CAUTION:
Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.
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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 6 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 for use to remotely communicate with a compatible Guidant or 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 Guidant or Boston Scientific PG. Not all Guidant or Boston Scientific PGs are compatible with the LATITUDE system. For contraindications for use related to the PG, refer to the System Guide for the Guidant or 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 and red alert notification can take up to 24 hours or the next business day. 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. This session must be initiated by the patient if he or she has a PG that uses inductive telemetry.
- 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. During this time, no new patient data, device data, or alert notifications since the last successful data transmission are available. See “Alerts” on page 6. See “Notification If Patient Data Is Not Received” on page 10.

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. Patients with inductive PGs may not perform interrogations as scheduled.

- **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 presents 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. There are two types of Communicators as shown in Figure 1. Communicators with ZIP™ Wandless Telemetry [a two-way radio frequency (RF) system] automatically read implanted device information at times scheduled by the patient's physician. The Wanded Communicator uses inductive telemetry and is used by patients to interrogate their implanted device on days scheduled by their physician or when instructed to do so by their physician. Both types of Communicators send data to the LATITUDE server through a standard analog telephone line.

NOTES:

- The Communicators do not reprogram or change any implanted device functions. The Communicator with ZIP Wandless Telemetry is for use with a different set of compatible Guidant and Boston Scientific PG devices than the Wanded Communicators.

- A Communicator is shipped to the patient 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. Before shipment, the Communicator is configured to communicate only with the patient's implanted device. If a LATITUDE patient receives a new or replacement device, the patient's Communicator will be deactivated when Boston Scientific receives and processes the new implanted device registration. A new Communicator configured to the patient's new implanted device will be shipped, and the patient will not be monitored by LATITUDE until the new Communicator is activated.

- 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.
Communicators with ZIP Wandless Telemetry

- Antenna (non-adjustable)
- Interrogate Button
- Action Button
- LCD Screen
- Power On Indicator
- Menu Selection Buttons (4)

Wanded Communicator (Inductive Telemetry)

- Cradle
- Wand

Menu Selection Buttons (on the screen)

Figure 1. LATITUDE Communicator Models
LATITUDE Customer Support

LATITUDE Customer Support has the capability to provide notification of alert conditions in addition to the notifications provided by the LATITUDE server (See “Alerts” on page 6 for information on alerts).

LATITUDE Customer Support or other designated Boston Scientific personnel can contact you to provide LATITUDE generated patient, implanted device, or alert data. 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, LATITUDE Customer Support personnel can contact you to inform you of that alert.

LATITUDE Customer Support may be contacted at 1-800-227-3422.

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 20 pounds from the previous day or more than 30 pounds 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 450 lbs. Do not place anything on the scale that is beyond the weighing capacity.

Optional Symptom Questions

The LATITUDE system also 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 40 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 message appears on screen when it is time to answer these questions.

The questions appear on the Communicator screen and the patient responds by pressing buttons on the Communicator. Responses appear with other patient information on the LATITUDE clinician 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 11.

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.

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

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 41.

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 clinician 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 uses a wireless (radio frequency) feature that offers daily and/or weekly status checks with physician notification. This feature can be activated for patients who have a device that uses ZIP Wandless Telemetry, and/or for patients who use the weight scale from the LATITUDE Heart Failure Management system.

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 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. By default, designated BSC personnel also provide notification by telephone to the device physician's red alert number. There are several notification options for red alerts as described in “Red Alert Notification Preferences.” on page 8. If the Communicator is not able to connect and transfer the red alert data in approximately 24 hours, the Communicator displays a message asking the patient to call LATITUDE Patient Services and report any error codes that appear on the Communicator screen. LATITUDE Customer Support or other designated Boston Scientific personnel will then call the physician with red alert information.
NOTE: During remote device interrogations, red alert conditions present in the device are also reported through the LATITUDE website. LATITUDE Customer Support 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 41):

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

- Device battery has reached end of life (EOL)
- 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 change due to magnet
- V-Tachy mode set to value other than Monitor + Therapy
- PG has detected a possible malfunction

Red Alert Notification Preferences

LATITUDE Patient Management’s process for communicating red alert notifications is to call the physician’s preferred phone number within 24 hours. The call is made during daytime hours, including weekends. Calls for red alerts conditions received after daytime hours are made during daytime hours the following day, including weekends. Federal holidays are treated as weekends.

With a Red Alert Notification form, physicians have the option to select between several notification options for red alerts. Physicians also have the option of having red alerts delivered to a member of their staff. A notification preference requested with a Red Alert Notification form takes precedence over the above notification process.

Yellow Alerts

Notification of yellow alerts is optional and may be selected by either of a patient’s LATITUDE physicians. Notification for yellow alerts is provided through the LATITUDE website and optionally by fax. LATITUDE Customer Support or other designated Boston Scientific personnel can also contact you if the data is not available on the LATITUDE website.

1. A PG switched to Fallback Mode will not provide positive identification to the Communicator. A PG other than the one assigned to the patient could be interrogated, if the patient's PG is in Fallback Mode. A PRM must be used to confirm the mode of the PG.
2. 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. Call 1-800-CARDIAC.
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 41):

- Device battery has reached Elective Replacement Indicator (ERI)
- Explant indicator reached
- Voltage was too low for projected remaining capacity
- Ventricular pacing leads
  - Low right ventricular intrinsic amplitude
  - High right ventricular intrinsic amplitude
  - Low left ventricular intrinsic amplitude
  - High left ventricular intrinsic amplitude
  - Low left ventricular pacing lead impedance
  - High left ventricular pacing lead impedance
- Atrial pacing leads
  - Low atrial intrinsic amplitude
  - High 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)
    
    **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 2 pounds or more over multiple days or a change of 5 pounds or more any time within a week

**Yellow Alert Faxes**

The LATITUDE system can 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. See “APPENDIX C: EXAMPLE YELLOW ALERT FAX” on page 43 for additional information and an example fax.
If the automated fax fails, LATITUDE Customer Support attempts to manually send the fax within two business days of receiving notice of the failure. 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 identifies 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 or more.

After notification, the clinic 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 different types of implanted device interrogations. Each interrogation type varies in the amount and type of data that are collected, as shown in Table 1. All interrogations can be scheduled by the physician or permitted/configured to allow patient initiated interrogations. Refer to “Setting Follow-up and Data Collection Schedules” on page 22.

### Table 1. 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></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Off</td>
</tr>
<tr>
<td>Daily Device Check (Fault Check)</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>• Daily</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Off</td>
</tr>
<tr>
<td>Patient Initiated (See page 10)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>As directed by physician</td>
</tr>
</tbody>
</table>

1. The Daily Device Check feature is available only for Guidant or Boston Scientific PG models that use ZIP Wandless Telemetry.
2. If a red alert is detected during the Weekly or Daily Device Check, a full interrogation with EGM is attempted.
3. 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. 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**

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 are granted permissions from a physician to perform remote follow-ups and review patient data under that physician’s supervision. This includes the ability to follow a patient's care and dismiss that patient from the Patients For Review list (page 28) when follow-up is complete.

**Clinic Staff**

The Clinic Staff type is assigned to users who need to work with patient data in a read-only support capacity within the clinic. This includes the ability to view patient status and print patient reports.

Medical Professionals or Clinic Staff accounts can be created by request to LATITUDE Customer Support or by the Clinic Account Manager (See “MANAGING USER ACCOUNTS” on page 37).

**User Roles**

LATITUDE users from the same clinic (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 2 and Table 3 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 2. 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 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 3. 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 or Medical Staff)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Delegate (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.

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 system generates different web views to present content for patients and clinicians/physicians.

The LATITUDE website is located at:

http://www.latitude.bostonscientific.com

**Patient View**

Patients can view information about their implanted device and condition from a personalized patient website, using a unique login and password. However, patients do not have access to the detailed personal data or device related information that their physicians can view.

Patients must register and have approval by their clinic (as checked on the patient enrollment form) to gain access to the patient website.

This information is displayed to the patient:

- Date of most recent device interrogation
- Date of next scheduled device interrogation
- Estimate of device battery status
Clinician View
The clinician website provides doctors and clinicians a convenient and secure way to review the
data and health-related information that 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 advanced 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

Figure 3. LATITUDE Initial Access Page

3. Select your country.

   You only need to enter your country the first time you access the LATITUDE website, unless you do so from a different computer.
4. Click the LATITUDE® - TACHY button to display the login screen shown in Figure 4.

![Login Page]

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 will be 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.
Navigating the Site

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

- **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 18.)
- **E** Link to help and contact information, patient enrollment and deactivation forms, and other documentation.
- **F** Ends the user’s login session.
- **G** Account name for the current login session and the date.
- **H** Link to a page that displays all patients on the clinician’s review list. (See “THE PATIENTS FOR REVIEW PAGE” on page 28.)
- **I** Link to page that displays all patients visible to the current user. (See “THE ALL PATIENTS PAGE” on page 34.)
- **J** If Patient Search was used previously in the session, the Search Results drop-down menu remains available during the entire session. The last set of search criteria and results are displayed. (See “PATIENT SEARCH” on page 18.)
- **K** Link to the enrollment form that enables Physicians and Physician Delegates to enroll new patients. (See “PATIENT UTILITIES” on page 36.)
- **L** Link to a page that enables clinicians to view the status of electronic medical record (EMR) reports. (See “APPENDIX D: LATITUDE EMR/CIS INTEGRATION” on page 44.)
- **M** Link to the Configuration Profile page for the current user. (See “THE CONFIGURATION PROFILE PAGE” on page 19.)

Figure 5. LATITUDE Banner
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

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:

- 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.

**Physician configuration items** provide user access to a physician’s configuration settings. The links read either View or Configure depending on the roles assigned to the current user.

**Member Roles** column lists the user type and role(s) assigned to each user, in relation to the clinic and the current user.

---

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

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Setting Alert Notifications

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.

Figure 9. Yellow Alert Settings Page (Physician)

To change settings on a Yellow Alert Settings Page:

1. From the appropriate Configuration Profile page, click the Configure 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 10-digit telephone number.

3. When changing physician yellow alert settings, deselect the following check box that appears near the top of the page.

   ![Check box for keeping alert settings same as clinic defaults]

   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 save the settings in the LATITUDE system or select Reset to restore settings to the last saved version.
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 10. 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 11).

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.

For a patient with an implanted device that uses ZIP Wandless Telemetry, actual interrogations occur automatically on the scheduled dates. The patient does not need to perform any action and these interrogations often occur without the patient’s knowledge. For patients who have an implanted device that uses inductive telemetry, their Wanded Communicator notifies and prompts them to interrogate their device on scheduled dates. These scheduled follow-ups are designed to help keep the patient on schedule and in compliance with prescribed therapy.

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.

   ![Keep settings same as Clinic defaults:](image)

   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.
This row provides links to other configurable items and events.

This link returns users to their Configuration profile page.

These check boxes are used for assigning the clinic’s configuration settings to the physician. Deselecting these check boxes activate the respective remote follow-up and data collection choices that follow. A summary of the clinic default schedule and data collection values are displayed.

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.

This section is used to schedule the interval and day of the month for regularly scheduled follow-up interrogations. If needed, the date for one of a patient’s scheduled follow-ups may be changed through the Patient’s Configure Patient tab or by clicking on the patient’s next follow-up date and using the scheduling calendar that is displayed.

This section is used to set other types of interrogations (daily device checks [available only with PGs that support ZIP Wandless Telemetry], weekly alert, and patient-initiated—see page 10). This section is also used for reporting of home health equipment measurements and enabling patient symptom questions.

Figure 10. Schedule Configuration Page (Physician)
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 11.

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.

![Remote Follow-up Scheduling Calendar](image)

**Figure 11. 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

**NOTE:** 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 12. 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 12. Clinic Delegate and Administrator Selection](image-url)

Figure 12. 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 13. 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.

![Figure 13. 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.

- 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.
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.

![Change password screen](image)

**Figure 14. Change password screen**
THE PATIENTS FOR REVIEW PAGE

The Patients for Review page (Figure 15) 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 name.

![LATITUDE Patient Management](image)

**Figure 15. Patients for Review Page**

A red flag indicates a patient with one or more red alerts and zero or more yellow alerts who have 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 will not be 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) are performed for all patients in the list.

**Patient Name/Patient ID/Device**

Click on the patient’s name to see detailed information for that patient. If defined, 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.

**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 15.

**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 PG data for that patient (for
example, from a scheduled remote follow-up, weekly interrogation, patient-initiated interrogation, or red alert interrogation). 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:

- 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 names (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 display 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 name that is listed in the Patients for Review or All Patients pages displays a Patient Detail page. Figure 16 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 16 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 16. Patient Detail Tabs and Links Quick Reference

Definitions of Symbols and Similar Terms

- 📧 Symbol for pulse generators that use ZIP Wandless Telemetry
- 📦 Symbol for pulse generators that use inductive telemetry

In-Office Test:
- Last In-Office Lead Test (Inductive PGs). Last in-office device-based lead test using the programmer (e.g., intrinsic amplitude and ventricular amplitude measurements, lead impedance measurements).
- Last Office Interrogation (ZIP PGs). 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 [i.e., daily (if a red alert is present), weekly, patient-initiated interrogation, or scheduled remote follow-up].

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).
FOLLOW-UP HISTORY

The Follow-up History page (Figure 17) 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>New Alert</th>
<th>New Events</th>
<th>Presenting EGM</th>
<th>Sent to EMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 Dec 2009</td>
<td>Scheduled</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Nov 2009</td>
<td>Patient-Initiated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Oct 2009</td>
<td>Scheduled</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Sep 2009</td>
<td>Scheduled</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Aug 2009</td>
<td>Presenting EGM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 17. 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 15).

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.

THE ALL PATIENTS PAGE

The All Patients page (Figure 18) 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 name. This page enables users to display data and print reports for any of their patients. A patient may automatically be removed from the list without notification if the patient is deceased or if the patient has an inactive or unsupported PG.

![Figure 18. All Patients Page](image-url)
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 Name/Patient ID**

Click on the patient’s name to see detailed information for that patient. If defined, 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**

- **Enrolled.** The patient’s enrollment has been processed by LATITUDE Customer Support, but a Communicator has not been shipped.
- **Shipped.** The patient’s Communicator has been shipped but not activated.
- **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.
- **Replacement Ordered.** A new Communicator has been ordered for the patient but has not been shipped. (This could occur for example, if a patient has a wanded/inductive implanted device replaced with an RF/wandless telemetry device, which requires providing a new Communicator.)
- **Replacement Shipped.** A new Communicator has been shipped to the patient but has not been activated.
PATIENT UTILITIES

The Patient Utilities tab (Figure 19) 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. See “EMR Log” on page 44.

![Figure 19. Patient Utilities Tab](image-url)
MANAGING USER ACCOUNTS

A user assigned the role of Clinic Account Manager can create user accounts for Medical Professionals and Clinic Staff. Only LATITUDE Customer Support personnel can create user accounts for physicians as requested in a physician's enrollment form. (Enrollment forms are available from the Help/Contact Us web page.)

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 20) to access all account management functions. This displays the Clinic Member List page as shown in Figure 20.

![Figure 20. Clinic Member List (Clinic Account Manager)](image)

Adding Accounts

Medical Professional 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. To delete a user, click on the Remove Member link associated with that user on the Clinic Member List page. Removing one of these accounts 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.

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

Deactivating Patient and Physician Accounts

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

To deactivate a physician account, the physician should contact the 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 an 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 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. However, the user's first name, middle initial, and last name can be modified. 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 login 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

Physicians who forget their password should contact LATITUDE Customer Support to have a new temporary password created. Medical Professionals and Clinic Staff can contact their LATITUDE Clinic Account Manager or LATITUDE Customer Support. 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 (for example, every Monday morning).

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.

Yellow Alert  Red Alert

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 configured on the individual patient.

<table>
<thead>
<tr>
<th>Battery</th>
<th>Tachy Devices</th>
<th>CRT Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device battery has reached end of life (EOL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote monitoring disabled due to limited battery capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device battery has reached Elective Replacement Indicator (ERI)</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>
</tbody>
</table>

**Shock Leads**

- Low shock lead impedance
- High shock lead impedance
- Low shock lead impedance detected when attempting to deliver a shock
- High shock lead impedance detected when attempting to deliver a shock

**Ventricular Pacing Leads**

- Low right ventricular pacing lead impedance
- High right ventricular pacing lead impedance
- Low right ventricular intrinsic amplitude
- High right ventricular intrinsic amplitude
- Low left ventricular intrinsic amplitude
- High left ventricular intrinsic amplitude
- Low left ventricular pacing lead impedance
- High left ventricular pacing lead impedance


Last Updated: 30 Oct 2013
### 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>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
</tr>
<tr>
<td>High atrial intrinsic amplitude</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
</tr>
<tr>
<td>Low atrial pacing lead impedance</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
</tr>
<tr>
<td>High atrial pacing lead impedance</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
</tr>
</tbody>
</table>

**Tachy Mode**

- V-Tachy Mode changed due to magnet
- V-Tachy Mode set to value other than Monitor + Therapy

**Arrhythmias**

- Shock therapy delivered to correct arrhythmia (Ventricular)
- Accelerated arrhythmia episode (Ventricular)
- Atrial Arrhythmia Burden in a 24 hour period (Dual-chamber devices only)
- Patient triggered event stored

**Pacing**

- Right Ventricular pacing
- Cardiac Resynchronization Therapy pacing

**High Voltage Detected on Shock Lead During Charge**

**Therapy history corruption detected**

<table>
<thead>
<tr>
<th>Possible Device Malfunction</th>
<th>☐ ☐ ☐ ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Parameter Error</td>
<td>☐ ☐ ☐ ☐ ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight (For patients with LATITUDE weight scales)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight gain of at least 5 lb. in a week or at least 2 lb. average over a two or more day period</td>
</tr>
<tr>
<td>Weight loss of at least 5 lb. in a week or at least 2 lb. average over a two or more day period</td>
</tr>
</tbody>
</table>

1. A PG switched to Fallback Mode will not provide positive identification to the Communicator. A PG other than the one assigned to the patient could be interrogated, if the patient’s PG is in Fallback Mode. A PRM must be used to confirm the mode of the PG.

**Figure 22. LATITUDE Alerts Report, Page 2**

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APPENDIX C: EXAMPLE YELLOW ALERT FAX

Figure 23 shows an example yellow alert fax.

**NOTE:** 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.

<table>
<thead>
<tr>
<th>LATITUDE® Patient Management</th>
<th>05 Mar 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facsimile Alert</td>
<td></td>
</tr>
</tbody>
</table>

**To**
Graham, Pat W M.D.

**Clinic**
Midwest Cardiology

**Fax Number**
303.902.5555

**From**
Boston Scientific LATITUDE Patient Management

**Phone Number**
800.227.3422

*If this transaction is not received in good order, please call 800.227.3422.*

**Patient**

<table>
<thead>
<tr>
<th>Patient:</th>
<th>Carson, Maria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth:</td>
<td>25 Feb 1924</td>
</tr>
<tr>
<td>Patient ID:</td>
<td>1234567</td>
</tr>
<tr>
<td>Patient Phone Number:</td>
<td>952.440.7290</td>
</tr>
<tr>
<td>Device:</td>
<td>CONTAK RENEWAL 3 RF H215/251533</td>
</tr>
<tr>
<td>Last Office Interrogation:</td>
<td>11 Jan 2008</td>
</tr>
<tr>
<td>Last Send:</td>
<td>05 Mar 2008</td>
</tr>
</tbody>
</table>

**Patient Alert Information**

- **05 Mar 2008** - High shock impedance detected on 05 Mar 2008. Schedule in-office follow-up to evaluate shock lead. Call 1-800-CARDIAC.
- **05 Mar 2008** - Shock therapy delivered to convert arrhythmia. Review episode detail in Arrhythmia Logbook.
- **05 Mar 2008** - Shock therapy delivered to convert arrhythmia. Review episode detail in Arrhythmia Logbook.

*This facsimile message is intended only for the individual to whom it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If you have received this facsimile in error, please notify us immediately by telephone and return the original message to us at the address below via the US Postal Service.*

Boston Scientific Corporation
4100 Hamline Avenue North St. Paul, MN 55112-5798

Tel 1.800.CARDIAC (800.227.3422)

Figure 23. Example Yellow Alerts Fax
APPENDIX D: 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 some 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 14.

**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.

**EMR Log**
Clinicians use the EMR Log page (Figure 14) 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 action button enables the retransfer of previously transferred patient records. If one or more patient records have been selected, the “Place in EMR Outbox” button changes 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 for all patients listed on the page. After selecting a check box, the “Place in EMR Outbox” button is activated and patient follow-up summary files can be retransferred to the clinic’s system.

- **D** Click on the patient’s name to see detailed information for that patient.

- **E** The user-initiated event that triggered the creation and attempted transfer of the patient follow-up summary file.

- **F** The date and time of the Activity.

- **G** 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 on the next page.

- **H** The date and time of the current status.

Figure 14. EMR LOG Page

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