CLINICIAN MANUAL
LATITUDE™ NXT

LATITUDE NXT Patient Management System

CAUTION: Federal law (USA) restricts this device to sale by
or on the order of a physician
trained or experienced in
device implant and follow-up
procedures.
This manual contains information about the LATITUDE NXT Patient Management System ("LATITUDE NXT System"), which includes two distinct types of Communicators, the Wave Wireless Communicator and the Touch-screen Wireless Communicator. See "LATITUDE Communicator Overview" on page 1-5 for more information on each model of Communicator.

Much of the Communicator information in this manual applies to both types of Communicators. In that case, the reference is simply to Communicator or LATITUDE Communicator. However, distinctions are specified when there are differences in how the two types of Communicators, as well different models of the same type of Communicator, relate to the LATITUDE NXT System.

Throughout this manual, three methods of connection to the LATITUDE NXT server are referenced: cellular, Internet, and standard telephone. Availability of methods of connection varies based on model. See "LATITUDE Communicator Overview" on page 1-5 for more information.

Intended Audience

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

Manual Conventions

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

Patient names displayed in screen illustrations are fictitious. Any resemblance to a real person, living or dead, is purely coincidental.

Unless serving as a heading, bold words within the text of this manual are intended to represent the actual words appearing on the LATITUDE NXT website.

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CHAPTER 1

This chapter contains the following topics:

- "INTRODUCTION: LATITUDE NXT PATIENT MANAGEMENT SYSTEM" on page 1-2
- "BASIC CONCEPTS" on page 1-7
INTRODUCTION: LATITUDE NXT PATIENT MANAGEMENT SYSTEM

The LATITUDE NXT Patient Management System ("LATITUDE NXT System") enables authorized members of a clinic to periodically monitor patient and device status remotely. (See "Alerts" on page 1-9 for device and patient conditions that are monitored.)

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

Intended Use

The LATITUDE NXT System is intended to remotely communicate with a compatible Boston Scientific implanted device and transfer data to a central database. The LATITUDE NXT System provides patient data that can be used as part of the clinical evaluation of the patient.

Contraindications

The LATITUDE NXT System is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE NXT System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

Precautions

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

Implanted device data and Alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to 14 days may elapse before the LATITUDE NXT server detects these conditions and the LATITUDE NXT website informs the clinic user that monitoring is not occurring. If both of these conditions occur at the same time, this notification could take up to 28 days. Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following:

- There may be system limitations. (See "System Limitations" on page 1-3.)
- The Communicator is unplugged.
- The Communicator is not able to connect to the LATITUDE NXT server through the configured method of connection.
- The implanted device and the Communicator cannot establish and complete a telemetry session.
- The Communicator is damaged or malfunctions.
• The patient is not compliant with prescribed use or is not using the LATITUDE NXT System as described in the patient manual.

The clinic user can identify any patients that are not being monitored as described above by using the Not Monitored filter on the View Patient List page. (See Figure 2–4 View Patient List Page on page 2-8.)

Adverse Effects

There are no known adverse effects.

System Limitations

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

The LATITUDE NXT System does not provide continuous 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:

• Implant device clock — Proper reporting of implanted device data and alert notifications by the LATITUDE NXT System depends on the implanted device clock being programmed accurately with a Programmer/Recorder/Monitor (PRM). Proper reporting may continue to be impacted for some period of time after the implanted device clock is programmed correctly, depending on the amount of data received with inaccurate time information and the time difference of the implanted device clock error.

• Patient environment — To transmit data, the Communicator must be plugged into an electrical outlet. The Communicator must also maintain regular connection with the LATITUDE NXT server. Patients must be within range of the Communicator at the appropriate times. Radio-frequency (RF) interference from wireless electronic products may interfere with communication between the implanted device and the Communicator.

• Methods of connection to the LATITUDE NXT System:
  – Telephone system — For patients using a standard telephone line, variations in infrastructure compatibility among telephone service providers, as well as variations in the quality of the telephone line from inside the patient’s home to telephone company equipment and switching stations can affect LATITUDE NXT System data delivery. Other equipment attached to the telephone line inside the patient’s home can also affect data delivery.
  – Cellular data service — For patients using a cellular data network, coverage is not guaranteed. A cellular adapter may need to be connected, as applicable. Actual coverage may be affected by such things as terrain, weather, foliage, buildings and other construction, signal strength, timely payment (as applicable), and other factors.
  – Internet connectivity — For patients using Internet connectivity, performance of the Communicator depends on an active Internet service. If using a USB Ethernet Adapter for connection, the adapter must remain connected to a functioning router/modem.

For patients using the hotspot feature on their mobile device for wireless Internet connectivity, the patient must enable hotspot and Bluetooth® wireless technology on their mobile device.
while near their Communicator for at least one hour each day and for manual device interrogations.

For patients using a **Wireless Internet Adapter** for Internet connectivity, the Communicator must use the USB Accessory Adapter. The Communicator must be within 30 meters (100 feet) of the Wireless Internet Adapter, and the adapter must remain connected to a functioning router/modem.

- **Communicator memory capacity** — Communicator memory used to store implanted device data may reach its capacity if the Communicator cannot connect to the LATITUDE NXT server for an extended period.
  
  – If this occurs in a **Wave Wireless Communicator**, the Communicator will delete the oldest collected implanted device data that does not contain any **Red Alerts** from its memory in order to store newly collected implanted device data. If all implanted device data contains **Red Alerts**, the oldest data is deleted.
  
  – If this occurs in a **Touch-Screen Wireless Communicator**, the oldest collected implanted device data will be deleted from memory in order to store the newly collected implanted device data.

- **Clinic environment** — Delays in contacting clinicians may occur for a variety of reasons, including computer equipment that may be down or offline, cell phones that may not be able to receive alert text messages, and the unavailability of clinical staff.

- **Schedule/configuration changes** — Under normal conditions, the patient’s Communicator should be plugged in continuously and operating properly as described in the patient manual. Under these normal conditions, changes in schedule and configuration settings can take up to eight days to be sent to the patient’s Communicator and become effective.

- **Data processing** — Data acquisition and delivery can be delayed or prevented due to:
  
  – Temporary, scheduled, and unscheduled downtime of computer servers.
  
  – Variations in server loads and processing times.
  
  – Other data processing issues.

**LATITUDE NXT Secure Server**

The LATITUDE NXT secure server is a centralized computer database that stores patient data, implanted device data, and sensor data sent from LATITUDE NXT Communicators and/or the LATITUDE Consult System. 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 Consult System**

The LATITUDE Consult System uses a LATITUDE Consult Communicator in a health care facility to read data from a patient’s compatible Boston Scientific implanted device. The LATITUDE Consult System can provide implanted device data that may be used as part of the clinical evaluation of the patient. The data is also provided to the LATITUDE NXT server if the patient is enrolled in the clinic using the LATITUDE NXT System.
LATITUDE Communicator Overview

Available Methods of Connection Per Model

A key component of the LATITUDE NXT System is the LATITUDE Communicator, an in-home monitoring device for patients. The Communicator reads implanted device information based on the schedule configured by the clinic. It then sends the data to the LATITUDE NXT server through one of three methods of connection: cellular, Internet, or standard telephone. Details for methods of connection and availability per model are shown below.

See "Models and Methods of Connection (Outside the United States, Canada, Puerto Rico, and Mexico)" on page 1-6 for more information.

**WAVE WIRELESS COMMUNICATOR** (Models 6498/6280/6290)

- For cellular connection:
  - All three models use the LATITUDE USB 3G Cellular Adapter for cellular communication.
- For Internet connection, all three models may use:
  - The LATITUDE USB Ethernet Adapter or
  - The LATITUDE Wireless Internet Adapter (requires USB Accessory Adapter) or
  - The hotspot feature on a mobile device (requires USB Accessory Adapter).
- For standard telephone connection:
  - All three models support only tone analog dialing mode.

**TOUCH-SCREEN WIRELESS COMMUNICATOR** (Model 6476)

- For cellular connection:
  - Model 6476 uses an external cellular adapter for cellular communication.
- For Internet connection:
  - Model 6476 does not support an Internet connection.
- For standard telephone connection:
  - Model 6476 supports both tone and pulse analog dialing mode.

For additional Communicator information, Troubleshooting Guides on the Help/Contact Us LATITUDE NXT website include Communicator Details for each model. For Communicator setup and operating information, refer to the applicable patient quick start guide or patient manual.

**NOTES:**

- The LATITUDE Communicator can only read data from an implanted device and cannot reprogram, command lead tests, or change any functions of the implanted device. The implanted device can only be reprogrammed with a Programmer/Recorder/Monitor (PRM).

- The LATITUDE Communicator does not provide continuous monitoring. It reads implanted device information at times scheduled by the clinic user.

- When the LATITUDE Communicator connects to the LATITUDE NXT server, it receives any schedule and configuration updates entered by a clinic user on the LATITUDE NXT website.

- The patient receives a LATITUDE Communicator from the clinic after the patient is enrolled in the LATITUDE NXT System. After the patient activates the Communicator according to the instructions in the patient manual, the Communicator is able to interrogate the patient's implanted device. (See "Implanted Device Interrogation" on page 1-12.)
• **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 (such as cellular telephones) and sources of electromagnetic energy (such as microwaves or computer monitors). For patients with an S-ICD supported on LATITUDE, the wireless communication between the Communicator and an S-ICD is orientation and distance sensitive. In some positions, the Communicator may need to be closer to the S-ICD to complete an interrogation. Contact LATITUDE Customer Support if the patient needs help finding a suitable location for their Communicator or if there are questions about possible sources of interference.**

• **The LATITUDE Communicator is designed for use by a single patient. Once a Communicator has been used by a patient, it cannot be reconfigured or distributed to a different patient.**

Models and Methods of Connection (Outside the United States, Canada, Puerto Rico, and Mexico)

The LATITUDE Communicator is designed to work in the following countries, designated by model as shown in the following table:

**Table 1–1. Communicator Models Per Country**

<table>
<thead>
<tr>
<th>Country</th>
<th>Model 6476</th>
<th>Model 6498</th>
<th>Model 6280</th>
<th>Model 6290</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Canada</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x(^a)</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Mexico</td>
<td></td>
<td></td>
<td>x</td>
<td>x(^a)</td>
</tr>
</tbody>
</table>

\(^a\) Does not apply to patients with an S-ICD—for patients with an S-ICD supported on LATITUDE, the Communicator is designed to work only in the United States and Puerto Rico.

A patient’s LATITUDE Communicator is designed to work in their resident country (country of clinic issuing the Communicator), as described in “Available Methods of Connection Per Model” on page 1-5, but may also work in other countries, depending on the model and the method of connection. Refer to the following table for details. Please contact LATITUDE Customer Support for more information.

**Table 1–2. Methods of Connection Per Model (Outside the United States, Canada, Puerto Rico, and Mexico)**

<table>
<thead>
<tr>
<th>Method of Connection</th>
<th>Model 6476</th>
<th>Model 6498</th>
<th>Model 6280</th>
<th>Model 6290(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard telephone line</td>
<td>Not supported</td>
<td></td>
<td>May be restricted due to radio-frequency (RF) laws</td>
<td>Supported in countries that have switch settings</td>
</tr>
<tr>
<td>Cellular data network</td>
<td>May be restricted due to RF laws</td>
<td></td>
<td></td>
<td>Allowed</td>
</tr>
<tr>
<td>Internet</td>
<td>Not supported</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) Patients with an S-ICD supported on LATITUDE may be restricted from using their Communicator in other countries due to RF laws.

**LATITUDE Customer Support**

LATITUDE Customer Support provides technical and general maintenance support to customers using the LATITUDE NXT System.
LATITUDE Customer Support telephone numbers are listed in the following table:

<table>
<thead>
<tr>
<th>LATITUDE Customer Support</th>
<th>1-800-227-3422</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients should contact Patient Services</td>
<td>1-866-484-3268</td>
</tr>
<tr>
<td>Customer Service (ordering product)</td>
<td>1-855-221-5686</td>
</tr>
</tbody>
</table>

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

**Optional Home Health Monitoring Equipment**

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

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

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

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

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

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

**CAUTION:** The maximum weighing capacity of the scale is 200 kg (450 lb). Do not place anything on the scale that is beyond the weighing capacity.

**BASIC CONCEPTS**

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

**Access to Patient Data**

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

Registered Users

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

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

Patient, Clinician, and Clinic Relationships

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

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

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

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

Patient Groups

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

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

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

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

Clinic User Privileges

Three types of privileges for clinic users control access to patient data as described below. The functions that each can perform are shown in the following table.
**Read-Only Access** – Intended for users who need to work with patient data but are not responsible for managing the patients within the system. Access is limited to patients in assigned Patient Groups.

**Limited Access** – Intended for users who are responsible for managing patients. These users have full capability to manage patients, but access is limited to patients in assigned Patient Groups.

**Complete Access** (Clinic Account Managers) – Intended for the user who is responsible for managing the clinic and the clinic’s users and patients. Access is open to all patients in all Patient Groups. User accounts can be created by the Clinic Account Manager.

### Table 1–4. Functions Permitted for Clinic Users by Privilege

<table>
<thead>
<tr>
<th>Function</th>
<th>Complete Access (Clinic Account Manager)</th>
<th>Limited Access</th>
<th>Read-Only Access</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Patient Groups</td>
<td>Assigned Patient Groups</td>
<td>Assigned Patient Groups</td>
</tr>
<tr>
<td>Add/Manage Clinic Users</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Add/Manage Patient Groups</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage schedule and alert</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>configurations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enroll/Manage patients</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Dismiss patients on the View Patient List page</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>View patients on the View Patient List page</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>View patient data and reports⁹</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

⁹ Viewing patient data or reports will record the action and may update Review Status from New Data to Viewed, even if using Read-Only Access.

### Alerts

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

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

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

Alert notification is provided through the View Patient List page on the LATITUDE NXT website (Figure 2–4 View Patient List Page on page 2-8). The LATITUDE NXT System sends one notification for an alert condition detected by the system. For most Alerts, it does not issue alert notifications for the same condition unless the condition is no longer detected and then reoccurs during a following data collection activity.
Designated Boston Scientific personnel may provide notification of alert conditions in place of the notifications provided by the LATITUDE NXT website. If the LATITUDE NXT System is unable to provide implanted device data, the LATITUDE NXT website or Boston Scientific personnel may provide alert notification. The clinic may be contacted regarding data that is currently not available on the LATITUDE NXT website. For example, if there is an alert condition that cannot be retrieved and displayed automatically by the LATITUDE NXT website, Boston Scientific personnel may contact you to inform you of that Alert.

**NOTE:** Most Daily Measurements and diagnostics are nominally On within the implanted device. However, if these features are programmed Off within the implanted device, the LATITUDE NXT System will not generate an Alert related to the feature(s) even if the corresponding LATITUDE Alert is configured On. The implanted device must first measure and record data before the LATITUDE NXT System will detect and generate a Red Alert 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
- Voltage too low for projected remaining 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

For S-ICD devices, **Red Alert** notifications occur for the following conditions:

• Device battery has reached End of Life (EOL)
• High electrode impedance
• Therapy Off
• Possible device malfunction

**Yellow Alerts**

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

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

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

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

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

- Patient triggered event stored
- Nonsustained ventricular arrhythmia episode(s)
- HeartLogic heart failure index at or above (a user-selectable threshold)

**NOTE:** When an Alert occurs, daily interrogation can be configured to occur until the condition is resolved.

- Cardiac Resynchronization Therapy pacing percentage (less than a user-selectable percentage)

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

- Right ventricular pacing percentage (exceeds a user-selectable percentage)
- Device Brady Mode Off
- Therapy history corruption detected
- Weight gain (exceeding a user-selectable limit in a user-selectable number of days)

For S-ICD devices, **Yellow Alert** notifications can be configured for the following conditions:

- Device battery has reached Elective Replacement Indicator (ERI)
- Shock therapy delivered to convert arrhythmia
- Untreated episode
- Sensing not fully optimized
- Measured AF within a 24-hour period (exceeding a user-selectable limit)

**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 1–5 Data Collection and Configuration Details for Each Interrogation Type on page 1-13.
### Table 1–5. Data Collection and Configuration Details for Each Interrogation Type

<table>
<thead>
<tr>
<th>Interrogation Type</th>
<th>Full Interrogation (with Presenting EGM/S-ECG)</th>
<th>Full Interrogation (with no Presenting EGM)</th>
<th>Red Alert Check</th>
<th>Yellow Alert Check</th>
<th>Configuration Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote Scheduled Follow-ups</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• Off/Manual&lt;br&gt;• 1 week&lt;br&gt;• 2 weeks&lt;br&gt;• Monthly intervals from 1 to 12 months&lt;br&gt;• Automatic except for S-ICD patients, for whom it is prompted</td>
</tr>
<tr>
<td>Alert Check(^b) (not available for S-ICD patients)</td>
<td>If Red or Yellow Alert is detected(^b)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• Daily&lt;br&gt;• Not configurable</td>
</tr>
<tr>
<td>Data Updated Interrogation(^b)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• A recent PRM interrogation has occurred(^b) or&lt;br&gt;• Sensors assigned and no full interrogation in seven days(^b) or&lt;br&gt;• HeartLogic feature enabled and no full interrogation in seven days(^b) or&lt;br&gt;• HeartLogic Index Alert detected within the past seven days and Daily Alert Interrogations are configured On(^b)</td>
</tr>
<tr>
<td>Weekly Implanted Device Alert Monitoring(^b)</td>
<td>If Red or Yellow Alert is detected(^b)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• Weekly&lt;br&gt;• Configurable&lt;br&gt;• Prompted</td>
</tr>
<tr>
<td>Weekly Implanted Device Alert Monitoring(^b)</td>
<td>If Red Alert is detected(^b)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• Weekly&lt;br&gt;• Configurable</td>
</tr>
<tr>
<td>Patient Initiated Interrogations (See &quot;Patient Initiated Interrogations* on page 1-14.)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>As directed by clinician</td>
</tr>
</tbody>
</table>

\(^a\) For S-ICD patients, a presenting S-ECG will not be collected if the S-ICD is in MRI Mode during the remote interrogation.

\(^b\) **NOTE**: Only S-ICD MRI devices will be able to be interrogated remotely in MRI Mode.

- A Red or Yellow Implanted Device Alert, or
- A recent PRM (Programmer/Recorder/Monitor) interrogation, or
- No full interrogation has occurred within the past seven days (for patients with assigned sensors), or
- No full interrogation has occurred within the past seven days (for patients with HeartLogic feature enabled), or
- HeartLogic Index Alert detected within the past seven days and Daily Alert Interrogations are configured On.

**TOUCH-SCREEN WIRELESS COMMUNICATOR** only: If a **Red Alert** is detected, the Communicator will also attempt to collect a full interrogation with presenting EGM.
NOTE: Boston Scientific personnel may contact the clinic if an implanted device uses too much RF telemetry to perform remote interrogations.

Automatic and Prompted Interrogations

Automatic interrogations occur without any lighted indication on the Communicator and require no action by the patient. In most cases, the patient is unaware that an interrogation is happening. Prompted interrogations, however, require action by the patient.

Prompted interrogations are indicated by a flashing white button on the Communicator. The patient must press the flashing white button to initiate the interrogation. For the TOUCH-SCREEN WIRELESS COMMUNICATOR, the patient also presses the Interrogate button displayed on the screen. (See the appropriate patient manual for more information about the Communicator.)

Generally, most patients are configured for automatic interrogations. However, all interrogations for S-ICD patients are prompted by a flashing white Heart button.

NOTE: A flashing white button may also indicate that the Communicator is unable to complete the interrogation. The patient is instructed in the patient manual to press the button any time it is flashing.

Patient Initiated Interrogations

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

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

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

Clinic users who are assigned to a Patient’s Group 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 or by pressing the blue button on the TOUCH-SCREEN WIRELESS COMMUNICATOR. (See the appropriate patient manual for more information about the Communicator.) The Communicator will not perform an interrogation if this feature is not enabled or the limit has been reached.

If the PII configuration setting is changed, the LATITUDE NXT server will send a notification to the patient’s Communicator the next time the Communicator calls the LATITUDE NXT server. It could take up to eight days for the Communicator to call the LATITUDE NXT server. If 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 1-2 and “System Limitations” on page 1-3.
CHAPTER 2

This chapter contains the following topics:

• “GETTING STARTED” on page 2-2
• “CLINIC AND PATIENT CONFIGURATION” on page 2-5
• “THE VIEW PATIENT LIST PAGE” on page 2-7
• “SEARCH PATIENTS TOOL” on page 2-12
• “ENROLLING PATIENTS AND MANAGING EQUIPMENT” on page 2-13
• “PATIENT INITIALIZATION” on page 2-15
• “MANAGING PATIENTS” on page 2-16
• “MANAGING PATIENT GROUPS” on page 2-17
• “MANAGING USER ACCOUNTS” on page 2-18
• “PASSWORDS” on page 2-19
• “EMR SYSTEM INTEGRATION” on page 2-21
• “TROUBLESHOOTING” on page 2-25
GETTING STARTED

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

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

LATITUDE NXT Mobile Application

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

For more information, from your iPhone navigate to:

- http://www.bostonscientific.com/latitudenxt-mobile

Requirements

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

- Internet Explorer™ Internet browser

  NOTE: While Internet Explorer 8 and 9 are supported for most website functions, users may experience some performance issues, including diminished graphing capabilities. To avoid this, the latest version of Internet Explorer is strongly recommended.

- Mozilla Firefox™ Internet browser

- Apple™ Safari™ on the Mac™, iPad™, and iPhone™ Internet browsers

If using an unsupported browser, not all functionality may work as intended.

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

A current anti-virus program is recommended.

Logging In and Out

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

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

   http://www.latitude.bostonscientific.com

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

1. The LATITUDE NXT website was developed with browsers that were current at that time. The LATITUDE NXT website may not function properly when using browser versions that were subsequently released. Call LATITUDE Customer Support for a list of supported Internet browsers.
2. The first time you access the LATITUDE NXT website or the first time you access the website from a different computer, select your country and language, as applicable.

   - During subsequent logins, country and language can be changed by clicking Change Country/Language on the login page, as shown in the following figure. This will bring you back to the initial access page.

   - Language can also be changed at any time by selecting the Language menu at the top of all pages. Language and country can also both be changed by selecting My Profile at the top of all pages.

3. Click the LATITUDE NXT button to display the login page shown in the following figure.
Navigating the Site

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

Figure 2–3. LATITUDE NXT System Banner
Table 2–1. Navigating the Site

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td><strong>My Profile</strong></td>
<td>Links to the Update Clinic User page for the current user</td>
</tr>
<tr>
<td>(2)</td>
<td><strong>Language</strong></td>
<td>Displays selected language; links to the Update Clinic User page for the current user where the selected language can be changed</td>
</tr>
<tr>
<td>(3)</td>
<td><strong>Help/ Contact Us</strong></td>
<td>Links to contact information, troubleshooting guides, and other resources</td>
</tr>
<tr>
<td>(4)</td>
<td><strong>Logout</strong></td>
<td>Ends the user’s session</td>
</tr>
<tr>
<td>(5)</td>
<td><strong>View Patient List</strong></td>
<td>Links to a page that provides a list of patients to which the current user has access (See Figure 2–4 View Patient List Page on page 2-8.)</td>
</tr>
<tr>
<td>(6)</td>
<td><strong>Search Patients</strong></td>
<td>Links to the Search Patients page</td>
</tr>
<tr>
<td>(7)</td>
<td><strong>Manage Clinic</strong></td>
<td>Displays clinic-related action links 8–11</td>
</tr>
<tr>
<td>(8)</td>
<td><strong>Manage EMR Integration</strong></td>
<td>Links to a page that enables clinicians to configure integration with their clinic’s electronic medical record (EMR) system and view the export status of their EMR files (See “EMR SYSTEM INTEGRATION” on page 2-21.)</td>
</tr>
<tr>
<td>(9)</td>
<td><strong>Manage Clinic Users</strong></td>
<td>Links to a list of clinic users and associated configuration information</td>
</tr>
<tr>
<td>(10)</td>
<td><strong>Manage Clinic Settings</strong></td>
<td>Links to clinic and Patient Group demographics and membership and associated configuration information</td>
</tr>
<tr>
<td>(11)</td>
<td><strong>Order Equipment</strong></td>
<td>Links to the eOrdering website</td>
</tr>
<tr>
<td>(12)</td>
<td><strong>Enroll Patient</strong></td>
<td>Links to enrollment form that enables clinicians to enroll new patients</td>
</tr>
</tbody>
</table>

**CLINIC AND PATIENT CONFIGURATION**

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

Table 2–2. Patient Groups Configuration

<table>
<thead>
<tr>
<th>Patient Groups</th>
<th>Manage Clinic ⇒ Manage Clinic Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Edit/View Schedule and Alert Defaults</td>
</tr>
<tr>
<td></td>
<td>• Remote Scheduled Follow-ups</td>
</tr>
<tr>
<td></td>
<td>• Weekly Implanted Device Alert Monitoring</td>
</tr>
<tr>
<td></td>
<td>• Patient Initiated Interrogations</td>
</tr>
<tr>
<td></td>
<td>• Alert Configuration</td>
</tr>
<tr>
<td></td>
<td>• Additional Alert Notification (SMS text and email messages)</td>
</tr>
</tbody>
</table>

Table 2–3. Individual Patient Configuration

<table>
<thead>
<tr>
<th>Individual Patient</th>
<th>View Patient List ⇒ Patient Summary Page (click patient's name)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Edit/View Schedule and Alert Configuration</td>
</tr>
<tr>
<td></td>
<td>• Next Scheduled Remote Follow-up</td>
</tr>
<tr>
<td></td>
<td>• Remote Scheduled Follow-ups</td>
</tr>
<tr>
<td></td>
<td>• Weekly Implanted Device Alert Monitoring (availability dependent on type of implanted device and model of Communicator)</td>
</tr>
<tr>
<td></td>
<td>• Patient Initiated Interrogations</td>
</tr>
<tr>
<td></td>
<td>• Alert Configuration</td>
</tr>
</tbody>
</table>
Table 2–3. Individual Patient Configuration (continued)

<table>
<thead>
<tr>
<th>Edit/View Patient and Equipment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• General Information</td>
</tr>
<tr>
<td>• Implanted Device</td>
</tr>
<tr>
<td>• Patient Group Membership</td>
</tr>
<tr>
<td>• Equipment</td>
</tr>
</tbody>
</table>

**Configuration Details**

**Saving Settings**

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

**Remote Scheduled Follow-ups**

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

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

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

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

- Except for a patient with an S-ICD implanted device, interrogations occur automatically on the scheduled dates. The patient does not need to perform any action. These interrogations often occur without the patient’s knowledge.

- For a patient with an S-ICD implanted device, interrogations do not occur automatically; instead, the patient is prompted with a flashing white Heart button to interrogate their implanted device.

**Weekly Implanted Device Alert Monitoring (Wave Wireless Communicator, Model 6290, S-ICD patients only)**

**Weekly Implanted Device Alert Monitoring** can be enabled or disabled. When enabled, the patient is prompted on a weekly basis with a flashing white Heart button to interrogate their implanted device. If a **Red** or **Yellow Implanted Device Alert** is detected, a recent PRM interrogation has occurred, or no full
interrogation has occurred within the past seven days (for patients with assigned sensors), the Communicator will attempt to collect a full interrogation with presenting S-ECG and upload the data.

**Weekly Implanted Device Alert Monitoring (Touch-Screen Wireless Communicator only)**

*Weekly Implanted Device Alert Monitoring* can be enabled or disabled. When enabled, an implanted device is interrogated weekly, the data is uploaded, and any configured *Alerts* detected are reported. If a *Red Alert* is detected, the Communicator will also attempt to collect a full interrogation with presenting EGM.

**Patient Initiated Interrogations**

*Patient Initiated Interrogations* (PIIs) can be enabled (five per week) or disabled. You can also configure one additional PII at any time. This additional PII can be configured from the *Edit/View Schedule and Alert Configuration* page. See "Patient Initiated Interrogations" on page 1-14.

**Additional Alert Notifications**

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

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

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

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

**Individual Patients**

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

**THE VIEW PATIENT LIST PAGE**

The *View Patient List* page (shown below) is the first page displayed after logging on to the LATITUDE NXT website. Upon initial login, by default, the page uses the *For Review* filter to display patients for all assigned Patient Groups. After initial login, the page remembers and retains the most recently used filter and *Viewing Patient Group* selection to display patients. Reports for one or more patients can be generated from this page.
The following subsections describe the filters, buttons, and columns that are available to efficiently navigate the View Patient List:

**Filters**

Two tools are provided to select and filter patient lists:

1. **Viewing Patient Group** pull-down menu – Provides a list of Patient Groups for which the user is assigned.

2. Filters – Each of the following filters may be used to further restrict patients within specific Patient Group(s):

   - **All Patients** – Lists all patients in the selected Patient Group(s). Patients are listed in alphabetical order.

   - **For Review** – Lists patients with reviewable data that have not been dismissed. Reviewable data includes data associated with Alerts, Remote Scheduled Follow-ups, LATITUDE Consult System, or Patient Initiated Interrogations. Patients are listed in order of Alert severity, followed by patient name in alphabetical order. The For Review list is the default filter when the user first logs in. After initial login, the page remembers and retains the most recently used filter selection to display patients.

   - **Missed Follow-up** – Lists patients that had a remote scheduled follow-up but a remote interrogation has not yet been completed successfully. Patients are listed in order of remote scheduled date, with the most recent listed first.
• **Not Monitored** – Lists patients that currently are not being monitored. See "Monitoring Status/Date" on page 2-10. Patients are listed in order of when the Not Monitored status was determined, with the most recent listed first.

• **Not Scheduled** – Lists patients that currently do not have a scheduled remote follow-up. Patients are listed in alphabetical order.

**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.

**Buttons**

• **Reports Menu for Selected Patients**

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

• **Print Patient List**

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

• **Dismiss From Review List**

One or more patients can be dismissed from the review list by selecting the checkboxes next to their names and clicking the Dismiss From Review List button. Dismiss From Review List is also available for each individual patient on the For Review list.

**Columns**

• **Checkbox**

You can select the checkbox for one or more patients. The Reports Menu for Selected Patients and Dismiss From Review List buttons at the top of the patient list are performed for all patients selected with the checkbox.

• **Patient/Patient ID/Device**

Click on the patient’s name to see detailed information for that patient. 📃 indicates a patient note. Hover over the icon to read the text; click the icon to add or edit text.

**NOTE:** A patient note is created from the patient summary page.

• **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.
- No flag 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
- Implant Device Alert
- Multiple Reasons
- LATITUDE Consult System

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

• **Next Remote Follow-up**

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

• **Monitoring Status/Date**

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, along with the date that status was determined.

- **Patient Transferred** – Applicable only for the clinic from which the patient transferred. (No date is shown for this status indication.)
- **No Primary Clinic** – Primary clinic is required for a patient to be remotely monitored.
- **No Communicator Assigned** – Patient does not have a Communicator currently assigned.

- **Implanted Device Replaced** – Remains until the Communicator has successfully collected data from the new implanted device and sent it to the LATITUDE NXT server.

- **Communicator Not Set Up** – Remains until the Communicator has successfully collected data from the implanted device and sent it to the LATITUDE NXT server.

- **Remote Monitoring Disabled** – Occurs because the implanted device has limited battery capacity.

- **Implanted Device Not Found** – Communicator has been unable to successfully communicate with the implanted device for 14 days or more from the date an interrogation was scheduled.

- **Software Mismatch** – Communicator does not support the implanted device's current software.

- **Communicator Not Connecting** – Communicator has not connected to the LATITUDE NXT server in 14 days or more.

A patient may have more than one **Not Monitored** status at a given time. In this case, the most recent status is displayed on the **View Patient List** page. Any other statuses are displayed on the patient detail pages.

**NOTE:** ⚖ indicates that the patient currently has more than one **Not Monitored** status.

After notification, the clinician is responsible for resolving the status condition. This may include referring the patient to LATITUDE Customer Support or Patient Services, as applicable, in the event the clinician is unable to resolve the condition. See "LATITUDE Customer Support” on page 1-6 for contact information. **Alert** identification and notification will not occur until the status condition is resolved.

Clicking on the status opens a window that displays the related section of the Troubleshooting Guides.

**• Actions**

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

**NOTE:** When the **Not Monitored** filter is selected on the **View Patient List** page, the **Actions** column is replaced by the **Patient Notes** column.

**Generating and Printing Patient Reports**

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

You may print multiple individual reports at a time. If you attempt to print more than the maximum number of reports allowed, a message will appear asking you to modify your selection to print fewer reports.

The following reports are available for applicable implanted devices:
• Quick Notes Report/S-ICD Summary Report

• Most Recent Presenting EGM/S-ECG Report

• Combined Follow-up Report

• Heart Failure Management Report

• Atrial Arrhythmia Report

• Arrhythmia Logbook Report

• LATITUDE Consult System Transmission Report (available only if there was LATITUDE Consult transmission for an implanted device)

• Event Detail Report

• Device Settings Report

The Quick Notes/S-ICD Summary, Combined Follow-up, Presenting EGM/S-ECG, Atrial Arrhythmia, LATITUDE Consult System Transmission, and Heart Failure Management Reports are available for previous interrogations from a patient’s Follow-up History page. The Follow-up History page lists remote interrogations that result in the patient being added to the For Review patient list.

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

SEARCH PATIENTS TOOL

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

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

This section provides information for enrolling patients in the LATITUDE NXT System, as well as ordering equipment (Communicator and, if applicable, weight scale and blood pressure monitor) and distributing equipment to patients.

Enrolling New Patients

Clinic users enroll new patients by clicking the Enroll Patient link under the Manage Clinic menu option as shown in the following figure. Patients are identified in the LATITUDE NXT System by their date of birth and the model and serial number of their implanted device.
Clinic users 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.

Equipment may be distributed to patients during or after enrollment. Equipment models and serial numbers may also be entered in the LATITUDE NXT System during or after enrollment. See "Ordering and Distributing Equipment" on page 2-14 for more information.

**Completion of patient enrollment in the LATITUDE NXT System requires the Communicator model and serial number.** When distributing a Communicator to patients from clinic stock, make sure to record these numbers in LATITUDE NXT. Patients without Communicator information will be listed on the Not Monitored View Patient List with a status of No Communicator Assigned.

**NOTES:**

- The patient will not be monitored until Communicator information has been entered and the patient has completed setup.
- Patient information, as well as equipment numbers, may already be entered in the LATITUDE NXT System from implant registration.

**Ordering and Distributing Equipment**

Clinics can order LATITUDE equipment by:

- Using the Boston Scientific eOrdering System.
- Contacting Customer Service at 1-855-221-5686.
Using the Boston Scientific eOrdering System

The Boston Scientific eOrdering System can only be accessed through the LATITUDE NXT website as follows:

- To order equipment to be shipped directly to the clinic, click the Order Equipment link under the Manage Clinic menu option as shown in the preceding figure or on the Help/Contact Us page. Clinic users with complete, limited, and read-only access can order equipment to be shipped directly to the clinic.

- To order equipment to be shipped directly to the patient during enrollment, follow Step 2 of the enrollment process, which allows selection of equipment for the patient and directs the clinic user to the eOrdering website. Additional equipment can be added to the order on the eOrdering website. Only clinic users with complete or limited access can order equipment to be shipped directly to the patient.

- To order equipment to be shipped directly to the patient after enrollment, select the checkbox to order new equipment to be shipped to the patient on the Edit/View Patient and Equipment Information page.

When equipment is shipped directly to the patient, the Communicator model and serial number (as well as those of the weight scale or blood pressure monitor, if applicable) typically auto-populate the patient’s record in the LATITUDE NXT System when the equipment is shipped. If this information does not appear as expected, check Order History or call LATITUDE Customer Support.

When equipment is distributed to the patient from clinic stock, equipment information needs to be entered manually into the LATITUDE NXT System. Recording of serial numbers for adapters is not required.

Enrolling Existing Patients

If a patient was 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 was 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.

Educating Patients

Even though each patient receives a patient manual and quick start guide with their Communicator, we recommend that clinics provide setup and general operating information about the Communicator to the patient during distribution so that they become familiar with how to use it. Additional copies of the patient manual and quick start guide can be ordered using the information on the back cover of this clinician manual or by contacting LATITUDE Customer Support.

The patient manual is also available online at www.bostonscientific-elabeling.com.

PATIENT INITIALIZATION

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

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

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

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

**MANAGING PATIENTS**

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

**Changing Patient Demographic and Equipment Information**

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

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

The Communicator performs several time-sensitive functions. If a patient moves or travels to a different time zone, the new time zone where the Communicator is being used needs to be selected on the Edit/View Patient and Equipment Information page.

Patients with a TOUCH-SCREEN WIRELESS COMMUNICATOR are able to select their time zone on their Communicator screen.

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

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

**Changing Patient Groups**

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

- The patient can be moved from one Patient Group to a new Patient Group. Only clinic users associated with the new Patient Group will have access to the patient. This change does not affect the patient’s data or status on the View Patient List page.

- The patient can be associated with a second Patient Group. The user must specify which Patient Group is primary (manages the patient’s device) and which is secondary. Users in both the original Patient Group and the second Patient Group will have access to the patient. Users in the secondary Patient Group will see the patient’s current data but will not be notified of Red Alerts and will not see any follow-up or alert history associated with the primary Patient Group.
Transferring Patients

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

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

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

Unenrolling Patients

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

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

NOTES:

• Once a patient account is unenrolled, patient data is no longer accessible by that clinic in the LATITUDE NXT System.

• Clinics are responsible for unenrolling patients if a clinic is no longer in practice. If a clinic dissolves, Boston Scientific personnel may contact LATITUDE NXT patients enrolled in the clinic.

MANAGING PATIENT GROUPS

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

Adding Patient Groups

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

Deleting Patient Groups

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

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

- Schedule and Alert Defaults – selecting the Edit/View Schedule and Alert Defaults button associated with a Patient Group allows clinic users to manage the schedule and alert defaults.

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

MANAGING USER ACCOUNTS

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

Clinic Account Managers can also perform certain user account management functions for all users within their clinic, including designating whether passwords of clinic users expire six months after being issued or never expire. Clinic Account Managers can also reset passwords.

**NOTE:** 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 Clinic Account Managers. To add a user, select the Add Clinic User button on the Manage Clinic Users page. The Add Clinic User page provides a set of required and optional data entry fields. Adding an account includes selecting the user’s privileges and assigning them to the desired Patient Groups.

Deleting User Accounts

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

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

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

Other User Account Management Functions

Other account management functions are available by selecting the Edit/View Demographics and Access Settings button associated with a user on the Manage Clinic Users page. The following functions are supported on the Update Clinic User page:
• The Clinic Account Manager may edit the demographic data for any user and save it into the LATITUDE NXT System. Values that can be modified include user information, User ID, user privileges, and assigned Patient Groups.

• **Reset Password** – If a user forgets their password, this function can be used by the Clinic Account Manager 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.

### 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.

Users can also select a preference on the **My Profile** page to **Enable Heart Failure Patient View**. If enabled, selecting the patient name takes you directly to their Health tab.

### PASSWORDS

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

A Clinic Account Manager can designate whether passwords expire six months after being issued or never expire. 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 2-20.

### 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 six months after being issued.

### Security Questions

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

A clinic user is prompted for their answer to one of these security questions if they forget their password and need to reset it. Clinic users can also ask their Clinic Account Manager to reset their passwords. Refer to "Resetting Your Forgotten Password" on page 2-20.

### Changing Your Password

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

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

The optional LATITUDE NXT Electronic Medical Record (EMR) system integration feature provides an automated way to export patient implanted device data to a clinic’s internal EMR application. Sensor data, sensor Alerts, and monitoring status are not included in data exported to an EMR application. Clinicians may want to refer to the Implantable Device Cardiac Observation (IDCO) integration specification of Boston Scientific for details on how its implanted device data is converted into IDCO messages, which are used to deliver patient data to the EMR application.

The data exported are based on the Quick Notes Report/S-ICD Summary Report and include Implant Device Alerts. The data may also include PDFs of the Presenting EGM/S-ECG Report, Combined Follow-Up Report, Heart Failure Management Report, Arrhythmia Logbook Report, and Event Detail 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 Implant Device Alerts, Remote Scheduled Follow-ups, Patient Initiated Interrogations, and data sent from the LATITUDE Consult System.
- Selects the data format for your EMR application.
- Displays details of each data export including time stamps and export status.
- Allows you to resend EMR data.

NOTES:

- The LATITUDE NXT System only exports EMR files when the Enable EMR Integration checkbox on the LATITUDE NXT website is selected. The system does not create or export EMR files for patient interrogation data received while EMR is not enabled. Refer to "Configuring the EMR Feature" on page 2-22.
- 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 Implant Device Alert has occurred.
- An EMR data export is not performed for a weight Alert. Sensor measurements are not exported.
- Any changes to data from within the EMR application will not change data in the LATITUDE NXT System.
- Some EMR applications may not directly import LATITUDE NXT data. You or your EMR vendor may have to provide additional software to import LATITUDE NXT data into your EMR application. Technical information is located separately in the Boston Scientific IDCO and HL7 integration specification documents.
- If an attempt to export an EMR file fails, the LATITUDE NXT System continues to attempt to export the file to your EMR application for up to 30 days. The LATITUDE NXT System will then discontinue
the attempt to export the EMR file and report a Failed status. If this occurs, you may resend the data using the Resend button.

Configuring the EMR Feature

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

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

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

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

![Figure 2–9. Edit/View Configuration Button](image)

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

**Important**: The identifier is required to complete the registration of the EMR integration software. The identifier is used to route your LATITUDE NXT System clinic records to your EMR application.
4. Click the click here link as shown above.

5. You are directed away from LATITUDE NXT to a website for the EMR integration software that needs to be installed. Follow the installation and setup instructions available on this website.

6. Complete installation, configuration, and registration of the software before enabling EMR Integration.

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

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

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

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

9. Click the **Save and Close** button.

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

**View EMR Log**

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

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

![View EMR Log Window](image)

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

- **Patient/Patient ID** – Patient name and patient identifier.

- **Review Reason** – The reason that the EMR export was initiated (same as on the **View Patient List**, see "Monitoring Status/Date" on page 2-10).

- **Device Transmission Date** – The date the implanted device interrogation associated with the EMR file was initiated.

- **Status** – The current status of the export. A link from each status opens an EMR history pop-up window that provides detailed information of the export processes for that patient. A description of each status follows:
  - **Initiated** – The EMR export has been initiated.
  - **Waiting for Clinic Computer** – All data for the file has been processed and the file is ready to be exported to your EMR application. Typically, file delivery will occur within 30 minutes. If this status persists for more than 30 minutes, please contact your IT professional who is responsible for monitoring your EMR integration software or EMR application.
  - **Transferred** – The EMR file has been successfully exported to your EMR application.
- **Resend Requested** – A resend of the EMR file has been requested.

- **Failed** – The attempt to export the EMR file failed. No further attempt will be made to export the EMR file. Once the reason for failure has been determined, the EMR data may be resent.

- Refer to the troubleshooting section of the installation instructions document for help with diagnosing and troubleshooting failures. This document is available on the LATITUDE NXT System EMR Integration software (EMR client) webpage.

- **Status Date/Time** – The date and time of the last change in status.

- **Actions** – Contains the **Resend** button that may be used to request another attempt to export the EMR file. A **Resend** can only be initiated when an EMR file has a status of **Transferred** or **Failed**.

**TROUBLESHOOTING**

The Troubleshooting Guides on the Help/Contact Us LATITUDE NXT website are intended to help clinicians resolve problems with patient Communicators and sensors. If you are unable to resolve a problem with a patient Communicator or sensor after following the recommendations provided, you or the patient may contact the appropriate LATITUDE Customer Support number listed in "LATITUDE Customer Support" on page 1-6.