

OPERATOR'S MANUAL

Network and Connectivity

Application for use with the LATITUDE™
Programming System

REF 3924 Network and Connectivity

REF 3300 LATITUDE™ Programming System

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INFORMATION FOR USE

Trademark Statement

The following are trademarks of Boston Scientific Corporation or its affiliates: LATITUDE, LATITUDE Link, and Quick Start.

Bluetooth® is a registered trademark of Bluetooth SIG.

DisplayPort is a trademark of the Video Electronics Standards Association (VESA)

Description and Use

The Networking application of the LATITUDE™ Programming System provides Ethernet and wireless connectivity for software download, Bluetooth® connectivity for data transfer, and Bluetooth® and USB connectivity for printing. The LATITUDE™ Programming System, Model 3300, is a portable cardiac rhythm management system designed to be used with Boston Scientific (BSC) systems, i.e. implantable pulse generators (PG) and leads.

NOTE: *The screen images used in this manual are representative and may not exactly match your screens.*

Intended Use

The LATITUDE Programming System is intended for use in hospital and clinical environments to communicate with Boston Scientific implantable systems. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literature for the pulse generator being interrogated.

Intended Audience

The Model 3300 Programmer device is intended for use by health care professionals trained or experienced in device implant and/or follow-up procedures.

Required Expertise and Knowledge

Users must be thoroughly familiar with electrotherapy of the heart. Only qualified medical specialists having the special knowledge required for the proper use of the device are permitted to use it.

Physician Supervision

The LATITUDE Programming System may only be operated under the constant supervision of a physician. During a procedure, the patient must be continuously monitored by medical personnel with the aid of a surface ECG monitor.

Medical Product Operator's Ordinance

National regulations may require that the user, manufacturer or manufacturer representative perform and document safety checks of the device during installation. They may also require that the manufacturer or its representative provide training to users on the proper use of the device and its accessories.

If you do not know the national regulations in your country, please contact your local Boston Scientific representative.

Contraindications

The LATITUDE Programming System is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator.

The Network and Connectivity application is contraindicated for use with any programming system other than the Boston Scientific Model 3300 LATITUDE™ Programming System.

For contraindications for use related to the pulse generator, refer to the associated product literature for the pulse generator being interrogated.

WARNINGS

Refer to the *LATITUDE Programming System Operator's Manual, Model 3300* for additional Warnings.



Use of unspecified cables and accessories. The use of any cables or accessories with the LATITUDE Programming System other than those provided by or specified by Boston Scientific could result in increased electromagnetic emissions, decreased electromagnetic immunity, or electrical shock of the LATITUDE Programming System. Anyone connecting such cables or accessories to the LATITUDE Programming System, including the use of MSOs (Multiple Socket Outlets), may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.



Connector contacts. Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor.



Programming System location. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



Equipment modifications. No modification of this equipment is allowed unless approved by Boston Scientific.

Precautions

Refer to the *LATITUDE Programming System Operator's Manual, Model 3300* for additional Precautions.

- **Leakage current.** Although optional external equipment connected to the Model 3300 Programmer must meet the applicable leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, all external equipment must be kept outside the patient environment.
 - Never touch the electrical contacts on the side panels of the Model 3300 Programmer and the patient, a telemetry wand, or any cable at the same time.
- **Ethernet.** If desired for use, connect the Ethernet cable only to the RJ45 Ethernet port connector on the Model 3300 Programmer. Insertion or removal of the Ethernet cable during operation may affect networking functions. The RJ45 Ethernet connection on the Model 3300 Programmer is for Local Area Networking (LAN) use only. It is not to be used for a telephone connection.
- **USB devices.** USB devices connected to the Programmer should be controlled to limit the potential introduction of malware.
- **Software.** Ensure that you have the latest software versions installed. As a backup, your local Boston Scientific representative can provide software updates using a USB pen drive.
- **System Power up.** Boston Scientific recommends attaching all necessary cables and devices before turning on the Model 3300 Programmer.

Software Updates and Download

Software updates and downloads are provided via Internet or USB pen drive.

The Utilities tab on the Model 3300 Programmer screen includes a Software Update selection. The user may choose to download and install all updates or to review and select updates from those available.

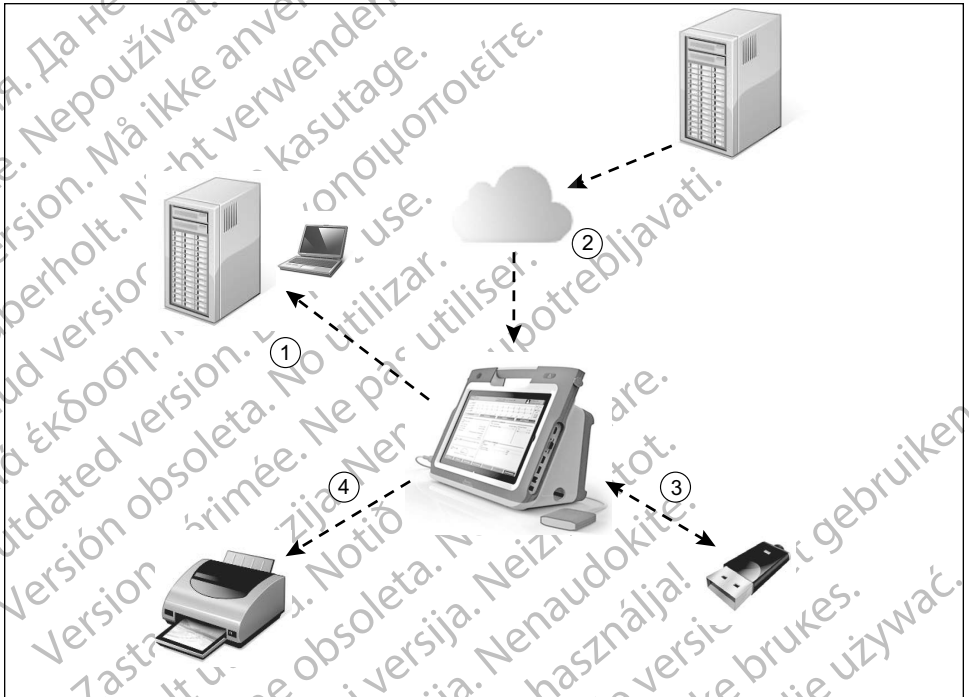
Refer to the *LATITUDE Programming System Operator's Manual, Model 3300* for additional information on downloading and installing software updates.

A loss of network connectivity can result in delays in installing software updates and, indirectly, reaping the use of those update benefits with respect to for the Model 3300 Programmer, PSA, or PG functionality. As a backup, your local Boston Scientific representative can provide software updates using a USB pen drive.

Networking and Connectivity

The LATITUDE Programming System provides Ethernet and wireless connectivity for software download. Bluetooth® connectivity is available for data transfer (e.g. to a laptop) and printing. Refer to Figure 1 for an illustration of possible networking connections.

Before device interrogation, refer to “Using Network and Connectivity Functions” on page 7 to connect to and configure network and connectivity functions.



[1] Data transfer using Bluetooth®; [2] Model 3300 Programmer software download from BSC using Internet via Ethernet or Wi-Fi; [3] Data transfer, Model 3300 Programmer software update via USB; [4] Report printing using Bluetooth® or USB cable

Figure 1. Networking Overview

Network Connectivity

The LATITUDE Programming System provides Ethernet, Wi-Fi, Bluetooth®, and USB connectivity.

Ethernet and Wi-Fi

Connecting to an IT network provides an information flow between the Model 3300 Programmer, the network, and devices on the network. Networking connectivity is used to download software from a secure Boston Scientific server and synchronize the date and time internal clock of the Model 3300 Programmer.

Software downloads are retrieved from a Boston Scientific server, sent over the Internet, and received by the Ethernet or Wi-Fi connection of the LATITUDE Programming System.

Loss of Network

If there is a loss of network (Ethernet or Wi-Fi) and you are unable to reconnect once the network is functioning again, here are some recovery actions:

- To recover Wi-Fi network functions, remove the Ethernet cable and restart the Wi-Fi activity.
- To recover Ethernet network functions, re-insert the Ethernet cable and restart the Ethernet activity.
- If the Ethernet cable is removed or inserted while a network function (download or transfer) is active, the network function will abort and be incomplete.
- To recover from an incomplete software download, check the network status and connection, and retry the download. If still unsuccessful, please contact Boston Scientific Corporation Technical Services using the information on the back cover of this manual or contact your local Boston Scientific representative.

Bluetooth®

Bluetooth® connectivity is used to communicate with Bluetooth® enabled printers to print patient data and reports and to communicate with another computer in order to transfer patient data to LATITUDE Link.

To recover from an incomplete Bluetooth® data transfer, retry the transfer. If still unsuccessful, please contact Boston Scientific Corporation Technical Services using the information on the back cover of this manual or contact your local Boston Scientific representative.

USB

Patient data and reports can be printed to a USB connected printer or saved to a USB pen drive for transfer to another device for printing.

To recover from an incomplete USB data transfer, retry the transfer or use a different USB pen drive. If still unsuccessful, please contact Boston Scientific Corporation Technical Services using the information on the back cover of this manual or contact your local Boston Scientific representative.

Optional External Equipment

Optional external equipment can be used with the LATITUDE Programming System. Contact your Boston Scientific sales representative to determine what external equipment can be used.

NOTE: If adding external equipment, you are configuring a medical system and are responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.



WARNING: Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor.

CAUTION: Although optional external equipment connected to the LATITUDE Programming System meets leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, all external equipment must be kept outside the patient environment.

External Printer

The LATITUDE Programming System supports a broad range of external USB printers. Refer to the instructions (“Connections” on page 7) to connect the appropriate USB 2.0 or 3.0 printer cable.

NOTE: *USB 3.0 printers can process print data faster than USB 2.0.*

Some Bluetooth® printers are also supported. Refer to “Bluetooth® Connectivity” on page 13.

DisplayPort for an External Monitor

You can use an external video or digital monitor (or equivalent) that can synchronize to any horizontal scan frequency to display the Programmer screen.

NOTE: *External monitors may require an adapter and/or cable to connect to the DisplayPort on the Programmer.*

NOTE: *Equipment connected to the external connections must comply with applicable standards (e.g., IEC/EN 60950-1 for data processing equipment and IEC/EN 60601-1 for medical equipment).*

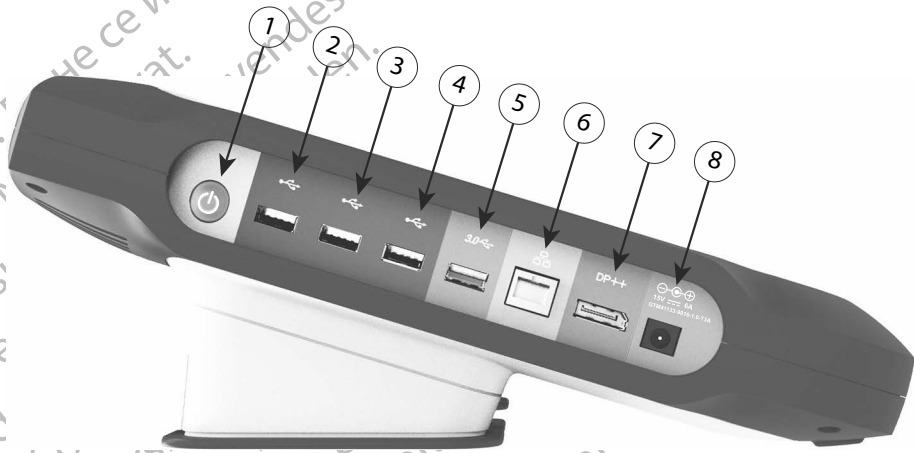


WARNING: The use of any cables or accessories with the LATITUDE Programming System other than those provided by or specified by Boston Scientific could result in increased electromagnetic emissions, decreased electromagnetic immunity, or electrical shock of the LATITUDE Programming System. Anyone connecting such cables or accessories to the LATITUDE Programming System, including the use of MSOs (Multiple Socket Outlets), may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.

CONNECTIONS

Refer to Figure 2 to identify the network and connectivity ports on the Model 3300 Programmer.

Physician side panel (left side)



[1] Power (ON/OFF) button [2] USB 2.0 port [3] USB 2.0 port [4] USB 2.0 port [5] USB 3.0 port [6] Ethernet Port [7] DisplayPort Out [8] DC Power connection (for Model 6689 power adapter)

Figure 2. Left side panel of the LATITUDE Programming System

USING NETWORK AND CONNECTIVITY FUNCTIONS

Network and Connectivity Cable Connections

As needed, make the following connections on the left side of the LATITUDE Programming System.



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1. **Ethernet:** To connect to a local area network (LAN), attach an Ethernet cable only to the Ethernet port.

NOTE: Additional steps need to be completed when using Bluetooth® or LAN communications. Refer to “Ethernet Connectivity” on page 16 and “Bluetooth® Connectivity” on page 13.

2. **External Monitor:** To connect an external monitor, connect the digital display cable^a to the DisplayPort Out connector. Ensure that the monitor is connected to external power. For some monitors to display appropriately, it may be necessary to remove and reinsert the DisplayPort connection to resynchronize the video.
3. **USB Printer:** To connect an external USB printer, attach the appropriate USB cable to the appropriate USB port on the Model 3300 Programmer. Then, ensure that the printer is connected to external power.

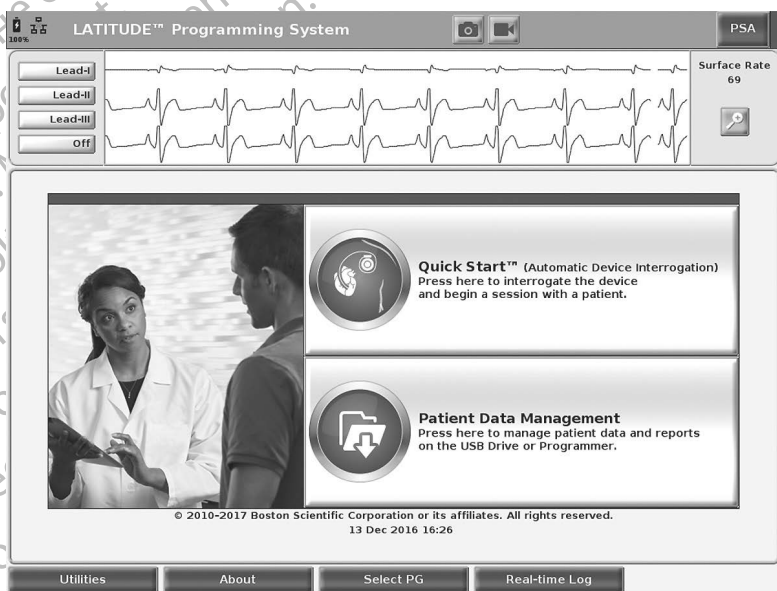
NOTE: The LATITUDE Programming System has Bluetooth® capability, which can be used to connect with Bluetooth® capable printers. See the “Bluetooth® Connectivity” on page 13.

a. Some display cables may require a DisplayPort adapter in order to connect to the DisplayPort.

Networking and Connectivity Setup

When the LATITUDE Programming System is powered On, wait until the main screen displays, which takes up to one minute. The Main screen displays as illustrated in Figure 3.

At the bottom of the screen is the Utilities button, which allows access to LATITUDE Programming System information and setup functions including Network Setup.



[1] Utilities button

Figure 3. Main screen

Utilities button

Before device interrogation, use the Utilities button to configure network and connectivity functions.

Clicking the Utilities button displays the Utilities panel tab selections. The Network Setup tab displays the Wireless, Bluetooth®, and Ethernet & Proxy tabs as shown in Figure 4.

Refer to the *LATITUDE Programming System Operator's Manual, Model 3300* for the additional functions of Setup, Date and Time, and Software Update.

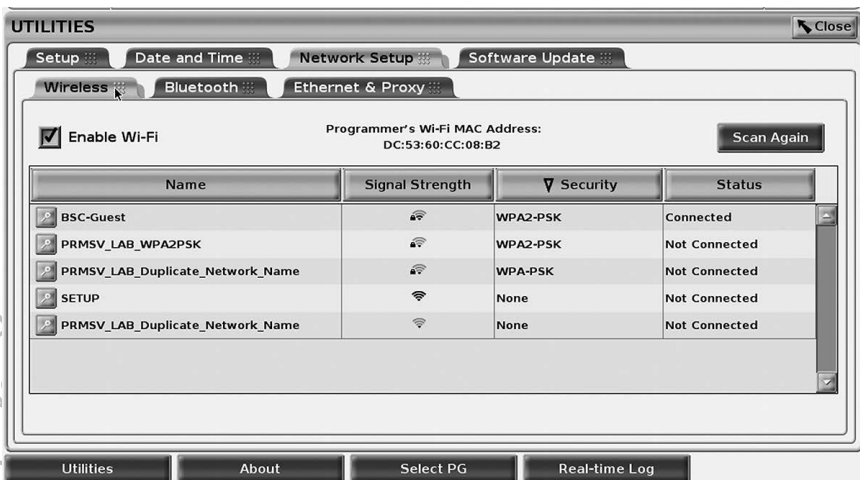


Figure 4. Utilities - Network Setup

Network Setup tab - overview

The Network Setup tab provides connectivity to networks and devices via Wi-Fi, Bluetooth® and Ethernet networking protocols. Refer to Figure 2 on page 7 for the Ethernet network connection port on the Model 3300 Programmer.

- **Wireless** setup connects to public/unsecured, WPA-PSK, and WPA2-PSK networks Wi-Fi networks (see “Wireless (Wi-Fi) Connectivity” on page 10).
- **Bluetooth®** setup connects to another device such as an external printer or computer (see “Bluetooth® Connectivity” on page 13).
- **Ethernet & Proxy** setup connects to a local area network (see “Ethernet Connectivity” on page 16).

NOTE: Please contact your local IT or IS system coordinator for specific configuration requirements. For further information, please contact Boston Scientific Corporation Technical Services using the information on the back cover of this manual.

Wireless (Wi-Fi) Connectivity

Wireless connectivity provides the following features:

- Wi-Fi supports only dynamic IP addressing (see Table 1 on page 18 for Wi-Fi specifications).
- Wi-Fi users can connect to public/unsecured, WPA-PSK, and WPA2-PSK networks.
- Wi-Fi connectivity is enabled and disabled by the Enable Wi-Fi button (see Figure 4 on page 10).


- The columns can be sorted by Name, Signal Strength, Security, and Status. The broadcasting Wi-Fi network list is refreshed every 30 seconds while on this screen.
- Users connect to a network using the Wi-Fi Details screen, reachable by selecting the magnify button to the left of the Wi-Fi name.
- Users can rename networks to more user-recognizable names using the “Alias Name” on the Wi-Fi Details screen (see Figure 8 on page 13).
- Users can configure the system to automatically (or manually) connect to Wi-Fi networks when in range.
- Up to 5 Wi-Fi networks can be stored in the Model 3300 Programmer and will automatically connect to those networks after the initial connection has been made. Adding additional networks after five will replace earlier entries.

NOTE: *If the user connects to an Ethernet network while a wireless (Wi-Fi) connection is downloading/uploading, the download/upload will stop, and that activity will need to be restarted. An information message displays indicating the application encountered an error. Disconnect the Ethernet cable and retry the wireless transfer.*

NOTE: *Wi-Fi connectivity is not permitted for Indonesia due to configuration requirements that are specific only to Indonesia.*

Wireless (Wi-Fi) Setup

To setup Wi-Fi communications perform the following steps:

1. Click the Enable Wi-Fi button to search for networks (Figure 5).
NOTE: *Once enabled, Wi-Fi remains On. To disable Wi-Fi connectivity, click the Enable Wi-Fi button to remove the check mark.*
2. The Programmer searches for all available Networks (Figure 6).
3. Click the magnify button  next to the desired network name to select it (Figure 7).
4. As required, enter the Wi-Fi Password and, optionally, an Alias Name (Figure 8).
5. Click the “Automatically join this network” button, to connect to this Wi-Fi network whenever it is in range (Figure 8).
6. Click the SAVE button, then Close the Wi-Fi Details window (Figure 8).

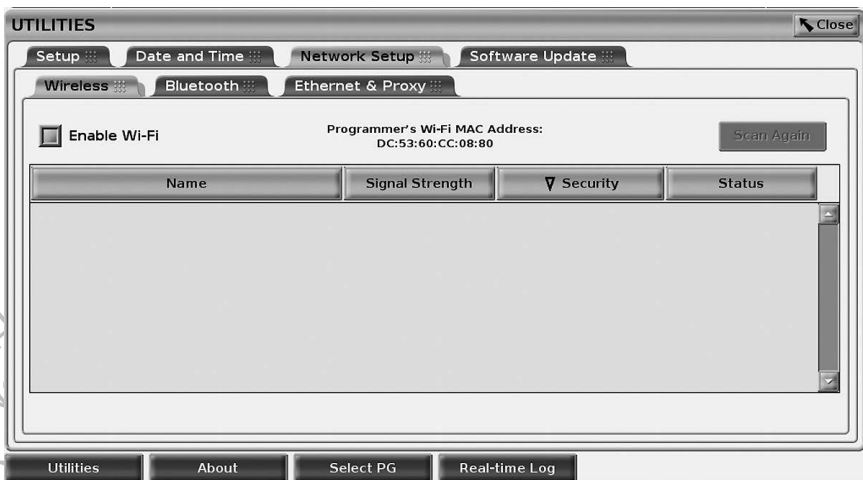


Figure 5. Utilities - Network Setup - Wireless - Enable



Figure 6. Utilities - Network Setup - Wireless - Network Search

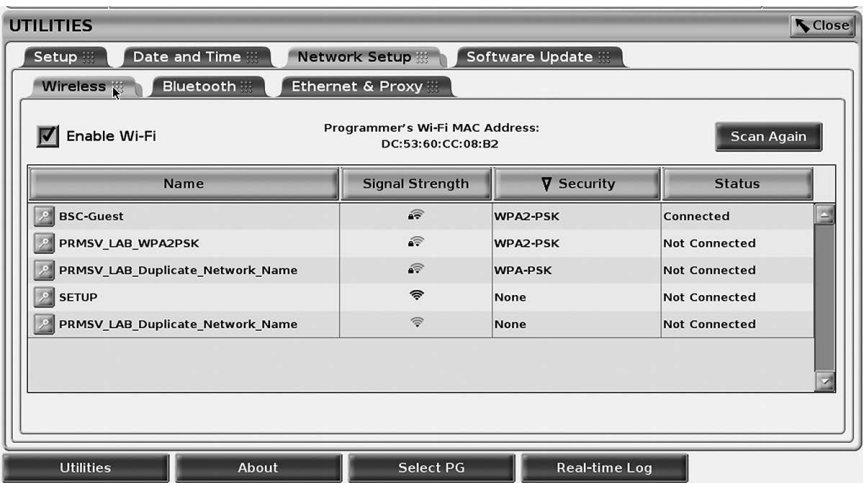


Figure 7. Utilities - Network Setup - Wireless - Network Display



Figure 8. Utilities - Network Setup - Wireless - Details

Bluetooth® Connectivity

Bluetooth® connectivity is used to communicate with Bluetooth® enabled printers and to communicate with another computer in order to transfer patient data to LATITUDE Link.

NOTE: Tablets, phones, and other mobile devices are not supported for Bluetooth® connectivity to the LATITUDE Programming System.

Once authorized, Bluetooth® pairing remains On. The Programmer remembers the connection, and future connections to the device (Bluetooth® capable PC, Laptop, or printer) are made automatically.

Bluetooth® capable PC setup

To enable Bluetooth® communications and connect to Bluetooth® capable PCs:


1. Click on the Enable Bluetooth® button on the Bluetooth® screen (see Figure 10) to begin a scan of Bluetooth® capable PCs within range (approximately 100 m [328 feet]).
2. When the scan is complete, click on the add button  to have a nearby Bluetooth® capable computer authorized and moved to the 'Authorized Computers' list. Authorized computers may be used for data transfer and display as destination options on data transfer screens.
3. If this is the first time connecting to the Bluetooth® PC, either enter the pairing code for the device or confirm the pairing code sent from the PC.



Figure 9. Utilities - Network Setup - Bluetooth® pairing code options

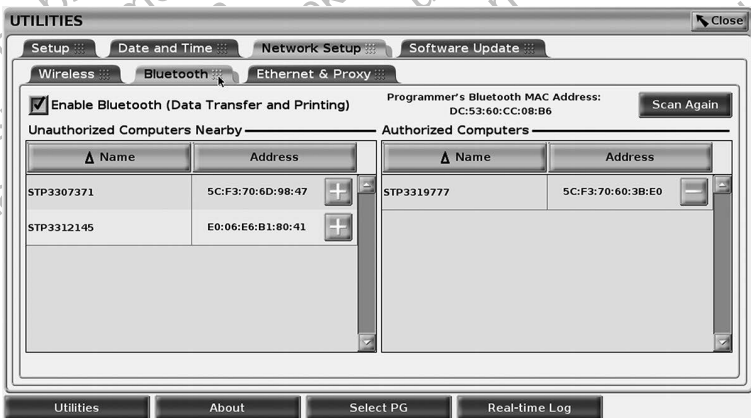



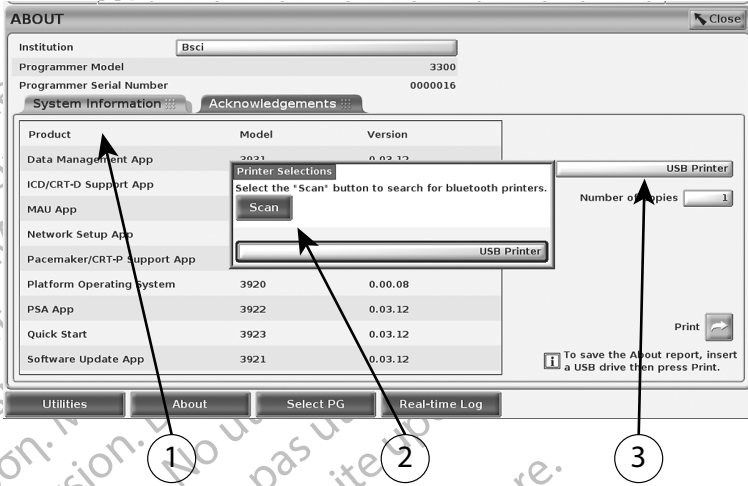
Figure 10. Utilities - Network Setup - Bluetooth® computers

Bluetooth® printer setup

To connect to Bluetooth® printers, refer to Figure 11 and perform the following:

1. Ensure that the Enable Bluetooth® button on the Bluetooth® tab is checked (refer to Figure 10 on page 14).
2. Click on the About tab at the bottom of the screen.
3. Click on the System Information tab.

- Click on the USB Printer selection button and then click on the Scan button in the pop up window
- When the scan is complete, click the add button  next to the desired printer in the Unauthorized Printers Nearby list to add it to the Authorized Printers list. See Figure 12 on page 15.



[1] System Information tab; [2] Scan button; [3] USB Printer selection bar

Figure 11. Bluetooth® Printer Setup

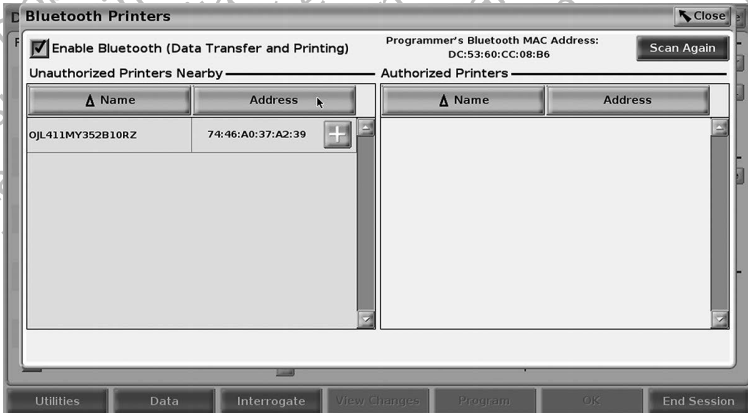


Figure 12. Bluetooth® Printer scan results

NOTE: The user can add and configure printers from the printer selection option in transvenous PG applications as well.

NOTE: If more than one printer displays in the Authorized Printers list, select the one desired, and it remains selected until a different printer is selected from the Authorized list on the Bluetooth Printers screen.

NOTE: The printer names cannot be edited or changed.

When Bluetooth® is enabled, if a screen displays printing capabilities, it will use the printer selected.

Ethernet Connectivity

Contact your network administrator and refer to Table 1 on page 18 for the settings required to connect to your Ethernet network. The Ethernet connection can be set to automatically connect to the network when the Ethernet cable is plugged in. Only one Ethernet connection can be defined at a time.

To use the Auto Connect feature, check the Auto Connect selection, and then press the Connect button. If the Connect button is not pressed, automatic connection will not be enabled.

NOTE: Connect the Ethernet cable only to the RJ45 Ethernet port connector on the Model 3300 Programmer.

NOTE: The Ethernet port on the Model 3300 Programmer is an RJ-45 connection. Do not connect a phone jack to this port. Refer to “Figure 2. Left side panel of the LATITUDE Programming System” on page 7 for the Ethernet connection port on the Model 3300 Programmer.

NOTE: When connected to an Ethernet network, the internal clock is set by the network. If an Ethernet connection is not used, the internal clock can drift up to 12 minutes per year, and therefore would need to be reset manually. If the internal clock needs to be corrected, please contact Boston Scientific Corporation using the information on the back cover of this manual.

Figure 13 illustrates the Ethernet & Proxy setup screen with Auto Connect established and Figure 14 illustrates the parameters required when using a Proxy server.

For Proxy settings, click on the “Use Proxy Server” button (Figure 13), then enter the proxy information as indicated in Figure 14.

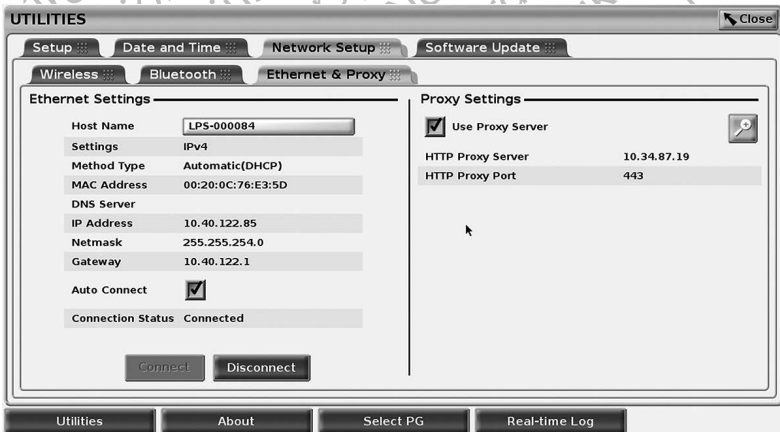


Figure 13. Utilities - Network Setup - Ethernet & Proxy

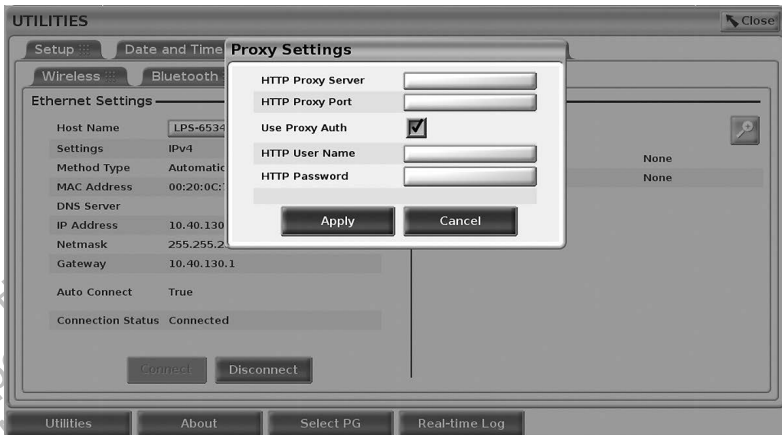


Figure 14. Utilities - Network Setup - Ethernet & Proxy - Proxy Settings

SERVICING

For questions regarding operation or repair of the LATITUDE Programming System, contact Boston Scientific using the information on the back cover of this manual. The LATITUDE Programming System must be serviced by Boston Scientific personnel only.

If the LATITUDE Programming System does not operate properly, check that electrical cords and cables are securely connected and that cords and cables are in good working order (i.e., free of visible defects). For external display or printer problems, refer to the manual for that device.

PROGRAMMING SYSTEM SECURITY

Sensible security practices are needed to protect patient data and the Programming System integrity when connected to a network. The Model 3300 Programmer incorporates features that facilitate management of network security. These features work in conjunction with the security practices of hospitals and clinics to provide safe and secure operation of the Model 3300 Programmer and protect the attached network.

NOTE: *All patient data is encrypted on the Model 3300 Programmer hard drive, and the Programmer has network security safeguards in place to prevent malicious attacks.*

Connection of the Model 3300 Programmer to the network that includes other equipment could result in previously unidentified risks. The hospital and/or clinic network administrator should identify, analyze, evaluate, and control these risks.

Network Security

The Model 3300 Programmer is designed and tested to limit how it communicates on a network. When communicating on a network, the Programmer uses industry-accepted protocols for authenticating servers and encrypting transmitted data. Only required network connections are open. Network communications are originated by the Programmer.

Unauthorized software is not permitted to originate communications with the Programmer. Only connect the Programmer to managed, secure networks. The Programmer has network security safeguards in place to prevent malicious attacks.

Physical controls

Maintain good physical controls over the Model 3300 Programmer. Having a secure physical environment prevents access to the internals of the Programmer. USB devices connected to the Programmer should be controlled to limit the introduction of malware. Patient sensitive information may be stored on the internal hard drive and appropriate precautions should be taken to secure the Programmer from unauthorized access.

Compromised Model 3300 Programmer

If you believe that the Model 3300 Programmer has been compromised by a security threat, turn off the Programmer, disconnect it from the network, then restart the Programmer. Discontinue use of the Model 3300 Programmer if it fails the start-up self test or does not operate as expected. Contact Boston Scientific Corporation Technical Services using the information on the back cover of this manual or contact your local Boston Scientific representative for further assistance.

NOTE: *The LATITUDE Programming System does not need to be connected to a network for safe operation.*

SPECIFICATIONS

Table 1. Network and Connectivity Characteristics and Configuration

Characteristic	Specification
Required Characteristics of IT network	
Ethernet	IEEE 802.3u, 100 Mbps full duplex and half duplex on 100BASE-TX IEEE 802.3ab, 1 Gbps full duplex and half duplex on 1000BASE-T
Wi-Fi	IEEE 802.11g, 802.11n, and 802.11ac

Characteristic	Specification
Hazardous situations resulting from network failure	None
Required Configuration of IT network	
Ethernet	Dynamic or Static IP addressing
Wi-Fi	Dynamic IP addressing, using IEEE 802.11g, 802.11n, or 802.11ac specifications to connect to networks that are public/unsecured, WPA-PSK, or WPA2-PSK
Ethernet MAC Address	The network MAC address can be displayed and the host name is editable (see Figure 13 on page 16)
Internet protocol	IPv4
Dynamic Host Configuration Protocol (DHCP) mode	Both manual and automatic DHCP modes are supported
Wi-Fi MAC Address	Displayable (See Figure 7 on page 13)

WARRANTY INFORMATION

For all warranty information, refer to the *LATITUDE Programming System Operator's Manual, Model 3300*.

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Outdated version. Do not use.
Versión obsoleta. No utilizar.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
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n überholt. Nicht verwenden.
unud version. Ärge kasutage.

αλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Versión obsoleta. No utilizar.
Version périmée. Ne pas utiliser.

Zastarjela verzija. Nemojte upotrebljavati.
Úreлт útгáфа. Notið ekki.
Versione obsoleta. Non utilizzare.
Pasenusi versija. Nenaudokite.
Elavult verzió. Ne használja!

Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.

Versiune expirată. A nu se utiliza.
Zastarana verzija. Ne pouzivat.
Vanhentunut versio. Älä käyttää.
Föråldrad version. Använd
ancel olmayan sürüm. K

рсия. Да не се използва.
erze. Nepoužívajte.
version. Må ikke anvendes.
n überholt. Nicht verwenden.
unud version. Ärge kasutage.

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IC: 4794A-CRM33007 (Contains IC:1000M-7265NG)



CE 2797

Authorized 2017

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360166-039 EN Europe 2019-11

