Boston Scientific
Advancing science for life™

LATITUDE™

Programming System, Model 3300

Security Overview

The LATITUDE™ Programming System, Model 3300 is a portable cardiac rhythm management (CRM) programming system designed to allow health care providers to interrogate, monitor and program Boston Scientific implantable pulse generators (IPGs). The programmers are owned by Boston Scientific and offered only to support Boston Scientific implantable devices.

Patient Data Management Security

- All patient data on the programmer hard drive is encrypted using Advanced Encryption Standards (AES) and up to 450 patient records can be saved.
- Most patient data stored on the programmer is automatically deleted after 14 days. The following patient data is automatically deleted after 90 days:
  1. Patients who are a candidate for a S-ICD that have been screened by the EMBLEM™ S-ICD Automated Screening Tool
  2. Patients who have an implanted S-ICD device
- The process of identifying patient data to delete is performed when the programmer is powered on.
- Boston Scientific recommends using the Purge All Data feature before returning the programmer for repairs or before moving the programmer to another clinic or hospital.

NOTE: There is no notification to the user that the deletion has occurred.

NOTE: All patient data is encrypted but data can be viewed on the programmer before it has been deleted.

Software Updates

- Boston Scientific cryptographically signs software updates on the LATITUDE Programming System, Model 3300.
- Only software approved by Boston Scientific may be installed and executed on the programmer.
- The installation of any other software is not permitted. Installed software is protected from change and is reverified upon each execution.
- Whenever software updates are available, it is recommended that they are installed as soon as possible.
- Software updates can be downloaded and installed from the Internet via the Software Update tab on the programmer or by your local Boston Scientific representative using a USB flash drive.
- The user has the option to install all updates or select specific updates from the options listed.
- If the installation of a software update does not successfully complete, the user may reinitiate the installation.

Bluetooth® Security

Only connect to known Bluetooth devices, as patient data could be transmitted to inappropriate printers or devices if this guidance is not followed. Additional Bluetooth security is accomplished by:

- The programmer's Bluetooth radio is only enabled when communication via Bluetooth is requested by the user.
- Bluetooth pairing requests are initiated by the programmer only and inbound Bluetooth pairing requests are ignored.

Heart Connect™ System Security

- The Heart Connect System incorporates security measures for protection of patient data and system integrity. These security measures support general security policies and practices.
- The online meeting, including any images being transmitted, is encrypted to ensure patient information and device data are protected.
- Boston Scientific recommends removing all individual contacts before returning the programmer for repairs or before moving the programmer to another clinic or hospital.
- Boston Scientific utilizes a private deployment of Zoom in conjunction with the Heart Connect System application which have Data Centers located only in the United States. This specific Zoom deployment includes additional security and privacy measures not present in the public version of Zoom.

Unsupported Hardware

Any unsupported hardware, including unsupported USB devices, is ignored by the programmer.

Security Vigilance

Boston Scientific analyzes security threats on an ongoing basis and evaluates the potential impact on the programmer.

Physical Controls

Maintain physical controls over the programmer because a secure physical environment reduces security risk. Although the Model 3300 programmer makes every attempt to limit malware exposure, it is advised that USB devices connected to the programmer be controlled to further limit exposure.

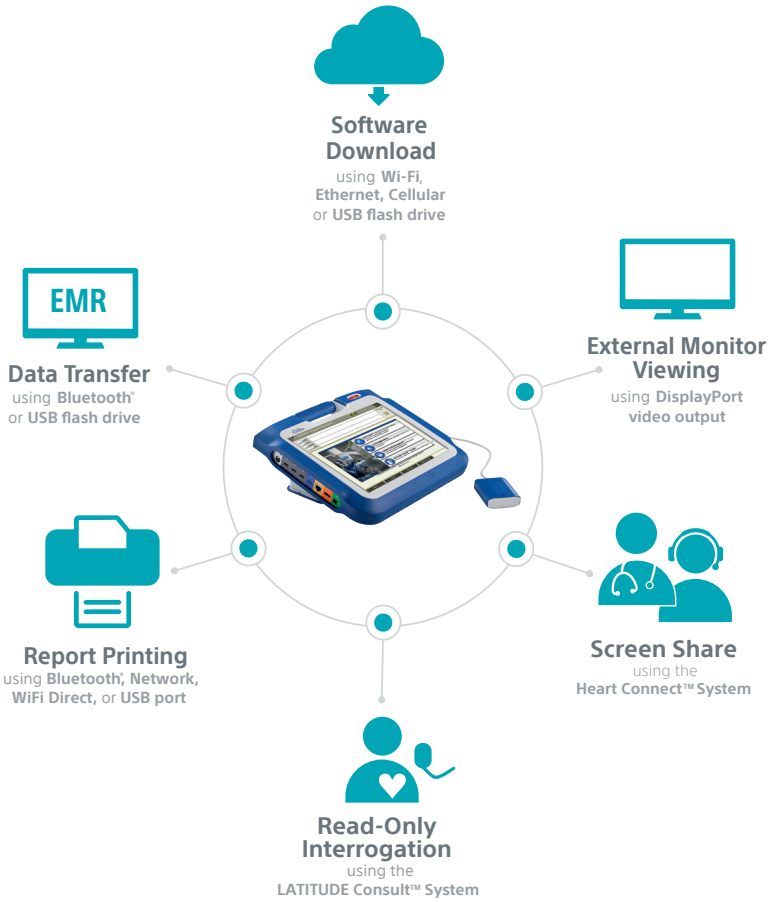
Programmer Integrity

If you suspect the programmer has been compromised by a security threat, power off the system, disconnect the programmer from the network and then restart. For further assistance, contact Boston Scientific Technical Services at 1-800-CARDIAC.

Firewall

The following are the specifications of the firewall and rules for the programmer:

- Disallowing incoming connections
- Disallowing IPv6 connection



Network and Connectivity Characteristics and Configuration

Required Characteristic of IT Network

Characteristic	Specification
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, 802.11ac
Hazardous situations resulting from network failure	None

Required Configuration of IT Network

Characteristic	Specification
Ethernet	Dynamic or Static IP addressing
Wi-Fi	Dynamic IP addressing, using IEEE 802.11g, 802.11n, or 802.11ac specification to connect to networks that are public/unsecured, WPA-PSK, WPA2-PSK, WPA2/WPA3 Transitional Personal, WPA/WPA2 Enterprise (PEAP-MSCHAPv2 or EAP-TLS), or Captive Portal
Ethernet MAC Address	The network MAC address can be displayed and the host name is editable
Internet Protocol	IPv4
Dynamic Host Configuration Protocol (DHCP) Mode	Both manual and automatic DHCP codes are supported
Wi-Fi MAC Address	Displayable

The following destinations should be reachable by the programmer.

URL	IP	Protocol/Port	Description
crm.iot.bsci.com	Varies	TCP: 443, 8443 (outbound)	Software updates
cumulocity-prod-crm-us-east-1.s3.us-east-1.amazonaws.com	Varies	TCP: 443, 8443 (outbound)	
cumulocity-prod-logs-crm-us-east-1.s3.us-east-1.amazonaws.com	Varies	TCP: 443, 8443 (outbound)	
https://slipstream.bostonscientific.com/glps/csr/v1/prm/	slipstream.bostonscientific.com	TCP: 443	
pool.ntp.org	Varies	UDP: NTP/123	Syncing Programmer Clock
heartconnect.bostonscientific.com heartconnectsso.bostonscientific.com	34.226.95.149, 44.195.132.212, 50.19.210.81, 54.159.247.211, 34.239.190.85, 34.231.96.140, 3.229.201.106, 52.70.211.114, 3.230.251.122	TCP: 80, 443	Heart Connect Remote Support/ Troubleshooting
xmpp.bostonscientific.com	52.203.143.235, 54.84.88.81, 54.197.76.94, 35.169.147.23, 3.210.90.209, 23.20.124.187, 3.226.141.204 , 34.200.121.54, 54.198.53.216	TCP: 443	
Zone Controller	3.215.222.76, 3.218.53.56	TCP: 443, 8802 UDP: 3478, 3479	
Multimedia Router	3.214.46.23, 54.86.233.213	TCP: 443, 8801 UDP: 8801 through 8810	
https://securegateway.bsci.com/3300idp	204.155.22.167, 132.189.82.23	TCP: 443	SSL Authentication (Heart Connect)
https://slipstream.bostonscientific.com/lwr/ss/upload	slipstream.bostonscientific.com	TCP: 443	TLS 1.2 Authentication

This document describes at a high level the data security features of the LATITUDE Programming System, Model 3300. The information contained here is not intended to replace the Boston Scientific Operator Manuals for the LATITUDE Programming System, Model 3300; Patient Data Management, Pacing System Analyzer, and Network and Connectivity. All Manuals can be found at www.BostonScientific.com/ifu. For further assistance, call 1-800-CARDIAC in North America or contact your local Boston Scientific representative.

The LATITUDE Programming System is intended for use by health care professionals trained or experienced in device implant and/or follow-up procedures.

LATITUDE PROGRAMMER

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Effects, and Operator's Instructions.

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 PG. For detailed software application instructions, refer to the associated product literature for the PG being interrogated.

CONTRAINDICATIONS The LATITUDE Programming System is contraindicated for use with any PG other than a Boston Scientific PG. For contraindications for use related to the PG, refer to the associated product literature for the PG being interrogated. The PSA application is contraindicated for use with any programming system other than the Boston Scientific LATITUDE Programming System, Model 3300.
The following uses of the PSA are contraindicated: • With AV conduction disorders; atrial single-chamber pacing • With competing intrinsic rhythms; asynchronous modes • With chronic atrial tachycardia as well as chronic atrial fibrillation or flutter; modes with atrial control (DDD, VDD) • With poor tolerance of high ventricular rates (e.g., with angina pectoris); tracking modes (i.e., atrial control modes) and propensity for atrial tachycardia • Use as an external pacemaker. During implantation, the PSA application is suitable for temporary external pacing while the patient is being continuously monitored by medical personnel.

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.• **Equipment modifications.** No modification of this equipment is allowed unless approved by Boston Scientific. Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment. • **Radio frequency (RF) communications equipment.** Keep all RF communications equipment (including peripherals such as antennas, wands, and cables) at least 30 cm (12 in.) away from the Model 3300 Programmer, including cables specified by Boston Scientific, to avoid degradation of the performance of this equipment. • **Connector contacts.** Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor. • **Electric shock.** To avoid the risk of electric shock, only connect the Programmer's Model 6689 Power Adapter with the appropriate power cord to a grounded/earthed power outlet. • **Battery access**. When accessing the battery, ensure that power to the Programmer is turned off. Do not touch the connector terminals in the battery compartment while removing or replacing the battery because an electrical charge is present. • **Electrostatic charges.** The PSA lead system is in electrical contact with the patient's heart and blood. • Do not touch the metal clips on the patient cable or the pacing lead. Electrical currents can be dangerous to the patient and the user. • Discharge any electrical static charge on your person by touching a grounded metal surface before touching the patient, the patient cables, or the device. • **Electrical currents.** Unused PSA cable connections contacting conductive surfaces can induce electrical currents into the patient's heart. • Attach unused cable connections to surgical draping near the patient or disconnect the unused cables from the system. • **Electrocautery.** The LATITUDE Programming System is designed and tested to be electrocautery safe. • While the device is designed and tested to be electrocautery safe, electrocautery can induce electrical currents in the PSA cables that can be conducted into the patient's heart. However, Boston Scientific recommends that the Programmer be placed as far from the electrocautery system and associated components as possible to minimize noise being introduced into the LATITUDE Programming System and patient cables. • Electrocautery may also produce unexpected behavior in the Programmer display or operation. If electrocautery is medically necessary, maintain a distance of at least 30 cm (12 inches) between electrocautery equipment and the Programmer and its associated components. Similarly, maintain this distance between the Programmer and its associated components and the patient during these procedures. • Do not drape electrocautery components or cables on or near the Programmer or associated cables and components. • Whenever possible disconnect the PSA cables from the pacing leads when performing an electrocautery procedure. • If the Programmer is connected to the patient during an electrocautery procedure, check its operation afterwards. • If the Programmer experiences an issue that causes an error condition, the Programmer will need to be power cycled. During the reset and reboot, which takes up to one minute, there will be no pacing support. For this reason, a backup PSA/pace resource must be available in case electrocautery is applied. • **LATITUDE Programming System location.** Use of the Model 3300 Programmer 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. • **LATITUDE Programming System must remain outside sterile field.** The Programmer is non-sterile and cannot be sterilized. Do not allow the device to enter a sterile zone in an implant environment. • **Physiological signals.** Operation of the LATITUDE Programming System with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. • LATITUDE Programming System is MR unsafe. The LATITUDE Programming System is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices. Under no circumstances should the LATITUDE Programming System be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas. • **Induction.** When activating PSA Burst Pacing, which may cause unpredictable arrhythmias, always have cardiac emergency equipment (e.g., external pacemaker, external defibrillator) in an operational status available for immediate life support. • Consider additional preemptive measures in patients where acceleration or a loss of rhythm could cause life-threatening danger. • **External defibrillation.** The LATITUDE Programming System is designed and tested to be defibrillation safe. • While the Programmer is designed and tested to be defibrillation safe, the patient can be endangered and the Programmer can be damaged. • The PSA cable must be disconnected from the lead(s) before using external defibrillation. • Whenever possible, disconnect all cables from the patient when using external defibrillation equipment. • If the LATITUDE Programming System is connected to the patient during defibrillation, verify that the Programmer is operating as expected after defibrillation. • **Loss of power.** Operating the Programmer with a depleted internal battery can suspend Programmer function. Operating the Programmer with no battery can suspend Programmer function if AC power is temporarily interrupted. • If the battery has been depleted to 10% or less, the Programmer may need to be powered Off to allow charging to begin and then may be powered back On to continue charging. • If an optional battery is used, do not use a depleted or unapproved battery. For additional patient safety, when the battery level indicator shows 25% or less remaining, connect the AC power to the Programmer. • When operating on battery power, do not attempt to replace the battery. • A yellow attention message displays on the Programmer screen when the battery reaches 25% depletion. When the battery reaches 10% depletion or less, a red warning message displays. At 5%, there is another red warning message followed by a 60–second automatic shutdown. • **Loss of pacing support.** Always have external cardiac pacing equipment in an operational status available for immediate life support. • Initially, when the Programmer is switched on, the pacing functions of the PSA are switched off while a self-test is conducted. It is not possible to initiate pacing support until after the self-test has completed, which can take up to one minute. • Connecting the PSA cable to the wrong lead may result in ineffective sensing and pacing behavior and loss of pacing support. • If the Programmer encounters a fault condition, pacing operation continues until a restart is initiated unless the fault was in the PSA component itself. • When the user manually restarts the Programmer, pacing support will be lost. The user must manually reinitiate PSA pacing after the system has completed the self-test. The self-test can take up to one minute. • If there is no battery installed or the battery is depleted (5% or less), pacing support will be lost if AC power is lost. • Consider additional preemptive measures in patients where loss of pacing could cause life threatening danger. • **Backup defibrillation protection.** Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death. • **Impaired AV conduction.** Single chamber atrial modes are contraindicated for patients with impaired AV conduction. • If the patient has impaired AV conduction, AAI programming and antegrade conduction tests must not be performed. • Abruptly terminating pacing. Abruptly terminating pacing may result in extended periods of asystole in some patients. • Gradually decrease the pacing rate until the patient's intrinsic rate is detected for a controlled transition from pace to intrinsic rhythm. • **Loss of capture.** Pacing threshold testing implies loss of capture. At loss of capture, asystole and pacing during vulnerable periods can occur. • Consider the health of the patient prior to performing a pacing threshold test. • **Use of protective sleeves.** Incorrect positioning of the protective silicone rubber sleeves over the PSA cable clip(s) can cause unintended electrical connections that can impair cable function and endanger the patient. • Before connecting cables, ensure correct position of protective sleeves. • **Do not use wet cables.** Moisture on wet cables can impair cable function and endanger the patient. • **Exposure to fluids.** Before cleaning and disinfecting the Programmer surfaces, power down the device and disconnect the external power supply. Before operating the LATITUDE Programming System, let cleaning and disinfection agents used on the Programmer evaporate. • **Emissions and interference.** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment. Other equipment may interfere with the LATITUDE Programming System, even if that equipment complies with the CISPR emission requirements. • **Lithium-ion battery.** The Model 6753 Battery is a Lithium-ion battery and, as such, is deemed a Dangerous Good in regards to shipping. Do not return the Model 6753 battery to Boston Scientific. Dispose of the battery as required by local regulations. If the battery must be shipped, contact your local shipper for instructions and shipping requirements. • **Power up.** Do not touch the screen while the Programmer is powering up, as this may cause the area that you touched to become unresponsive when pressed later on.

PRECAUTIONS Electrical and magnetic interference. Electrical interference or "noise" from devices such as electrocautery and monitoring equipment, monitors, or strong magneticfields may interfere with establishing or maintaining telemetry for interrogating or programming the device and may produce unexpected behavior in the Programmer display or operation. In the presence of such interference, move the Programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. Electrical interference or "noise" from concomitant implanted devices such as a ventricular assist device (VAD), drug pump, or insulin pump may interfere with establishing or maintaining telemetry for interrogating or programming the pulse generator. In the presence of such interference, place the wand over the pulse generator and shield both with a radiation-resistant material.

For specific information on precautions, read the following sections of the product labeling: General, Maintenance and Handling, and Radio Frequency (RF) Performance.

ADVERSE EVENTS The following list includes the possible adverse effects associated with programming pulse generators described in this manual: • Asystole • Atrial arrhythmia • Bradycardia • Tachycardia • Ventricular arrhythmia
92436264 (Rev. C)

HEART CONNECT™ SYSTEM

INTENDED USE The Heart Connect System is an optional data-sharing system intended to display and share physiological and/or other medical data from the Model 3300 Programmer. The Heart Connect System provides health care providers and Boston Scientific personnel with means to establish an online meeting and share the display of the Model 3300 Programmer with individuals in a remote location.

CONTRAINDICATIONS The Heart Connect System is contraindicated for use with medical equipment that is not compatible with system characteristics as defined in the manual.

WARNINGS Refer to the LATITUDE Programming System Operator's Manual, Model 3300 for additional Warnings. The use of any cables or accessories with the Heart Connect System, other than those included with the Heart Connect could result in increased electromagnetic emissions or decreased electromagnetic immunity, or electrical shock of the LATITUDE Programming System. The LATITUDE Programming System is MR unsafe and must remain outside the magnetic resonance imaging (MRI) site Zone III (and higher).

PRECAUTIONS Refer to the LATITUDE Programming System Operator's Manual, Model 3300 for additional Precautions. The Model 3300 Programmer transmits display content that may include patient data that are protected health information. Patient data should only be accessed by authorized healthcare providers and Boston Scientific personnel.

ADVERSE EFFECTS Refer to the LATITUDE Programming System Operator's Manual, Model 3300 for Adverse Effects. 92495688 (Rev. A)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Boston Scientific
Advancing science for life™

Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.866.484.3268

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