

INSTALLATION AND OPERATION GUIDE

LATITUDE Link™

DATA MANAGEMENT SYSTEM

Model 6215 LATITUDE Link™ Viewer

Model 6216 LATITUDE Link™ Import Utility

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LATITUDE LINK™ DATA MANAGEMENT SYSTEM OVERVIEW

The purpose of this document is to provide health care providers and information technology personnel with a basic understanding of the LATITUDE Link™ Data Management System. These persons may use this document to:

- Become familiar with components of the system
- Determine how to install and configure the system
- Understand how to use and maintain the system

Having a basic understanding of the system components, processes, and associated terminology can help support the system and troubleshoot any problems that might arise.

Intended Use

The LATITUDE Link Data Management System is intended to transfer select patient and device data from Boston Scientific programming systems to Electronic Medical Record (EMR) systems or to Boston Scientific systems. The LATITUDE Link Data Management System also makes select patient and device data available for viewing.

Contraindications

The LATITUDE Link Data Management System is contraindicated for use with any implanted device data other than data from compatible Boston Scientific implanted devices. Not all Boston Scientific implanted device data sets are compatible with the LATITUDE Link Data Management System.

How the LATITUDE Link Data Management System Works

Health care providers conduct follow-ups or other device checks on patients with Boston Scientific implanted devices using Boston Scientific programming systems.

The health care provider uses removable media (e.g. a USB flash drive or a microSD™ card) or other means (e.g. *Bluetooth* wireless technology) to import patient data from a programming system into the LATITUDE Link Data Management System.

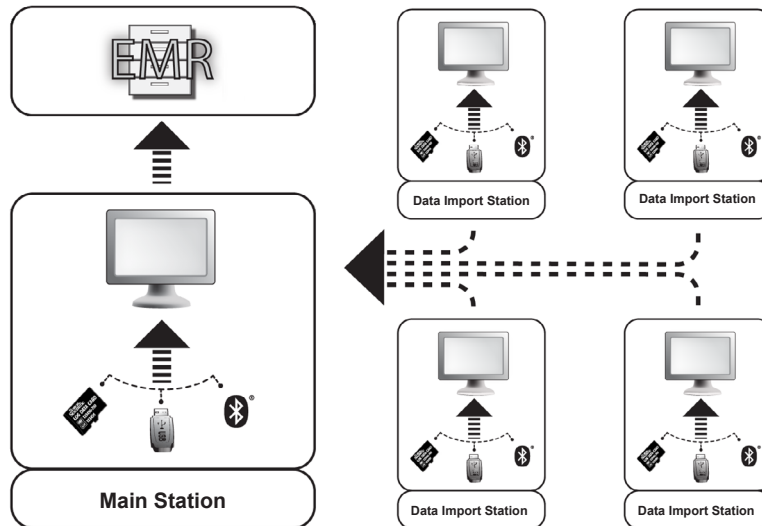
The LATITUDE Link Data Management System transfers the data to the EMR system and (for S-ICD devices) uploads the data to Boston Scientific.

Health care providers can use the LATITUDE Link Data Management System to view transfer and upload status of data records, re-send records, and (for S-ICD devices) view device data and reports associated with a record.

INSTALL AND SET UP THE LATITUDE LINK™ DATA MANAGEMENT SYSTEM

Installation Overview

The LATITUDE Link™ Data Management System uses a single designated computer (the main station) to transfer device data received from Boston Scientific programming systems to the clinic EMR system in a compatible format. Other computers on the clinic network may be used as data import stations. These computers can collect programming system data and forward it to the main station.



The LATITUDE Link Data Management System consists of two software applications:

1. **The LATITUDE Link™ Import Utility** (installed on both the main and data import stations)
The Import Utility imports programming system device data using any of the following means:
 - Removable media (such as the USB flash drive on Model 3120 Programmer/Recorder/Monitor or the microSD™ card on Model 3200 programming system)
 - *Bluetooth* wireless technology (such as Model 3200)
2. **The LATITUDE Link™ Viewer** (installed on the main station)
The Viewer receives programming system device data from one or more Import Utility installations and transfers the data to an EMR system in a configured data format. The Viewer makes S-ICD device data and reports available for viewing and may also upload S-ICD data to Boston Scientific servers to help facilitate Boston Scientific technical support services. Other computers connected to the network can be used to access the LATITUDE Link Viewer using a web browser.

IMPORTANT: In order to avoid sending duplicate records to the EMR system, install the LATITUDE Link Viewer software on the designated main station only. Do not install it on the data import stations.

NOTE: To ensure correct installation, software updates, and application function the following conditions must be met:

- Both the main station and data import stations must maintain a connection to the Internet.
- The main station must maintain a network connection to the desired EMR system.
- Each data import station must maintain a network connection to the main station.

Install and Set Up the Main Station

NOTE: Installation of the LATITUDE Link Viewer requires administrator-level access on the main station. If you do not have that level of access, ask your system administrator to perform the installation.

1. Use the “Information Required For Latitude Link Viewer Setup” form to gather information about your clinic’s EMR system.
2. Go to the LATITUDE Link download site (www.bostonscientific.com/latitudelink) from the designated main station. Download and run the LATITUDE Link Viewer installation file. Follow the on-screen prompts and instructions to perform the installation. When the installation process is complete the Viewer itself will start and a configuration screen will appear.
3. The LATITUDE Link Viewer URL listed on the configuration screen is used when installing the LATITUDE Link™ Import Utility on other computers. Record the URL if you plan to do this.

URL: _____

4. Enter the configuration information from the setup information form completed in step 1 above.

IMPORTANT: Incorrect EMR Connectivity settings could lead to the transfer of follow-up data—including personal data—to an unintended destination.

5. Once the required configuration information has been entered, review and modify the remaining options as desired.
6. Go to the LATITUDE Link download site (www.bostonscientific.com/latitudelink). Download and run the LATITUDE Link Import Utility installation file.

NOTE: Installing the LATITUDE Link Import Utility does not require administrative privileges.

7. The Import Utility window will be displayed after installation. Close this window. You can access the Import Utility at any time by using its icon in the system tray, which is located near the computer’s date and time display.
8. Setup of the main station is now complete.

NOTE: The Import Utility is installed specifically for each user account on the computer. If other users log into this computer and intend to use the Import Utility, each user must install the software from their account. Repeat steps 6 and 7 for each additional user.

9. If you want to set up additional computers that can send implanted device data from a programming system to your EMR system, please go to each of these computers and follow the instructions in the “Install and Set Up Additional Data Import Stations (Optional)” section of this document.

INFORMATION REQUIRED FOR LATITUDE LINK VIEWER SETUP

The following configuration parameters are used to complete the setup of the main station. Check with your system administrator to determine each value.

Clinic name to use in the EMR system

Clinic or facility name _____

EMR Integration format

Generic HL7 2.3.1 ORU version 1

XML version 5.0 (Paceart)

HL7 2.3.1 ORU version 1 (Centricity)

IDCO (IHE PCD-09 revision 2.0)

EMR Transfer Method & Connection Information

File Drop

File Drop Location: _____

MLLP

MLLP Host Name: _____ Port: _____

HTTP (used with Paceart XML format)

HTTP Host Name: _____ Port: _____

EMR Message Language

Language used in EMR system messages _____

Install and Set Up Additional Data Import Stations (Optional)

IMPORTANT: *Optional data import stations should have only the LATITUDE Link™ Import Utility software installed. Do not install the LATITUDE Link™ Viewer software that was installed on the main station on a data import station.*

1. Go to the LATITUDE Link download site (www.bostonscientific.com/latitudelink). Download and run the LATITUDE Link Import Utility installation file.

NOTE: *Installing the LATITUDE Link Import Utility does not require administrative privileges.*

2. After the application is installed, it will start automatically and open to the configuration window.
3. De-select the option that indicates the LATITUDE Link Viewer is installed on this computer.
4. Replace the contents of the LATITUDE Link Viewer URL field with the network location that you recorded during step 3 of the Install and Set Up the Main Station section.

NOTE: *The LATITUDE Link Viewer URL is found on the manage configuration option of the Viewer's manage clinic menu.*

5. Save the configuration and close the Import Utility window. You can access the Import Utility at any time by using its icon in the system tray, which is located near the computer's date and time display.
6. Setup of the data import station is now complete.

NOTE: *The Import Utility is installed specifically for each user account on the computer. If other users log into this computer and intend to use the Import Utility, each user must install the software from their account. Repeat steps 1-5 for each additional user.*

USING THE LATITUDE LINK™ DATA MANAGEMENT SYSTEM

Import and Transfer Data to the EMR System

Follow-up data can be imported into the LATITUDE Link Data Management System using removable media or *Bluetooth* wireless technology.

NOTE: *Follow-up data imported into the LATITUDE Link Data Management System can include personal data of the type that is generally kept protected. Please refer to "APPENDIX A: OTHER INFORMATION" on page 9 for further information.*

Import from removable media

To import follow-up data from removable media—such as a USB flash drive or a microSD™ card—insert the media into a computer that has the LATITUDE Link Import Utility installed. The Import Utility will retrieve the data and send it to the LATITUDE Link Viewer, where it can be transferred (either automatically or manually) to the EMR system or uploaded to Boston Scientific.

Import using *Bluetooth* file transfer

In order to successfully transfer follow-up data using *Bluetooth* wireless technology, the data-exporting equipment (e.g. programming system) must first be paired with the LATITUDE Link Import Utility computer. Follow the pairing instructions provided with the sending equipment to accomplish this. Next, the LATITUDE Link Import Utility application must be configured to import data from its own computer's *Bluetooth* exchange folder. Check the *Bluetooth* settings of the computer to determine the folder path that is in use.

Access the LATITUDE Link Import Utility configuration by clicking on its application icon—found in the system tray which is located near the computer's date and time display—and selecting the change configuration option. Enter the computer's *Bluetooth* exchange folder path into the folder configuration field.

Follow-up data is sent to the LATITUDE Link Data Management System by initiating the file transfer process on the external system (e.g. programming system) once the *Bluetooth* connection has been established. The Import Utility will retrieve the data and send it to the LATITUDE Link Viewer, where it can be transferred (either automatically or manually) to the EMR system or uploaded to Boston Scientific.

View Follow-up List

The LATITUDE Link Viewer provides the ability to view the list of follow-ups that have been imported into the LATITUDE Link Data Management System, as well as the status of their transfer to the EMR system. Follow-ups can also be sent or re-sent to the EMR system by selecting the desired records and initiating the transfer to EMR. Detailed S-ICD follow-up data may be viewed by selecting the individual record.

By default, the Viewer is automatically launched after a data import operation is complete. It may also be accessed independently by using the shortcut located in the Boston Scientific folder within the start menu.

(Start > All Programs > Boston Scientific folder)

Manage Clinic

Manage Configuration

The LATITUDE Link Data Management System offers several post-installation configuration options. These include the following:

- choice of which reports to include in EMR messages (available reports from this group are combined into one file for EMR transfer);
- whether or not follow-up data is automatically transferred to the EMR system;
- whether or not follow-up data is automatically uploaded to Boston Scientific;
- EMR connectivity settings; and
- secure communication management (See “Enabling Secure Communication” on page 9).

Manage Data Upload to BSC

Imported S-ICD data may be uploaded to Boston Scientific (BSC) and can be used if assistance is needed from Boston Scientific Technical Services. A list of follow-ups and their BSC upload status may be viewed—and follow-ups may be sent or re-sent to BSC—by selecting the desired records and initiating the upload to BSC.

NOTE: *The default configuration is that S-ICD follow-up data is automatically uploaded to Boston Scientific. This data may be aggregated with data from other LATITUDE Link Data Management Systems. The automatic upload feature can be disabled via the Manage Configuration user interface.*

Manage Clinic Users

LATITUDE Link user access control is not enabled by default during installation. A designated administrator may enable this feature following installation in order to create and manage user accounts.

Delete Follow-up Data

The LATITUDE Link Data Management System stores all imported follow-up data indefinitely. This makes it possible for users to re-send follow-ups to the EMR system and/or BSC, or to view details for select implanted devices. Follow-up data records can be deleted from the LATITUDE Link Data Management System at any time, if desired.

IMPORTANT: Follow-ups that have been deleted from the LATITUDE Link Data Management System will not be available for re-sending or viewing, and they cannot be re-imported into the LATITUDE Link Data Management System.

MAINTENANCE

Software Updates

Software updates for either the LATITUDE Link Viewer or the LATITUDE Link Import Utility may become available. User notification will be provided when updates are released.

To update the LATITUDE Link Viewer, run the LATITUDE Link Updater program installed with the application and follow the provided instructions.

To update the LATITUDE Link Import Utility, simply select the software update option when it is presented.

IMPORTANT: The installed software must be kept up-to-date in order to ensure that important changes have been applied. Continued use of software that is out-of-date can increase exposure to possible issues with data accuracy or functionality that are addressed in the updated software.

Backing-up and Restoring data

Follow-up data stored by the LATITUDE Link Data Management System may be backed up by copying the entire contents of the installed database location to a suitable location. The data may be restored by completely overwriting the installed database location with the backup contents.

APPENDIX A: OTHER INFORMATION

Protecting LATITUDE Link™ Data

Follow-up data imported into LATITUDE Link™ Data Management System includes *personal data* which is stored unencrypted in the LATITUDE Link Data Management System database. In order to keep this *personal data* protected, the file system location containing the system database must have appropriate access controls in place. Data encryption and file security are not part of the LATITUDE Link Data Management System.

The LATITUDE Link Data Management System employs the computer's basic "delete" function when commanded by the user to remove follow-up data from its database. Therefore, deleted follow-up data—which contains personal data—should be protected by making deleted file data unrecoverable at the computer file system level.

Enabling Secure Communication

IMPORTANT: *This setup requires a computer administrator with expertise in SSL communication.*

Secure communication with the LATITUDE Link Viewer is not enabled by default during installation. Enabling secure communication allows for encrypted communication between the Import Utility and the Viewer and between a web browser and the Viewer. In order to enable this capability, an encryption key pair and certificate must be provided to the application. The following steps should be performed by someone with SSL expertise and with administrative-level access to the main station where the Viewer is installed:

1. Retrieve Key Pairs and Certificates

Coordinate with an existing public key infrastructure (either internal to your organization or through a third party) to generate the following items:

A key pair consisting of a public key and a private key.

A certificate signed by a trusted Certificate Authority.

IMPORTANT: *The certificate must list the common name that matches the LATITUDE Link Viewer fully qualified network name. This can be found on the Viewer configuration page as the LATITUDE Link Viewer URL. For example, if the configuration page shows the URL **http://computer123.myclinic.com/ladc**, then the network name to use would be **computer123.myclinic.com**.*

Provide the key pair and certificate in a PKCS#12 formatted file that is protected with the password provided by the public key infrastructure.

IMPORTANT: *If the signing Certificate Authority is an intermediary, the PKCS#12 store must have the certificate chaining included.*

2. Configure the LATITUDE Link Viewer

From the computer with the Viewer software installed, navigate to the installation folder and the “config” subfolder.

Edit the file *latitude-link.properties* with the following changes:

- Update *latitude.link.keystore.path* to add the keystore path and file name (e.g. *latitude.link.keystore.path=<path and filename>*). If the file name is specified with no path, the current path is used (i.e. the *config* subfolder).
- Update *latitude.link.keystore.password* to add the keystore password provided by the public key infrastructure (e.g. *latitude.link.keystore.password=<password>*).
- Update *latitude.link.ssl.port* to specify the desired SSL port number (e.g. *latitude.link.ssl.port=<port number>*).

IMPORTANT: *This configuration file will contain critical information about accessing the security key information. In order to keep this information protected, ensure that proper file system access controls are in place for this file.*

3. Restart the LATITUDE Link Viewer service via the Windows Services program.

SSL communication will be enabled once these steps have been completed. This can be confirmed by navigating to the main Viewer page and ensuring that the browser has secure communication enabled (i.e. the https protocol is in use and the security padlock icon indicates a secure connection).

System Requirements

The LATITUDE Link Viewer and Import Utility were developed to run on the Windows operating system.

The LATITUDE Link Viewer was developed to support the following web browsers:

- Internet Explorer
- Mozilla Firefox
- Google Chrome

NOTE: *The LATITUDE Link Viewer and Import Utility were developed with operating systems and browsers that were current at that time. The software may not function properly when using operating system or browser versions that were subsequently released. Contact Boston Scientific Technical Services at 1-800-CARDIAC (227-3422) or your local affiliate for a list of supported operating systems and web browsers.*

Boston Scientific

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

1.800.CARDIAC (227.3422)
+1.651.582.4000

www.bostonscientific.com

Guidant Europe NV/SA
Boston Scientific
Green Square,
Lambroekstraat 5D
1831 Diegem, Belgium

1.800.CARDIAC (227.3422)
+1.651.582.4000

www.bostonscientific.com

Cardiac Pacemakers Incorporated
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

Manufactured at:
Cardiac Pacemakers Incorporated
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

1.800.CARDIAC (227.3422)

+1.651.582.4000



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