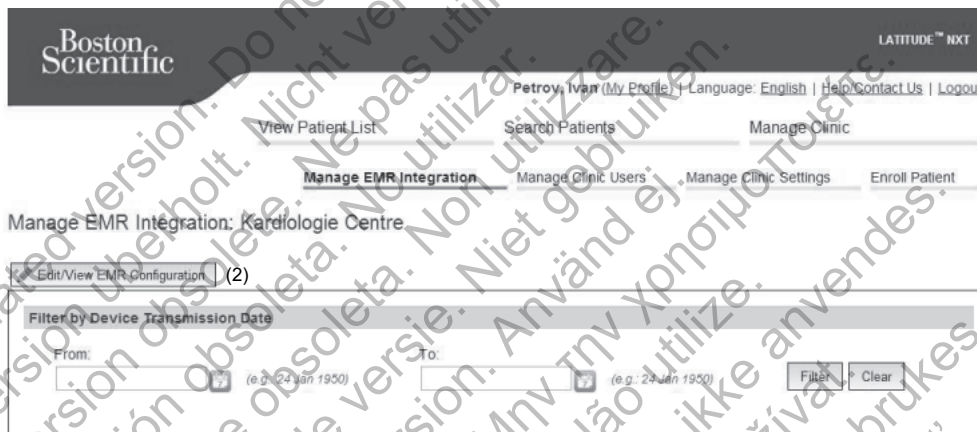


Figure 2-9. Edit/View Configuration Button

3. Record the **EMR/CIS Clinic Identifier** that is provided on this page (as shown below).

Important: The identifier is required to complete the registration of the EMR integration software. The identifier is used to route your LATITUDE NXT System clinic records to your EMR application.



Figure 2-10. Edit/View EMR Configuration Page

4. Click the **click here** link as shown above.
5. You are directed away from LATITUDE NXT to a website for the EMR integration software that needs to be installed. Follow the installation and setup instructions available on this website.
6. Complete installation, configuration, and registration of the software before enabling EMR Integration.

NOTE: Once installation and registration are complete, no further EMR integration software configuration should be required. However, Boston Scientific personnel may contact you regarding additional configuration tasks.

7. Return to the LATITUDE NXT **Edit/View EMR Configuration** page and select the **Enable EMR Integration** checkbox. Any patient interrogation data received while EMR integration is not enabled will not be exported to your EMR application.

Notice: By selecting the **Enable EMR Integration** function, you agree and assert to the following terms and conditions:

- You have installed the EMR integration software on your organization's system in order to download LATITUDE NXT data to your organization's medical record system.
 - You will not use the EMR integration software for any other purpose without Boston Scientific's written approval.
 - You accept responsibility for the security of the data you are receiving from Boston Scientific.
8. Select the appropriate **EMR Integration Format** from the pull-down menu as shown above. The format selected must be appropriate for your EMR application. Supported formats are listed in the pull-down menu.
 9. Click the **Save and Close** button.

Clicking the **Last Updated By** link opens a pop-up window that displays the date and time the EMR configuration was last changed and the name of the user who changed it.

View EMR Log

The **View EMR Log** window on the bottom section of the **Manage EMR Integration** page (shown below) lists EMR files exported to your EMR application. The log only lists patients that are in Patient Groups of which the clinic user has access. Clinic Account Managers will see entries for all patients in the clinic.

You can filter the patient list by entering dates in the fields above the log window. One or both of the date fields may be empty.

View EMR Log 1 - 5 of 5

Patient ID/ Patient	Review Reason	Device Transmission Date	Status	Status Date/Time	Actions
KC-108 da Silva, Joao	Patient Initiated	Sep 13, 2011	Transferred	Sep 13, 2011 11:41 CET	<input type="button" value="Resend"/>
KC-218 Dupont, Jean	Patient Initiated	Sep 13, 2011	Transferred	Sep 13, 2011 09:02 CET	<input type="button" value="Resend"/>
KC-128 Modaal, Jan	Patient Initiated	Sep 13, 2011	Transferred	Sep 13, 2011 09:02 CET	<input type="button" value="Resend"/>
KC-146 Castaneda, Mara	Scheduled	Sep 13, 2011	Transferred	Sep 13, 2011 01:51 CET	<input type="button" value="Resend"/>
KC-281 Lange, Albert	Scheduled	Sep 13, 2011	Transferred	Sep 13, 2011 01:23 CET	<input type="button" value="Resend"/>

View EMR Log 1 - 5 of 5

View EMR Log 1 - 4 of 4

Patient/ Patient ID	Review Reason	Device Transmission Date	Status	Status Date/Time	Actions
佐々木 和也 (Sasaki Kazuya) g043599-2	Implanted Device Alert	18 Dec 2013	Transferred	17 Dec 2013 19:39 JST	<input type="button" value="Resend"/>
田中 一郎 (Tanaka Ichiro) g043599-4	Patient Initiated	29 Oct 2013	Transferred	17 Dec 2013 21:37 JST	<input type="button" value="Resend"/>
加藤 大輔 (Kato Daisuke) g043599-3	Patient Initiated	29 Sep 2013	Transferred	18 Dec 2013 00:52 JST	<input type="button" value="Resend"/>
森 秀夫 (Mori Hideo) g043599-5	Patient Initiated	09 Sep 2013	Transferred	18 Dec 2013 04:01 JST	<input type="button" value="Resend"/>

View EMR Log 1 - 4 of 4

Figure 2-11. View EMR Log Window

The following list, sorted by device transmission date, provides a description of each column of the **View EMR Log** window:

- **Patient ID/Patient** – Patient identifier and patient name.
- **Review Reason** – The reason that the EMR export was initiated (same as on the **View Patient List**, see "Monitoring Status" on page 2-10).
- **Device Transmission Date** – The date the implanted device interrogation associated with the EMR file was initiated.
- **Status** – The current status of the export. A link from each status opens an EMR history pop-up window that provides detailed information of the export processes for that patient. A description of each status follows:
 - **Initiated** – The EMR export has been initiated.
 - **Waiting for Clinic Computer** – All data for the file has been processed and the file is ready to be exported to your EMR application. Typically, file delivery will occur within 30 minutes. If this status persists for more than 30 minutes, please contact your IT professional who is responsible for monitoring your EMR integration software or EMR application.
 - **Transferred** – The EMR file has been successfully exported to your EMR application.
 - **Resend Requested** – A resend of the EMR file has been requested.

- **Failed** – The attempt to export the EMR file failed. No further attempt will be made to export the EMR file. Once the reason for failure has been determined, the EMR data may be resent.
- Refer to the troubleshooting section of the installation instructions document for help with diagnosing and troubleshooting failures. This document is available on the LATITUDE NXT System EMR Integration software (EMR client) webpage.
- **Status Date/Time** – The date and time of the last change in status.
- **Actions** – Contains the **Resend** button that may be used to request another attempt to export the EMR file. A **Resend** can only be initiated when an EMR file has a status of **Transferred** or **Failed**.

Outdated version. Do not use.
 Version überholt. Nicht verwenden.
 Version obsolète. Ne pas utiliser.
 Versión obsoleta. No utilizar.
 Versiões obsoletas. Não utilize.
 Verouderde versie. Niet gebruiken.
 Föråldrad version. Använd ej.
 Παλιά έκδοση. Μην χρησιμοποιείτε.
 Versão obsoleta. Não utilize.
 Forældet version. Må ikke anvendes.
 Zastaralá verzia. Nepoužívať.
 Utdatert versjon. Skal ikke brukes.
 Zastaraná verzia. Nepoužívať.
 Elavult verzió. Ne használja!
 Wersja nieaktualna. Nie używać.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verzia. Nepoužívať.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

EDUCATING PATIENTS ABOUT THE LATITUDE COMMUNICATOR

CHAPTER 3

This chapter contains the following topics:

- “LATITUDE COMMUNICATOR OVERVIEW” on page 3-2
- “WAVE WIRELESS COMMUNICATOR” on page 3-2
- “TOUCH-SCREEN WIRELESS COMMUNICATOR” on page 3-12

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
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Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

LATITUDE COMMUNICATOR OVERVIEW

The information in the following two sections has been selected from relevant Communicator patient manuals to assist the clinician in educating patients about the basic setup and operation of their Communicator.

For general information about the LATITUDE Communicator, refer to "LATITUDE Communicator Overview" on page 1-4.

WAVE WIRELESS COMMUNICATOR

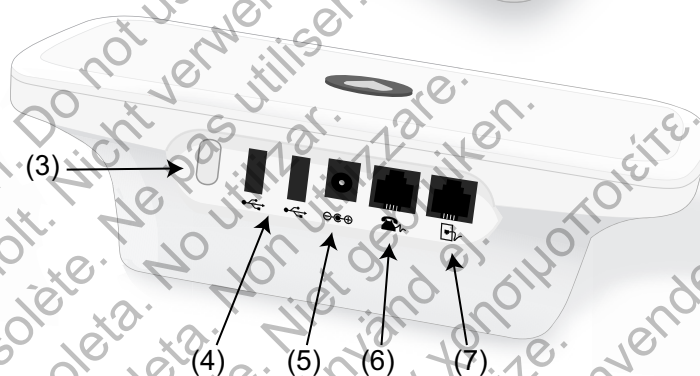
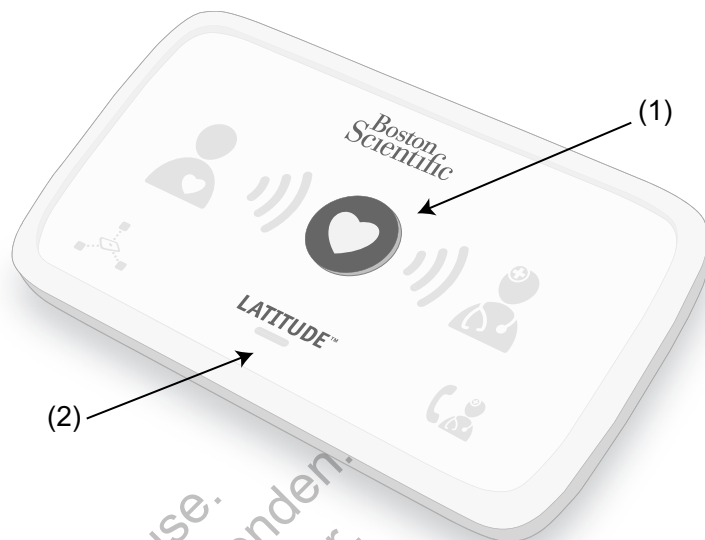
Communicator Placement

For best results, the patient should place the Communicator:

- Near an electrical outlet that is easily accessible.
- Within 3 meters (10 feet) of where they sleep or near their bedside. If this is not possible, the patient should place their Communicator where they spend a considerable amount of time each day.
- Where they can sit comfortably and see the front of the Communicator.
- Where the Communicator and all its cables and accessories will be kept dry and not exposed to humidity or potential water contact.
- Additionally, depending on the communication method used:
 - Standard telephone line: Near a telephone wall jack.
 - Cellular data network: In a location that gets a good signal.
 - Internet (using the LATITUDE USB Ethernet Adapter): Near the Internet modem/router.
 - Internet (using the hotspot feature on the patient's mobile device and the USB Accessory Adapter) (not available in all geographies): In a location where the mobile device will be near the Communicator. Hotspot and Bluetooth® wireless technology must be enabled on the patient's mobile device while they are near their Communicator for at least one hour each day and for manual device interrogations.

Identifying Buttons, Connectors, and Indicators

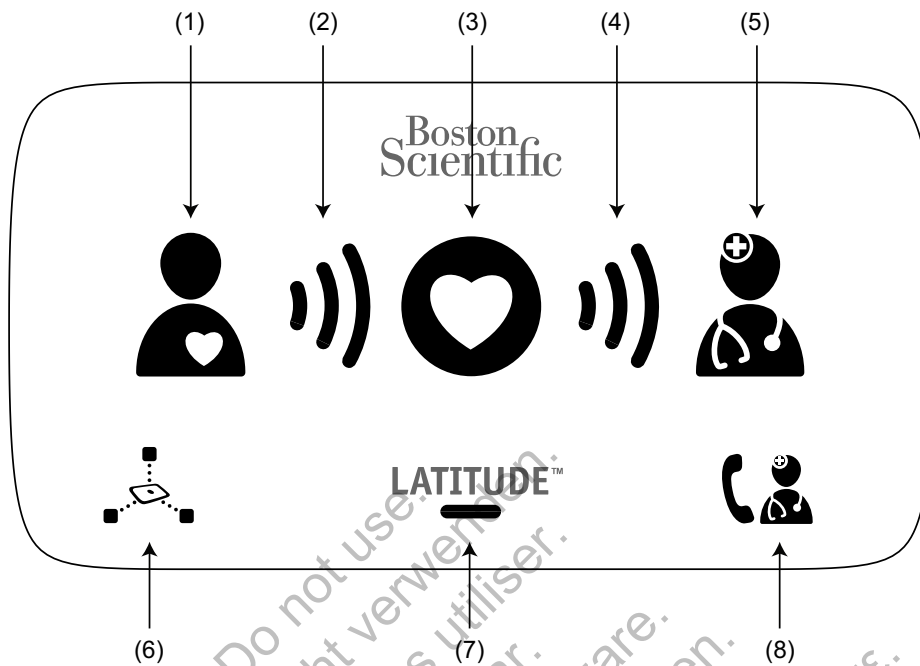
The following figure shows the buttons, connectors, and LATITUDE indicator on the front and back of the Communicator.



(1) Heart button, (2) LATITUDE indicator, (3) Status button, (4) USB ports (used to connect the USB Accessory Adapter and/or the USB Cellular Adapter or USB Ethernet Adapter), (5) power input, (6) to telephone (optional), (7) to telephone wall jack

Figure 3-1. WAVE WIRELESS COMMUNICATOR Buttons, Connectors, and Indicator

The following figure shows all the indicators. Refer to "Indicator Descriptions" on page 3-4 for a description of each indicator.



(1) Patient icon, (2) Collecting Waves, (3) Heart button, (4) Sending Waves, (5) Doctor icon, (6) Sensor Reading icon, (7) LATITUDE indicator, (8) Call Doctor icon

Figure 3-2. WAVE WIRELESS COMMUNICATOR INDICATORS

Indicator Descriptions



Patient Icon

Indicates the Communicator is interrogating (collecting data from) the patient's implanted device.

- Lights solid blue when the Heart button is pressed and an interrogation has started.
- Lights solid blue for two minutes after a successful interrogation.



Collecting Waves

Indicate the Communicator is collecting data from the patient's implanted device or an error occurred while collecting data.

- Flash green in sequence and repeat, showing the Communicator is interrogating the patient's implanted device.
- Light green for two minutes to indicate the interrogation was successful.
- Refer to "Troubleshoot Yellow Collecting Waves" on page A-1 in the Troubleshooting Guide Appendix.



Heart Button

Flashes with a white light if the patient needs to complete a previously scheduled interrogation.

- Lights a solid white for two minutes to indicate the interrogation is complete.
- Can also be used to manually initiate an interrogation of the patient's implanted device, if **Patient Initiated Interrogations** are enabled by the clinic user.



Sending Waves

Indicate the Communicator is connecting to the LATITUDE NXT server or an error occurred while sending data.

- Flash green in sequence and repeat, indicating a connection to the LATITUDE NXT server is in progress.
- Light green for two minutes to indicate the connection to the LATITUDE NXT server was successful and any collected device data was sent.
- Refer to "Troubleshoot Yellow Sending Waves" on page A-3 in the Troubleshooting Guide Appendix.



Doctor Icon

Lights blue for two minutes to indicate the Communicator has successfully connected to the LATITUDE NXT server.

- The Communicator sends any data from the patient's implanted device, weight scale, or blood pressure monitor that is stored in the Communicator's memory.



Sensor Reading Icon

Indicates the Communicator has successfully communicated with a prescribed weight scale or blood pressure monitor.

- Flashes green five times and lights solid green for five minutes to indicate the Communicator successfully received a weight or blood pressure measurement.



LATITUDE Indicator

Indicates the Communicator is connected to electrical power. It also indicates if the Communicator startup process is being performed or if the Communicator is ready to use.

- Lights green to indicate the Communicator is connected to electrical power and is ready to use.
- Flashes yellow during the startup process.
- May flash yellow for an extended period. This indicates a software upgrade that was downloaded from the server is being installed on the Communicator.
- If an error exists, the LATITUDE indicator stays yellow for 60 minutes or until the error is resolved.



Call Doctor Icon

Lights yellow or red (flashing or solid) to indicate a problem was detected that should be communicated to the clinic user.

A red light ranks higher than a yellow light. If an error for each color occurs at the same time, only the red light is displayed.

- A red light indicates that the Communicator has detected a red alert condition in the implanted device and it has been unable to send the alert data to the LATITUDE NXT server for 24 hours.
- A yellow light indicates that one of the following conditions has occurred:
 - The Communicator has detected an **Implanted Device Not Found** condition and has been unable to send that status to the LATITUDE NXT server for up to 36 hours.
 - Monitoring by the Communicator has been suspended.
 - The Communicator may not be working properly, and the patient may need a replacement Communicator.
- In addition, the Call Doctor Icon flashes yellow briefly after the Communicator is plugged into electrical power. The light turns off after the Communicator successfully completes the startup process. If the startup process does not complete, it lights solid yellow.
- Refer to "Red/Yellow Call Doctor Icon" on page A-5 in the Troubleshooting Guide Appendix.

The Status Button

The following figure shows the Status button on the back of the Communicator.

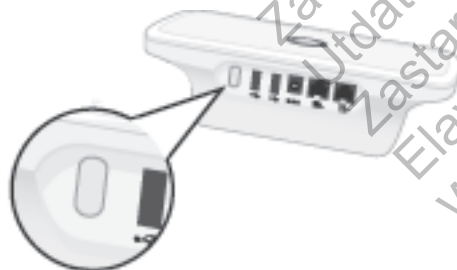


Figure 3-3. Status Button

The Status button performs one of the following actions depending on how long the button is pressed:

- **Press for less than three seconds:** The Communicator indicators will light to display:

- The status of the last interrogation.
- The status of the last connection to the LATITUDE NXT server.

The indicators will light for two minutes. If the Call Doctor icon was flashing, it will stop flashing and light solid.

- **Press and hold for more than three seconds:** The Sending Waves flash green in sequence and repeat while the Communicator connects to the LATITUDE NXT server.

Explaining the WAVE WIRELESS COMMUNICATOR Setup

When distributing a WAVE WIRELESS COMMUNICATOR to a patient, we recommend briefly explaining its functions and how to set it up. This section provides an overview of the initial WAVE WIRELESS COMMUNICATOR setup. For detailed instructions, refer to the patient manual and quick start guide.

When the patient arrives home with their new WAVE WIRELESS COMMUNICATOR, they need to place it near an electric power outlet and in the best location for their method of connection to the LATITUDE NXT System. Refer to "Communicator Placement" on page 3-2. The patient needs to use one, and only one, of the following methods of connection:

- **Standard Telephone Line**

The following figure shows power supply and telephone jack connections to the Communicator.

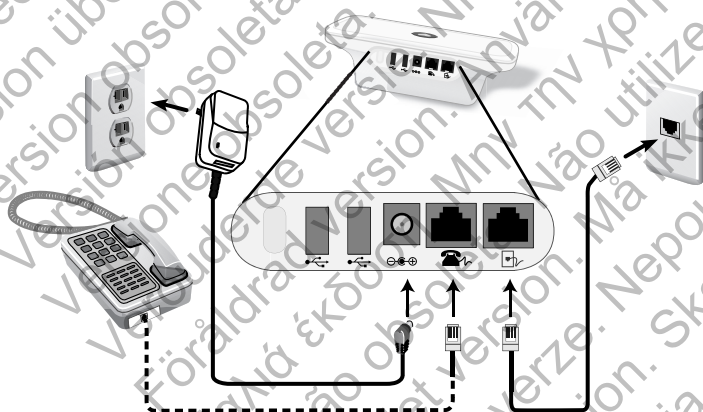
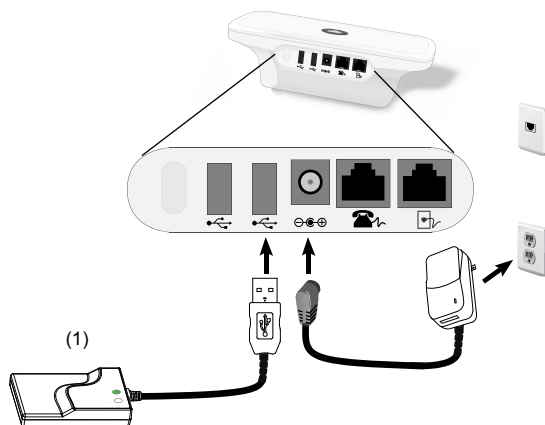


Figure 3-4. Connecting with a Standard Telephone Line

Connecting a telephone is optional. The Communicator and a telephone can share the same telephone wall jack; however, they cannot be used at the same time. A telephone adapter may be required between the telephone cable and the wall jack.

- **Cellular Data Network**

The following figure shows power supply and USB Cellular Adapter connections to the Communicator for a patient subscribed to the cellular data network.



(1) USB Cellular Adapter

Figure 3–5. Connecting with the Cellular Data Network

The cellular data network uses a data-only network. It does not send voice signals and cannot be used with the patient's existing cellular phone service.

Use of the cellular data network does not guarantee coverage. Actual coverage may be affected by such things as terrain, weather, foliage, buildings and other construction, signal strength, user equipment, and other factors.

The patient or clinic should contact LATITUDE Customer Support to subscribe to the cellular data network, to update the subscription if the patient receives replacement equipment, or to discontinue use of the cellular data network.

Model 6288 has built-in capability to connect the WAVE WIRELESS COMMUNICATOR to the LATITUDE NXT System, and *Model 6290* uses a USB Cellular Adapter, as shown in the above figure.

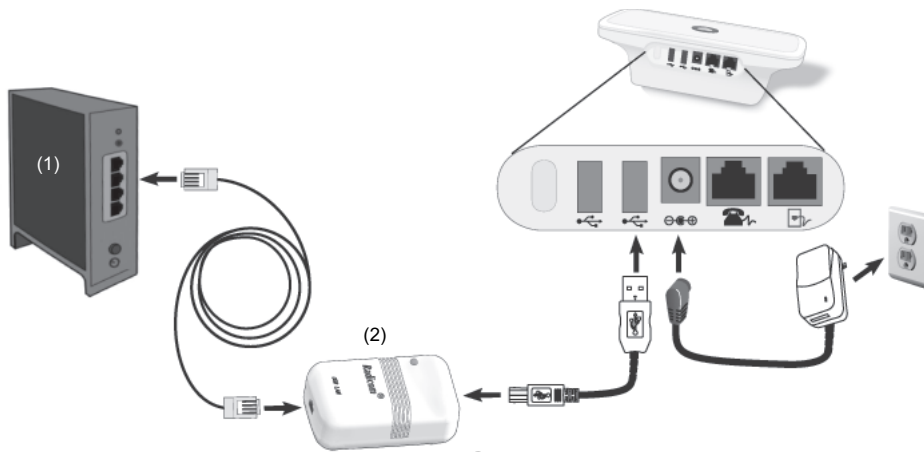
When using a USB Cellular Adapter, it is important that the patient:

- Maintain a distance of at least 15 cm (6 inches) between the USB Cellular Adapter and their implanted device
- Place their USB Cellular Adapter away from other electronic products or metal surfaces and alongside the Communicator and not under or on top of it.

NOTE: *The Communicator is designed to use an Internet connection, if available, or a standard telephone connection if it is plugged into an active telephone jack. If connected, the Communicator may send implanted device data over the Internet or standard telephone connection even if the patient is subscribed to the cellular data network.*

• **USB Ethernet Adapter**

The following figure shows power supply and USB Ethernet Adapter connections to the Communicator.



(1) Internet router or modem, (2) USB Ethernet Adapter

Figure 3-6. Connecting with the USB Ethernet Adapter

- **Hotspot Feature**

The patient may use the hotspot feature on their mobile device to connect the WAVE WIRELESS COMMUNICATOR to the LATITUDE NXT System. To use hotspot, a USB Accessory Adapter must be plugged into the Communicator (as shown in Figure 3-9 Connecting the USB Accessory Adapter on page 3-12). The pairing PIN number is “123456”. The patient must enable hotspot and *Bluetooth*® wireless technology on their mobile device while near the Communicator for at least one hour each day and for manual device interrogations to allow enough time for the Communicator to contact the LATITUDE NXT System.

NOTES:

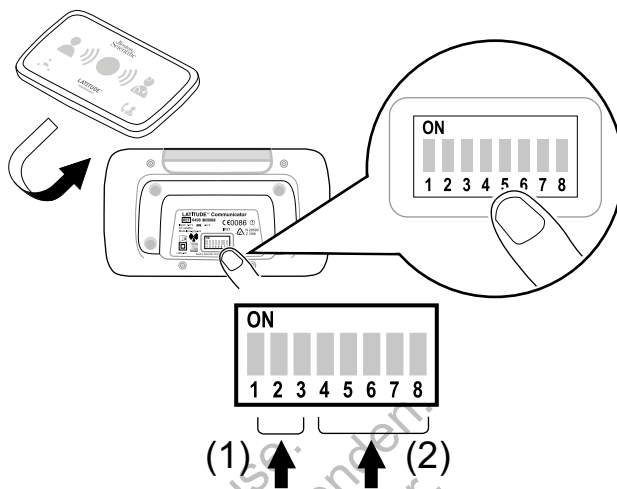
- If the patient’s Communicator is already using a USB Accessory Adapter for the weight scale or blood pressure monitor, the USB Accessory Adapter can remain connected and can also be used for the hotspot connection.
- The hotspot feature may not be available in all geographies.

Setting the WAVE WIRELESS COMMUNICATOR Switches

In order for the Communicator to connect with the LATITUDE NXT System, the eight switches on the bottom of the WAVE WIRELESS COMMUNICATOR must be properly set, regardless of the method of connection. The following figure shows the location of the two sets of switches.

- **Dial-out Number:** Switches 1–3 apply to patients who use a standard telephone line for connection to the LATITUDE NXT System and who use a dial-out number or prefix to place an external telephone call.
- **Country Code:** Switches 4–8 apply to all methods of connection—standard telephone line, cellular data network, or Internet—and must be set for the country where the WAVE WIRELESS COMMUNICATOR will be used.

NOTE: Country code switches are set at the factory for certain specified countries.



(1) Dial-out number, (2) country code

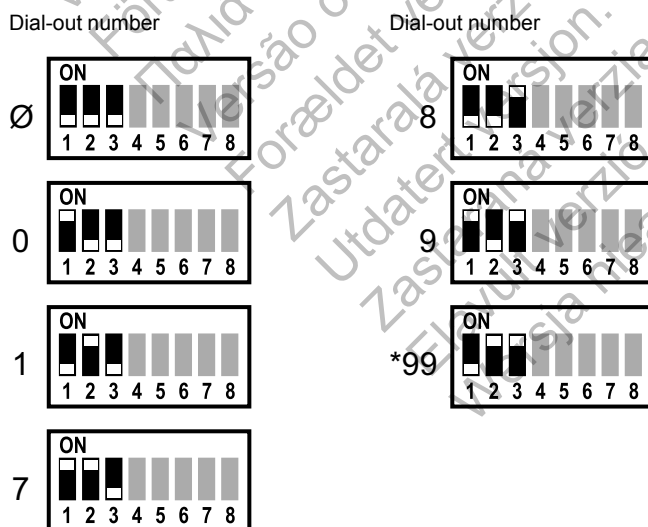
Figure 3-7. Switch Location

Dial-out Number (Switches 1-3)

NOTE: This section applies only to the standard telephone line method of connection to the LATITUDE NXT System. For cellular or Internet methods of connection, any of the settings for switches 1-3 shown below will work.

The WAVE WIRELESS COMMUNICATOR may be used in a managed care facility, hotel, or other location that requires a dial-out number or prefix to place an external call. For example, some facilities require first dialing a 9 to access an outside line. The first three switches (1, 2, and 3) on the bottom of the WAVE WIRELESS COMMUNICATOR must be set to match the dial-out number. Refer to the following figure.

NOTE: If the patient travels to a location with a different dial-out prefix, these switches must be adjusted.



(∅ = no dial-out number required)

Country Code (Switches 4–8)

Switches 4 through 8 need to be set for the country where the WAVE WIRELESS COMMUNICATOR will be used.

NOTE: If the patient uses the standard telephone line method of connection to the LATITUDE NXT System and travels to a different country, these switches must be adjusted for the new country. However, there may be restrictions due to radio-frequency (RF) laws to using the Communicator outside the country of the patient's clinic. Contact LATITUDE Customer Support for more information.

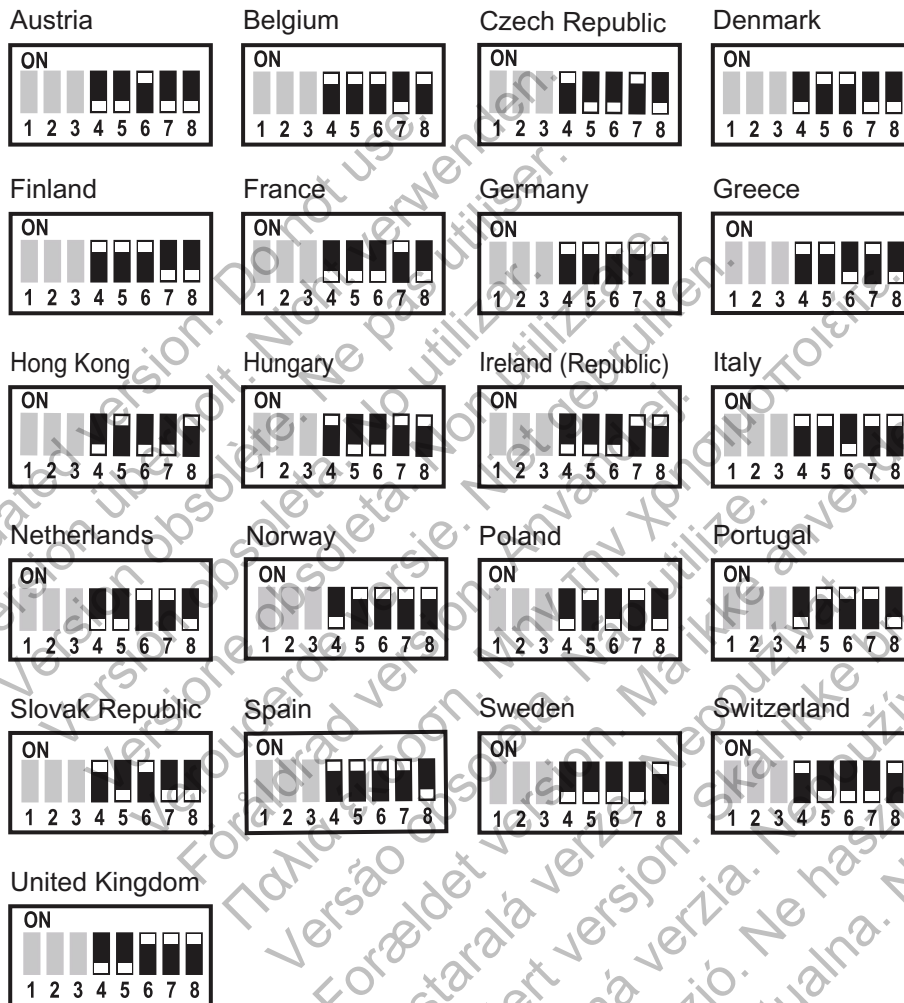


Figure 3-8. Country Code Switch Settings

Verifying the Connection

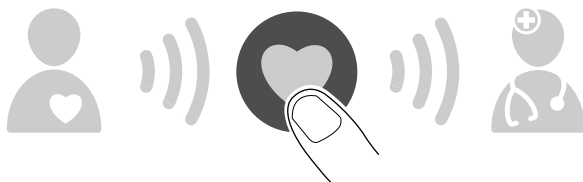
The patient can verify the Communicator's connection to the LATITUDE NXT System by following the instructions in the patient manual, beginning with pressing the Status button to make a call to the LATITUDE NXT server. (Refer to "The Status Button" on page 3-5.) If the connection was successful, all three of the Sending Waves will light green for two minutes. If the connection was unsuccessful, one or more of the Sending Waves will light yellow.

The patient should also check the connection if they move the Communicator, travel to another location, or change the connection method.

Refer to "Troubleshoot Yellow Sending Waves" on page A-3 in the Troubleshooting Guide Appendix.

Heart Button Interrogation Sequence

After the Heart button is pressed, the Communicator interrogates the patient's implanted device and then sends the device data to the LATITUDE NXT server. The following sequence describes how the indicators illuminate after the Heart button is pressed. More detailed information describing the colors and purpose of all the indicators is provided in "Indicator Descriptions" on page 3-4.



The Communicator begins interrogating the patient's implanted device after the Heart button is pressed.



The Patient icon lights blue. The Collecting Waves flash green in sequence and repeat while the Communicator interrogates the patient's device.



All three Collecting Waves will light solid green. The Heart button lights solid white, indicating the interrogation was successful.



The Sending Waves flash green in sequence and repeat while the Communicator places a call and starts sending the patient's device data to the LATITUDE NXT server.



The Doctor icon lights blue, indicating the Communicator successfully sent the patient's data to the LATITUDE NXT server. All the indicators shown stay lit for two minutes to indicate the entire process was successful.

Connecting the USB Accessory Adapter

NOTE: The USB Accessory Adapter is not available in all geographies.

The USB Accessory Adapter is required for a wireless connection between:

- The weight scale and blood pressure monitor and the WAVE WIRELESS COMMUNICATOR.

- The WAVE WIRELESS COMMUNICATOR and the LATITUDE NXT System for patients using the hotspot feature on their mobile device.

Only one USB Accessory Adapter is required for the above wireless functions.

To connect the USB Accessory Adapter, remove the cap and plug the USB Accessory Adapter into either of the USB ports on the back of the Communicator, as shown in the following figure.

The USB Accessory Adapter should remain plugged into the Communicator so the Communicator can receive measurements whenever the patient uses their weight scale or blood pressure monitor or when needed for wireless methods of connection from the Communicator to the LATITUDE NXT System.

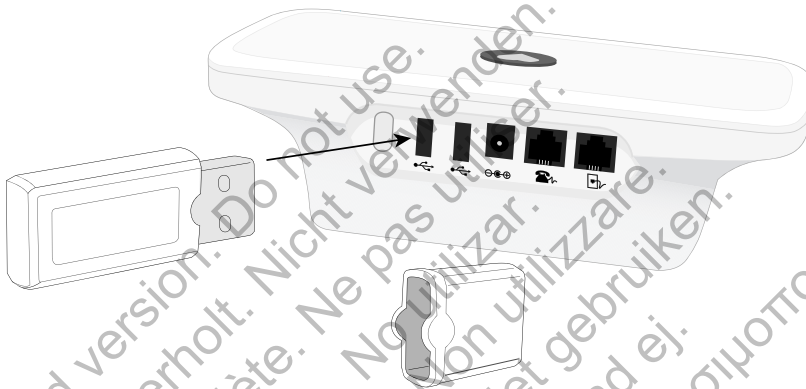
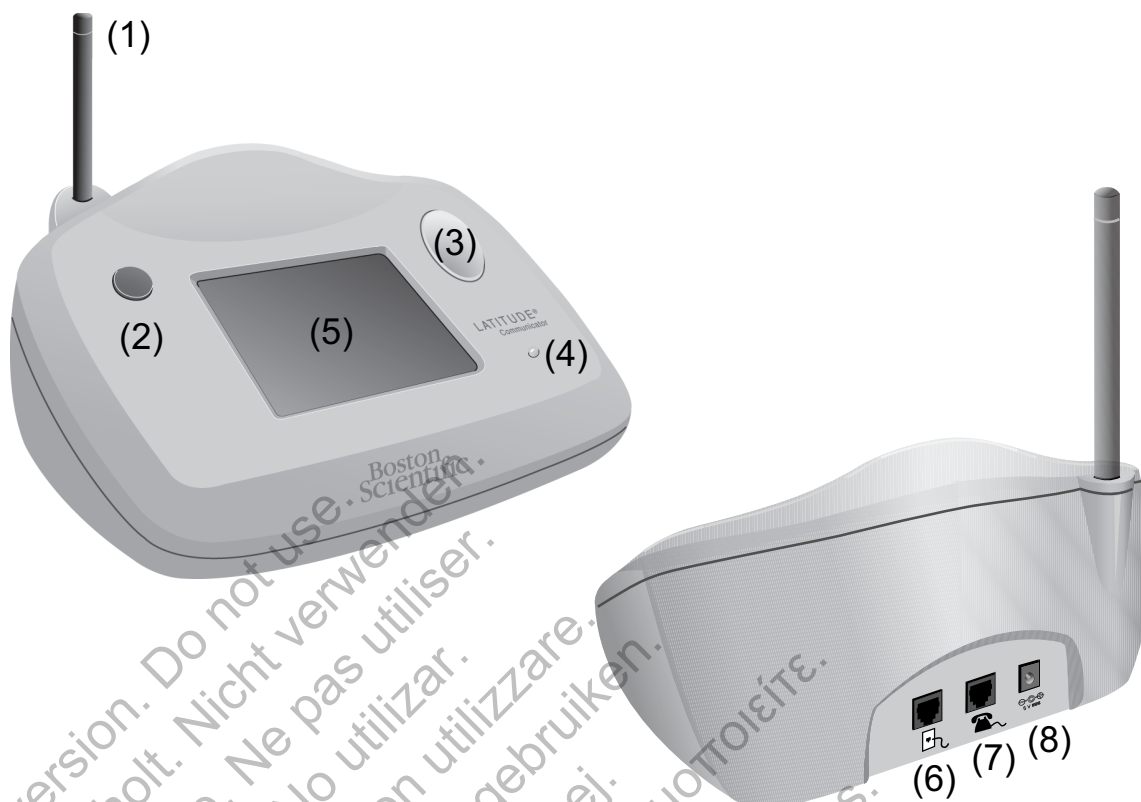


Figure 3-9. Connecting the USB Accessory Adapter

TOUCH-SCREEN WIRELESS COMMUNICATOR

Identifying Buttons, Connectors, and Indicator

The following figure shows the buttons, connectors, and Power On indicator on the front and back of the TOUCH-SCREEN WIRELESS COMMUNICATOR. Refer to "Button and Indicator Light Descriptions" on page 3-13 for the meaning of each light and indicator.



(1) Non-adjustable antenna, (2) blue Interrogate button, (3) Action button, (4) Power On indicator, (5) LCD touch screen, (6) to telephone wall jack, (7) to telephone (optional), (8) power input

Figure 3-10. TOUCH-SCREEN WIRELESS COMMUNICATOR Buttons, Connectors, and Indicator

Button and Indicator Light Descriptions

Table 3-1. Button and Indicator Light Descriptions

Button/Light	Color	Meaning
Action button	White light	Interrogate implanted device. Patients should respond to the information displayed on the touch screen.
	Yellow light	Respond to Communicator alert. Indicates some type of Communicator problem. Patients should respond to the information displayed on the touch screen.
	Red light	The patient's immediate response is required. Indicates that the Communicator identified a potential problem in the implanted device that the physician asked to be alerted about. The patient should write down any codes that appear in alert messages, call their physician to report any codes, then press the OK button.
Interrogation button	Blue	Used to initiate an interrogation of the implanted device. Patients should refer to the patient manual before using this button. Clinicians may refer to "Patient Initiated Interrogation" on page 1-13.
Power On	Green light	Indicates the Communicator is connected to power.

Touch-Screen Display

The Communicator has a sensitive touch-screen display. Touching the screen will activate the display. Respond to onscreen instructions or questions by touching the desired button with your fingertip. Do not use tools or sharp objects as they can damage the touch screen. If you need to use the Communicator and the touch screen is dim (black), simply touch any part of the screen or press the Action button to activate the screen.

Explaining the TOUCH-SCREEN WIRELESS COMMUNICATOR Setup

When distributing a TOUCH-SCREEN WIRELESS COMMUNICATOR to a patient, we recommend briefly explaining its functions and how to set it up. This section provides an overview of the initial TOUCH-SCREEN WIRELESS COMMUNICATOR setup. For detailed instructions, refer to the patient manual and installation guide.

When the patient arrives home with their new TOUCH-SCREEN WIRELESS COMMUNICATOR, they need to place it near an electric power outlet and telephone jack if using a standard telephone line to connect to the LATITUDE NXT System. If the patient will be using the optional external cellular adapter rather than a standard telephone line to connect to the LATITUDE NXT System, they need to place the Communicator near an electric power outlet in a location that receives a good signal. The patient needs to use either a standard telephone line or the cellular data network to connect to the LATITUDE NXT System.

The Communicator's touch screen displays step-by-step instructions during the setup process, as well as during general operation.

- **Standard Telephone Line**

The following figure shows power supply and telephone jack connections to the Communicator.

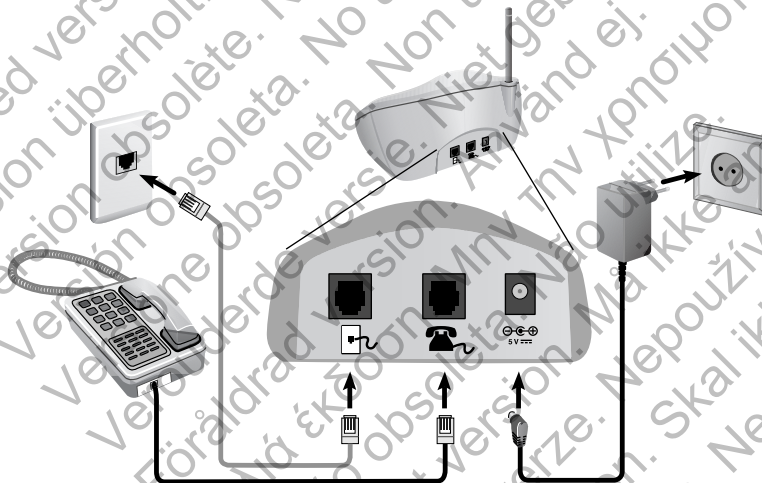


Figure 3–11. Connecting with a Standard Telephone Line

Connecting a telephone is optional. The Communicator and a telephone can share the same telephone wall jack; however, they cannot be used at the same time. A telephone adapter may be required between the telephone cable and the wall jack.

- **Cellular Data Network**

The following figure shows power supply and connection to an external cellular adapter for a patient subscribed to the cellular data network.



Figure 3-12. Connecting with the Cellular Data Network

The cellular data network uses a data-only network. It does not send voice signals and cannot be used with the patient's existing cellular phone service.

Use of the cellular data network does not guarantee coverage. Actual coverage may be affected by such things as terrain, weather, foliage, buildings and other construction, signal strength, user equipment, and other factors.

The patient or clinic should contact LATITUDE Customer Support to subscribe to the cellular data network, to update the subscription if the patient receives replacement equipment, or to discontinue use of the cellular data network.

The patient should not connect a telephone to the Communicator's telephone jack when using an external cellular adapter.

If the Communicator cannot connect to the LATITUDE NXT System, a **LATITUDE is temporarily unavailable** message may appear. If this happens, the patient should move the Communicator to another location and check the connection. If this does not work, contact LATITUDE Customer Support for assistance. If the Communicator is not able to connect, have the patient try plugging the Communicator into an active telephone jack.

Verifying the Connection

The patient can verify the Communicator's connection to the LATITUDE NXT System by navigating to the **Options** menu screen, selecting the **Connect to LATITUDE** button, and following the instructions on the screen. The patient should also check the connection if they move the Communicator, travel to another location, or change the connection method.

The Action button alert lights described in "Button and Indicator Light Descriptions" on page 3-13 notify the patient that an action needs to be taken. The patient should write down any codes that appear in alert messages and respond as soon as possible.

Refer to "TOUCH-SCREEN COMMUNICATOR" on page A-8 in the Troubleshooting Guide Appendix.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verzia. Nepoužívať.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať!
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

TROUBLESHOOTING GUIDE

APPENDIX A

This appendix duplicates the Communicator and Sensor sections of the Troubleshooting Guides on the **Help/Contact Us** LATITUDE NXT website and is intended to help clinicians resolve problems with patient Communicators and sensors. If you are unable to resolve a problem with a patient Communicator or sensor after following the recommendations provided, have the patient contact LATITUDE Customer Support.

This Troubleshooting Guide mimics the LATITUDE NXT website and contains separate sections for the WAVE WIRELESS COMMUNICATOR and the TOUCH-SCREEN WIRELESS COMMUNICATOR. Within each section, there are two main areas of information: Communicator and Sensor, with topics under each.

NOTE: *The Troubleshooting Guides on the **Help/Contact Us** LATITUDE NXT website also include a section about Monitoring Status for each type of Communicator. Monitoring Status is not included in this appendix.*

WAVE COMMUNICATOR

This section provides information to help resolve WAVE WIRELESS COMMUNICATOR problems.

COMMUNICATOR

This section provides information to help resolve Communicator problems for the WAVE WIRELESS COMMUNICATOR.

Troubleshoot Yellow Collecting Waves

Yellow Collecting Waves indicate that the Communicator was not able to connect with the implanted device.

Troubleshooting for Yellow Collecting Waves includes performing a patient initiated interrogation (PII) by pressing the Heart button. If the patient is not allowed to perform PIIs, allow one PII on the patient's **Edit/View Schedule and Alert Configuration** page. If the patient's phone is using the same landline as the Communicator, the patient will need to hang up the phone prior to performing the interrogation.

- **One Yellow Collecting Wave**

The Communicator is unable to locate the implanted device.

Recommendations:

Try one or more of the following actions:

- Verify that the implanted device model and serial number recorded in the LATITUDE NXT System match the values on a PRM (Programmer/ Recorder/Monitor) report.
- Verify that the Communicator model and serial number match the model and serial number recorded on the **Edit/View Patient and Equipment Information** page.
- Verify the Communicator is optimally placed:
 - The Communicator is near where the patient sleeps, or near the bedside, within 3 meters (10 feet). If this is not possible, place the Communicator where the patient spends a considerable amount of time each day.

- The Communicator is level with the patient and clear of any obstructions.
- Ask the patient to turn off and, if necessary, unplug wireless electronics (such as cordless phones or baby monitors) within 1 meter (3 feet) of the Communicator.
- The patient should be facing the Communicator and should remain comfortably still during the interrogation.
- Ask the patient to perform a patient initiated interrogation by pressing the Heart button on the Communicator and staying within 1 meter (3 feet) during the interrogation.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully interrogated the implanted device and transmitted the interrogation when the Doctor icon is blue.

As appropriate, verify the implanted device's telemetry and operation by interrogating it with a PRM (Programmer/Recorder/Monitor).

- **Two Yellow Collecting Waves**

The Communicator is able to locate the implanted device but is not able to complete an interrogation.

Recommendations:

Try one or more of the following actions:

- Verify that the implanted device model and serial number recorded in the LATITUDE NXT System match the values on a PRM (Programmer/ Recorder/Monitor) report.
- Verify that the Communicator model and serial number match the model and serial number recorded on the **Edit/View Patient and Equipment Information** page.
- Verify the Communicator is optimally placed:
 - The Communicator is near where the patient sleeps, or near the bedside, within 3 meters (10 feet). If this is not possible, place the Communicator where the patient spends a considerable amount of time each day.
 - The Communicator is level with the patient and clear of any obstructions.
 - Ask the patient to turn off and, if necessary, unplug wireless electronics (such as cordless phones or baby monitors) within 1 meter (3 feet) of the Communicator.
 - The patient should be facing the Communicator and should remain comfortably still during the interrogation.
- Ask the patient to perform a patient initiated interrogation by pressing the Heart button on the Communicator and staying within 1 meter (3 feet) during the interrogation.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully interrogated the implanted device and transmitted the interrogation when the Doctor icon is blue.

- **Three Yellow Collecting Waves**

The patient is not allowed to perform a patient initiated interrogation (PII). Three Collecting Waves are also shown when the patient has cancelled an interrogation.

Recommendations:

Try one or more of the following actions:

- Enable **Patient Initiated Interrogations** (PII) for the patient or allow one PII:
 - Navigate to the patient's **Edit/View Schedule and Alert Configuration** page.
 - If PIIs are not enabled for this patient, then enable them or allow one PII.
- Ask the patient to retry the patient initiated interrogation by pressing the Heart button on the Communicator and staying within 1 meter (3 feet) during the interrogation.
- Ensure patient doesn't press the Heart button while the interrogation is in progress as this will cancel the interrogation attempt.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully interrogated the implanted device and transmitted the interrogation when the Doctor icon is blue.

Troubleshoot Yellow Sending Waves

Yellow Sending Waves indicate that the Communicator was not able to connect with the LATITUDE NXT System.

The Communicator is able to use the following to connect:

- a landline
- a cellular data network
- an Internet connection (USB Ethernet Adapter)
- **One Yellow Sending Wave**

The Communicator does not detect one or more of the following:

- a dial tone (landline)
- a cell signal (cellular data network)
- an Internet connection (USB Ethernet Adapter)

Recommendations:

Try one or more of the following actions:

For a landline:

- Verify that the patient used the provided phone cord and that the cord is firmly connected to both the Communicator and an active telephone wall jack.

- If the patient has DSL internet service, make sure they are using a DSL filter between the Communicator and the telephone wall jack.
- Verify that the patient is using the provided adapter, if needed.

For cellular data network:

- If the patient has a Communicator which requires an external cellular adapter, verify it is connected securely to the Communicator. The adapter has a power indicator that should be lit when it is properly connected.
- Ask the patient to move the Communicator to another location that may have a better signal.

For Internet (USB Ethernet Adapter):

- Verify the USB cable provided with the USB Ethernet Adapter is connected at one end to the USB Ethernet Adapter and at the other end to the Communicator.
- Verify the Ethernet cable provided with the USB Ethernet Adapter is firmly connected at one end to the USB Ethernet Adapter and at the other end to the Ethernet port for the Internet service.
- If the green light on the USB Ethernet Adapter is not lit, ensure that the Internet modem/router is powered on.

To verify troubleshooting was successful, have the patient connect to the LATITUDE NXT System by pressing and holding the Status button on the back of the Communicator until the Sending Waves light green in sequence and repeat.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully connected with the LATITUDE NXT System when the Doctor icon is blue and the Sending Waves are green.

• **Two Yellow Sending Waves**

The Communicator is unable to make a network connection (landline or Internet) or cannot register with the cellular data network.

Recommendations:

Try one or more of the following actions:

For a landline:

- Verify that the patient used the provided phone cord and that the cord is firmly connected to both the Communicator and an active telephone wall jack.
- Verify that no one picked up the phone while the Communicator was trying to connect.
- Ask the patient to remove any splitters between the Communicator and the telephone wall jack.
- If the patient has DSL internet service, make sure they are using a DSL filter between the Communicator and the telephone wall jack.

- Ask the patient to locate the switches on the bottom of the Communicator. Verify that the Communicator is set to the appropriate country code and dial-out number.

For cellular data network:

- Ask the patient to move the Communicator to another location that may have a better signal.

For Internet (USB Ethernet Adapter):

- Verify the Ethernet cable is connected to the Ethernet port for the Internet service.

To verify troubleshooting was successful, have the patient connect to the LATITUDE NXT System by pressing and holding the Status button on the back of the Communicator until the Sending Waves light green in sequence and repeat.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully connected with the LATITUDE NXT System when the Doctor icon is blue and the Sending Waves are green.

- **Three Yellow Sending Waves**

The Communicator is unable to complete the connection to the LATITUDE NXT server.

Recommendations:

Try one or more of the following actions:

- Verify the patient is enrolled in the LATITUDE NXT System using the patient list or **Search Patients**.
- Verify that the Communicator model and serial number match the model and serial number recorded on the **Edit/View Patient and Equipment Information** page.
- Ask the patient to locate the switches on the bottom of the Communicator. Verify that the Communicator is set to the appropriate country code and dial-out number.
- If the patient is using an Internet connection (USB Ethernet Adapter), verify that other computers or devices connected to the Internet modem/router are able to access the Internet.

To verify troubleshooting was successful, have the patient connect to the LATITUDE NXT System by pressing and holding the Status button on the back of the Communicator until the Sending Waves light green in sequence and repeat.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully connected with the LATITUDE NXT System when the Doctor icon is blue and the Sending Waves are green.

Red/Yellow Call Doctor Icon

- **Call Doctor Icon is Red**

The Communicator has detected a Red Alert and has been unable to upload complete data about the alert to the server for more than 24 hours.

Recommendations:

Try one or more of the following actions:

- Using a PRM (Programmer/Recorder/Monitor), interrogate the implanted device to investigate and resolve the Red Alert.
- Once the Red Alert has been addressed in the implanted device, you will still need to troubleshoot any issues with the Communicator for it to continue monitoring the patient.
 - Ask the patient if the Sending or Collecting Waves are illuminated. If not, ask the patient to press the Status button on the back of the Communicator for approximately 1 second.
 - Identify which Waves are illuminated and follow the appropriate troubleshooting sections for any yellow Waves.

NOTE: If you elect to troubleshoot the Communicator before interrogating the implanted device with a PRM, be aware that this can further delay investigating the Red Alert. In addition, the upload may not be able to successfully complete depending on the issue observed with the Communicator.

For further assistance, you may direct your patient to LATITUDE Customer Support.

• Call Doctor Icon is Yellow

There are several possible reasons for the Call Doctor Icon to be yellow:

- The Communicator has detected the **Implanted Device not Found** condition and has been unable to communicate it to the server.
- The Communicator has been suspended due to replacement or **No Primary Clinic** condition.
- The Communicator has detected an unrecoverable Communicator error and needs to be replaced.

Recommendations:

Try one or more of the following actions:

- Check for yellow Collecting or Sending Waves:
 - Ask the patient to press the Status button on the back of the Communicator for approximately one second.
 - Identify which Waves are illuminated and follow the appropriate troubleshooting sections for any yellow Waves.
- Verify that the Communicator model and serial number match the model and serial number recorded on the **Edit/View Patient and Equipment Information** page.
- Check the patient's monitoring status on the LATITUDE NXT System. If the patient is no longer enrolled in your clinic, or if the status is **No Primary Clinic**, the Communicator is suspended. Refer to the **No Primary Clinic** steps to resolve the issue.

- If none of the above steps resolve the issue, ask the patient to unplug the Communicator from the wall power outlet. Wait 30 seconds and ask the patient to plug the Communicator back into the wall power outlet. If the Call Doctor icon is solid yellow and no other lights have illuminated, the Communicator may not be working properly and needs to be replaced.

For further assistance, you may direct your patient to LATITUDE Customer Support.

SENSOR

This section provides information to help resolve sensor problems for the WAVE WIRELESS COMMUNICATOR.

Weight Scale or BPM Readings not Received

The patient has a weight scale or blood pressure monitor (BPM) assigned, but readings are not being received by the LATITUDE NXT System. The patient is given 20 minutes to retake readings. Note that readings do not upload immediately. Unless an alert is detected, readings are transmitted with the next scheduled connection to the LATITUDE NXT System (up to seven days).

Recommendations:

Try one or more of the following actions:

- Ask the patient to connect to the LATITUDE NXT System by pressing and holding the status button on the back of the Communicator until the Sending Waves light green in sequence and repeat. This will send any readings collected by the Communicator to the LATITUDE NXT System.
- Verify that the USB adapter is securely plugged into the Communicator.
- Verify that the slide switch on the bottom of the weight scale is set correctly to **Weight B kg**.
- Ask the patient to install new, non-rechargeable batteries in the correct direction.
- Verify that the weight scale or blood pressure monitor serial number matches the serial number recorded on the **Edit/View Patient and Equipment Information** page.
- Verify the patient is using the sensor correctly:
 - The patient has pressed the start button on the weight scale or blood pressure monitor before taking a reading.
 - The weight scale or blood pressure monitor is within 6 meters (20 feet) of the Communicator.
 - For the weight scale, the patient waits until 0.0 appears before stepping on the scale.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator's Sensor Reading icon will be green when a reading has been received. Once uploaded to the LATITUDE NXT System, readings are visible on the patient's **Health** page.

Blood Pressure Monitor Error

The patient is receiving an error from a blood pressure monitor.

Recommendations:

Try one or more of the following actions:

- Common blood pressure monitor errors:
 - ERR CUF – the cuff is not fastened correctly. Verify the patient is using it correctly:
 - Verify the patient is using the correct size cuff. The cuff comes in three sizes for patient comfort: Small (18–22 cm), Medium (22–32 cm) and Large (32–45 cm). You may want to measure the patient's arm, just above the elbow, to determine the correct cuff size.
 - The cuff should be about one inch (2-3 cm) above the elbow.
 - Two fingers should fit comfortably between the cuff and the patient's arm.
 - The patient's arm should be extended at chest level resting comfortably.
 - Ask the patient to refasten the cuff and try again.
 - ERR – the monitor did not get a good reading. Ask the patient to unplug and reconnect the hose. Ask the patient to retake the reading, remaining still.

For further assistance, you may direct your patient to LATITUDE Customer Support.

TOUCH-SCREEN COMMUNICATOR

This section provides information to help resolve TOUCH-SCREEN WIRELESS COMMUNICATOR problems.

COMMUNICATOR

This section provides information to help resolve Communicator problems for the TOUCH-SCREEN WIRELESS COMMUNICATOR.

Incorrect Language Displayed**Recommendations:**

Try one or more of the following actions:

- Ask the patient to unplug the Communicator, then plug it back in to restart the setup process.
- The Communicator prompts for language. Ask the patient to press the button for the desired language, and then complete the setup process. The remainder of the setup process will be in the desired language.
- If the patient has already completed setup of the Communicator and wishes to change the language, ask the patient to contact LATITUDE Customer Support.

“No dial tone”

The Communicator does not detect a dial tone.

Recommendations:

Try one or more of the following actions:

For a landline:

- Verify that the phone cord is firmly connected to both the Communicator and an active telephone wall jack.
- Verify that the patient is using the appropriate phone jack adapter.
- If the patient has DSL internet service, make sure they are using a DSL filter between the Communicator and the telephone wall jack.
- If the patient has a phone connected to the back of the Communicator, have them pick up the phone and verify that they hear a dial tone.

For cellular data network:

- Verify that the cellular adapter is properly connected to the Communicator.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has detected a dial tone when it displays a message indicating that the phone cord has been attached.

“LATITUDE is temporarily unavailable”

The Communicator is unable to complete the connection to the LATITUDE NXT System.

NOTE: *The Communicator will often provide a 13-digit code with the **LATITUDE is temporarily unavailable** message. This is used by LATITUDE Customer Support for in-depth troubleshooting after the following steps have been performed.*

Recommendations:

Try one or more of the following actions:

For a landline:

- Verify that the Communicator serial number matches the serial number recorded on the **Edit/View Patient and Equipment Information** page.
- Verify that no one picked up the phone while the Communicator was trying to connect.
- Verify that the patient is using the provided (or a newer) phone cord and that the cord is firmly connected to both the Communicator and an active telephone wall jack.
- Verify that the patient is using the appropriate phone line adapter.
- Ask the patient to remove any splitters between the Communicator and the telephone wall jack.
- If the patient has DSL internet service, make sure they are using a DSL filter between the Communicator and the telephone wall jack.

To verify troubleshooting was successful, have the patient to press the **Try Again** button on the Communicator screen.

For cellular data network:

- Verify that the patient has a current subscription to the cellular data network. You can confirm this with LATITUDE Customer Support, if needed.
- Verify that the cellular adapter is properly connected to the Communicator.
- Ask the patient to move the Communicator to another location that may have a better signal.
- If other locations do not provide a connection using the cellular data network, the patient may need to plug the Communicator into an active telephone wall jack to send data.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully connected with the LATITUDE NXT System when it displays a message indicating information has been sent to LATITUDE.

“Interrogation could not be completed”

The Communicator was unable to complete an interrogation.

Troubleshooting the **Interrogation could not be completed** message includes performing a patient initiated interrogation (PII). If the patient is not allowed to perform PIIs, allow one PII on the patient's **Edit/View Schedule and Alert Configuration** page. If the patient's phone is using the same landline as the Communicator, they will need to hang up the phone prior to performing the interrogation.

Recommendations:

Try one or more of the following actions:

- Verify that the implanted device model and serial number recorded in the LATITUDE NXT System match the values on a PRM (Programmer/Recorder/ Monitor) report.
- Verify the Communicator is optimally placed:
 - The Communicator is near where the patient sleeps, or near the bedside, within 3 meters (10 feet) of the patient. If this is not possible, place the Communicator where the patient spends a considerable amount of time each day.
 - The Communicator is level with the patient and clear of any obstructions.
- Ask the patient to turn off and, if necessary, unplug wireless electronics (such as cordless phones or baby monitors) within 1 meter (3 feet) of the Communicator.
- The patient should be facing the Communicator and should remain comfortably still during the interrogation.
- Have patient try again by either pressing **Try Again** on the screen or by pressing the blue PII button in the top left corner of the Communicator.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator has successfully connected with the LATITUDE NXT System when it displays a message indicating information has been sent to LATITUDE.

Monitoring Suspended

The patient does not have a primary clinic, which is required to be remotely monitored.

NOTE: *If the Communicator displays a code with the Monitoring Suspended message, have the patient call LATITUDE Customer Support for further assistance.*

Recommendations:

Try one or more of the following actions:

- Enroll the patient at your clinic, or work with the patient to find a new primary clinic.
- You can unenroll the patient by navigating to the patient's **Edit/View Patient and Equipment Information** page. This will remove all access to the patient and their data.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Blank Screen and the Action Button is Yellow

Try one or more of the following actions:

- Have the patient press the **Action** button.
 - If Communicator displays **No dial tone** message, follow “No Dial Tone” troubleshooting.
 - If Communicator displays a monitoring suspended message, follow Monitoring Suspended troubleshooting.
 - If Communicator is unresponsive and the screen remains blank, have the patient unplug the power cord from the electrical wall outlet and wait 30 seconds, then have the patient plug the power cord back in. If the action button is yellow and the screen remains blank, the Communicator may not be working properly and needs to be replaced.

For further assistance, you may direct your patient to LATITUDE Customer Support.

The Action Button on the Communicator is Red

The Communicator has detected a Red Alert and has been unable to upload complete data about the alert to the server for more than 24 hours.

Recommendations:

Try one or more of the following actions:

- Using a PRM (Programmer/Recorder/Monitor), interrogate the implanted device to investigate and resolve the Red Alert.
- Once the Red Alert has been addressed in the implanted device, you will still need to troubleshoot any issues with the Communicator for it to continue monitoring the patient. Ask the patient to press the **Options** button on the Communicator screen, then press the **Connect to LATITUDE** button (if the patient's phone is using the same landline as the Communicator, they will need to hang up the phone prior to pressing the **Connect** button). This will either send the alert data to the LATITUDE NXT System or give a message which can be used to troubleshoot.

NOTE: If you elect to troubleshoot the Communicator before interrogating the implanted device with a PRM, be aware that this can further delay investigating the Red Alert. In addition, the upload may not be able to successfully complete depending on the issue observed with the Communicator.

For further assistance, you may direct your patient to LATITUDE Customer Support.

SENSOR

This section provides information to help resolve sensor problems for the TOUCH-SCREEN WIRELESS COMMUNICATOR.

Weight Scale or BPM Readings not Received

The patient has a weight scale or blood pressure monitor assigned, but readings are not being received by the LATITUDE NXT System. The Communicator waits two hours from the first sensor reading to send the data to the LATITUDE NXT System.

Recommendations:

Try one or more of the following actions:

- Ask the patient to press the **Options** button on the Communicator screen, then press the **Connect to LATITUDE** button. This will send any readings collected by the Communicator to the LATITUDE NXT System.
- Verify that the slide switch on the bottom of the weight scale is set correctly to **Weight B kg**.
- Ask the patient to install new, non-rechargeable batteries in the correct direction.
- Verify that the weight scale or blood pressure monitor serial number matches the serial number recorded on the **Patient and Equipment Information** page.
- Verify the patient is using the sensor correctly:
 - The patient has pressed the start button on the weight scale or blood pressure monitor before taking a reading.
 - The weight scale or blood pressure monitor is within 6 meters (20 feet) of the Communicator.
 - For the weight scale, the patient waits until 0.0 appears before stepping on the scale.

For further assistance, you may direct your patient to LATITUDE Customer Support.

Resolution:

The Communicator will display a message when a reading has been received. Once uploaded to the LATITUDE NXT System, readings are visible on the patient's **Health** page.

Blood Pressure Monitor Error

The patient is receiving an error from a blood pressure monitor.

Recommendations:

Try one or more of the following actions:

- Common blood pressure monitor errors:

- ERR CUF – the cuff is not fastened correctly. Verify the patient is using it correctly:
 - Verify the patient is using the correct size cuff. The cuff comes in three sizes for patient comfort: Small (18–22 cm), Medium (22–32 cm) and Large (32–45 cm). You may want to measure the patient's arm, just above the elbow, to determine the correct cuff size.
 - The cuff should be about one inch (2-3 cm) above the elbow.
 - Two fingers should fit comfortably between the cuff and the patient's arm.
 - The patient's arm should be extended at chest level resting comfortably.
 - Ask the patient to refasten the cuff and try again.
- ERR – the monitor did not get a good reading. Ask the patient to unplug and reconnect the hose. Ask the patient to retake the reading, remaining still.

For further assistance, you may direct your patient to LATITUDE Customer Support.




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SYMBOLS

APPENDIX B

Table B-1. Explanation of Symbols

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	CE mark of conformity with the identification of the notified body authorizing use of the mark

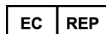
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