

CLINICIAN MANUAL

# **LATITUDE™ NXT**

LATITUDE NXT Patient Management System

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## ABOUT THIS MANUAL

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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. Availability of the TOUCH-SCREEN WIRELESS COMMUNICATOR varies by region. 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 and region. See "LATITUDE Communicator Overview" on page 1-5 for more information. Availability of sensors (weight scale and blood pressure monitor) and the USB Accessory Adapter varies by region.

### Intended Audience

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

This manual is intended for LATITUDE NXT (Therapy); however, LATITUDE Clarity (Diagnostic) is referenced throughout due to the anticipated user interface of the LATITUDE website. LATITUDE Clarity may not be available at this time for all geographies. References to LATITUDE Clarity may be disregarded if not yet available at your clinic.

**NOTE:** When information in this manual is specific to one or the other, LATITUDE NXT and LATITUDE Clarity are referenced. When information applies generally to both, LATITUDE website, or simply LATITUDE, is referenced.

### 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 or as emphasis, bold words within the text of this manual are intended to represent the actual words appearing on the LATITUDE NXT website.

Throughout this manual, "LATITUDE NXT" and "LATITUDE" may be used interchangeably to refer to the same system, website, server, etc.

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# THE LATITUDE NXT PATIENT MANAGEMENT SYSTEM

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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 1-10

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## INTRODUCTION: LATITUDE NXT PATIENT MANAGEMENT SYSTEM

The LATITUDE NXT Patient Management System ("LATITUDE NXT System") enables authorized members of a clinic to periodically monitor patient and device status remotely. (See "Alerts" on page 1-11 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.

### Clinical Benefits of the LATITUDE NXT System

When used as indicated in conjunction with in-person clinical evaluation, the Latitude NXT system allows for compatible devices to be interrogated remotely which, compared to in-person clinical evaluation alone, may reduce the need for in-person device interrogations. Remote monitoring with LATITUDE NXT allows for earlier evaluation of monitored parameters (including cardiac events and device parameters) as compared to in-person only clinical evaluations.

#### Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (Eudamed) website: <https://ec.europa.eu/tools/eudamed>.

### 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.

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

### 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. (SMS text messages are not available in all geographies.)

Implanted device data and Alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to 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.)

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

**CAUTION:** Misunderstanding of the data presented may result in misdiagnosis of patient condition or device status.

**CAUTION:** Risks of missing or incorrect device data may result in misdiagnosis of patient condition or device status.

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

In Europe, there is a difference in the maximum weighing capacity of the scale depending on type of Communicator: 200 kg (450 lb) when using the WAVE WIRELESS COMMUNICATOR and 150 kg (330 lb) when using the TOUCH-SCREEN WIRELESS COMMUNICATOR.

The Latitude NXT Patient Management System has not been evaluated for pediatric use.

## Adverse Effects

Patients may also experience psychological effects of anxiety related to remote patient monitoring.

## 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.

Do not utilize remote monitoring to replace in-person, non-device clinical evaluation. Changes in patient condition may be missed as a result of reduced patient contact.

LATITUDE provides limited information about the patient and should not be relied upon to confirm the overall health of the patient.

**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:

- **Implanted device clock** – Proper reporting of implanted device data and alert notifications by the LATITUDE NXT System depends on the implanted device clock being programmed accurately with a Programmer/Recorder/Monitor (PRM). Proper reporting may continue to be impacted for some period of

time after the implanted device clock is programmed correctly, depending on the amount of data received with inaccurate time information and the time difference of the implanted device clock error.

- **Patient environment** – To transmit data, the Communicator must be plugged into an electrical outlet. The Communicator must also maintain regular connection with the LATITUDE NXT server. Patients must be within range of the Communicator at the appropriate times. Radio-frequency (RF) interference from 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, 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 (not available in all geographies), the patient must enable hotspot and *Bluetooth*® wireless technology on their mobile device while near their Communicator for at least one hour each day and for manual device interrogations.
- **Communicator memory capacity** – Communicator memory used to store implanted device data may reach its capacity if the Communicator cannot connect to the LATITUDE NXT server for an extended period.
  - If this occurs in a **WAVE WIRELESS COMMUNICATOR**, the Communicator will delete the oldest collected implanted device data that does not contain any Red Alerts from its memory in order to store newly collected implanted device data. If all implanted device data contains Red Alerts, the oldest data is deleted.
  - If this occurs in a **TOUCH-SCREEN WIRELESS COMMUNICATOR**, the oldest collected implanted device data will be deleted from memory in order to store the newly collected implanted device data.
- **Clinician 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.

## 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

### 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 as follows:

See "Communicator Models Per Country" on page 1-6 and "Methods of Connection Per Country and Model (Outside Resident Country)" on page 1-7 for region-specific information.

#### WAVE WIRELESS COMMUNICATOR (Models 6288/6290—availability of models varies by region)

- For cellular connection, all models use a:
  - LATITUDE USB Cellular Adapter.
- For internet connection, all models use the:
  - LATITUDE USB Ethernet Adapter or
  - Hotspot feature on a mobile device (requires USB Accessory Adapter—availability varies by region).
- For standard telephone connection, where available, all models:
  - Support only tone analog dialing mode.



#### TOUCH-SCREEN WIRELESS COMMUNICATOR (Models 6468/6496—availability of models varies by region)

- For cellular connection:
  - Model 6468 uses an external cellular adapter.
  - Model 6496 does not support a cellular connection.
- For internet connection:
  - Does not support an internet connection.
- For standard telephone connection:
  - Supports tone and pulse analog dialing mode.



For additional information, Communicator Details for each model are included in Troubleshooting Guides on the **Help/Contact Us** LATITUDE NXT website. 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 "Device Interrogation" on page 1-14.)
- 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.

### Communicator Models Per Country

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

Country	Touch-Screen Wireless Communicator Models		Wave Wireless Communicator Models	
	6468	6496	6288	6290
Australia and New Zealand		x	x	x
Austria	x		x	x
Belgium	x		x	x
China*				x
Czech Republic	x		x	x
Denmark	x		x	x
Finland	x		x	x
France	x		x	x
Germany	x		x	x
Greece			x	x
Hong Kong				x
Hungary			x	x
Iceland*				x
Ireland (Republic)	x		x	x
Italy	x		x	x
Kuwait*				x
Lebanon*				x
Malaysia*				x
Netherlands	x		x	x
Norway	x		x	x
Poland	x		x	x
Portugal	x		x	x

Table 1-1. Communicator Models Per Country (continued)

Country	Touch-Screen Wireless Communicator Models		Wave Wireless Communicator Models	
	6468	6496	6288	6290
Qatar*				X
Saudi Arabia*			X	X
Singapore*				X
Slovak Republic			X	X
South Africa*				X
South Korea*				X
Spain	X		X	X
Sweden	X		X	X
Switzerland	X		X	X
Thailand*				X
United Arab Emirates*				X
United Kingdom	X		X	X

**NOTE:** Countries shown with an asterisk do not support switch settings for a telephone connection.

**Methods of Connection Per Country and Model (Outside Resident Country)**

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. The following tables are organized by resident country and specify how a Communicator may work outside that resident country. Please contact LATITUDE Customer Support for more information.

**Australia and New Zealand**

Method of Connection	Model 6496	Model 6288	Model 6290
Communicator use in countries outside Australia and New Zealand:			
Standard telephone line	May be restricted due to radio-frequency (RF) laws		Supported in countries that have switch settings for a telephone connection
Cellular data network or internet	Not supported	May be restricted due to RF laws	Allowed

**Europe**

Method of Connection	Model 6468	Model 6288	Model 6290
Communicator use in European Economic Area (EEA) countries outside those listed in Table 1-1 Communicator Models Per Country on page 1-6:			
Standard telephone line		Not supported	
Cellular data network		Allowed	
Internet	Not supported		Allowed
Communicator use in countries outside the EEA: <sup>a</sup>			
Standard telephone line	Not supported	May be restricted due to RF laws	Supported in countries that have switch settings for a

Method of Connection	Model 6468	Model 6288	Model 6290
			telephone connection
Cellular data network	May be restricted due to RF laws		Allowed
Internet	Not supported	May be restricted due to RF laws	

- a. When traveling to a country outside of the EEA, the data transmitted from the Communicator will be subject to laws of that country, which may provide less privacy protection for the patient's data than the laws of the patient's resident country. Please contact LATITUDE Customer Support for specific information about data privacy.

**China, Hong Kong, Iceland, Kuwait, Lebanon, Malaysia, Qatar, Singapore, South Africa, South Korea, Thailand, and United Arab Emirates**

The Model 6290 LATITUDE Communicator is designed to work in China, Hong Kong, Iceland, Kuwait, Lebanon, Malaysia, Qatar, Singapore, South Africa, South Korea, Thailand, and United Arab Emirates but is allowed to be used in other countries as well. Please contact LATITUDE Customer Support for more information.

**Saudi Arabia**

Method of Connection	Model 6288	Model 6290
Communicator use in countries outside Saudi Arabia:		
Cellular data network or internet	May be restricted due to RF laws	Allowed

## LATITUDE Customer Support

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

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

**Table 1-2. LATITUDE Customer Support Telephone Numbers**

Country	Number
Australia	1800 528 488
Austria	0800 202289
Belgium	0800 80697
China	4008801427
Czech Republic	239 016 657
Denmark	70 10 01 82
Finland	010 80 48 19
France	0805 5404 22
Germany	069 51709 481
Greece	442 035 647 788
Hong Kong	852 8105 5433
Hungary	06 80 981 579
Iceland	8004174
Ireland (Republic)	1800 851861
Italy	848 781164
Kuwait	22089688
Lebanon	+961 1 956 777

**Table 1-2. LATITUDE Customer Support Telephone Numbers (continued)**

Country	Number
Malaysia	(603) 7808 8000
Netherlands	0800 0292077
New Zealand	0508 200 886
Norway	81 00 00 47
Poland	22 306 07 33
Portugal	800844729
Qatar	800 6520
Saudi Arabia	1 800 844 8246
Singapore	18006224909
Slovak Republic	02 686 223 89
South Africa	800228000
South Korea	+82-2-3483-1782
Spain	900 806108
Sweden	020 160 57 07
Switzerland	0844 000110
Thailand	1800012420
United Arab Emirates	800035770015
United Kingdom	0800 678 16 44

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. Sensors are not available in all geographies.

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

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

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

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

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

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

In Europe, there is a difference in the maximum weighing capacity of the scale depending on type of Communicator: 200 kg (450 lb) when using the WAVE WIRELESS COMMUNICATOR and 150 kg (330 lb) when using the TOUCH-SCREEN WIRELESS COMMUNICATOR.

## 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 created for the efficient management of patients. For example, patient groups can be organized by physician and/or location. 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, if applicable, 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

There are three types of privilege levels assigned to clinic users that control access to patient data, described as follows. 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 users and patients. Access is open to all patients in all Patient Groups. User accounts can be created by the Clinic Account Manager.

Table 1-3. 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 Patient Groups	✓		
Add/Manage clinic users	✓		
Enroll/Manage patients	✓	✓	
Manage schedule and alert configurations	✓	✓	
View patients on the <b>View Patient List</b> page	✓	✓	✓
Dismiss patients on the <b>View Patient List</b> page	✓	✓	
View patient data and reports <sup>a</sup>	✓	✓	✓
Edit EMR integration configuration	✓		
Send data to EMR	✓	✓	

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

## Alerts

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

There are two levels of alert conditions: Red Alerts and Yellow Alerts. 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 the clinic to inform them 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 > programmed amplitude or suspended<sup>1</sup>
- Left ventricular intrinsic amplitude out of range
- Left ventricular pacing lead impedance out of range
- Left ventricular automatic threshold detected as > programmed amplitude or suspended<sup>1</sup>
- Atrial intrinsic amplitude out of range
- Atrial pacing lead impedance out of range
- Atrial automatic threshold detected as greater than programmed amplitude or suspended<sup>1</sup>
- 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.

- 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.

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.

- Cardiac Resynchronization Therapy pacing percentage (< 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 (> 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)
- Signal Artifact Monitor (SAM) device diagnostic

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)
- SMART Pass Disabled

## Device Interrogation

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

Table 1-4. Data Collection and Configuration Details for Each Interrogation Type

Interrogation Type	Full Interrogation (with Presenting EGM/S-ECG) <sup>a</sup>	Full Interrogation (with no Presenting EGM)	Red Alert Check	Yellow Alert Check	Configuration Details
Remote Scheduled Follow-ups	✓		✓	✓	<ul style="list-style-type: none"> <li>• Off/Manual</li> <li>• 1 week</li> <li>• 2 weeks</li> <li>• Monthly intervals from 1 to 12 months</li> <li>• Automatic except for S-ICD patients, for whom it is prompted</li> </ul>
Alert Check <sup>b</sup> (not available for S-ICD patients)	If Red or Yellow Alert is detected <sup>b</sup>		✓	✓ WAVE WIRELESS COMMUNICATOR only	<ul style="list-style-type: none"> <li>• Daily</li> <li>• Not configurable</li> </ul>
Data Updated Interrogation <sup>b</sup> WAVE WIRELESS COMMUNICATOR only	✓		✓	✓	<ul style="list-style-type: none"> <li>• A recent PRM interrogation has occurred<sup>b</sup> or</li> <li>• Sensors assigned and no full interrogation in seven days<sup>b</sup> or</li> </ul>

Table 1-4. Data Collection and Configuration Details for Each Interrogation Type (continued)

Interrogation Type	Full Interrogation (with Presenting EGM/S-ECG) <sup>a</sup>	Full Interrogation (with no Presenting EGM)	Red Alert Check	Yellow Alert Check	Configuration Details
					<ul style="list-style-type: none"> <li>HeartLogic feature enabled and no full interrogation in seven days<sup>b</sup> or</li> <li>HeartLogic Index Alert detected within the past seven days and Daily Alert Interrogations are configured On<sup>b</sup></li> </ul>
<b>Weekly Implanted Device Alert Monitoring<sup>b</sup></b> WAVE WIRELESS COMMUNICATOR, Model 6290, S-ICD patients only	If Red or Yellow Alert is detected <sup>b</sup>		✓	✓	<ul style="list-style-type: none"> <li>Weekly</li> <li>Configurable</li> <li>Prompted</li> </ul>
<b>Weekly Implanted Device Alert Monitoring</b> TOUCH-SCREEN WIRELESS COMMUNICATOR only	If Red Alert is detected <sup>b</sup>	✓	✓	✓	<ul style="list-style-type: none"> <li>Weekly</li> <li>Configurable</li> </ul>
<b>Patient Initiated Interrogations</b> (See "Patient Initiated Interrogations" on page 1-16.)	✓		✓	✓	As directed by clinician

- 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.
- NOTE:** Only S-ICD MRI devices will be able to be interrogated remotely in MRI Mode.
- b. WAVE WIRELESS COMMUNICATOR only: If any of the following are detected during an Alert Check (or during **Weekly Implanted Device Alert Monitoring** for an S-ICD), the Communicator will also attempt to collect a full interrogation with presenting EGM/S-ECG:
1. A Red or Yellow Implanted Device Alert, or
  2. A recent PRM (Programmer/Recorder/Monitor) interrogation, or
  3. No full interrogation has occurred within the past seven days (for patients with assigned sensors), or
  4. No full interrogation has occurred within the past seven days (for patients with HeartLogic feature enabled), or
  5. 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. For the WAVE WIRELESS 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. 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.

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, it will take effect 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. 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.

## USING THE LATITUDE NXT PATIENT MANAGEMENT SYSTEM

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### 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 2-12
- "System Setup" on page 2-14
- "Managing Patients" on page 2-14
- "Managing Patient Groups" on page 2-15
- "Managing User Accounts" on page 2-16
- "Passwords" on page 2-17
- "EMR System Integration" on page 2-19
- "Troubleshooting" on page 2-23

## 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.

## Mobile Application

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

For more information, from your iPhone navigate to:

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

## Requirements

The LATITUDE website was developed to support the following internet browsers<sup>1</sup>:

- 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.

- Microsoft Edge internet browser
- Mozilla Firefox™ internet browser
- Apple™ Safari™ on the Mac™, iPad™, and iPhone™ internet browsers
- Google Chrome™ browser

If using an unsupported browser, the LATITUDE website may not 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 website by doing the following:

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

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

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

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



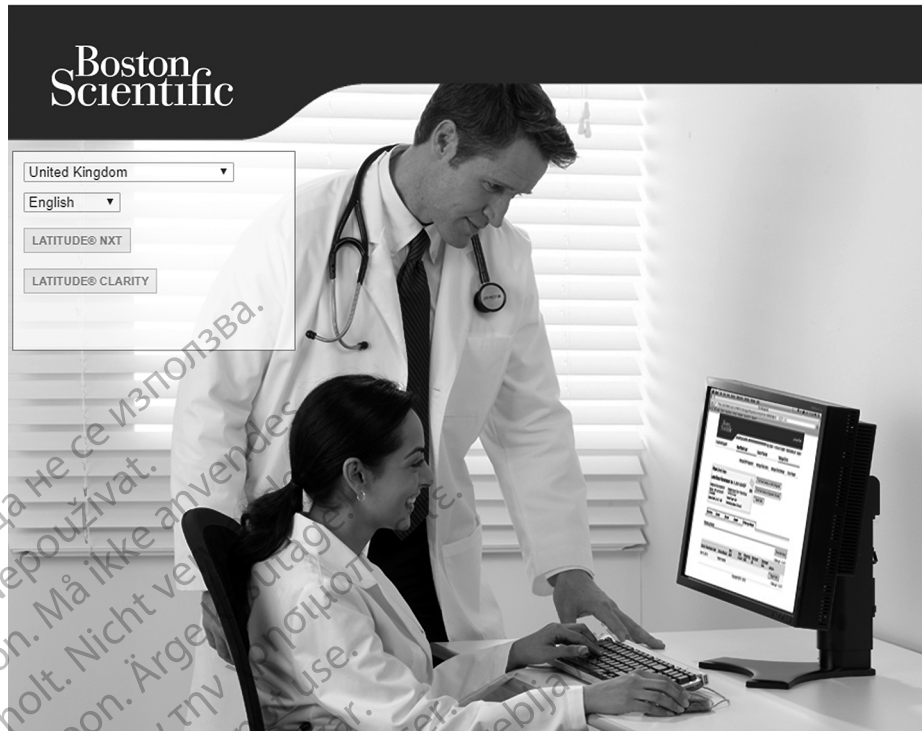


Figure 2-1. LATITUDE Initial Access Page

2. The first time you access the LATITUDE 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** or **LATITUDE Clarity** button to display the login page shown in the following figure.



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

Figure 2-2. Login Page

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

**NOTE:** Clicking the link for LATITUDE Customer Support provides a list of phone numbers to call for help.

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

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

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

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

**NOTE:** TFA authentication, as well as SMS text message and email, may not be available in all geographies.

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

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

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

## Navigating the Site

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

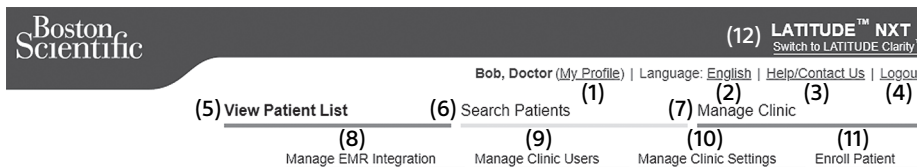


Figure 2-3. LATITUDE NXT System Banner

Table 2-1. Navigating the Site

(1)	<b>My Profile</b>	Links to the <b>Update Clinic User</b> page for the current user.
(2)	<b>Language</b>	Displays selected language; links to the <b>Update Clinic User</b> page for the current user where the selected language can be changed.
(3)	<b>Help/ Contact Us</b>	Links to contact information, troubleshooting guides, and other resources. (See "Troubleshooting" on page 2-23.)
(4)	<b>Logout</b>	Ends the user's session.
(5)	<b>View Patient List</b>	Links to a page that provides a list of patients to which the current user has access. (See Figure 2-4 View Patient List Page on page 2-8.)
(6)	<b>Search Patients</b>	Links to the <b>Search Patients</b> page. <b>NOTE:</b> <i>Not available in Norway.</i>
(7)	<b>Manage Clinic</b>	Displays clinic-related action links 8-11.
(8)	<b>Manage EMR Integration</b>	Links to a page that enables clinicians to configure integration with their clinic's electronic medical record (EMR) system, access and download necessary software for EMR integration, and view the export status of their EMR files. (See "EMR System Integration" on page 2-19.)
(9)	<b>Manage Clinic Users</b>	Links to a list of clinic users and associated configuration information. (See "Managing User Accounts" on page 2-16.)
(10)	<b>Manage Clinic Settings</b>	Links to clinic and Patient Group demographics and membership and associated configuration information. (See "Managing Patient Groups" on page 2-15.)
(11)	<b>Enroll Patient</b>	Links to enrollment form that enables clinicians to enroll new patients. (See "Enrolling New Patients" on page 2-13.)
(12)	<b>LATITUDE NXT Switch to LATITUDE Clarity</b>	Links to <b>All Patient Groups</b> page of LATITUDE Clarity website.

## 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

<b>Patient Groups</b>	<b>Manage Clinic ⇒ Manage Clinic Settings</b>
	<b>Edit/View Patient Group Defaults</b> <ul style="list-style-type: none"> <li>• <b>Remote Scheduled Follow-ups</b></li> <li>• <b>Weekly Implanted Device Alert Monitoring</b></li> <li>• <b>Patient Initiated Interrogations</b></li> <li>• <b>Alert Configuration</b></li> <li>• <b>Additional Alert Notification</b> (SMS text and email messages) (SMS text messages not available in all geographies)</li> </ul>

Table 2-3. Individual Patient Configuration

<b>Individual Patient</b>	<b>View Patient List ⇒ Patient Summary Page</b> (click patient's name)
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Table 2-3. Individual Patient Configuration (continued)

	<b>Edit/View Schedule and Alert Configuration</b> <ul style="list-style-type: none"> <li>• <b>Next Scheduled Remote Follow-up</b></li> <li>• <b>Remote Scheduled Follow-ups</b></li> <li>• <b>Weekly Implanted Device Alert Monitoring</b> (availability dependent on type of implanted device and model of Communicator)</li> <li>• <b>Patient Initiated Interrogations</b></li> <li>• <b>Alert Configuration</b></li> </ul>
	<b>Edit/View Patient and Equipment Information</b> <ul style="list-style-type: none"> <li>• <b>General Information</b></li> <li>• <b>Implanted Device</b></li> <li>• <b>Patient Group Membership</b></li> <li>• <b>Equipment</b></li> </ul>

## Configuration Details

### Saving Settings

You must 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 1-16.

### Additional Alert Notification

**Additional Alert Notification** is available through text (SMS) and email messages. (SMS text messages are not available in all geographies.) These reminders can only be configured at the Patient Group level. They can be configured for **Red 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 a day, 7 days a week** or **Custom Business Hours (except Holidays)**. If **Custom Business Hours (except Holidays)** is selected, holidays may be excepted by clicking **Add Holiday** and entering the **Holiday Name** and **Date**. 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 as follows) is the first page displayed after logging on to the LATITUDE NXT website. The numbers in the figure refer to the numbered items below the figure. 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.



**LATITUDE™ NXT**  
Switch to LATITUDE Clarity™

Bob, Doctor (My Profile) | Language: English | [Help/Contact Us](#) | [Logout](#)

**View Patient List**
Search Patients
Manage Clinic

---

View Patient List

Viewing Patient Group: All Patient Groups (1)

All Patients (11) | [For Review](#) (4) | [Missed Follow-up](#) (1) | [Not Monitored](#) (6) | [Not Scheduled](#) (8) (2)

[Show More](#)  
View Patient List 1 - 11 of 11

Patient ID/ Patient/ Device	Review Status	Latest Device Transmission	Alerts	Review Reason	Next Remote Follow- up	Monitoring Status/ Date	Actions
<input type="checkbox"/> pid92074 Hill, Landon INCEPTA CRT-D P162	New Data	11 Oct 2019	None	LATITUDE Consult™ System	None	Monitored	<input checked="" type="button" value="Dismiss From Review List"/> <input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid39546 Hughes, Leah ACCOLADE L300	New Data	14 Oct 2019	None	Multiple Reasons	None	Monitored	<input checked="" type="button" value="Dismiss From Review List"/> <input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid746761 Martinez, Jason RESONATE ELICD D420	N/A	None	None	N/A	None	Communicator Not Setup 15 Oct 2019	<input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid353268 Phillips, Gavin PERCIVA MINI ICD D418	N/A	None	None	N/A	15 Oct 2020	Communicator Not Setup 15 Oct 2019	<input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid454631 Scott, Zoe AUTOGEN X4 CRT-D R1G177	N/A	None	None	N/A	None	Communicator Not Setup 15 Oct 2019	<input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid862438 Smith, Anna PERCIVA HF ICD D512	New Data	15 Oct 2019	None	Scheduled	None	Monitored	<input checked="" type="button" value="Dismiss From Review List"/> <input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid52074 Stewart, Liam RESONATE HF CRT-D G324	Dismissed	15 Aug 2019	None	N/A	Missed 13 Oct 2019	Monitored	<input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid194598 Turner, Kevin ENERGEN ICD F143	New Data	11 Oct 2019	None	Patient Initiated	None	Monitored	<input checked="" type="button" value="Dismiss From Review List"/> <input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid433599 Watson, Olivia INOGEN CRT-D G141	N/A	None	None	N/A	None	Communicator Not Setup 15 Oct 2019	<input type="button" value="Reports Menu"/>

Figure 2-4. View Patient List 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 Groups:
  - **All Patients** – Lists all patients in the selected Patient Groups. 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**, 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 have not completed their remote scheduled follow-up. 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 ID/Patient/Device**

Click on the patient's ID 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**
- **Implanted Device Alert**
- **Multiple Reasons**

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

- **Next Remote Follow-up**

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

- **Monitoring Status/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 1-8 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.

Multiple individual reports may be printed at one time. If attempting to print more than the maximum number of reports allowed, the system will advise 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
- Event Detail Report
- Device Settings Report

Select one or more reports, then click **GENERATE REPORT(S)**.

The Quick Notes/S-ICD Summary, Combined Follow-up, Presenting EGM/S-ECG, Atrial Arrhythmia, 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 who generated the reports 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

**NOTE:** This feature is not available in Norway. Accordingly, the **Search Patients** menu item will not be visible on the LATITUDE NXT website to clinicians in Norway.

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.

**Search Patients**

**Patient Data**

Last Name:  First Name:  Patient ID:

Date of Birth:  Model:  Lead/Electrode/ICM/CRM Pacemaker Model:

dd/mm/yyyy -Select Model- Patient Group:

Search Tags:  -Select Patient Group-

**Next Remote Follow-up Information**

From:  To:

dd/mm/yyyy dd/mm/yyyy

Use Exact Match

Patient ID/ Patient/ Device	Review Status	Latest Device Transmission	Alerts	Review Reason	Next Remote Follow-up	Monitoring Status/ Date	Actions
<input type="checkbox"/> pid746761 Martinez, Jason RESONATE EL ICD D420	N/A	None	None	N/A	None	Communicator Not Setup 15 Oct 2019	<input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid454631 Scott, Zoe AUTOGEN X4 CRT-D R1G177	N/A	None	None	N/A	None	Communicator Not Setup 15 Oct 2019	<input type="button" value="Reports Menu"/>
<input type="checkbox"/> pid194598 Turner, Kevin ENERGEN ICD F143	New Data	11 Oct 2019	None	Patient Initiated	None	Monitored	<input type="button" value="Dismiss From Review List"/> <input type="button" value="Reports Menu"/>
<input type="checkbox"/> 12345678 DYNAGEN X4 CRT-D G158	N/A	None	None	N/A	20 Jan 2020	Communicator Not Setup 15 Oct 2019	<input type="button" value="Reports Menu"/>

Figure 2-5. Search Patients Tool

## 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.

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

## 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.

**Figure 2-6. Enroll Patient Page**

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.

**Completion of patient enrollment in the LATITUDE NXT System requires the Communicator model and serial number.** During patient enrollment, the clinic user enters the model and serial number of the patient's Communicator.

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

## Ordering and Distributing Equipment

Clinics can order Communicators, weight scales, and blood pressure monitors by contacting LATITUDE Customer Support. Model and serial numbers are entered at enrollment but may be updated later through the **Edit/View Patient and Equipment Information** pages.

Clinics can also order cellular or internet adapters by contacting LATITUDE Customer Support. 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.

**NOTE:** *Patients in Norway who were previously enrolled may not always be able to be enrolled in a new clinic, and their existing data may not be available to a new clinic. Call LATITUDE Customer Service for assistance. See "LATITUDE Customer Support" on page 1-8.*

## 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](http://www.bostonscientific-elabeling.com).

## SYSTEM SETUP

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 on the **Edit/View Patient and Equipment Information** page by clicking the patient's name on the **View Patient List** page. Update of some data is restricted to users in the primary clinic.

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

**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.

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 new clinic enrolls a patient, the user in the previous clinic will see an indication that the patient is being followed by a different clinic. Once the user in the new clinic 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 previous clinic. They will not see any follow-up or alert history from the previous clinic.

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

**NOTE:** *Patients in Norway cannot always be transferred from an existing clinic to a new clinic. Contact LATITUDE Customer Support for assistance.*

## 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.

**NOTE:** *Clinics are responsible for unenrolling patients if a clinic is no longer in practice. If a clinic dissolves, Boston Scientific personnel may contact patients enrolled in that clinic.*

## MANAGING PATIENT GROUPS

The list of existing Patient Groups can be viewed via **Manage Clinic > Manage Clinic Settings**. Clinic users only see the Patient Groups to which they are assigned.

## Adding Patient Groups

A Clinic Account Manager can add a Patient Group by selecting the **Add Patient Group** button 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 the **Edit/ View Demographics and User Membership** button associated with a Patient Group on the **Manage Clinic Settings** page. Then click the **Remove Patient Group** button.

## Other Patient Group Management Functions

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

- **Edit/View Patient Group Defaults** – selecting this button associated with a Patient Group allows clinic users to manage **Remote Scheduled Follow-ups, Weekly Implanted Device Alert Monitoring, Patient Initiated Interrogations,** and **Alert Configuration.**
- **Edit/View Demographics and User Membership** – selecting this 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.
- **Edit/View Clinic Demographics** – selecting this button allows clinic users to update **General Information,** including a check box selection for **User passwords expire every 180 days, Contact Information,** and whether to include **Clinic Name in Alert Notification.**

## MANAGING USER ACCOUNTS

Clinic Account Managers have access to all account management functions for each clinic user (except themselves) via **Manage Clinic > Manage Clinic Users > Edit/View Demographics and Access Settings** button > **Update Clinic User** page. The Clinic Account Manager can access their own **Update Clinic User** page by clicking the **My Profile** link associated with their name at the top of every page on the LATITUDE website.

## 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.

## Update Clinic User Page

Additional account management functions are available for both the Clinic Account Manager and clinic user on the **Update Clinic User** page.

- The Clinic Account Manager can access this page by selecting **Manage Clinic > Manage Clinic Users**, then selecting the **Edit/View Demographics and Access Settings** button associated with a user.
- A clinic user can access the **Update Clinic User** page by clicking **My Profile**, associated with their name at the top of every page.

The following table shows the functions available on the **Update Clinic User** page:

Function	Description	Clinic Account Manager For All Clinic Users (Except Themselves)	Clinic User (and Clinic Account Manager via My Profile)
User Information	Includes name, phone number, and e-mail address.	X	X
Website Language and Country	Can also be changed on the login page. See "Logging In and Out" on page 2-2.		X
Login Information, User ID and Password	Change User ID	X	X
	Reset Password <ul style="list-style-type: none"> <li>• If a user forgets their password, this function can be used by the Clinic Account Manager to assign a temporary password. Clicking the <b>Reset Password</b> link assigns a temporary password and displays it in a pop-up window. The user will use the temporary password at the next login attempt but then will be required to create a new password.</li> </ul>	X	
	Change Password		X
Login Information, Security	View/Edit Security Questions		X
Login Information, Security	Get Two Factor Verification Code – (not available in all geographies) If two factor authentication is required, the Clinic Account Manager may create a one-time verification code for a clinic user to use at their next login, which must be within 10 minutes. The link to create the verification code is in the <b>Login Information / Security</b> section. Also see "Logging In and Out" on page 2-2.	X	
Access Settings	Provides ability to assign <b>Privileges</b> and <b>Assigned Patient Groups</b> .	X	
Heart Failure Patient View	Provides check box to <b>Enable Heart Failure Patient View</b> , which sends the user directly to the Health tab when selecting the patient name from the <b>View Patient List</b> page.	X	X

## PASSWORDS

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

A Clinic Account Manager can designate whether passwords expire 180 days after being issued or never expire via **Manage Clinic > Manage Clinic Settings > Edit/View Clinic Demographics** page. A user's account is locked after six consecutive login attempts with an incorrect password (or verification code in Europe). 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 "Update Clinic User Page" on page 2-17 and "Resetting Your Forgotten Password" on page 2-18.

**NOTE:** Passwords expire three months after being issued in Italy.

## 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 gives 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.

**NOTE:** In Italy, temporary passwords expire three months after being issued.

## Security Questions

A clinic user is prompted to change their password the first time they log in with their temporary password. The clinic user must enter answers to three selected security questions.

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

## Changing Your Password

A clinic user can change their own password by clicking the **My Profile** link associated with their name at the top of every page on the LATITUDE website, and then by clicking the **Change Password** link in the **Login Information** section. Enter the old and new passwords as shown in the following figure. Click the **Save and Close** button. The new password will take effect at the next login.

**Boston Scientific** LATITUDE™ NXT  
Switch to LATITUDE Clarity™

Bob, Doctor (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 2-7. Change Password

## Resetting Your Forgotten Password

If a clinic user forgets their password or their login account is locked, the password can be reset any time by using the **Forgot Password?** link (shown in the following figure). An answer to one of the security questions is required in order to reset the password. The Clinic Account Manager may also reset a password.



Figure 2-8. Forgot Password? Link

## EMR SYSTEM INTEGRATION

The optional LATITUDE Electronic Medical Record (EMR) system integration feature, if enabled, provides an automated way to export patient device data to a clinic's internal EMR application. Clinicians may want to refer to the Implantable Device Cardiac Observation (IDCO) integration specification of Boston Scientific for details on how device data are converted into IDCO messages, which are used to deliver patient data to the EMR application.

The data may 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).
- Exports patient data, as configured, to your EMR application each time a patient appears on the **For Review** list, except for a weight change. The data provided is associated with **Implanted Device Alerts**, **Remote Scheduled Follow-ups**, and **Patient Initiated Interrogations**.
- Selects the data format for your EMR application.
- Displays details of each data export including time stamps and export status.
- Allows you to resend EMR data.

### NOTES:

- The LATITUDE NXT System only exports EMR files when the **Enable EMR Integration** checkbox on the LATITUDE NXT website is selected. The system does not create or export EMR files for patient interrogation data received while EMR is not enabled. Refer to "Setting Up EMR Integration" on page 2-20.
- Connection difficulties may delay or prevent EMR file delivery to the EMR application. The LATITUDE NXT System is the system of record for remote patient management. Clinicians should not rely on the presence of data in the EMR application to determine if a remote follow-up or **Implanted Device Alert** has occurred.
- An EMR data export is not performed for a weight alert. Sensor measurements are not exported.

- Any changes to data from within the EMR application will not change data in the LATITUDE NXT System.
- Some EMR applications may not directly import LATITUDE NXT data. You or your EMR vendor may have to provide additional software to import LATITUDE NXT data into your EMR application. Technical information is located separately in the Boston Scientific IDCO and HL7 integration specification documents.
- If an attempt to export an EMR file fails, the LATITUDE NXT System continues to attempt to export the file to your EMR application for up to 30 days. The LATITUDE NXT System will then discontinue the attempt to export the EMR file and report a **Failed** status. If this occurs, you may resend the data using the **Resend** button.

## Setting Up EMR Integration

The LATITUDE EMR integration feature must be enabled and configured before EMR files can be exported to a clinic's internal EMR application.

### Installing, Configuring, and Registering EMR Integration Software

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

Complete the following steps to install the EMR integration software (numbers in the figures refer to the related step):

1. Navigate to the **Manage EMR Integration** page from the **Manage Clinic** drop-down list.
2. Click the **Edit/View EMR Configuration** button.

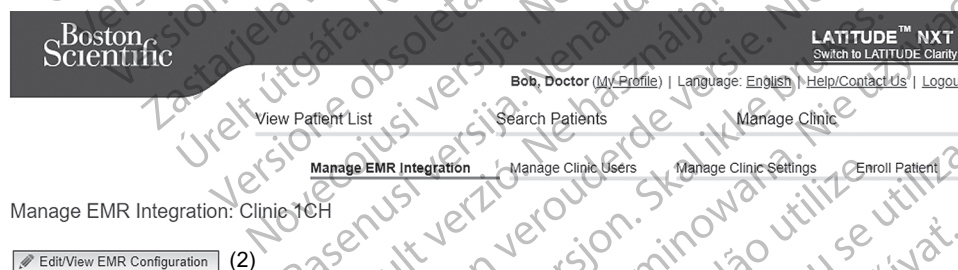


Figure 2-9. Edit/View EMR Configuration Button

3. Press the applicable toggle key for **LATITUDE NXT Output** or **LATITUDE Clarity Output**:

**Boston Scientific** **LATITUDE™ NXT**  
Switch to LATITUDE Clarity™

Bob, Doctor (My Profile) | Language: English | Help/Contact Us | Logout

View Patient List    Search Patients    Manage Clinic

---

Edit/View EMR Configuration: Clinic 1GB

EMR Configuration Last Updated By

For information to be transferred to your EMR, LATITUDE™ EMR Integration Client Software must be installed on your EMR system then must be enabled below.  
To download the LATITUDE™ EMR Integration Client Software, click here (5)

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.

LATITUDE™ NXT Output (8)	LATITUDE Clarity™ Output (8)												
<p><b>ENABLE</b> (3) <input checked="" type="checkbox"/> On</p> <p>EMR/CIS Clinic Identifier: sapid1gb-5687846576</p> <p>EMR Integration Format: Please Select Your EMR System (data format) (9)</p> <p>Maximum Output File Size: 50 MB</p> <p><b>When to Send Data</b></p> <p><input checked="" type="checkbox"/> Upon arrival <i>Note: Turning this off will require manual action to send data.</i></p> <p><b>Report Configuration</b></p> <p><input type="checkbox"/> Include PDF reports</p> <p><input type="checkbox"/> Combine all reports into a single PDF</p>	<p><b>ENABLE</b> (3) <input checked="" type="checkbox"/> On</p> <p>EMR/CIS Clinic Identifier: Select clinic identifier (4)</p> <p>EMR Integration Format: IDCO (IHE PCD-09 revision 2.0) (9)</p> <p>Maximum Output File Size: 50 MB</p> <p><b>When to Send Data</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Reason</th> <th>When to Send</th> </tr> </thead> <tbody> <tr> <td>Scheduled</td> <td>select option</td> </tr> <tr> <td>Daily w/ Alert</td> <td>select option</td> </tr> <tr> <td>Patient Initiated</td> <td>select option</td> </tr> <tr> <td>Clinic Interrogation</td> <td>select option</td> </tr> <tr> <td>Data Updated</td> <td>select option</td> </tr> </tbody> </table> <p><b>Report Configuration</b></p> <p><input checked="" type="checkbox"/> Include PDF reports</p> <p><input type="checkbox"/> Combine all reports into a single PDF</p> <p>Select which reports to include in PDF(s):</p> <p><input checked="" type="checkbox"/> Follow-up Report</p> <p><input checked="" type="checkbox"/> Event Detail Reports</p> <p><input checked="" type="checkbox"/> Presenting S-ECG Report</p> <p><b>Additional Report Options:</b></p> <p><input checked="" type="checkbox"/> Include Trends and Histograms with Follow-up Reports</p> <p><input checked="" type="checkbox"/> For Event Detail Reports with "Symptom + Device Detected" events, trim S-ECG to display only the portion from the device detected event</p>	Reason	When to Send	Scheduled	select option	Daily w/ Alert	select option	Patient Initiated	select option	Clinic Interrogation	select option	Data Updated	select option
Reason	When to Send												
Scheduled	select option												
Daily w/ Alert	select option												
Patient Initiated	select option												
Clinic Interrogation	select option												
Data Updated	select option												

(10) Save and Close Close Without Saving

Figure 2-10. Edit/View EMR Configuration Page

4. For **LATITUDE Clarity Output**, select a clinic identifier from the **Select clinic identifier** drop-down list.
  - If you want the exports to go to the same output location as LATITUDE NXT, select the first identifier, which should be identical to the **EMR/CIS Clinic Identifier** shown in the **LATITUDE NXT Output** section.
  - If you want the exports to go to a separate output location from LATITUDE NXT output, select the second identifier.

Record the **EMR/CIS Clinic Identifier** identifier for the desired output.

**Important:** The identifier is required to complete the registration of the EMR integration client software. The identifier is used to route LATITUDE clinic records to the clinic's EMR application.

5. Click the **click here** link to download the EMR integration software.
6. You are then directed away from LATITUDE to a website for the EMR integration software that needs to be installed. Follow the installation and setup instructions available on this website.
7. Before enabling EMR Integration, complete installation and registration of the software.

**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.

#### Enabling EMR Integration for LATITUDE

8. Return to the **Edit/View EMR Configuration** page and press the toggle key to enable EMR integration.
9. Select the appropriate **EMR Integration Format** from the drop-down list. The format selected must be appropriate for your EMR application. Supported formats are listed in the drop-down list.
10. Click the **Save and Close** button.

**Notice:** By enabling EMR, 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 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.

Clicking the **Last Updated By** link at the top of the page 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 in the bottom section of the **Manage EMR Integration** page (shown as follows) lists EMR files for which EMR transmission applies. 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.

The log may optionally be filtered by entering dates in one or both date fields of the **Filter by Device Transmission Date** section and then clicking the **Filter** button.

**Filter by Device Transmission Date**

From:  (e.g.: 24/01/1950) To:  (e.g.: 24/01/1950)

View EMR Log 1 - 25 of 29  
[Next >](#) [Last >>](#)

Patient Info	Reason	Device Transmission Date	Status	Status Date/Time	Actions
Kelly, Anna ID: pid164502	Patient Initiated	13 Sep, 2019	<a href="#">Initiated</a>	13 Sep, 2019 15:36 CET	<input type="button" value="Send to EMR"/>
Kelly, Anna ID: pid164502	Patient Initiated	13 Sep, 2019	<a href="#">Initiated</a>	20 Sep, 2019 15:37 CET	<input type="button" value="Send to EMR"/>
Bell, Ethan ID: pid769219	Alerts	26 Aug, 2019	<a href="#">Transferred</a>	20 Sep, 2019 11:54 CET	<input type="button" value="Send to EMR"/>

**Figure 2-11. View EMR Log Window**

The EMR log is sorted by **Device Transmission Date**. The following table provides a description of each column of the **View EMR Log** window:

Column	Description
<b>Patient Info</b>	Provides a list of patient names and identifiers for whom EMR transmission applies.
<b>Reason</b>	Provides the reason that the EMR export was initiated. Options are: <ul style="list-style-type: none"> <li>• <b>Scheduled</b></li> <li>• <b>Alerts</b></li> <li>• <b>Patient Initiated</b></li> <li>• <b>Data Updated</b></li> </ul>
<b>Device Transmission Date</b>	Provides the date the device interrogation associated with the EMR file was initiated.
<b>Status</b>	<ul style="list-style-type: none"> <li>• Provides the current status of the export.</li> <li>• Clicking the status link opens an EMR history pop-up window that provides detailed information of the export processes for that EMR export.</li> <li>• The options for <b>Status</b> are: <ul style="list-style-type: none"> <li>• <b>Initiated</b> – The EMR export has been initiated.</li> <li>• <b>Waiting for Clinic Computer</b> – 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 the IT professional responsible for monitoring EMR integration software or EMR application.</li> <li>• <b>Transferred</b> – The EMR file has been successfully exported.</li> <li>• <b>Manual Send</b> – An export attempt of the EMR file has been requested.</li> <li>• <b>Failed</b> – 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.</li> <li>• <b>Not Initiated</b> – The EMR export has not been initiated based on the EMR export configuration settings.</li> <li>• <b>Dismissed</b> – The EMR export attempt of the EMR file has been initiated due to patient dismissal.</li> </ul> </li> <li>• Refer to the troubleshooting section of the installation instructions document available on the LATITUDE EMR Integration software (EMR client) webpage for help with diagnosing and troubleshooting failures.</li> </ul>
<b>Status Date/Time</b>	Provides the date and time of the last change in status.
<b>Actions</b>	If EMR is enabled, provides an active <b>Send to EMR</b> button. If EMR is not enabled, the button is inactive.

## 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 1-8.

Остаряла версия. Да не се използва.  
Zastaralá verze. Nepoužívat.  
Forældet version. Må ikke anvendes.  
Version überholt. Nicht verwenden.  
Version outdated. Μην την χρησιμοποιείτε.  
Αεγονud versioon. Ärge kasutage.  
Παλιά έκδοση. Μην την χρησιμοποιείτε.  
Outdated version. Do not use.  
Version obsoleta. Ne utilizar.  
Version périmée. Ne pas utiliser.  
Zastarjela verzija. Nemojte upotrebljavati.  
Úreлт útgáfa. Notið ekki.  
Versione obsoleta. Non utilizzare.  
Pasenusi versija. Neizmantot.  
Elavult verzió. Ne használd!  
Dit is een verouderde versie. Niet gebruiken.  
Wersja przeterminowana. Nie używać.  
Versão expiratã. Não utilize.  
Zastaraná verzia. Nepoužívat.  
Zastarela različica. Ne uporabite.  
Vanhentunut versio. Älä käytä.  
Föråldrad version. Använd ej.  
Güncel olmayan sürüm. Kullanmayın.

# SYMBOLS

## APPENDIX A

Table -1. Explanation of Symbols

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Australian sponsor address

Остаряла версия. Да не се използва.  
 Zastaralá verze. Nepoužívat.  
 Forældet version. Må ikke anvendes.  
 Version überholt. Nicht verwenden.  
 Version obsolete. Άργε kasutage.  
 Παλιά έκδοση. Μην την χρησιμοποιείτε.  
 Outdated version. Do not use.  
 Versión obsoleta. Ne utilizar.  
 Version périmée. Ne pas utiliser.  
 Zastarjela verzija. Neizmantot.  
 Úreлт útgáfa. Notið ekki.  
 Versiune obsolete. Nemojте upotrebljavati.  
 Pasenusi versija. Non utilizzare.  
 Elavult verzió. Ne használd.  
 Dit is een verouderde versie. Niet gebruiken.  
 Utdatert versjon. Nenaudokite.  
 Wersja przeterminowana. Nie używać.  
 Versão obsoleta. Não utilize.  
 Versiune expirată. A nu se utiliza.  
 Zastaraná verzia. Nepoužívať.  
 Zastarela različica. Ne uporabite.  
 Vanhentunut versio. Älä käytä.  
 Föråldrad version. Använd ej.  
 Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.  
Zastaralá verze. Nepoužívat.  
Forældet version. Må ikke anvendes.  
Version überholt. Nicht verwenden.  
Version outdated. Μην την χρησιμοποιείτε.  
Παλιά έκδοση. Μην την χρησιμοποιείτε.  
Outdated version. Do not use.  
Version obsoleta. Ne utilizar.  
Version périmée. Ne pas utiliser.  
Zastarjela verzija. Nemojte upotrebljavati.  
Úrejt útgáfa. Notið ekki.  
Versione obsoleta. Non utilizzare.  
Pasenusi versija. Neizmantot.  
Elavult verzió. Ne használja!  
Wersja przeterminowana. Niet gebruiken.  
Dit is een verouderde versie. Niet gebruiken.  
Utdatert versjon. Skal ikke brukes.  
Versão obsoleta. Não utilize.  
Versiune expirată. A nu se utiliza.  
Zastaraná verzia. Nepoužívať.  
Zastarela različica. Ne uporabite.  
Vanhentunut versio. Älä käytä.  
Föråldrad version. Använd ej.  
Güncel olmayan sürüm. Kullanmayın.



Остаряла версия. Да не се използва.  
Zastaralá verze. Nepoužívát.  
Forældet version. Må ikke anvendes.  
Version überholt. Nicht verwenden.  
Aegunud versioón. Myn þyn Χρησιμοποιείτε.  
Παλιά έκδοση. Μην την Χρησιμοποιείτε.  
Outdated version. Do not use.  
Version obsoleta. No utilizar.  
Zastarjela verzija. Nemojte upotrebljavati.  
Úrelt útgáfa. Notið ekki.  
Versione obsolete. Non utilizzare.  
Zastarjela verzija. Neizmantot.  
Novcojusi versija. Nenaudokite.  
Pasenusi versija. Ne használja!  
Elavult verzió. Ne használja!  
Dit is een verouderde versie. Niet gebruiken.  
Utdatert versjon. Skal ikke brukes.  
Wersja przeterminowana. Nie używać.  
Versão expiratã. A nu se utiliza.  
Zastaraná verzia. Nepoužívát.  
Zastarela različica. Ne uporabite.  
Vanhentunut versio. Älä käytä.  
Föråldrad version. Använd ej.  
Güncel olmayan sürüm. Kullanmayın.



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