

**Boston
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CLINICIAN MANUAL

LATITUDE™ NXT Patient Management System

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This manual contains information about the LATITUDE™ NXT Patient Management 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
Distinction between Models 6288 and 6290
WAVE WIRELESS COMMUNICATORS will also be shown as necessary.



TOUCH-SCREEN WIRELESS COMMUNICATOR (Model 6468)
This Communicator is not available in all geographies.

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

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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 12 for device conditions that are monitored.)

Data collected from the implanted device at times scheduled by the clinic 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 Patient Management 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 Patient Management System is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE NXT system. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

Precautions

Alerts may appear on the LATITUDE NXT website on a daily basis. Primary notification of alert conditions is through the **View Patient List** page on the LATITUDE NXT website. The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Although secondary notification through email and SMS text messages is available, these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the LATITUDE NXT website.

Implanted device data and alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is

unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to two weeks may elapse before the LATITUDE NXT server detects these conditions and 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:

- System limitations (see page 2).
- The Communicator is unplugged.
- The Communicator is not able to connect to the LATITUDE NXT server through the configured phone system.
- The implanted device and the Communicator cannot establish and complete a telemetry session.
- The Communicator is damaged or malfunctions.
- The patient is not compliant with prescribed use or is not using the LATITUDE NXT system as described in the patient manual.

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 27).

Adverse Effects

None known.

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. It must also be connected to a telephone line if the patient is not subscribed to the LATITUDE GSM Data Plan. (If the patient is connected to the LATITUDE GSM Data Plan, a cellular adapter may need to be connected, as applicable.) Other equipment attached to the telephone line can adversely impact the ability of the Communicator to transmit information to the LATITUDE NXT server. Patients may not be within radio-frequency (RF) range of the Communicator at the appropriate times. RF interference from wireless electronic products may interfere with communication between the implanted device and the Communicator.
- Cellular data service. Subscription to the LATITUDE GSM Data Plan does not guarantee coverage. Actual coverage may be affected by such things as terrain, weather, foliage, buildings and other construction, signal strength, timely payment, and other factors.
- 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 data delivery.
- Communicator memory capacity. Communicator memory used to store implanted device data may reach its capacity if the Communicator cannot connect to the LATITUDE NXT system 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 8 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,
 - and 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 system is the LATITUDE Communicator, an in-home monitoring device for patients. The Communicator automatically reads implanted device information for daily device checks and scheduled follow-ups. It then sends the data to the LATITUDE NXT server through a standard analog telephone line or over a cellular data network using the LATITUDE GSM Data Plan (with a cellular adapter, as applicable).

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



WAVE WIRELESS COMMUNICATOR

- Model 6288 has built-in capability for cellular communication
- Model 6290 uses a USB cellular adapter for cellular communication
- Supports only tone analog dialing mode



TOUCH-SCREEN WIRELESS COMMUNICATOR (Model 6468)

- Uses an external cellular adapter for cellular communication
- Supports both tone and pulse analog dialing mode

For setup and general operating information about the WAVE WIRELESS COMMUNICATOR, refer to page 54; for the TOUCH-SCREEN WIRELESS COMMUNICATOR, refer to page 67. For information about the LATITUDE GSM Data Plan, refer to page 52.

NOTES:

- *The LATITUDE Communicator does not reprogram or change any implanted device functions. The implanted device can only be reprogrammed with a Programmer/Recorder/Monitor (PRM).*
- *The LATITUDE Communicator does not provide continuous real-time monitoring. It automatically 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 17). 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). 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.*
- *WAVE WIRELESS COMMUNICATOR only: The LATITUDE Communicator has been designed to work in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland (Republic), Italy, Netherlands, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, and the United Kingdom. Use of the Communicator in other European Economic Area (EEA) countries is allowed with the LATITUDE GSM Data Plan. Please contact LATITUDE Customer Support for specific information.*
- *TOUCH-SCREEN WIRELESS COMMUNICATOR only: The LATITUDE Communicator has been designed to work in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland (Republic), Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. Use of the Communicator in other European Economic Area (EEA) countries is allowed with the LATITUDE GSM Data Plan. Please contact LATITUDE Customer Support for specific information.*

- *Use of the TOUCH-SCREEN WIRELESS COMMUNICATOR and Model 6288 WAVE WIRELESS COMMUNICATOR outside of the EEA is restricted due to radio frequency (RF) laws.*
- *Boston Scientific personnel may contact the clinic if a patient returns their assigned Communicator to Boston Scientific. They may also contact the clinic if a patient's Communicator is reported lost or stolen or the security credentials are compromised.*

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LATITUDE Customer Support

LATITUDE Customer Support provides LATITUDE technical and general maintenance support to customers using the LATITUDE NXT system. LATITUDE Customer Support telephone numbers are listed in Table 1.

Table 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
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

Optional Home Health Monitoring Equipment

The LATITUDE Weight Scale and LATITUDE Blood Pressure Monitor are optional components of the LATITUDE NXT Patient Management 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 sensor adapter must be plugged into the Communicator to communicate with the patient's sensors.

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, readings are transmitted with the next scheduled connection to the LATITUDE system (up to 7 days). For the TOUCH-SCREEN WIRELESS COMMUNICATOR, readings are 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 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 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 Corporation (BSC) personnel also have access to patient data. All user access of LATITUDE patient data is logged.

Registered Users

Any LATITUDE NXT user, including but not limited to a clinic's third party vendors, must be associated with a clinic that has direct responsibility and authority for the health care treatment of a patient. All LATITUDE NXT users must be registered within that clinic's LATITUDE account.

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 (including, in the U.S., the LATITUDE Business Associate 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 clinic user has a user account that is associated with a specific clinic.

Each LATITUDE NXT 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 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 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 Table 2:

- **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 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	✓	✓	
View patients on the View Patient List page	✓	✓	✓
View patient data and reports ¹	✓	✓	✓

¹ 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, which 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 interrogations, 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 (page 27). The LATITUDE NXT system sends one notification for an alert condition detected by the system. 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 Corporation (BSC) 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 Corporation (BSC) 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, BSC 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 non-physiologic 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

Yellow Alerts

Notification of yellow alerts is configurable and may be selected by either of a patient's LATITUDE NXT 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)

¹ While the device has an automatic capture feature through PaceSafe, LATITUDE NXT 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.

- 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 threshold in a user-selectable number of days)

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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 Table 3.

Table 3. Data Collection and Schedule Intervals for Each Interrogation Type

Interrogation Type	Full Interrogation (with Presenting EGM)	Full Interrogation (with no Presenting EGM)	Red Alert Check	Yellow Alert Check	Available Schedule Intervals
Remote Scheduled Follow-ups	✓		✓	✓	<ul style="list-style-type: none"> Off/Manual 1 week 2 weeks Monthly intervals from 1 to 12 months
Alert Check ¹			✓	WAVE WIRELESS COMMUNICATOR only ✓	<ul style="list-style-type: none"> Daily Not configurable
Alert Interrogation ¹	✓				<ul style="list-style-type: none"> If red or yellow alert is detected¹
Post-PRM Interrogation WAVE WIRELESS COMMUNICATOR only	✓		✓	✓	<ul style="list-style-type: none"> A recent PRM interrogation has occurred¹
Weekly Implanted Device Alert Monitoring TOUCH-SCREEN WIRELESS COMMUNICATOR only		✓	✓	✓	<ul style="list-style-type: none"> Weekly Configurable
Patient Initiated (See page 18)	✓		✓	✓	As directed by clinician

¹ WAVE WIRELESS COMMUNICATOR: If a red or yellow alert is detected or a recent PRM (Programmer/Recorder/Monitor) interrogation has occurred, the alert interrogation will attempt to collect a full interrogation with presenting EGM.

TOUCH-SCREEN WIRELESS COMMUNICATOR: If a red alert is detected, the alert interrogation will 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 Interrogation

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:

- 5 per week (if enabled)
- 0 (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 PIIs. PIIs are configured for all patients in a Patient Group or for an individual patient through their **Edit/View Schedule and Alert Configuration** page. If PIIs 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 13 on page 54) or by pressing the blue button on the TOUCH-SCREEN WIRELESS COMMUNICATOR (see Figure 22 on page 67). The Communicator will not perform an interrogation if this feature is not enabled or the limit has been reached.

If the PII 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 8 days for the Communicator to call the LATITUDE NXT server. If PIIs 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 and "System Limitations" on page 2.

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 or Clinic Members in the LATITUDE NXT website.

Requirements

- The LATITUDE NXT website was developed to support the following web browsers¹:
 - Internet Explorer
 - Mozilla Firefox
 - Apple Safari on the Mac, iPad and iPhone
- Adobe Acrobat Reader program or compatible PDF viewer (to view reports that are created in Portable Document Format [PDF]).
- Use of a current virus protection program is recommended.

Logging In and Out

To log in:

1. Launch your web browser.
2. Enter the LATITUDE URL to display the initial access page shown in Figure 1:

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

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 web browsers.



Figure 1. LATITUDE Initial Access Page

3. Select your country. If the **Select Language** menu appears after you select a country, select your preferred language.

You only need to enter your country and language the first time you access the LATITUDE NXT website, unless you do so from a different computer. The LATITUDE NXT website is available in several languages based on the selected country.

4. Click the **LATITUDE NXT** button to display the login screen shown in Figure 2.

LATITUDE™ NXT

Please enter your User ID and Password to enter the Boston Scientific LATITUDE Clinician website

*Indicates Required Field

*User ID:

*Password:

Login Reset

A [Change Country/Language: United Kingdom/English](#)

[Forgot Password?](#)

For additional assistance, call [LATITUDE™ Customer Support](#)

- A** Click this link to change your country or language.

Figure 2. Login Page

5. 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 43.)

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 30 minutes, the session is automatically closed, effectively logging the user out. The user is redirected to the login page.

Login difficulties for reasons including forgotten IDs and passwords can delay access to the LATITUDE NXT website.

To log out:

1. Click the **Logout** link in the upper-right corner of the screen.
2. The logout confirmation window is displayed. Users are advised to close their web browsers to complete the log out process.

To change your country or language:

1. To change your country or the language displayed on the LATITUDE NXT website, click the **Change Country/Language** link before you log on. Refer to (A) in Figure 2.
2. The initial access screen (Figure 1) is displayed from which you can change your country or preferred language.

You can also use the **Language** menu at the top of all pages. Refer to (B) in Figure 3.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolete. Ne pas utiliser.
Versione obsoleta. No utilizar.
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.
Elavult verzio. Ne használját.
Wersja nieaktualna. Nie używać.

Navigating the Site

Figure 3 shows the top banner and navigation buttons that appear on all webpages. Descriptions are listed below.

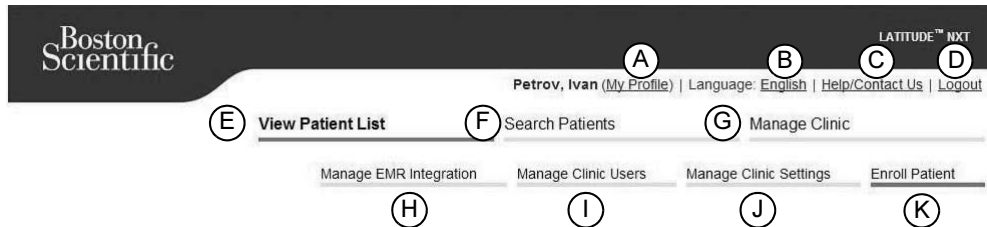


Figure 3. LATITUDE NXT Banner

Table 4. Navigating the Site

(A) My Profile	Links to the Update Clinic User page for the current user
(B) Language	Displays selected language; links to the Update Clinic User page for the current user where the selected language can be changed
(C) Help/Contact Us	Links to contact information, troubleshooting guides, and other resources
(D) Logout	Ends the user's session
(E) View Patient List	Links to a page that provides a list of patients to which the current user has access (See "THE VIEW PATIENT LIST PAGE" on page 27.)
(F) Search Patients	Links to the Search Patients page
(G) Manage Clinic	Displays clinic-related action links H-K
(H) 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 45.)
(I) Manage Clinic Users	Links to a list of clinic users and associated configuration information
(J) Manage Clinic Settings	Links to clinic and Patient Group demographics and membership and associated configuration information
(K) Enroll Patient	Links to enrollment form that enables clinicians to enroll new patients

CLINIC AND PATIENT CONFIGURATION

Figure 4 shows the webpage locations, buttons, and types of information that can be configured for Patient Groups and individual patients. The information in “Configuration Details” on page 25 provides important details about configuration settings.

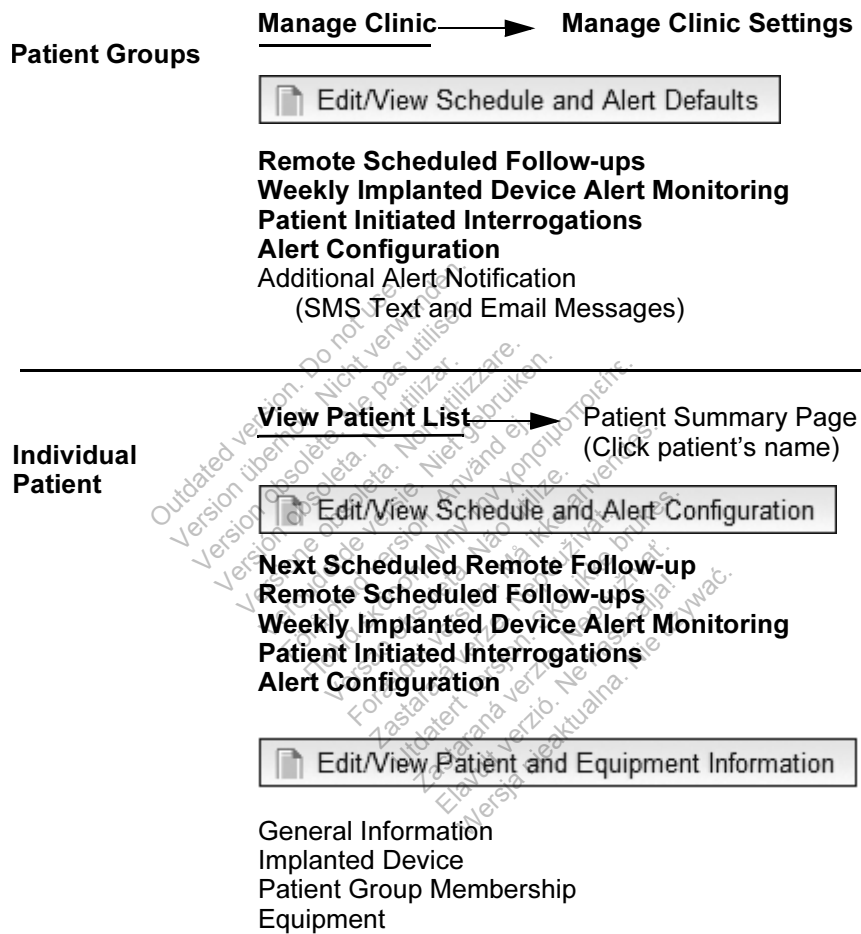


Figure 4. Patient Group and Individual Patient Configuration

Configuration Details

Saving Settings

Remember to select the **Save and Close** button to ensure any changes you make to 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 sent to the affected patient's Communicator the next time the Communicator connects to the LATITUDE NXT server. It could take up to 8 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, actual 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.

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

Weekly yellow 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 not detected, the weekly interrogation will not include presenting EGM.

Patient Initiated Interrogations

Patient initiated interrogations (PIIs) can be enabled (5 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 18.

Additional Alert Notifications

Additional alert notification is available through text 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 (page 27).

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.

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. 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 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 (Figure 5) 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 (Figure 5):

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

Boston Scientific LATITUDE™ NXT

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

View Patient List Search Patients Manage Clinic

View Patient List

Viewing Patient Group: All Patient Groups (A)

All Patients (8) | For Review (3) | Missed Follow-up (0) | Not Monitored (0) | Not Scheduled (8) (B)

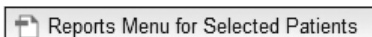
Reports Menu for Selected Patients Print Patient List View Patient List 1 - 3 of 3

Patient ID/ Patient/ Device	Review Status	Latest Device Transmission	Alerts	Review Reason	Next Remote Follow-up	Monitoring Status	Actions
<input type="checkbox"/> KC-108 da Silva, Joao INGENIO J174	Viewed	31 May 2013		Scheduled	02 Nov 2013	Monitored	Dismiss From Review List Reports Menu
<input type="checkbox"/> KC-218 Dupont, Jean INVIVE CRT-P W172	Viewed	23 May 2013		Multiple Reasons	02 Nov 2013	Monitored	Dismiss From Review List Reports Menu
<input type="checkbox"/> KC-128 Modaal, Jan INGENIO J174	Viewed	21 May 2013	None	Patient Initiated	02 Nov 2013	Monitored	Dismiss From Review List Reports Menu


View Patient List 1 - 3 of 3

Figure 5. 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 the reports and save the report file.

 Print Patient List

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 30.
- **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,** and **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 Scheduled 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 system in 14 days or more.

Clicking on the status opens a window that displays the related section of the troubleshooting guide. Refer to "APPENDIX A: TROUBLESHOOTING GUIDE" on page 71 for a description and troubleshooting recommendations of each status.

Actions

Provides 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 the reports and save the report file.

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
- Combined Follow-up
- Presenting EGM
- Arrhythmia Logbook
- Event Detail
- Device Settings
- HF PERSPECTIV™ Report

The Quick Notes, Combined Follow-up, and Presenting EGM 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 (Figure 6) 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 a selected patient(s) or dismiss a patient that is for review.

The screenshot shows the 'Search Patients' tool interface. At the top, the Boston Scientific logo and 'LATITUDE™ NXT' are visible. The user is logged in as 'Petrov, Ivan'. The navigation bar includes 'View Patient List', 'Search Patients', and 'Manage Clinic'. The search form contains the following fields:

- Last Name: modaal
- Date of Birth: [Date Picker]
- First Name: [Text Field]
- Model: [Dropdown Menu]
- Patient ID: [Text Field]
- Leads Model: [Text Field]
- Patient Group: [Dropdown Menu]
- Search Tags: [Text Field]

Below the search form is the 'Next Remote Follow-up Information' section with 'From:' and 'To:' date pickers, a 'Use Exact Match' checkbox, and 'Search' and 'Clear' buttons. At the bottom, there is a table with one patient record:

Patient ID/ Patient/ Device	Review Status	Latest Device Transmission	Alerts	Review Reason	Next Remote Follow-up	Monitoring Status	Actions
<input type="checkbox"/> KC-128 Modaal, Jan INGENIO J174	Viewed	21 May 2013	None	Patient Initiated	02 Nov 2013	Monitored	Dismiss From Review List Reports Menu

Figure 6. 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.
- Communicator 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 Figure 7. A patient is identified by their implanted device's model and serial number and by their date of birth.

Patient enrollment through the LATITUDE NXT system cannot be completed without the Communicator model and serial numbers. 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.

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.

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., 23 Jan 1990)

Figure 7. Enroll Patient Page

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.

Communicator 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 5*
- *LATITUDE GSM Data Plan on “LATITUDE GSM Data Plan” on page 52*
- *Setup and general operating information about the WAVE WIRELESS COMMUNICATOR on page 54*
- *Setup and general operating information about the TOUCH-SCREEN WIRELESS COMMUNICATOR on page 67*

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolete. Ne pas utiliser.
Versione obsoleta. No utilizar.
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.
Elavult verzija. Ne használat!
Wersja nieaktualna. Nie używać.

PATIENT INITIALIZATION

When the patient is first enrolled, they appear on the **Not Monitored** list, with a status of **Communicator Not Set Up**.

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 8 days) or when the patient performs a patient initiated interrogation (PII).

If the patient has difficulties completing setup, 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 all Patient's Detailed Summary pages.

NOTE: *When the patient's implanted device is replaced, all transferred 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. 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 second 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 un-dismissed 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 by 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 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:

- **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.
- 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.

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. 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 43.

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 he or she logs 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 43.

Changing Your Password

1. Click the **My Profile** link next to your name at the top of the page to display the **Update Clinic User** page with your data.
2. Click the **Change Password** link in the Login Information section.
3. Enter your old and new password (Figure 8).
4. Click the **Save and Close** button.

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

- Password must be between 8 and 32 characters in length
- Password must contain at least one character (a-zA-Z) and either one number (0-9) or one special character (!@#%&*()_+!~='<>?./)
- Password is case-sensitive
- The new password cannot be the same as any of the previous three
- Passwords cannot contain your username

*Indicates Required Field

*Old Password:

*New Password:

*Confirm New Password:

Figure 8. Change Password

5. Your Clinic User page is redisplayed. Your new password will take effect the next time you login.

Resetting Your Forgotten Password

If you forgot your password or your login account was locked, you can reset your password at any time using the **Forgot Password?** link (Figure 9). 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.

To reset your password:

1. Click the **Forgot Password?** link on the LATITUDE NXT login page (Figure 9).

LATITUDE™ NXT

Please enter your User ID and Password to enter the Boston Scientific LATITUDE Clinician website

*Indicates Required Field

*User ID:

*Password:

Login Reset

[Change Country/Language: United Kingdom/English](#)

[Forgot Password?](#)

For additional assistance, call LATITUDE™ Customer Support

Figure 9. Forgot Password? Link

2. Follow the on screen prompts. You will then receive a message indicating your new password was successfully entered. You are prompted to login to the LATITUDE NXT website using your new password.

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 IDCO integration specification of Boston Scientific for details on how its implanted device data is converted into IDCO messages.

The data that are exported are based on the Quick Notes report and include implanted device alerts. The data may also include a PDF of the presenting EGM and Combined Follow-Up 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 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 46.*
- *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 specifications.
- 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 IT professional responsible for administering your systems.

The following steps need to be completed 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 (Figure 10).

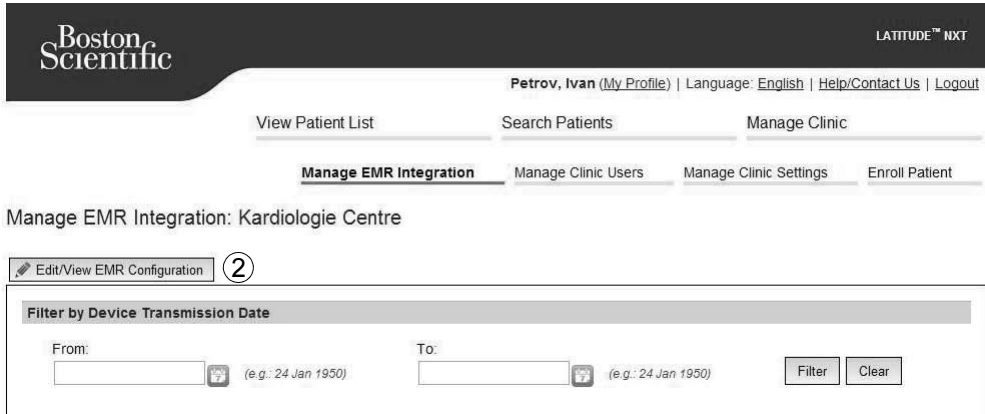


Figure 10. Edit/View EMR Configuration Button

- Record the **EMR/CIS Clinic Identifier** that is provided on this page (Figure 11).

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

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

Edit/View EMR Configuration: Kardiologie Centre

EMR/CIS Clinic Identifier: sapida-8420265034-5873498976 ③

EMR Configuration Last Updated By

For information to be transferred to your EMR, EMR Integration software must be installed on your EMR system then must be enabled below. To download the EMR integration software, [click here](#). ④

ⓘ By selecting the **ENABLE** function, you agree and assert to the following:

- You have installed the EMR Export Client on your organization's system in order to download LATITUDE data on your organization's medical record system.
- You will not use the EMR Export Client 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.

⑦ Enable EMR Integration
EMR Integration Format:
Generic HL7 2.3.1 ORU version 1 ⑧

⑨ Save and Close Close Without Saving

Figure 11. Edit/View EMR Configuration Page

4. Click the **click here** link as shown in Figure 11.
5. You are directed away from the LATITUDE NXT website to a webpage for the EMR integration software that needs to be installed. Follow the installation and setup instructions available on this webpage.
6. You must 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. You must return to the LATITUDE NXT **Edit/View EMR Configuration** page and select the **Enable EMR Integration** checkbox before patient data can be exported to your EMR application. 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 in Figure 11. The format selected must be appropriate for your EMR application. Supported formats are listed in the pull-down menu.
 9. Make sure you select the **Save and Close** button.

You can click the **Last Updated By** link to open a pop-up window that displays the date and time the EMR configuration was last changed and the name of the user who changed the EMR configuration.

View EMR Log

The **View EMR Log** window on the bottom section of the **Manage EMR Integration** page (Figure 12) 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

Figure 12. 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 page 30).
- **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 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.
 Versión obsoleta. No utilizar.
 Versione obsoleta. Non utilizzare.
 Verouderde versie. Niet gebruiken.
 Föråldrad version. Använd ej.
 Πρωτὴ ἐκδόση. Μην τὴν χρησιμοποιεῖτε.
 Versão obsoleta. Não utilize.
 Forældet version. Må ikke anvendes.
 Zastaralá verze. Nepoužívat.
 Utdatert versjon. Skal ikke brukes.
 Zastarana verzija. Ne uporabljajte.
 Elavult verzió. Ne használja!
 Wersja nieaktualna. Nie używać.

LATITUDE GSM DATA PLAN

The LATITUDE GSM Data Plan uses a cellular data network rather than a standard telephone line to send the patient's implanted device data to the LATITUDE NXT server. The LATITUDE GSM Data Plan is an optional service.

The patient needs either a standard analog telephone line or the LATITUDE GSM Data Plan (using a cellular adapter, as applicable) to use the LATITUDE NXT Patient Management System.

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

Activating the LATITUDE GSM Data Plan

The patient or clinic should contact LATITUDE Customer Support to subscribe to the LATITUDE GSM Data Plan or to update the subscription if the patient receives replacement equipment.

Verifying the Connection

Once the LATITUDE GSM Data Plan is activated, the patient can verify the connection by:

- **WAVE WIRELESS COMMUNICATOR:** Following the instructions in "Checking that the Communicator Can Connect to the LATITUDE System" in their patient manual, which provides instructions on how to press the Status button to make a call to the LATITUDE NXT server.
- **TOUCH-SCREEN WIRELESS COMMUNICATOR:** Navigating to the **Options** menu screen, selecting the **Connect to LATITUDE** button, and following the instructions on the screen.
- Ensuring proper placement and connection of the cellular adapter, as applicable, according to instructions in the appropriate patient manual.

If the patient travels to another location with their Communicator, they should check the connection from that location.

Troubleshooting and Support

Subscription to the LATITUDE GSM Data Plan 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.

If the Communicator cannot connect through an activated LATITUDE GSM Data Plan:

- WAVE WIRELESS COMMUNICATOR: One or two Sending Waves may light yellow.
- TOUCH-SCREEN WIRELESS COMMUNICATOR: 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 to LATITUDE using the LATITUDE GSM Data Plan, try plugging the Communicator into an active telephone jack.

Discontinuing the LATITUDE GSM Data Plan

Contact LATITUDE Customer Support to discontinue use of the LATITUDE GSM Data Plan.

LATITUDE COMMUNICATOR

Information contained in the following two sections has been selected from the respective patient manuals to provide setup and operating information for the WAVE WIRELESS COMMUNICATOR and TOUCH-SCREEN WIRELESS COMMUNICATOR. This basic information is provided so that clinicians can help patients become familiar with their Communicators to foster acceptance and success in the operation of their Communicators.

For an overview of the LATITUDE NXT Patient Management System, refer to "LATITUDE Communicator Overview" on page 5.

WAVE WIRELESS COMMUNICATOR

Identifying Buttons, Connectors, and Indicators

Figure 13 shows the buttons, connectors, and LATITUDE indicator on the front and back of the Communicator, and Figure 14 shows all the indicators. Refer to “Indicator Descriptions” on page 56 for a description of each indicator.

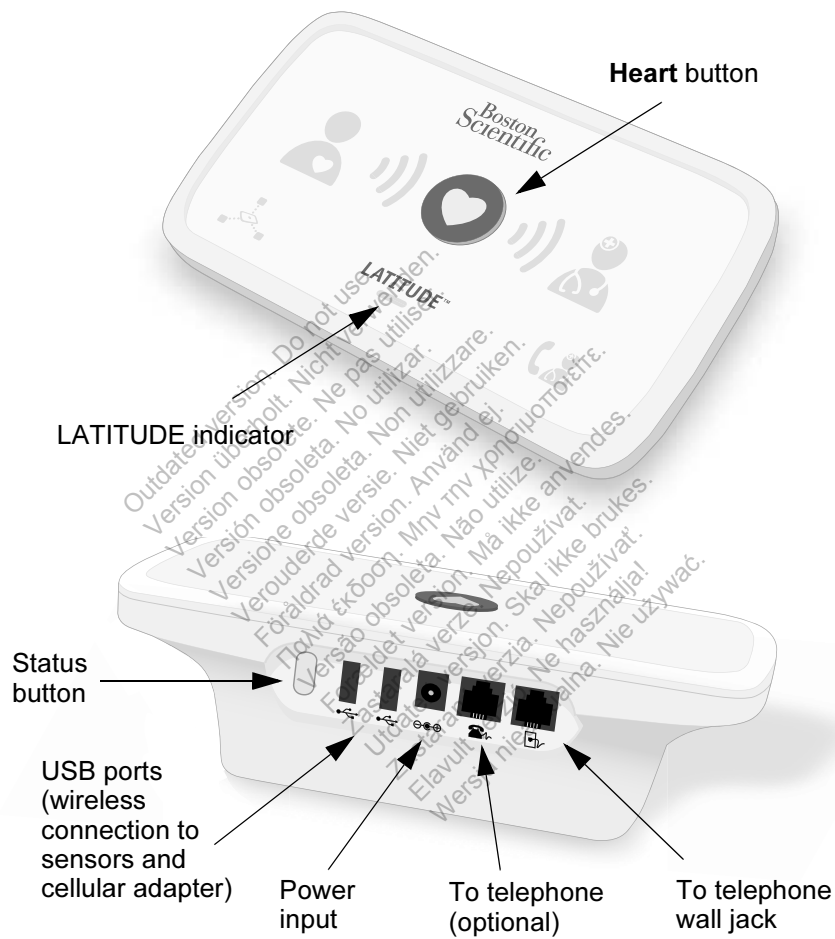


Figure 13. WAVE WIRELESS COMMUNICATOR Buttons, Connectors, and Indicator

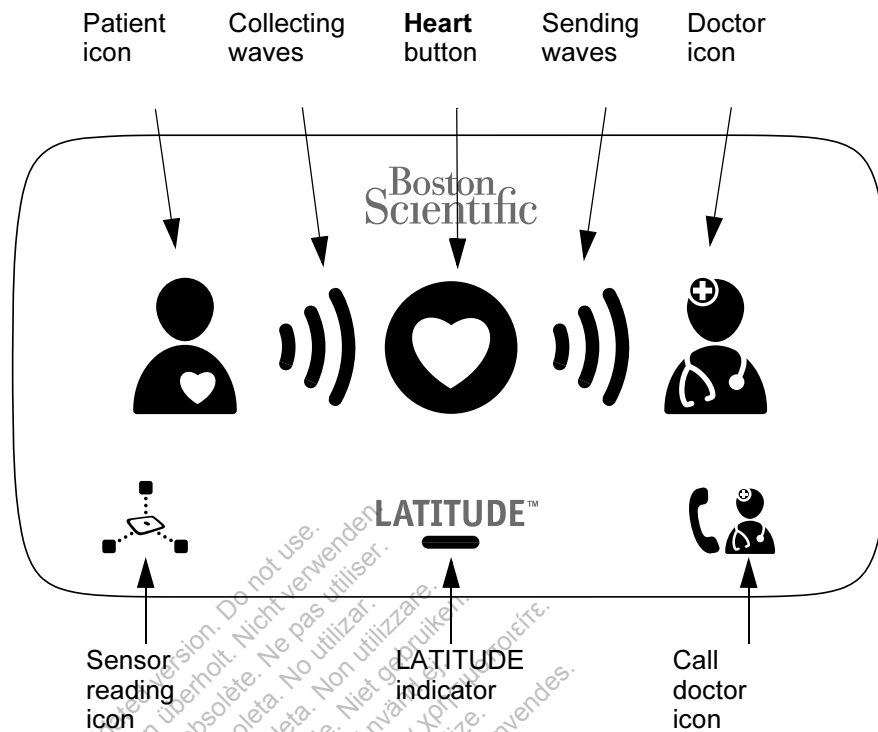


Figure 14. WAVE WIRELESS COMMUNICATOR Indicators

Indicator Descriptions



Patient Icon

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

- Lights blue when the **Heart** button is pressed and an interrogation has started. The Patient icon stays illuminated for 2 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. Refer to "Troubleshoot Yellow Collecting Waves" on page 71.

- Light green in sequence and repeat, showing the Communicator is interrogating the patient's implanted device.
- Light green for 2 minutes to indicate the interrogation was successful.



Heart Button

Flashes with a white light if the patient needs to complete a previously scheduled interrogation. The **Heart** button lights a solid white to indicate the interrogation is complete.

The **Heart** button 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. Refer to “Troubleshoot Yellow Sending Waves” on page 75.

- Light green in sequence and repeat, indicating a connection to the LATITUDE NXT server is in progress.
- Light green for 2 minutes to indicate the connection to the LATITUDE NXT server was successful and any collected device data was sent.



Doctor Icon

Lights blue 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 5 times and remains illuminated for 5 minutes to indicate the Communicator successfully received a weight or blood pressure measurement.

LATITUDE™



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 only 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 to indicate a problem was detected that should be communicated to the clinic user.

- 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 website 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 (refer to “Implanted Device Not Found” on page 95) and has been unable to send that status to the LATITUDE NXT website for 24 hours.
 - Monitoring by the Communicator has been suspended.

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 79 in the Troubleshooting Appendix.

The Status Button

Figure 15 shows the Status button on the back of the Communicator.

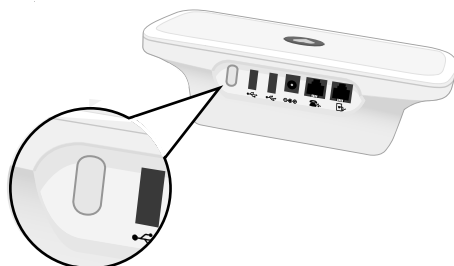


Figure 15. Status button

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

- Press for less than 3 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 2 minutes. If the Call Doctor icon was blinking, it will stop blinking and stay lit.

- Press and hold for more than 3 seconds: The Sending Waves light green and show progress 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 installation guide.

When the patient arrives home with their new WAVE WIRELESS COMMUNICATOR, they need to place it near an electric power outlet and telephone jack, if the patient is not subscribed to the LATITUDE GSM Data Plan.

Figure 16 shows power supply and telephone jack connections to the Communicator.

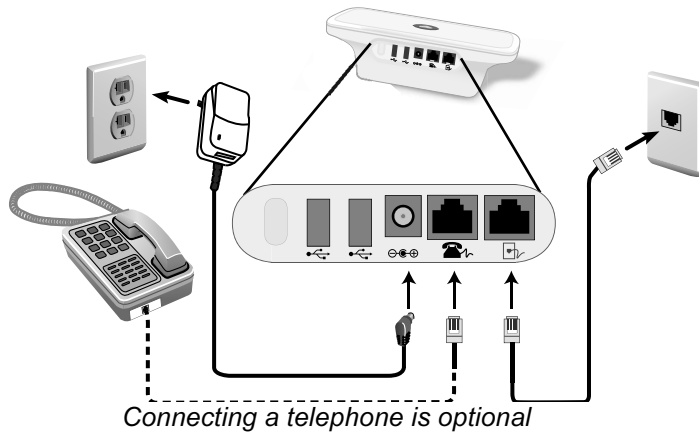


Figure 16. Connecting to a Telephone Wall Jack

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.

If a patient is subscribed to the LATITUDE GSM Data Plan, they do not need to connect the Communicator to a telephone line. Instead, *Model 6288* has built-in capability that connects the WAVE WIRELESS COMMUNICATOR to the LATITUDE NXT system; and *Model 6290* uses a USB cellular adapter, as shown in Figure 17, to connect the WAVE WIRELESS COMMUNICATOR to the LATITUDE NXT system.

If the patient will use 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 a telephone line if it is connected to an active telephone jack. If connected, the Communicator will send the patient's device data over the telephone line even if the patient is subscribed to the LATITUDE GSM Data Plan.*

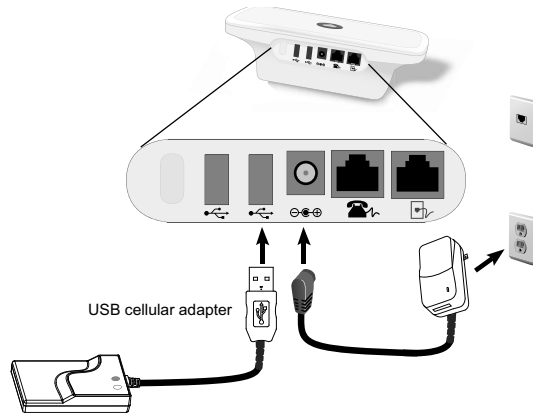


Figure 17. Connecting with the LATITUDE GSM Data Plan

To ensure proper operation, the WAVE WIRELESS COMMUNICATOR switches must be properly set, as described in the following section.

Setting the WAVE WIRELESS COMMUNICATOR Switches

There are eight switches on the bottom of the WAVE WIRELESS COMMUNICATOR that need to be set to the proper position. Refer to Figure 18.

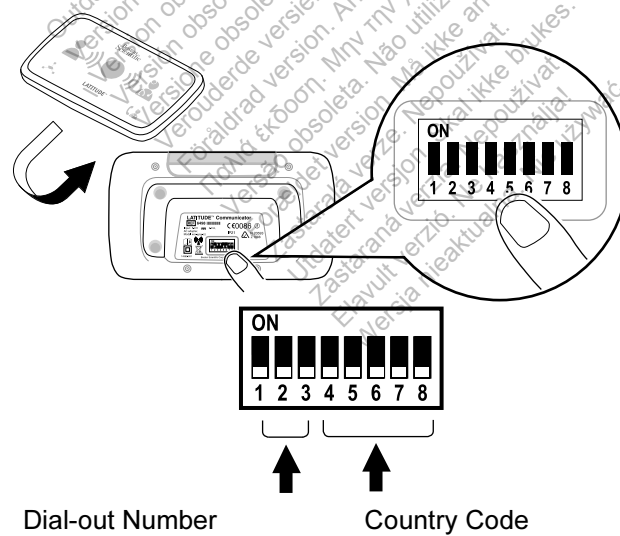
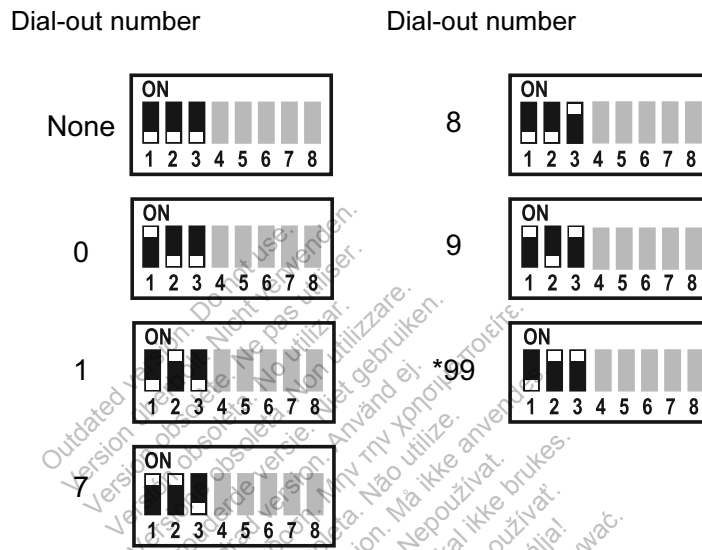


Figure 18. Switch Location

Dial-out Number

(This section applies only to landline telephone connections. If using the LATITUDE GSM Data Plan, switches 1-3 do not matter.) 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 Figure 19.



NOTE: If the patient travels to a location with a different dial-out prefix, these switches must be adjusted. Patients are instructed to do this in the patient manual.

Figure 19. Dial-out Number Switch Settings

Country Code

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

NOTE: If the patient travels to a different country, these switches must be adjusted. Patients are instructed to do this in the patient manual.

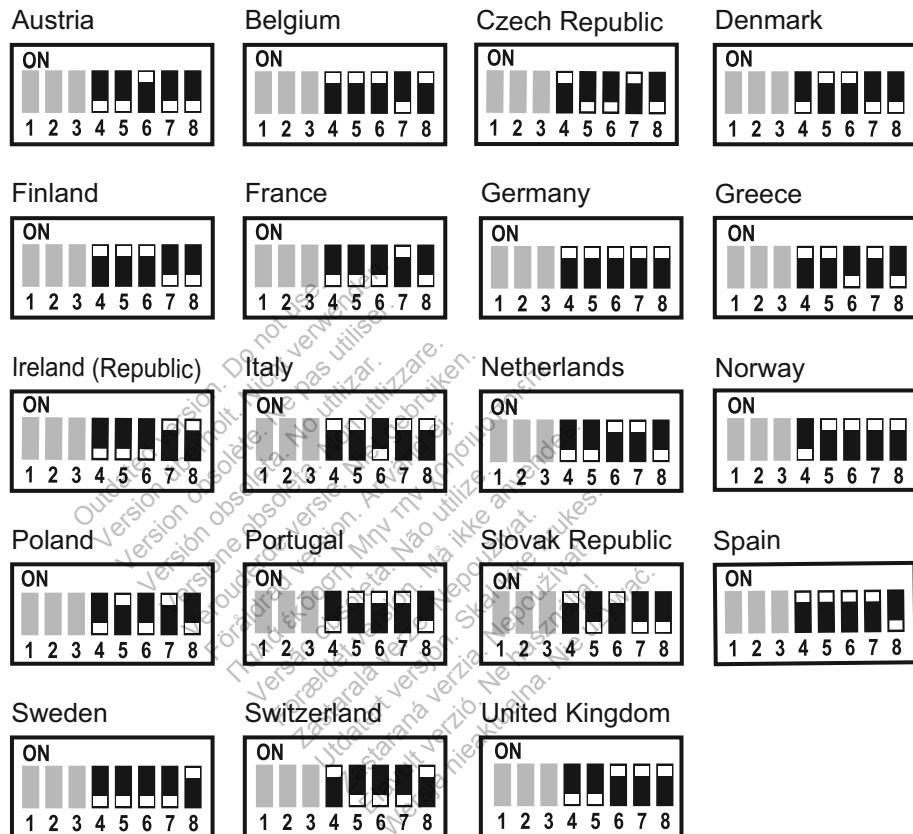
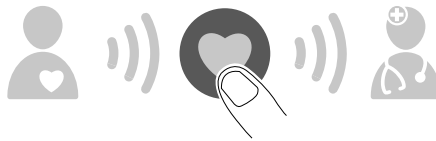


Figure 20. Country Code Switch Settings

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 56.



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



The Patient icon illuminates blue. The Collecting Waves will illuminate green and show progress (illuminate in sequence and repeat) while the Communicator interrogates the patient's device.



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



The Sending Waves light green and show progress 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 illuminated for 2 minutes to indicate the entire process was successful.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolete. Ne pas utiliser.
Versione obsoleta. No utilizar.
Verouderde versie. Niet gebruiken.
Föraldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastarana verzija. Ne uporabljati.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Connecting the USB Sensor Adapter

The USB sensor adapter provides a wireless connection between the weight scale and blood pressure monitor and the Communicator.

To connect the USB sensor adapter, remove the cap and plug the USB sensor adapter into either of the USB ports on the back of the Communicator, as shown in Figure 21.

The USB sensor adapter should remain plugged into the Communicator so the Communicator can receive measurements whenever the patient uses his or her scale or blood pressure monitor.

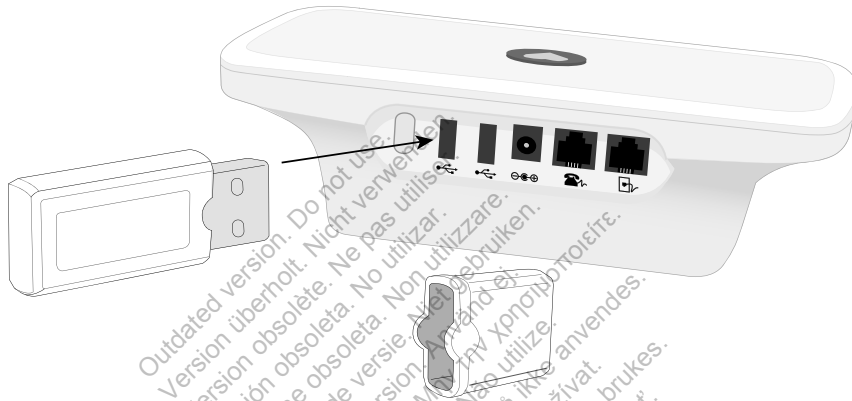


Figure 21. Connecting the USB Sensor Adapter

TOUCH-SCREEN WIRELESS COMMUNICATOR

Identifying Buttons, Connectors, and Indicator

Figure 22 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 68 for the meaning of each light and indicator.

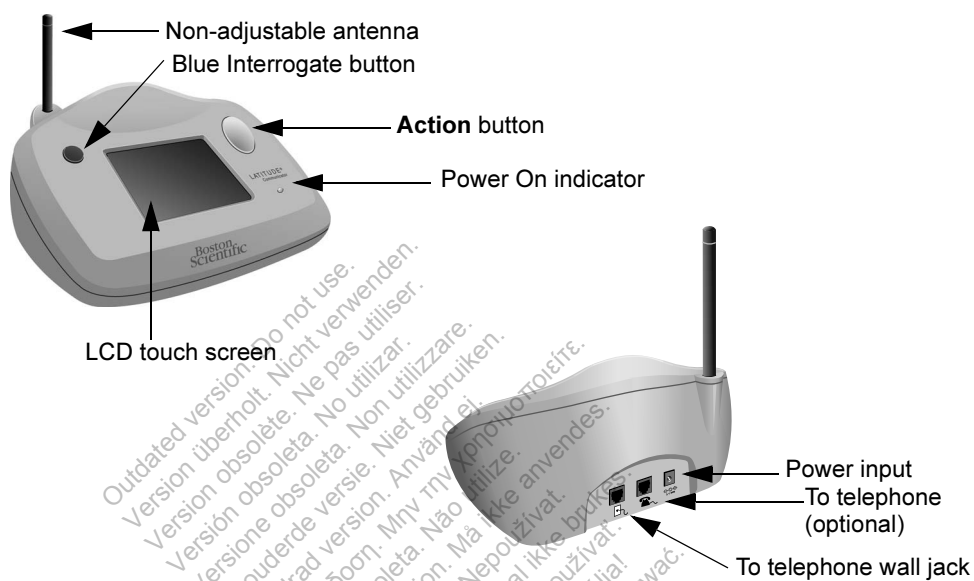


Figure 22. TOUCH-SCREEN WIRELESS COMMUNICATOR Buttons, Connectors, and Indicator

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 change 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 18.
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 the patient is not subscribed to the LATITUDE GSM Data Plan.

Figure 23 shows power supply and telephone jack connections to the Communicator.

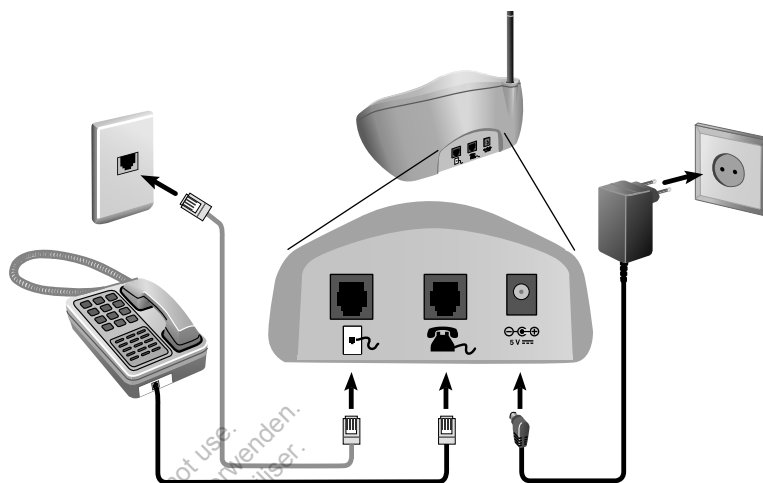


Figure 23. Connecting to a Telephone Wall Jack

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.

If a patient is subscribed to the LATITUDE GSM Data Plan, they do not need to connect the Communicator to a telephone line. Figure 24 shows the connection to an external cellular adapter.

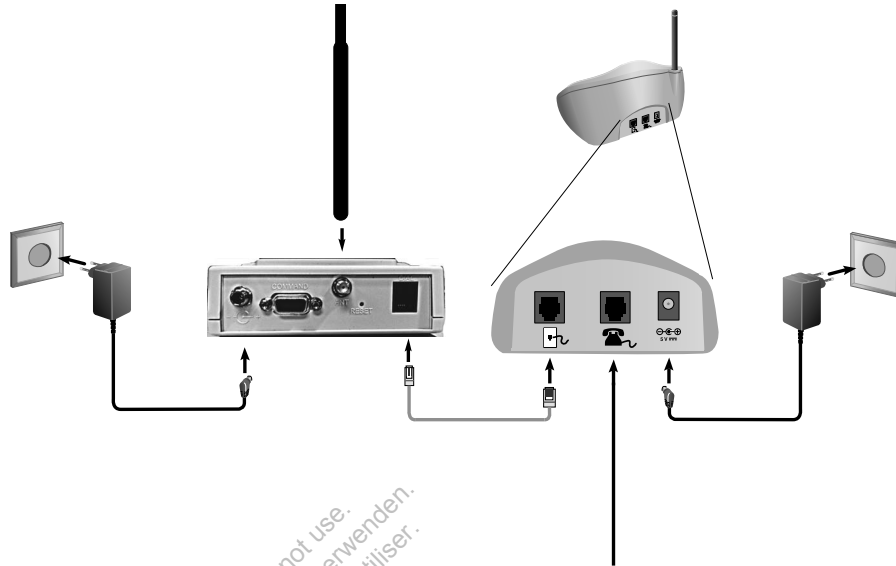


Figure 24. Connecting to an External Cellular Adapter for the LATITUDE GSM Data Plan

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

The **Action** button alert lights described in "Button and Indicator Light Descriptions" on page 68 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.

APPENDIX A: TROUBLESHOOTING GUIDE

This appendix duplicates the Troubleshooting Guides on the **Help/Contact Us** LATITUDE NXT website. Its purpose is to help clinicians resolve status conditions on the website, as well as providing information for clinicians to help 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.

As on the LATITUDE NXT website, this Troubleshooting Guide contains separate sections for the WAVE WIRELESS COMMUNICATOR and the TOUCH-SCREEN COMMUNICATOR. Within each section, there are three main areas of information: Communicator, Sensor, and Monitoring Status, with topics under each. The footer at the bottom of each page of this Troubleshooting Guide indicates the information covered on that page: The Communicator type, the main area of information, and the topic.

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 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 within 3 meters (10 feet) of the patient.
 - 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.

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 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 within 3 meters (10 feet) of the patient.
 - 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.

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.
- 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 system.

The Communicator is able to use either a landline or the subscription-based LATITUDE™ GSM Data Plan to connect.

Landline: If the Communicator is plugged into an active telephone wall jack, it will use the landline to connect with the LATITUDE system.

LATITUDE™ GSM Data Plan: If the Communicator is not plugged into a wall jack it will use the LATITUDE™ GSM Data Plan to connect with the LATITUDE system. The patient must be subscribed to the LATITUDE™ GSM Data Plan for this to be successful.

NOTE: *Some Wave Communicators have cellular capability built in and some require an external cellular adapter.*

To determine if the patient is connecting the Communicator through a landline or the LATITUDE™ GSM Data Plan, ask the patient if they have the Communicator plugged into an active telephone wall jack.

- **One Yellow Sending Wave**

The Communicator does not detect a dial tone (landline) or cannot find a cell signal (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, the patient may need to plug the Communicator into an active telephone wall jack to send data.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 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 cannot register with the cell network (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- Ask the patient to move the Communicator to another location that may have a better signal.
- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, ask the patient to plug the Communicator into an active telephone wall jack.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 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 server (landline or LATITUDE™ GSM Data Plan).

Recommendations:

Try one or more of the following actions:

- Verify the patient is enrolled in LATITUDE 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.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 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 1 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 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 7 days).

Recommendations:

Try one or more of the following actions:

- Ask the patient to connect to LATITUDE 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 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 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.

Monitoring Status

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

Patient Transferred

Another clinic has responsibility for the remote monitoring of this patient.

Recommendations:

Try one or more of the following actions:

- Print any reports needed for your records from the **Follow-up History** page.
- Navigate to the patient's **Edit/View Patient and Equipment Information** page and unenroll the patient. This will remove access to the patient and his/her data.
- If you believe this to be an error, contact the patient for consent to re-enroll the patient with your clinic.

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

No Primary Clinic

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

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. Unenrollment will remove all access to the patient and their data.

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

No Communicator Assigned

This patient does not have a Communicator assigned and is not being remotely monitored.

Recommendations:

Try one or more of the following actions:

- Navigate to the patient's **Edit/View Patient and Equipment Information** page.
- Select the appropriate model number and enter the serial number under the **Communicator** section.

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

Resolution:

The issue has been resolved when the patient's **No Communicator Assigned** status has cleared.

Implanted Device Replaced

The patient's implanted device has been replaced and is not yet being remotely monitored. This status remains until the Communicator has successfully sent data from the new implanted device to the LATITUDE system.

Recommendations:

Try one or more of the following actions:

- Ask the patient to press and hold the **Status** button on the back of the Communicator for approximately 3 seconds until the Sending Waves are green and show progress (light in sequence and repeat). (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 Status button.)
 - The Communicator will connect to the LATITUDE system and receive the new implanted device configuration.
 - The **Implanted Device Replaced** status will clear after the next interrogation (usually the next day) or patient initiated interrogation is sent to the LATITUDE system.

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

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

Communicator Not Set Up

The patient has not set up the Communicator. Their implanted device is not being remotely monitored.

Recommendations:

Try one or more of the following actions:

- Verify that the patient has attempted to set up their Communicator. The Communicator prompts the patient to perform setup by flashing the **Heart** button.
- Verify that the Communicator model and serial numbers match the model and serial numbers recorded on the **Edit/View Patient and Equipment Information** page.
- Verify the Communicator is plugged in. Ask the patient if the power indicator on the front of the Communicator under the word LATITUDE is lit.
- Verify the Communicator is connected to an active telephone wall jack or that the patient has a current subscription to the LATITUDE™ GSM Data Plan.
- 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 troubleshooting instructions below:

- **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 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 within 3 meters (10 feet) of the patient.
 - 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.

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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

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 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 within 3 meters (10 feet) of the patient.
 - 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.

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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **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.
- 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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **Troubleshoot Yellow Sending Waves**

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

The Communicator is able to use either a landline or the subscription-based LATITUDE™ GSM Data Plan to connect.

Landline: If the Communicator is plugged into an active telephone wall jack, it will use the landline to connect with the LATITUDE system.

LATITUDE™ GSM Data Plan: If the Communicator is not plugged into a wall jack it will use the LATITUDE™ GSM Data Plan to connect with the LATITUDE system. The patient must be subscribed to the LATITUDE™ GSM Data Plan for this to be successful.

NOTE: *Some Wave Communicators have cellular capability built in and some require an external cellular adapter.*

To determine if the patient is connecting the Communicator through a landline or the LATITUDE™ GSM Data Plan, ask the patient if they have the Communicator plugged into an active telephone wall jack.

- **One Yellow Sending Wave**

The Communicator does not detect a dial tone (landline) or cannot find a cell signal (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:**

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, the patient may need to plug the Communicator into an active telephone wall jack to send data.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **Two Yellow Sending Waves**

The Communicator is unable to make a network connection (landline) or cannot register with the cell network (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:**

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- Ask the patient to move the Communicator to another location that may have a better signal.

- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, ask the patient to plug the Communicator into an active telephone wall jack.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **Three Yellow Sending Waves**

The Communicator is unable to complete the connection to the LATITUDE server (landline or LATITUDE™ GSM Data Plan).

Recommendations:

Try one or more of the following actions:

- Verify the patient is enrolled in LATITUDE 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.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **Troubleshoot Red or 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **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 1 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 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

Remote Monitoring Disabled

LATITUDE is no longer able to monitor this patient's device due to limited battery capacity.

For more information, you may contact LATITUDE™ Customer Support.

Implanted Device Not Found

The Communicator has been unable to successfully communicate with the implanted device for 14 days or more. A complete interrogation is required for the implanted device information displayed on the LATITUDE system to be updated.

Recommendations:

Try one or more of the following actions:

- If the patient is not allowed to perform PII's, allow one PII on the patient's **Edit/View Schedule and Alert Configuration** page.
- Ask the patient to perform a patient initiated interrogation (PII) by pressing the **Heart** button on the Communicator. (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.)

- 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 troubleshooting instructions below:
- **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 PII's, 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 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 within 3 meters (10 feet) of the patient.
 - 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.

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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

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 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 within 3 meters (10 feet) of the patient.
 - 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.

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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **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.
- 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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Troubleshoot Yellow Sending Waves**

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

The Communicator is able to use either a landline or the subscription-based LATITUDE™ GSM Data Plan to connect.

Landline: If the Communicator is plugged into an active telephone wall jack, it will use the landline to connect with the LATITUDE system.

LATITUDE™ GSM Data Plan: If the Communicator is not plugged into a wall jack it will use the LATITUDE™ GSM Data Plan to connect with the LATITUDE system. The patient must be subscribed to the LATITUDE™ GSM Data Plan for this to be successful.

NOTE: *Some Wave Communicators have cellular capability built in and some require an external cellular adapter.*

To determine if the patient is connecting the Communicator through a landline or the LATITUDE™ GSM Data Plan, ask the patient if they have the Communicator plugged into an active telephone wall jack.

- **One Yellow Sending Wave**

The Communicator does not detect a dial tone (landline) or cannot find a cell signal (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, the patient may need to plug the Communicator into an active telephone wall jack to send data.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Two Yellow Sending Waves**

The Communicator is unable to make a network connection (landline) or cannot register with the cell network (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- Ask the patient to move the Communicator to another location that may have a better signal.
- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, ask the patient to plug the Communicator into an active telephone wall jack.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Three Yellow Sending Waves**

The Communicator is unable to complete the connection to the LATITUDE server (landline or LATITUDE™ GSM Data Plan).

Recommendations:

Try one or more of the following actions:

- Verify the patient is enrolled in LATITUDE 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.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Troubleshoot Red or 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **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 1 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 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

Software Mismatch

The patient's Communicator does not support the implanted device's current software.

For more information you may contact LATITUDE™ Customer Support.

Communicator Not Connecting

The Communicator has not connected to the LATITUDE system in 14 days or more. Data collected from the patient's implanted device, weight scale and/or blood pressure monitor in the last 14 days has not been sent to the LATITUDE system.

Recommendations:

Try one or more of the following actions:

- Verify the Communicator is plugged in. Ask the patient if the green power light in the lower right corner of the Communicator is lit.
- Verify the Communicator is connected to an active telephone wall jack or that the patient has a current subscription to the LATITUDE™ GSM Data Plan.
- 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 troubleshooting instructions below.

- **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 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 within 3 meters (10 feet) of the patient.
 - 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.

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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

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 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 within 3 meters (10 feet) of the patient.
 - 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.

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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **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.
- 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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Troubleshoot Yellow Sending Waves**

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

The Communicator is able to use either a landline or the subscription-based LATITUDE™ GSM Data Plan to connect.

Landline: If the Communicator is plugged into an active telephone wall jack, it will use the landline to connect with the LATITUDE system.

LATITUDE™ GSM Data Plan: If the Communicator is not plugged into a wall jack it will use the LATITUDE™ GSM Data Plan to connect with the LATITUDE system. The patient must be subscribed to the LATITUDE™ GSM Data Plan for this to be successful.

NOTE: *Some Wave Communicators have cellular capability built in and some require an external cellular adapter.*

To determine if the patient is connecting the Communicator through a landline or the LATITUDE™ GSM Data Plan, ask the patient if they have the Communicator plugged into an active telephone wall jack.

- **One Yellow Sending Wave**

The Communicator does not detect a dial tone (landline) or cannot find a cell signal (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, the patient may need to plug the Communicator into an active telephone wall jack to send data.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Two Yellow Sending Waves**

The Communicator is unable to make a network connection (landline) or cannot register with the cell network (LATITUDE™ GSM Data Plan).

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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. You can confirm this with LATITUDE™ Customer Support, if needed.
- Ask the patient to move the Communicator to another location that may have a better signal.
- 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.
- If other locations do not provide a connection using the LATITUDE™ GSM Data Plan, ask the patient to plug the Communicator into an active telephone wall jack.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Three Yellow Sending Waves**

The Communicator is unable to complete the connection to the LATITUDE server (landline or LATITUDE™ GSM Data Plan).

Recommendations:

Try one or more of the following actions:

- Verify the patient is enrolled in LATITUDE 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.
- To verify troubleshooting was successful, have the patient connect to LATITUDE 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 system when the Doctor icon is blue and the Sending Waves are green. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **Troubleshoot Red or 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **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 1 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 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolete. Ne pas utiliser.
Versione obsoleta. No utilizar.
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.
Etlavult verzija. Ne használat!
Wersja nieaktualna. Nie używać.

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

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 LATITUDE™ GSM Data Plan:

- 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 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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. 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 LATITUDE™ GSM Data Plan, 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 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 system match the values on a PRM (Programmer/Recorder/Monitor) report.
- Verify the Communicator is optimally placed:
 - The Communicator is within 3 meters (10 feet) of the patient.
 - 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 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

Recommendations:

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 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 LATITUDE.

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 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 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 2-3 cm (one inch) 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.

Monitoring Status

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

Patient Transferred

Another clinic has responsibility for the remote monitoring of this patient.

Recommendations:

Try one or more of the following actions:

- Print any reports needed for your records from the **Follow-up History** page.
- Navigate to the patient's **Edit/View Patient and Equipment Information** page and unenroll the patient. This will remove access to the patient and his/her data.
- If you believe this to be an error, contact the patient for consent to re-enroll the patient with your clinic.

For more information you may contact LATITUDE™ Customer Support.

No Primary Clinic

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

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. Unenrollment will remove all access to the patient and their data.

For more information you may contact LATITUDE™ Customer Support.

No Communicator Assigned

This patient does not have a Communicator assigned and is not being remotely monitored.

Recommendations:

Try one or more of the following actions:

- Navigate to the patient's **Edit/View Patient and Equipment Information** page.
- Select the appropriate model number and enter the serial number under the **Communicator** section.

For more information you may contact LATITUDE™ Customer Support.

Resolution:

The issue has been resolved when the patient's **No Communicator Assigned** status has cleared.

Implanted Device Replaced

The patient's implanted device has been replaced and is not yet being remotely monitored. This status remains until the Communicator has successfully sent data from the new implanted device to the LATITUDE 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. (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.)
 - The Communicator will connect to the LATITUDE system and receive the new implanted device configuration.
 - The **Implanted Device Replaced** status will clear after the next interrogation or a patient initiated interrogation is sent to the LATITUDE system.

For further assistance, you may contact LATITUDE™ Customer Support.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

Communicator Not Set Up

The patient has not set up the Communicator. Their implanted device is not being remotely monitored.

Recommendations:

Try one or more of the following actions:

- Verify that the patient has attempted to set up their Communicator.
- Verify that the Communicator model and serial numbers match the model and serial numbers recorded on the **Edit/View Patient and Equipment Information** page.
- Verify the Communicator is plugged in. Ask the patient if the green power light in the lower right corner of the Communicator is lit.
- Verify the Communicator is connected to an active telephone wall jack or that the patient has a current subscription to the LATITUDE™ GSM Data Plan.
- Ask the patient if any of the following errors have occurred:
- ***The Communicator Displays an Incorrect Language***

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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- ***The Communicator Displays a Blank Screen and the Action Button is Yellow***

Recommendations:

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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **"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 LATITUDE™ GSM Data Plan:

- 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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

- **"LATITUDE is temporarily unavailable"**

The Communicator is unable to complete the connection to the LATITUDE 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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. 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 LATITUDE™ GSM Data Plan, 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 system when it displays a message indicating information has been sent to LATITUDE. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**

- **"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 system match the values on a PRM (Programmer/Recorder/Monitor) report.
- Verify the Communicator is optimally placed:
 - The Communicator is within 3 meters (10 feet) of the patient.
 - 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 system when it displays a message indicating information has been sent to LATITUDE. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page has changed to **Monitored**.

Remote Monitoring Disabled

LATITUDE is no longer able to monitor this patient's device due to limited battery capacity.

For more information you may contact LATITUDE™ Customer Support.

Implanted Device Not Found

The Communicator has been unable to successfully communicate with the implanted device for 14 days or more. A complete interrogation is required for the implanted device information displayed on the LATITUDE system to be updated.

Recommendations:

Try one or more of the following actions:

- If the patient is not allowed to perform PII's, allow one PII on the patient's **Edit/View Schedule and Alert Configuration** page.
- Ask the patient if the action button on the Communicator is flashing white.
 - If the action button is flashing white, have the patient press it and follow the instructions on the screen.
 - If the action button is not flashing white, have the patient perform a patient initiated interrogation by pressing the blue button on the Communicator. (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.)
- If the patient is unable to complete the interrogation, ask the patient if any of the following errors have occurred.

- **"Interrogation could not be completed"**

The Communicator was unable to complete the 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 system match the values on a PRM (Programmer/Recorder/Monitor) report.
- Verify the Communicator is optimally placed:
 - The Communicator is within 3 meters (10 feet) of the patient.
 - 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 system when it displays a message indicating information has been sent to LATITUDE. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **"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 LATITUDE™ GSM Data Plan:

- 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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **"LATITUDE is temporarily unavailable"**

The Communicator is unable to complete the connection to the LATITUDE 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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. 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 LATITUDE™ GSM Data Plan, 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 system when it displays a message indicating information has been sent to LATITUDE. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- ***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 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

Software Mismatch

The patient's Communicator does not support the implanted device's current software.

For more information, you may contact LATITUDE™ Customer Support.

Communicator Not Connecting

The Communicator has not connected to the LATITUDE system in 14 days or more. Data collected from the patient's implanted device, weight scale and/or blood pressure monitor in the last 14 days has not been sent to the LATITUDE system.

Recommendations:

Try one or more of the following actions:

- Verify the Communicator is plugged in. Ask the patient if the green power light in the lower right corner of the Communicator is lit.
- Verify the Communicator is connected to an active telephone wall jack or that the patient has a current subscription to the LATITUDE™ GSM Data Plan.
- 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.)
- If the **No dial tone** or **LATITUDE temporarily unavailable** message appears, follow the troubleshooting instructions for those messages:

- **The Communicator Displays a Blank Screen and the Action Button is Yellow**

Recommendations:

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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **"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 LATITUDE™ GSM Data Plan:

- 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. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **"LATITUDE is temporarily unavailable"**

The Communicator is unable to complete the connection to the LATITUDE 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 LATITUDE™ GSM Data Plan:

- Verify that the patient has a current subscription to the LATITUDE™ GSM Data Plan. 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 LATITUDE™ GSM Data Plan, 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 system when it displays a message indicating information has been sent to LATITUDE. The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

- **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 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.

Resolution:

The issue has been resolved when the patient's monitoring status on the **Patient Summary** page or patient list has changed to **Monitored**.

Table 5. Explanation of Product and Labeling Symbols

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community

Outdated version. Do not use.
 Version überholt. Nicht verwenden.
 Version obsolete. Ne pas utiliser.
 Versione obsoleta. No utilizar.
 Verouderde versie. Niet gebruiken.
 Föråldrad version. Använd ej.
 Πρωτό έκδοση. Μην την χρησιμοποιείτε.
 Versão obsoleta. Não utilize.
 Forældet version. Må ikke anvendes.
 Zastaralá verze. Nepoužívat.
 Utdatert versjon. Skal ikke brukes.
 Zastarana verzija. Ne uporabljati.
 Elavult verzió. Ne használni!
 Wersja nieaktualna. Nie używać.

Outdated version. Do not use.
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Version obsoleta. No utilizar.
Versione obsoleta. Non utilizzate.
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Föraldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet versjon. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastarana verzija. Ne uporabljajte.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

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