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LATITUDE PATIENT MANAGEMENT INTRODUCTION

The LATITUDE™ Patient Management system enables physicians to periodically monitor patient and device status remotely (See “Alerts” on page 7 for device conditions that are monitored).

Data collected from the implanted device at times scheduled by the physician are combined with responses to symptom questions and data from an optional weight scale or blood pressure monitor. By combining these internal and external measurements with historical information, physicians can use the LATITUDE system to develop an informed understanding of the patient's implanted device and health status. Clinicians can periodically monitor devices remotely and bring patients into the office when appropriate.

Intended Use

The LATITUDE Patient Management system is intended to remotely communicate with a compatible Boston Scientific pulse generator (PG) and transfer data to a central database. The LATITUDE system provides patient data that can be used as part of the clinical evaluation of the patient.

Contraindications

The LATITUDE Patient Management system is contraindicated for use with any PG other than a compatible Boston Scientific PG. Not all Boston Scientific PGs are compatible with the LATITUDE system. For contraindications for use related to the PG, refer to the System Guide for the Boston Scientific PG being interrogated.

Precautions

The LATITUDE system is designed to notify clinicians within 24 hours if new PG red alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. PG data is typically available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability can take up to 24 hours or the next business day. Red alert conditions are available for viewing when the data is posted on the website. However, notification by Boston Scientific personnel of red alerts is provided during business hours only. As a result, this notification may take more than 24 hours.

Note that PG data will not be available and alert notification cannot occur if:

- The Communicator is unplugged.
• The Communicator is not able to connect to the LATITUDE system through an active phone line.

• The PG 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 system as described in the patient manual.

Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above. Additional time may be required for clinic notification and resolution of the condition. Clinics are notified of equipment problems through the Equipment Review List (see page 42). During this time, no new patient data, device data, or alert notifications since the last successful data transmission are available. See “Alerts” on page 7. See “Notification If Patient Data Is Not Received” on page 11.

Adverse Effects

None known.

System Limitations

The LATITUDE system does not provide continuous monitoring. As a remote monitoring system, the LATITUDE 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 PG and patient information as intended by the clinician. These factors include:

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

• **Patient environment.** The Communicator may not be plugged into an electrical outlet or telephone line. Other equipment attached to the telephone line can adversely impact the ability of the Communicator to transmit information to the LATITUDE server. Patients may not be within RF range of the Communicator at the appropriate times. RF interference from wireless electronic products may interfere with communication between the PG and Communicator.
• **Communicator memory capacity.** Communicator memory used to store PG data may reach its capacity if the Communicator cannot connect to the LATITUDE system for an extended period. If this occurs, the Communicator will delete the oldest collected PG data from its memory in order to store newly collected PG data. The deleted PG data may contain alert information.

• **Telephone system.** Variations in infrastructure compatibility among telephone service providers as well as variations in the quality of the telephone line from inside the patient's home to telephone company equipment and switching stations can affect LATITUDE data delivery.

• **Clinic environment.** Delays in contacting clinicians may occur for a variety of reasons including clinic fax and computer equipment that may be down or offline, 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 alert configuration settings can take up to 8 days to be sent to the patient's Communicator and become effective.

• **Data processing.** Data acquisition and delivery can be delayed or prevented due to:
  - temporary, scheduled and unscheduled downtime of computer servers,
  - variations in server loads and processing times,
  - and other data processing issues.

  Under these conditions, notification of alert data and delivery of clinical data may take more than 24 hours.

**LATITUDE Secure Server**

The LATITUDE secure server is a centralized computer database that stores patient data, implanted device data sent from patients’ LATITUDE Communicators, and physician and clinician configuration information. The LATITUDE secure server provides the data presented on the LATITUDE website, which is readily available over the Internet to authorized users. The LATITUDE system presents up to 18 months of patient data and physician specific alert history data for the entire life of the patient’s currently implanted device. All patient data that are older than 18 months are archived by the system.
LATITUDE Communicator

A key component of the system is the LATITUDE Communicator, an easy-to-use in-home monitoring device for patients. The Communicator (Figure 1) automatically reads implanted device information at times scheduled by the patient's physician. The Communicator sends data to the LATITUDE server through a standard analog telephone line.

NOTES:

• The Communicator does not reprogram or change any implanted device functions.

• The patient receives a Communicator from the clinic after the patient is enrolled in the LATITUDE 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 according to the LATITUDE schedule set by the clinic. During patient enrollment, the Communicator is configured to communicate only with the patient's implanted device.

• The LATITUDE Communicator is intended to be used by a single patient. A Communicator received by a patient may not be reconfigured and/or distributed to a different patient.

Figure 1. LATITUDE Communicator
LATITUDE Customer Support

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

Table 1. LATITUDE Customer Support Telephone Numbers

<table>
<thead>
<tr>
<th>Country</th>
<th>Voice Number</th>
<th>FAX Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>1-800-227-3422</td>
<td>1-877-382-2954</td>
</tr>
</tbody>
</table>

Optional Home Health Monitoring Equipment

The LATITUDE Scale and LATITUDE Blood Pressure Monitor are optional components of the LATITUDE Patient Management system. These components, transmit measurements over a wireless connection to the patient’s Communicator. The Communicator automatically sends these measurements to the LATITUDE secure server where they are made available for physician’s review. The weight scale and blood pressure monitor are intended to be used by a single patient. A weight scale and blood pressure monitor received by a patient may not be reconfigured and/or distributed to a different patient.

Although the patient may use the scale and blood pressure monitor at any time, only one daily reading is reported on the LATITUDE website. The reading displayed is the last reading within a window (10 minutes for the scale and 20 minutes for the blood pressure monitor) that starts with the first reading of the day. The purpose of the window is to allow patients to retake their reading if necessary. If a replacement Communicator is assigned, the LATITUDE system will not process any new readings it receives that were taken before the date the replacement Communicator was assigned.

Weight measurements that differ by more than 9.1 kg from the previous day or more than 13.6 kg from the previous week are considered invalid and are not reported on the website. Invalidating widely varying values is not done with blood pressure measurements.

**CAUTION:**

- The maximum weighing capacity of the scale is 200 kg (450 lbs). Do not place anything on the scale that is beyond the weighing capacity.
Optional Symptom Questions

The LATITUDE system provides physicians the option of asking patients to respond to a series of symptom questions on a weekly basis. These six questions are most relevant for heart failure patients. (See “APPENDIX A: PATIENT QUESTIONS” on page 54 for a list of the questions and possible answers.)

If this option is selected, the patient receives a reminder on the Communicator. The Action button illuminates and a message appears on screen when it is time to answer the questions.

The questions appear on the Communicator and the patient responds by pressing buttons on the touch screen. Responses appear with other patient information on the LATITUDE website.

BASIC CONCEPTS

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

Access to Patient Data

The LATITUDE system collects patient data that are protected health information. Access to patient data is provided only to the patient’s LATITUDE physicians and other LATITUDE users authorized by the patient’s LATITUDE physicians. Designated Boston Scientific Corporation (BSC) personnel also have access to patient data. All user access of LATITUDE patient data is logged.

Registered Users

Any LATITUDE user, including but not limited to third party vendors, must be associated with a clinic that has direct responsibility and authority for the health care treatment of a patient. All LATITUDE users must be registered within that clinic’s LATITUDE account as one of the User Types described on page 13.

LATITUDE reserves the right to deactivate any user or account that uses or accesses the LATITUDE system contrary to the LATITUDE Licensing Agreement (including, in the U.S., the LATITUDE Business Associate Agreement), any policies related to LATITUDE, or any relevant privacy and data protection laws or regulations.
Patient, Physician, and Clinic Relationships

The LATITUDE system is based on the relationship of patients to physicians. Each LATITUDE physician has a user account that is associated with a specific clinic.

Each LATITUDE patient can be associated with two different physicians, potentially at different clinics:

- **Device following physician** (typically an electrophysiologist)
  This physician is typically responsible for managing a patient's device, including regularly scheduled device follow-ups. This physician is also responsible for managing any red alerts detected any time the patient's implanted device is interrogated (and yellow alerts if notification has been configured/selected). All LATITUDE patients must have an assigned device following physician.

- **Health following physician** (typically a cardiologist or heart failure specialist)
  A patient may also be assigned a second (health following) physician. This second physician is not notified of red alerts, but may select to be notified about any of the yellow alert conditions as guided by the type of care they are providing for that patient. Specifically, for a patient with heart failure, this second physician may be the specialist who more closely monitors the patient's condition through the use of weight, blood pressure, health status questions, and relevant device measured trends.

Alerts

The LATITUDE system generates alert notifications for a number of conditions, which vary depending on the implanted device model. See “APPENDIX B: ALERT CONDITIONS” on page 55.

There are two levels of alert conditions: red alerts and yellow alerts. The alerts are designed to notify the physician of potential health or device problems. 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 website and reviewing supporting diagnostic information stored in the implanted device.

Alert conditions can be detected during daily and weekly status checks, scheduled follow-up interrogations, and patient-initiated interrogations. The LATITUDE system notifies the patient's physician(s) of any detected alert conditions.
The LATITUDE system sends one notification for an alert condition detected by the system. It does not issue alert notifications for the same condition unless the condition is no longer detected and then reappears during a following data collection activity.

Designated Boston Scientific Corporation (BSC) personnel have the capability to provide notification of alert conditions in addition to the notifications provided by the LATITUDE server. You may be contacted regarding data that is currently not available on the LATITUDE website or to clarify data that is available on the LATITUDE website. For example, if there is an alert condition that cannot be retrieved and displayed automatically by the LATITUDE server, BSC personnel can contact you to inform you of that alert.

NOTES:

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

- **If Daily Measurements and other programmable features are not activated (programmed on) in the implanted device, the LATITUDE system cannot generate an alert for an event even if the LATITUDE alert is configured on. Data must be measured and recorded within the implanted device for the LATITUDE system to detect and generate an alert notification for these types of events.**

Red Alerts

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

The LATITUDE website is designed to notify the device following physician if a red alert is detected on the LATITUDE secure server. The website is the primary means of notification of an alert. BSC personnel may provide additional telephone notification (if indicated in red alert preferences). Phone calls will typically be provided within the next business day following alert detection by the LATITUDE server (excluding weekends and holidays). If the Communicator is not able to connect and transfer the red alert data after 24 hours, the Communicator displays a message asking the patient to call his or her physician and report any error codes that appear on the Communicator screen.
NOTE: Even if the physician preference is to receive a telephone call, designated BSC personnel will not call for red alerts that have previously been reviewed, including:

- Alerts dated prior to the most recent programmer interrogation
- Alerts for which notification has previously been provided
- Alerts that have previously been reviewed and/or dismissed from the LATITUDE system

Red alert notifications occur for the following conditions, depending on device model. (See “APPENDIX B: ALERT CONDITIONS” on page 55.)

- Daily Measurement Red Alerts
  - High or low shock lead impedance
  - High or low right ventricular pacing lead impedance
- Red Alerts Indicating Potential Loss of Therapy
  - Remote monitoring disabled due to limited battery capacity
  - High or low shock lead impedance detected when attempting to deliver a shock
  - High voltage detected on shock lead during charge
  - V-Tachy mode set to value other than Monitor + Therapy
  - PG has detected a possible malfunction
  - Device parameter error

Red Alert Notification Form

The LATITUDE system is configured to provide alert notification on the LATITUDE website. Clinics can select additional notification preferences by completing a Red Alert Notification Form. The form is available from your LATITUDE representative.

Yellow Alerts

Notification of yellow alerts is optional and may be selected by either of a patient’s LATITUDE physicians. As with red alerts, the primary means of notification for yellow alerts is...

---

1. PG faults detected by the Communicator initiate a red alert that LATITUDE displays to the clinician. On the Patient Summary screen, this is displayed as: Possible device malfunction occurred on (Date). Schedule in-office follow-up to investigate.
alerts is the LATITUDE website. The LATITUDE system may provide additional notification of yellow alerts by fax, if configured in the yellow alert settings page. LATITUDE Customer Support or other designated Boston Scientific personnel can also contact you should the data not be available on the LATITUDE website.

Yellow alerts are detected by the LATITUDE server when the Communicator transfers implanted device interrogation and health equipment information. A physician may choose to receive some, all, or none of the yellow alerts.

Yellow alert notifications can be configured for the following conditions, depending on device model. (See “APPENDIX B: ALERT CONDITIONS” on page 55.)

- Explant indicator reached
- Voltage was too low for projected remaining capacity
- Ventricular pacing leads
  - Low right ventricular intrinsic amplitude
  - Low left ventricular intrinsic amplitude
  - Low left ventricular pacing lead impedance
  - High left ventricular pacing lead impedance
- Atrial pacing leads
  - Low atrial intrinsic amplitude
  - Low atrial pacing lead impedance
  - High atrial pacing lead impedance
- Arrhythmias
  - Shock therapy delivered to convert arrhythmia (ventricular)
  - Accelerated arrhythmia episode (ventricular)
  - Atrial arrhythmia burden within a 24-hour period (exceeding a user selectable limit)

\textbf{NOTE:} A false positive alert may be generated if an ATR episode is still in progress from a previous interrogation and the ATR episode ends before the current interrogation begins.

- Patient triggered event stored
- Therapy history corruption detected
• Pacing
  • Cardiac resynchronization therapy pacing percentage (less than a user selectable percentage). This condition will not generate an alert if the PG’s Pacing Chamber parameter is programmed to right ventricular (RV) only.
  • Right ventricular pacing percentage (exceeds a user selectable percentage)
• An average daily weight change of 0.91 kg or more over multiple days or a change of 2.27 kg or more any time within a week

Yellow Alert Faxes
If designated, the LATITUDE system may send faxes notifying a physician of yellow alerts. If more than one alert condition (both yellow and red) for a patient/physician pair exists, the red alert description is also displayed in the alert fax. If the automated fax fails, LATITUDE Customer Support will attempt to manually send the fax, or you may be contacted by LATITUDE Customer Support or other designated Boston Scientific personnel.

LATITUDE Customer Support may attempt to use a different notification method if they are unable to transmit a fax for a yellow alert. If the yellow alert has been previously reviewed or dismissed through the LATITUDE website, they will not make any further attempts to notify the intended recipient.

Notification If Patient Data Is Not Received
The LATITUDE system notifies the clinician through the equipment task list when:
• PG data has not been received within 14 days of the expected date.
• A LATITUDE weight scale has been provided, weight alerts are configured, and the Communicator has not connected to the LATITUDE system for 14 days.

After notification, the clinician is responsible for resolving the condition. This may include referring the patient to LATITUDE Customer Support in the event the clinician is unable to resolve the condition. Until resolution, alert identification and notification will not occur.
Implanted Device Interrogation

The Communicator can perform several types of implanted device interrogations. Each interrogation type varies in the amount and type of data that are collected, as shown in Table 2. All interrogations can be scheduled by the physician. Refer to “Changing Patient Demographic and Equipment Information” on page 25.

Table 2. Data Collection and Schedule Intervals for Each Interrogation Type

<table>
<thead>
<tr>
<th>Interrogation Type</th>
<th>Full Interrogation (no Presenting EGM)</th>
<th>Collect Presenting EGM</th>
<th>Red Alert Check</th>
<th>Yellow Alert Check</th>
<th>Available Schedule Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote Follow-up</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• 1 week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 2 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Monthly intervals from 1 to 12 months</td>
</tr>
<tr>
<td>Weekly Device Alert</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• 1 week</td>
</tr>
<tr>
<td>Daily Device Check (Fault Check)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>• Daily</td>
</tr>
<tr>
<td>Patient Initiated (See page 12)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>As directed by physician</td>
</tr>
</tbody>
</table>

1. If a red alert is detected during the Weekly or Daily Device Check, a full interrogation with presenting EGM is attempted.
2. If the Daily Device Check is enabled, the Communicator attempts to interrogate the PG daily to check for all the above red alert conditions except device parameter errors, which are checked for during weekly, scheduled, and patient initiated interrogations.

Patient Initiated Interrogation

The Communicator supports non-scheduled, patient initiated interrogations, which are equivalent to a full interrogation with presenting EGM. The physician determines whether this feature is available.

The Communicator limits the number of patient initiated interrogations to one of the following limits as specified by the LATITUDE server:

• 5 per week (if enabled)
• 0 (when feature is disabled)

Patients initiate an interrogation by pressing the blue Interrogate button on the Communicator (see Figure 1 on page 4). The Communicator will not perform an interrogation if this feature is not enabled or the limit has been reached.
The patient's LATITUDE physicians or physician delegates can enable or disable patient initiated interrogations. If this setting is changed, the LATITUDE server will send a notification to the patient's Communicator the next time the Communicator calls the LATITUDE server. It could take up to eight days for the Communicator to call the LATITUDE server. If patient initiated interrogations are disabled in the Communicator and the patient attempts to interrogate, the Communicator will call the LATITUDE server to check for updated information.

User Types

Three basic user types control access to patient data and maximize workflow efficiency within the clinic. These user types are:

- Physicians
- Medical Professionals
- Clinic Staff

Physicians, Medical Professionals, or Clinic Staff accounts can be created by sending a request to the Clinic Account Manager. (See “MANAGING USER ACCOUNTS” on page 50.)

Physicians

The Physician type is assigned only to a user who has medical responsibility for a patient being remotely monitored by the LATITUDE system.

Medical Professionals

The Medical Professional type is assigned to users who have some medical training and work with patient data in a full-support capacity within the clinic. This includes the ability to follow a patient's care and dismiss that patient from the Patients For Review list (page 34) when follow-up is complete.

Clinic Staff

The Clinic Staff type has the same permissions as Medical Professionals but can be used by a clinic to differentiate between different types of employees such as technicians and nurses. Clinic Staff typically perform a support role. When assigned as Physician Delegates, Clinic Staff have the right to view patient status and print patient reports.
User Roles

LATITUDE users (Physicians, Medical Professionals, and Clinic Staff) may be assigned one or more of the following roles:

- Clinic Account Manager
- Clinic Administrator
- Physician Administrator
- Physician Delegate

Table 3 and Table 4 show the functions each user role can perform for either the clinic or physicians. There are no constraints on the number of additional roles a particular clinic user can be given.

Table 3. Clinic Functions Permitted for Each User Role

<table>
<thead>
<tr>
<th>User Role</th>
<th>Define Clinic Follow-up Schedules</th>
<th>Select Clinic Alert Settings</th>
<th>Assign Clinic Default Delegates</th>
<th>Manage User Accounts for Physicians, Medical Prof. and Clinic Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic Account Manager</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Clinic Administrator</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4. Physician Functions Permitted for Each User Role

<table>
<thead>
<tr>
<th>User Role</th>
<th>Define Physician Follow-up Schedules</th>
<th>Select Physician Alert Settings</th>
<th>Assign Physician Delegates</th>
<th>Assign Physician Administrators</th>
<th>Patients for Review</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Review &amp; Print Records</td>
</tr>
<tr>
<td>Clinic Account Manager</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Physician Administrator</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Delegate (Physician, Medical Staff, or Clinic Staff)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

NOTES:

- One or more Physician Administrators and one or more Physician Delegates can be assigned to a physician. The physician and Clinic Account Manager can assign Physician Administrators. The Physician, Clinic Account Manager, and Physician Administrator can assign Physician Delegates.

- Medical Professionals and other physicians can be assigned the role of Physician Delegate to enable them to work with patient information in a full-support capacity. This includes the ability to follow a patient’s care and perform a complete follow-up.

- A Physician Delegate can be assigned as the Clinic Default Delegate.
Configuration Hierarchy

Alert, schedule, and delegate settings defined for the clinic are automatically inherited by physicians, as shown in Figure 2. Likewise, patients inherit the settings of their physicians. This hierarchy provides the flexibility to apply the clinic settings to all of a physician’s patients or to apply the physician’s own settings to some or all of his or her patients. Medical Professional and Clinic Staff users do not have alert, schedule, and delegate settings.

CAUTION: Ensure that each patient’s alert settings are appropriate prior to use.

Each clinic has a set of default settings that may be changed as needed by a Clinic Account Manager or Clinic Administrator.

Physicians inherit the clinic settings. If physicians elect to keep their settings the same as the clinic settings, they will be affected by any changes to the clinic settings. Physicians also have the option of creating their own customized settings. The physician's customized settings are inherited by all his or her patients, unless a patient’s individual settings are customized. A Physician Delegate can be assigned as the Clinic Default Delegate.

Patients inherit the clinic settings or customized physician settings. Individual patients can have customized settings that differ from the clinic or physician settings. Delegate roles are not used at the patient level.

Figure 2. Configuration Settings Hierarchy
Web Views

Access to a patient’s comprehensive device data and relevant health information are available from the LATITUDE website.

The LATITUDE website is located at:

http://www.latitude.bostonscientific.com

The website is available in several languages which are listed in the Select Language menu (Figure 3).

The website provides doctors and clinicians a convenient and secure way to review the data they scheduled the Communicator to receive from a patient’s implanted device. The website is available to both a patient’s device following physician as well as his or her health following physician. The website provides analysis and trending tools to help the clinician improve patient care and clinic efficiency.

GETTING STARTED

This section describes how to log in and out and navigate the website.

Requirements

• Internet Explorer 6.0, 7.0, or 8.0

• Adobe Acrobat Reader program, version 5.1 or higher
  (to view reports that are created in Portable Document Format [PDF])

Use of a current virus protection program is recommended.
Logging In and Out

To log in:

1. Launch your browser.

2. Enter the LATITUDE URL to display the initial access page shown in Figure 3:

   http://www.latitude.bostonscientific.com

   ![LATITUDE Initial Access Page](image)

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

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

4. Click the LATITUDE - Tachy button to display the login screen shown in Figure 4.

Figure 3. LATITUDE Initial Access Page

18 - Clinician Manual
Figure 4. Login Page

5. Enter your user ID and password and click the Submit button.

Users accessing the website for the first time are prompted to change their temporary password.

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

To log out:

1. Click the LOG OUT link in the upper-right corner of the screen.

2. The Logout Confirmation window is displayed. Users are advised to close their browsers to complete the log out process.
To change your country or language:

1. To change your country or the language displayed on the LATITUDE website, click the Choose Country/Language link before you log on. Refer to A in Figure 4.

2. The initial access screen (Figure 3) is displayed from which you can change your country or preferred language.

You can also use the Website Language menu from the Configuration Profile page. Refer to F in Figure 8.

Navigating the Site

Figure 5 shows the top banner and navigation buttons that appear on all clinician web pages. Descriptions are listed below.

![Figure 5. LATITUDE Banner](image)

- **A** Link to Boston Scientific corporate website.
- **B** Title of page being viewed.
- **C** Content sensitive line displaying the name of the clinic, physician, or patient depending on the information being displayed and the type or role of the user.
- **D** Link to the Patient Search tool. (See “PATIENT SEARCH” on page 21.)
- **E** Link to help, contact information, patient transfer and deactivation forms, and other documentation.
- **F** Ends the user’s login session.
- **G** Account name for the current login session, the date, and language.
- **H** Link to a page that displays all patients on the clinician’s review list. (See “THE PATIENTS FOR REVIEW PAGES” on page 34.)
PATIENT SEARCH

A link to the Patient Search tool is located in the toolbar across the top of all webpages. The Patient Search tool (Figure 6) enables a user to search for patient records from all those that the user is authorized to access. One or more fields can be used to search for patient records. Searches using multiple fields are performed using all the words entered into each field.

Clicking the Go button displays the results webpage and any matching patient records (Figure 7). Any changes made on the current webpage are discarded. The Patient Search tool provides an OK button to continue the search and a Cancel button to cancel the search and stay on the current webpage.

![Figure 6. Patient Search Drop-down Menu](image)

Configuration Profile page for the current user. (See “THE CONFIGURATION PROFILE PAGE” on page 22.)
Figure 7. Search Results Page

From the Search Results page (Figure 7), you can print the search results list, access details of a patient appearing in the list, and print reports for a selected patient(s). The Edit Search Criteria link opens the drop-down menu where you can modify the last set of search criteria and perform a new search.

THE CONFIGURATION PROFILE PAGE

The Configuration Profile page (Figure 8) is the starting page for most configuration options for all users of the LATITUDE clinician web pages.

The Configuration Profile page is used to configure these physician and clinic items:
- Website display language
- Clinic default language
- Alert notification settings
- Patient follow-up schedules
  - Remote follow-up
  - Between follow-up data collection
- Physician delegate and administrator lists
- Clinic member list, delegates, and administrators
- Passwords
Your Profile provides links to items that can be changed by the current user: alerts, follow-up schedules, delegates and administrators, and the user’s password. The links displayed change depending on the user type of the person logged in.

Clinic Profile provides links for clinic configurable items. Some users are able to configure items and others are only able to view them. Only Clinic Account Managers and Clinic Administrators can make changes.

Clinic Members section lists all other members of the clinic.

---

**Figure 8. Configuration Profile Page (Clinic Account Manager)**

| A | Your Profile provides links to items that can be changed by the current user: alerts, follow-up schedules, delegates and administrators, and the user’s password. The links displayed change depending on the user type of the person logged in. |
| B | Clinic Profile provides links for clinic configurable items. Some users are able to configure items and others are only able to view them. Only Clinic Account Managers and Clinic Administrators can make changes. |
| C | Clinic Members section lists all other members of the clinic. |
Figure 9 shows the Yellow Alert Settings page.

**NOTE:** Notification of red alerts is not configurable, as the device following physician is always notified through the LATITUDE website if a red alert is detected. The device following physician’s telephone number is configured during enrollment and may be changed on the Red Alert Settings page.

**To change settings on a Yellow Alert Settings Page:**

1. From the appropriate Configuration Profile page, click the **Configure Your Alert Settings** link to display the Alert Settings Page.
2. If desired, select the Send Yellow Alerts by Fax check box and enter the appropriate telephone number.
3. When changing physician yellow alert settings, deselect the following check box that appears near the top of the page.

   - Keep alert settings same as Clinic defaults (not shown below)

   Deselecting this check box activates the remaining check boxes and enables physicians to set their own alert settings rather than using the default clinic alert settings.
4. Select or deselect the desired settings on the lower portion of the page.
5. Select Save to store the settings in the LATITUDE system or select Reset to restore settings to the last saved version.
Changing Patient Demographic and Equipment Information

Users can view and edit patient demographic, implanted device, physician, and LATITUDE equipment information from the Patient/Equipment Information page (Figure 10). Users can add or change information by clicking the links provided on the right side of each category. A link to the Patient/Equipment Information page appears on the Summary and Configure Patient tabs of the Patient’s Detailed Summary page. The LATITUDE 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.
Figure 10. Patient/Equipment Information Page

Setting Follow-up and Data Collection Schedules

Remote follow-up and data collection schedules for the clinic and physician are set from the Schedule configuration page as shown in Figure 11. To change settings for individual patients, go to the Configure Patient tab on the Patient Detail page for that patient or click on the patient’s next scheduled follow-up to display the scheduling calendar (Figure 12).

Schedules are based on a follow-up interval and a day of the week. A monthly interval is based on 30 days, plus the number of days needed to match the configured day of the week. If you change the patient’s follow-up interval, the date of the patient’s next scheduled follow-up does not change unless you specifically change that date.
While the follow-up interrogation schedule is set by the physician, actual interrogations occur automatically on the scheduled dates. The patient does not need to perform any action. These interrogations often occur without the patient’s knowledge.

To change settings on a Schedule Page:

1. When changing physician remote follow-up schedule settings, deselect the following check box that appears near the top of the page.

   ![Check box](Image)

   **Keep settings same as Clinic defaults:**

   Deselecting this check box enables physicians to create their own schedule settings rather than using the default clinic schedule settings.

2. To change the type of data collected between follow-ups from the clinic default settings, deselect the second “Keep settings same as Clinic defaults” check box. Then select the desired settings on the lower portion of the page.

3. Select Save to save the settings in the LATITUDE system or select Reset to restore settings to the last saved version.
Figure 11. Schedule Configuration Page (Physician)

- **A** This row provides links to other configurable items and events.
- **B** This link returns users to their Configuration profile page.
- **C** These check boxes are used for assigning the clinic's configuration settings to the physician. Deselecting these check boxes activates the remote follow-up and data collection choices that follow. A summary of the clinic default schedule and data collection values are displayed.
- **D** The Save and Reset buttons are activated when any item is changed. Click the Save button to save changes to settings. Click the Reset button to restore settings to the last saved version.
Changing Individual Patient Remote Follow-ups Using the Scheduling Calendar

Remote follow-up dates can be changed by clicking on the patient’s next remote follow-up date, as listed on the Patients for Review and All Patients pages, or under the patient’s Configure Patient tab. Clicking on a follow-up date displays the scheduling calendar shown in Figure 12.

Changing the next remote follow-up date establishes a new baseline for future remote follow-ups for the patient. The patient’s future follow-ups are calculated based on the new remote follow-up date plus the configured follow-up interval and day of the week.

Figure 12. Remote Follow-up Scheduling Calendar
Assigning Delegates and Administrators

Users need access to LATITUDE patient data to make changes to alert notifications, follow-up schedules, and assigned delegates and administrators. The Configuration Profile pages enable:

- Clinic Account Managers to assign a Clinic Default Delegate list and Clinic Administrators
- Physicians to assign Physician Delegates and Administrators

A user who is delegated role responsibilities is not able to grant those rights to other users.

Clinic Member List: Delegates and Administrators

To facilitate simpler clinic-wide management of delegate lists, the LATITUDE system provides a Clinic Default Delegate list as shown in Figure 13. To access this list, select the Configure Clinic Member List link from the Configuration Profile page.

Each physician can use the Clinic Default Delegates rather than maintain a separate list. When physicians use the Clinic Default Delegate list, their delegates change whenever the clinic list is changed, reducing the need to manage the list when clinic members and roles change.
Figure 13. Clinic Delegate and Administrator Selection

**Physician Member List: Delegates and Administrators**

Physicians grant other users access to patient data by placing them on their Physician Delegate List as shown in Figure 14. This list is accessed from the physician’s Configuration Profile page, by selecting the Configure Physician’s Delegates and Administrators link.

Physician Delegates may be any other user type in that clinic—other Physicians, Medical Professionals or Clinic Staff. Physicians may establish their own default delegate list, or use the clinic’s default delegate list, which is maintained by the Clinic Account Manager or Clinic Administrator.

<table>
<thead>
<tr>
<th>Kardiologie Centre</th>
<th>Clinic Default Delegate</th>
<th>Clinic Administrator</th>
<th>Remove Member</th>
<th>Manage Member Account</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castaneda, Mara</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical profession</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leong, Albert &amp;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Papi, Remond</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peteoy, Ivan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 14. Physician Delegates and Administrators List

To select delegates and administrators on either Clinic or Physician Member pages:

1. Select the check box for the desired user(s).

   The following check box is provided on the Physician Delegates and Administrators page to enable physicians to use the Clinic Default Delegates rather than manage their own separate list. Members of the clinic who are on the Clinic Default Delegate list are indicated with blue squares.

   ![Check box example](image)

   Keep alert settings same as Clinic defaults ( ■ shown below)

2. Select Save to save the settings in the LATITUDE system or select Reset to restore settings to the last saved version.

---

<table>
<thead>
<tr>
<th>Cardiology Centre</th>
<th>Physician Delegate</th>
<th>Physician Administrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campana, Maria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lange, Albert B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mueller, Otto</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pepin, Reyward</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rossi, Maria</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Changing Your Password

1. Click the **CONFIGURE** tab to display your configuration profile.

2. Click the **Change Your Password** link under the Your Profile section.

3. Enter your old and new password and click the **Submit** button.

![Figure 15. Change Password Page](image-url)
THE PATIENTS FOR REVIEW PAGES

The PATIENTS FOR REVIEW tab provides links to the following two lists:

- Patients Review List (page 34)
- Equipment Review List (page 42)

Patients For Review List

The Patients for Review List (Figure 16) is generally the first page displayed after logging on to the LATITUDE website. A summary line is displayed for each patient assigned or delegated to the current user if the patient has an outstanding alert or a scheduled remote follow-up. Patients are listed in order of alert severity, followed by order of patient ID.

![Patients for Review List](image)

Figure 16. Patients for Review List
A red flag indicates a patient with one or more red alerts and zero or more yellow alerts who has not been dismissed.

Once dismissed, a patient does not appear on the list for the same condition unless another instance of that condition occurs.

A yellow flag indicates a patient with only yellow alerts who has not been dismissed.

The Physician must have notification for that yellow alert event configured in order for the patient to appear in the physician’s review list. A patient may appear in a review list due to a new yellow alert identified during any data collection event scheduled by either physician.

No Flag

Patients that do not have any alerts but are scheduled for remote follow-ups or have performed a patient initiated interrogation.

NOTE: The My Alerts column displays an alert flag for a patient with an alert, if notification of that type of alert is configured for the patient. Once an alert flag is acknowledged by dismissing the patient from the list, that alert is considered inactive and is not shown again for the same event. In contrast, the Device Status column displays a symbol for a Device Status condition as long as device interrogations continue to report the same device or lead condition. Physician notification only occurs for conditions that appear in the My Alerts column.

The following list provides a description of each column of the Patients for Review list.

All

You can select the check box for one or more patients or the All check box for all patients listed on the page. When selecting the All check box, any of the blue action buttons (Print Reports or Dismiss Patient) is performed for all patients in the list.

Patient ID/Patient Name/Device

Click on the patient's ID to see detailed information for that patient. The Patient Name is optional and may not appear.
**My Alerts**

Indicates the patient has alerts that match those you have configured for that patient. Alerts persist from the time the patient is put on the Patients for Review list until they are dismissed from the review list. The symbol in front of an alert flag enables you to expand/contract the alert detail area as shown in Figure 16.

**Device Status**

Indicates current status of device, independent of alert selections. Yellow triangles indicate less severe conditions, red diamonds indicate more severe conditions. A device status symbol remains active until the underlying device or lead condition is resolved.

**Events since Last Follow-up**

Displays event counters since the last follow-up and provides a link to the Arrhythmia Logbook page for that patient. The last follow-up is the most recent scheduled remote follow-up or in-office visit where the counters were reset using a programmer.

The 👍 symbol indicates the event counters are since the last scheduled remote follow-up.

The ⚠️ symbol indicates the event counters are since an in-office visit where the counters were reset with a programmer.

These symbols are also used in the patient detail pages.

**Physician(s)**

Names of LATITUDE responsible physicians. If two names appear, the first line is the device following physician and the second line is the health following physician. The bold name indicates the patient record is displayed using that physician’s configured settings. A patient could be listed twice due to different follow-up or alert settings between the device and health following physicians.

**Latest Send/Next Remote**

The Latest Send date appears on the first line. The second line is the Next Remote date. The Latest Send date is the last time the LATITUDE server received implanted device data for that patient. The Next Remote date is 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.
Disposition

The type and status of the follow-up event are used to define the patient’s disposition. The follow-up type is the reason the patient was added to the Patients for Review list. The follow-up status is the state of the patient’s record.

Click on a disposition status to display reviewers who have accessed the patient’s record since being added to the Patients for Review list.

Follow-up Type:

Scheduled. Indicates the patient was added due to a scheduled follow-up.

Patient-Initiated. Indicates the patient was added as a result of the patient performing a patient-initiated interrogation.

Daily/Weekly. Indicates the patient was added because an alert was detected during a daily device check or weekly interrogation.

Weight Change. Indicates the patient was added because a weight change that caused a weight alert was detected.

New Patient/New PG. Indicates the patient was added because their Communicator called in for the first time, their implanted device was replaced, or a physician was added or replaced.

Follow-up Status:

Ready for Review. Status when the patient first appears on the list.

Review Started. Status automatically changes to this state when the patient’s record has been viewed or a report for the patient has been printed.

New Patient/New PG. Any of the following three conditions could generate this disposition:

• The patient initializes their Communicator
• An existing patient gets a new implanted device
• A physician is added for the patient (or an existing physician replaced)

Follow-up Pending. Status of a patient that is scheduled for review, but for whom an interrogation has not yet been completed successfully.

Follow-up Missed. Indicates some type of failure regarding collection or reporting of data from the patient’s Communicator.
If the follow-up status of the patient is Ready for Review or New Patient/New PG, the follow-up status changes to Review Started after the Print Reports function is selected.

**Reviewing Patients**

Actions on a patient may be performed by selecting the check box next to one or more patient IDs (or the All check box for all patients) and then clicking on one of the blue action buttons. The function of each button is described below:

- **Reports Menu**: Opens a separate browser window to generate one or more reports for the selected patient(s). Clicking the **Return to Patients for Review** link closes the Reports window and returns the user to the Patients for Review page.

- **Dismiss Patient**: Removes the patient from the Patients for Review list. Dismissing the patient for a scheduled remote follow-up resets the Since Last Remote Follow-up counters.

**Generating and Printing Patient Reports**

Reports can be generated for one or many patients by selecting the Print Reports button.

When printing reports, report information is retrieved, and a single PDF file is generated. Once the selected report(s) are generated, the user can print the reports and save the report file.

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

The date, time, and user that generated the report is logged and is displayed in the disposition status window. The Print Reports button is available on all web pages listing patients or patient data.
Displaying Patient Information

Clicking a patient's identifier on the Patients for Review or All Patients pages displays a Patient Detail page. Figure 17 shows the top portion of a Patient Detail page followed by five tabs and information links for each tab. The link that is not underlined is the first page displayed for that tab. Figure 17 provides a quick-reference for finding specific patient information.

NOTE: The availability of each of the above tabs and features varies depending on the patient’s PG model.

Figure 17. Patient Detail Tabs and Links Quick Reference

Definitions of Symbols and Terms

Symbol for PGs that use ZIP Wandless Telemetry
**Last Office Interrogation.** Last in-office interrogation of the device by the programmer (may or may not include device-based lead tests done using programmer).

**Latest Send.** The most recently received device data from any remote interrogation.

**Last Remote Follow-up.** The most recently received device data from a dismissed (completed) scheduled remote follow-up (does not include daily, weekly, or patient-initiated interrogations).

**Next Remote Follow-up.** The next scheduled remote follow-up (does not include daily, weekly or patient-initiated interrogations).

**Follow-up History**

The Follow-up History page (Figure 18) lists remote interrogations that resulted in the patient being added to the Patients For Review page. A patient is listed on the Patients For Review page if they had a scheduled follow-up, a device alert was detected during a daily device check or a weekly interrogation, or the patient performed a patient-initiated interrogation.

A summary line is displayed for each remote interrogation to enable users to print reports and view available presenting and stored EGM data for that interrogation. The Follow-up History page lists remote interrogations created in the last 18 months.
Figure 18. Follow-up History Page

The following list provides a description of each column of the Follow-up History page.

**Date**

Indicates the date the interrogation was performed by the LATITUDE system. Click on the date link to display a menu for printing reports for the interrogation.

**Type**

Indicates the record type for the interrogation as determined when the record was created. The type listed is the same as the Disposition follow-up type listed on the Patients For Review page (Figure 16).

**New Alert**

A red or yellow flag is displayed if one or more new alerts were generated for the interrogation.
New Events
A check mark is displayed if one or more new events were detected for the interrogation. A new event is one which hasn't been accounted for in a previous interrogation. If the interrogation does not contain any new events, no check mark is displayed.

Presenting EGM
A symbol is displayed if presenting EGM data is available for the interrogation. Clicking the symbol opens a window to view the presenting EGM data.

Sent to EMR
A check mark is displayed if an EMR message was sent to and received by the EMR system configured for the LATITUDE system. This column is not displayed if the EMR feature is not enabled.

Equipment Review List
The Equipment Review List (Figure 19) displays common equipment tasks that need to be resolved for each patient on the list. A summary line is displayed for each patient who has one or more outstanding equipment tasks and has an assigned physician or physician delegate. Users can view tasks assigned to the physician, create and amend notes for the patient, and dismiss tasks from the list.
The following list provides a description of each column of the Equipment Review list.

**Patient ID/Patient Name/Phone Number**

Lists the patient’s ID, name, and telephone number. Click on the patient’s ID to display a Patient Detail page for that patient.

**Task Notes**

Provides a Create Note link to open the note editor window where users can capture information related to resolving the tasks for that patient. When you create or amend a note, the status of all New tasks for the patient are changed to In Progress. All clinic users who have access to a patient’s record can view and add notes for that patient. The notes remain on the list until all of the tasks for that patient are resolved. Only one note editor window can be open. If the user opens another note, clicks on a task description, or navigates to a different webpage, the note editor window is closed and unsaved changes are lost.

**NOTE:** Task notes are not intended to contain clinical information or become part...
of a patient’s record. They are intended to be used to track the resolution of unresolved equipment tasks.

**Date Notified**

The date the task first appeared on the user’s equipment review list.

**Task Description**

Defines the type of task. Click on the name of the task to display a task description with recommendations for resolving and verifying the task. All tasks are sent to the Device Following Physician except for the “Pending Sensor Setup” which is sent to the physician that ordered the scale and blood pressure monitor.

**Communicator Not Connecting.** The Communicator has not called into the LATITUDE system in 14 days. Any data collected from the patient’s implanted device in the last 14 days has not been received by the LATITUDE system. This task usually coincides with the Implanted Device Data Collection Failure task. To minimize overlap for clinics, this task appears on the Equipment Review List only if the patient does not already have an Implanted Device Data Collection Failure task, and the patient has a weight scale and a physician with weight alerts configured.

**Implanted Device Data Collection Failure.** Implanted device data from a scheduled interrogation has not been received by the LATITUDE system for 14 days. An interrogation must be completed before implanted device data can be updated on the LATITUDE website.

**Incomplete Interrogation.** The Communicator was able to start but not complete an interrogation. An interrogation must be completed and the data transferred to the LATITUDE system before implanted device data can be updated on the LATITUDE website.

**Communicator Not Assigned.** The patient was not assigned a replacement Communicator for more than 30 days. This patient is not being monitored by the LATITUDE system.

**Pending Communicator Setup.** The patient’s Communicator has not called the LATITUDE server within 30 days of the patient being enrolled. Their implanted device is not being monitored by the LATITUDE system.

**Pending Sensor Setup.** The patient’s weight scale or blood pressure monitor was not setup within 30 days of being assigned. The patient’s weight or blood pressure is not being collected by the LATITUDE system.
Resolution Status

Defines the task status: New, In Progress, or Resolved. Click on the name of the task in the Task Description column to display a troubleshooting help window. This help window provides recommendations for resolving the task. Creating a note or clicking the task description changes the status of all the patient’s tasks from New to In Progress. When an issue is resolved, the status automatically changes from In-Progress to Resolved.

All

You can select the check box for one or more tasks or select the All check box for all tasks listed on the page. When selecting the All check box, any of the blue action buttons (Remove Task(s) or Remove All Resolved Tasks) are performed on all the tasks for every patient in the list.

Removing Tasks

There are several ways tasks can be removed from the list:

• Manually: Select the task using the check boxes in the All column and click the Remove Task(s) button.

• Automatically: The system removes the task if it:
  • is resolved and has a status of New or Resolved,
  • has a status of Resolved and has been on the list for more than 30 days.

The function of each button used to remove selected or resolved equipment tasks from the list is described below:

Remove Task(s)

Removes all tasks that are selected in the All column from the user’s Equipment Task List regardless of their individual status. A confirmation pop-up window is displayed if more than one task is selected.
The All Patients page (Figure 20) displays a summary line for all patients for which the physician or physician’s delegate is responsible. Patients are sorted in ascending order by Patient ID. This page enables users to display data and print reports for any of their patients.

![Figure 20. All Patients Page](image)

**Task Counts:** New (4) | In Progress (1) | Resolved (0)

Displays the number of tasks for each of the three types of resolution status.

Remove All Resolved Tasks

Removes all resolved tasks from the user’s Equipment Task List. A task is automatically set to Resolved in the **Resolution Status** column if it is resolved within the LATITUDE system.
The following list provides a description of each column of the All Patients page.

**All**

You can select the check box for one or more patients or select the All check box for all patients listed on the page. After selecting the All check box, the Print Reports button is activated and reports can be created for all patients in the list.

**Patient ID/Patient Name**

Click on the patient’s ID to see detailed information for that patient. The patient’s identification number assigned by the clinic associated with the current user is displayed. A patient may have multiple Patient IDs, one for each clinic in which they are enrolled. A unique patient ID may be used for your clinic. You can assign or edit a patient ID from the Patient Information page or when enrolling a patient.

**Device Name, Model/Serial**

The name, model, and serial number of the patient's implanted device.

**Date of Birth**

The patient’s date of birth.

**Last Follow-up/Next Remote**

The dates of the last scheduled remote follow-up interrogation and the next scheduled remote follow-up interrogation. Click on a follow-up date to display the scheduling calendar and set a new date.

**Physician(s)**

Names of LATITUDE responsible physicians. If two names appear, one is the device following physician and the other is the health following physician.

**Status**

*Monitored*. The Communicator has been activated and the patient is being monitored.

*Not Monitored*. The Communicator is not monitoring the patient because there has been a Communicator failure or the Communicator has been set to stop monitoring by LATITUDE Customer Support.

*Communicator Not Connecting*. The Communicator has not called into the LATITUDE system in 14 days. Any data collected in the last 14 days from the patient's implanted device, weight scale, or blood pressure monitor has not been received by the LATITUDE system. This notification is only generated if that patient has a weight scale and weight alerts are configured.
Communicator Not Assigned. The patient was not assigned a replacement Communicator for more than 30 days. The patient is not being monitored by the LATITUDE system.

Implanted Device Data Collection Failure. Implanted device data from a scheduled interrogation has not been received by the LATITUDE system for 14 days. A scheduled interrogation includes a Daily Device Check, Weekly Device Alert, or Remote Follow-up (Table 2). This status can appear if the Communicator fails to collect data from the implanted device or fails to upload the data to the LATITUDE system.

Incomplete Interrogation. The Communicator was able to start but not complete an interrogation. An interrogation must be completed and the data transferred to the LATITUDE system before implanted device data can be updated on the LATITUDE website.

Pending Communicator Setup. The patient’s Communicator has not called the LATITUDE server within 30 days of the patient being enrolled. Their implanted device is not being monitored by the LATITUDE system.

Pending Sensor Setup. The patient’s weight scale or blood pressure monitor was not setup within 30 days of being assigned. The patient's weight or blood pressure is not being collected by the LATITUDE system.

PATIENT UTILITIES

The PATIENT UTILITIES tab (Figure 21) provides links to the online enrollment form and the EMR log utility.

Enroll Patient. The enrollment form allows Physicians and Physician’s delegates to enroll new patients. The user must assign a physician from a selectable list before submitting the multiple webpage form. Physician and clinic information is automatically included when the form is submitted. A confirmation of enrollment is displayed and can be printed.

EMR Log. The EMR Log enables users to view the status of patient data summary files exported from the LATITUDE system. Authorized users can also attempt to retransfer these patient files if needed. The page displays a summary line, sorted by date, for each dismissed patient assigned to the physician or physician’s delegate. A link from each status line opens a Transfer History pop-up window that provides detailed information of the file transfer processes for that patient. Refer to “EMR Log” on page 58.
### PATIENT ENROLLMENT


**Instructions:** Fill out the form below and press the "Next" button at the bottom of the page to confirm the information entered for the enrollment.

* Indicates required field

**Step 1: Enter information about the patient's implanted device**

* Model: [Select Model]

* Serial Number: 

* Implant Date: [Month] [Day] [Year] (e.g., 02/10/2018)

**Step 2: Select a Responsible Physician**

* Physician: [Select Physician]

* Physician Type: 
  - Device Following Physician
  - Health Following Physician

[Next]  [Reset Form]

---

**Figure 21. Patient Utilities Tab**
MANAGING USER ACCOUNTS

A user assigned the role of Clinic Account Manager can create user accounts for Medical Professionals, Physicians, and Clinic Staff.

Clinic Account Managers can also perform certain user account management functions for all users within their clinic, including resetting and unlocking passwords.

A Clinic Account Manager must click on the Configure Clinic Member List link from the Configuration Profile page (Figure 8 on page 23) to access all account management functions. This displays the Clinic Member List as shown in Figure 22.

Figure 22. Clinic Member List (Clinic Account Manager)
Adding Accounts

Medical Professional, Physician, and Clinic Staff accounts can be added by selecting the Add New Member link on the Clinic Member List page. The Add Member page provides a set of required and optional data entry fields.

Deleting User Accounts

Medical Professional and Clinic Staff accounts can be removed by Clinic Account Managers. Contact LATITUDE Customer Support to have a physician account removed. To delete a user, click on the Remove Member link associated with that user on the Clinic Member List page. Removing an account removes that user from all delegation lists within the clinic and disables that user’s account.

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

Deactivating Patient and Physician Accounts

To deactivate a patient account, the patient's clinic can contact LATITUDE Customer Support to request deactivation. The patient's clinic can also submit a completed Patient Deactivation Form. Forms are available by clicking the HELP/CONTACT US link.

To deactivate a physician account, the physician should contact LATITUDE Customer Support.

NOTES:

• If a Device Following Physician is deactivated from the LATITUDE system, his or her patients are no longer monitored unless another Device Following Physician is assigned. The Device Following Physician is responsible for responding to red alerts for all his/her patients for up to 30 days if another Device Following Physician is not assigned.

• Once a patient account is deactivated, patient records are no longer accessible in the LATITUDE system.
Other User Account Management Functions

Other account management functions are available by selecting the Manage Member Account link associated with a user on the Clinic Member List page. Three functions are supported:

- Reset Password – If users forget their password, this function can be used to assign a new temporary password. Clicking the Reset Password button assigns a new password to the account and displays a new temporary password in a popup window. The user must change this temporary password at the next login attempt.

- Unlock Password – If users attempt to log in too many times with an incorrect password, their account is locked for approximately one hour. If users need access before their account is unlocked, the Clinic Account Manager can force an account to be unlocked by clicking the Unlock Password button. This assigns a new temporary password to the account and displays the temporary password in a popup window. The user must change this temporary password at the next login attempt. If users forget their password, the Reset Password function should be used. If users have no knowledge of a lock having occurred, it may mean that someone else has been trying to inappropriately log in to their account. If this happens frequently, please contact LATITUDE Customer Support.

- Update Demographic Information – For Medical Professional, Physician, and Clinic Staff accounts, the Clinic Account Manager may edit the demographic data for that user and save it into the LATITUDE system. The user ID and user type cannot be changed from the Manage Member Account page. Values that can be modified include the user’s first name, middle initial, last name, address, city, postal code, country, and office telephone numbers. To change user types, a new account (with new user name) must be created.
Passwords

User passwords are stored in an irreversible encrypted format. Passwords cannot be retrieved, not even by an administrator. Password rules and suggestions for creating a good password are provided on the website.

Passwords expire every six months. Users receive notification before their password is about to expire.

LATITUDE Customer Support personnel can create a user account and assign a new temporary password to a user’s account.

A user’s account is locked after six consecutive login attempts with an incorrect password. The account is unlocked one hour after no further failed login attempts are recorded.

Temporary Passwords

Medical Professionals, Physicians, and Clinic Staff who forget their password can contact their LATITUDE Clinic Account Manager or LATITUDE Customer Support to obtain a new temporary password. Each new user is assigned a temporary one-time password and must change this password when logging in for the first time. Temporary passwords expire a few days after being issued.
APPENDIX A: PATIENT QUESTIONS

Physicians can configure the option of having patients answer a set of six symptom questions on a weekly basis. If this option is selected, the patient will receive a reminder on their Communicator when it is time to answer these questions.

Here are the six questions and the available responses for each question:

Are you feeling unusually fatigued?
• no
• yes

Have you felt faint or dizzy over the past few days?
• no
• once
• twice
• several times

Describe the swelling in your ankles, legs, or abdomen over the past few days:
• decreased noticeably
• remained about the same
• increased noticeably
• I had no swelling

Describe your ability to walk or climb stairs over the past few days:
• increased noticeably
• remained about the same
• decreased noticeably
• no difficulty

How many pillows did you sleep with last night?
• none or 1
• 2
• 3 or more
• slept sitting up

How often did you wake up breathless last night?
• none
• once
• a few times
• more than a few times
APPENDIX B: ALERT CONDITIONS

The LATITUDE Alerts report lists the conditions for which the LATITUDE system is able to automatically generate alert notifications (if the condition is configured). The conditions that apply to each supported device model are listed in the report.

<table>
<thead>
<tr>
<th>LATITUDE™ Patient Management</th>
<th>LATITUDE Alerts</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is a list of alerts that are supported by LATITUDE-enabled Boston Scientific devices. Note that these alerts will only be generated if the particular alert type is turned on for the individual patient.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Tachy Devices</th>
<th>CRT Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Battery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage was too low for projected remaining capacity</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>Explant indicator reached</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>Remote monitoring disabled due to limited battery capacity</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td><strong>Shock Lead Shorted, Open, or Impedance Out of Range</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low shock lead impedance</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>High shock lead impedance</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>Low shock lead impedance detected when attempting to deliver a shock</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>High shock lead impedance detected when attempting to deliver a shock</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td><strong>Ventricular Pacing Leads</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low right ventricular pacing lead impedance</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>High right ventricular pacing lead impedance</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>Low right ventricular intrinsic amplitude</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>Low left ventricular intrinsic amplitude</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>Low left ventricular pacing lead impedance</td>
<td>✨</td>
<td>✨</td>
</tr>
<tr>
<td>High left ventricular pacing lead impedance</td>
<td>✨</td>
<td>✨</td>
</tr>
</tbody>
</table>

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Last Updated: 17 Aug 2010

Figure 23. LATITUDE Alerts Report, Page 1

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### LATITUDE™ Patient Management

#### Alert Matrix

<table>
<thead>
<tr>
<th>Atrial Pacing Leads (Dual-chamber devices only)</th>
<th>Tachy Devices</th>
<th>CRT Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low atrial intrinsic amplitude</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Low atrial pacing lead impedance</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>High atrial pacing lead impedance</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tachy Mode</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>V-Tachy Mode set to value other than Monitor + Therapy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arrhythmias</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Shock therapy delivered to convert arrhythmia (Ventricular)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Accelerated arrhythmia episode (Ventricular)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atrial Arrhythmia Burden in a 24 hour period (Dual-chamber devices only)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Patient triggered event stored</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pacing</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Right ventricular pacing</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Cardiac Resynchronization Therapy pacing</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>High Voltage Detected on Shock Lead During Charge</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy history corruption detected</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Possible Device Malfunction</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Parameter Error</th>
<th></th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Weight (For patients with LATITUDE weight scales)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight gain of at least 2.27 kg in a week or at least 0.91 kg average over a two or more day period</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Weight loss of at least 2.27 kg in a week or at least 0.91 kg average over a two or more day period</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

---

**Figure 24. LATITUDE Alerts Report, Page 2**

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APPENDIX C: LATITUDE EMR/CIS INTEGRATION

The optional LATITUDE Electronic Medical Record (EMR)/Clinical Information System (CIS) integration feature provides an automated way to send patient PG data to a clinic’s internal CIS. It enables the clinician to dismiss a LATITUDE patient and send summary information to the CIS in a single step.

The LATITUDE CIS integration feature may not be available to all customers. LATITUDE Customer Support must activate this feature in the clinic’s LATITUDE account. There may be a charge associated with the activation of this feature. Your CIS vendor may have to provide software to import LATITUDE information into your CIS. Contact LATITUDE Customer Support for more detailed information.

The primary components and processes of the LATITUDE CIS integration feature are described below:

**Patient Dismissal**
Once the LATITUDE CIS integration feature is activated, clinicians can send patient data summary files exported from the LATITUDE system to their CIS through the normal LATITUDE patient dismissal process. After reviewing the patient’s data, the clinician clicks on the “Dismiss Patient” button to dismiss the patient and create a dismissed patient record.

**Transfer to a Clinical Information System**
When the patient is dismissed, the patient’s LATITUDE data summary file is put into the “EMR Outbox”, making it available for retrieval by the CIS. At this time, the status of the delivery is updated and may be viewed in the LATITUDE EMR log.

**Retransferring Patient Summary Files**
In the event that a patient's summary file is lost, either during transfer or after it has been retrieved by the CIS, it may be retransferred. A patient’s summary file is retransferred by selecting the check box next to one or more patient names (or the All check box for all patients) and then clicking on the blue “Place in EMR Outbox” button. See Figure 25.

**Direct Link Back**
Each LATITUDE patient summary file that is sent to the CIS includes a direct link to that patient’s LATITUDE webpage where the clinician can access detailed information for that patient. Using this link, a clinician can launch a browser window from within their CIS to connect to the LATITUDE system. If the user is already logged in to LATITUDE, the clinician does not need to re-enter a user name and password, if their browser is configured appropriately.
Clinicians use the EMR Log page (Figure 25) to view the status of the patient summary files. Authorized users can also attempt to retransfer these patient files if needed. The page displays a summary line, sorted by date, for each dismissed patient assigned to the physician or physician’s delegate. A link from each status line opens a Transfer History pop-up window that provides detailed information of the file transfer processes for that patient.

The following list provides a description of each button, field, and column of the EMR Log page.

A. This button enables the retransfer of previously transferred patient records. If one or more patient records have been selected, the “Place in EMR Outbox” button will change from gray to blue.

B. These data fields enable a clinician to view EMR Log entries within a specified date range. Enter the range and click the “Go” button to display patient records for a specified period.

C. You can select the check box for one or more patients or select the All check box to select all patients listed on the page.

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

Figure 25. EMR LOG Page
The user-initiated event that triggered the creation and attempted transfer of the patient follow-up summary file.

The date and time of the Activity.

The current status of the patient’s summary file. Click on the Status to open a Transfer History window that lists (by date in ascending order) all changes in status of that patient summary file. The four status types are described below.

The date and time of the current status.

**Transferred to Clinic**

Indicates the successful transfer of the patient summary file from the LATITUDE system to the clinic.

**In EMR Outbox**

Indicates the patient summary file was created and is waiting to be transferred from the LATITUDE system to the clinic.

**Unable to transfer**

Indicates the LATITUDE system was unable to create or transfer the patient summary file due to an unrecoverable error.

**Pending recovery**

Indicates the LATITUDE system may be able to successfully create the patient file after Boston Scientific personnel initiate a recovery process.
### EXPLANATION OF PRODUCT AND LABELING SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="symbol.png" alt="Manufacturer Symbol" /></td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>