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 400 patient records can be saved.
- Patient data stored on the programmer is automatically deleted after 14 days.
- 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:

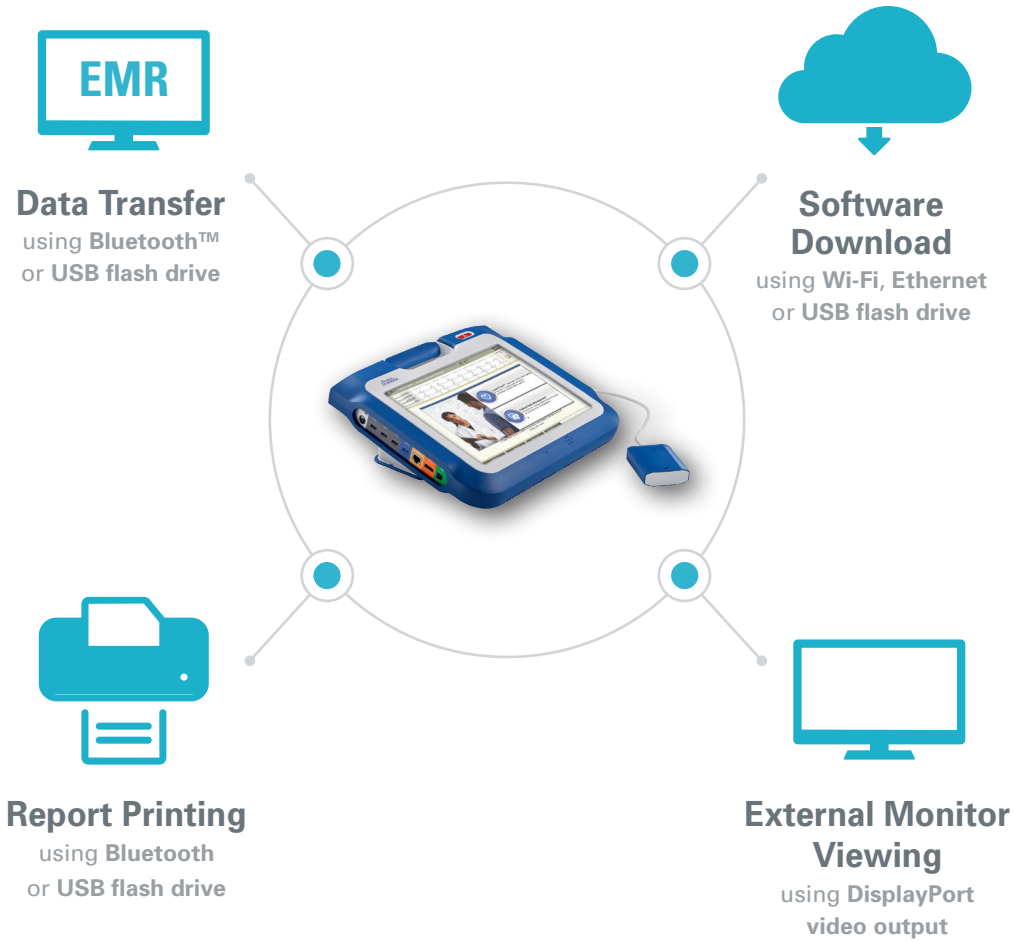
- The programmer's Bluetooth service is only set to be discoverable when needed during user pairings requests.
- The programmer's Bluetooth radio is only enabled when communication via Bluetooth is requested by the user.
- Bluetooth pairing requests are initiated by 3300 only and inbound Bluetooth pairing requests are ignored.

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.



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	IEEE 802.11g, 802.11n, 802.11ac
Ethernet MAC Address	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
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 to allow for updated software to be installed from the network:

URL	IP	Port
Gas-aus.axeda.com	122.202.65.179	80, 17001, 17002
Ghsj1.axeda.com	52.8.160.235	80, 17001, 17002
Ghsom1.axeda.com	209.202.157.179	80, 17001, 17002
bostonscientific.axeda.com	209.202.167.222	80, 443, 5800, 5920, 1900-19003
Gas-aus.axeda.com	122.202.65.179	80, 17001, 17002
Ghsj1.axeda.com	52.8.160.235	80, 17001, 17002
Ghsom1.axeda.com	209.202.157.179	80, 17001, 17002

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.

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 Model 3300 LATITUDE Programming System. 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

Warnings The use of any cables or accessories with the LATITUDE Programming System other than those specified by Boston Scientific could result in increased electromagnetic emissions, decreased electromagnetic immunity, or electrical shock of the LATITUDE Programming System. Keep all RF communications equipment at least 30 cm (12 in) away from the Model 3300 Programmer. Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor. To avoid the risk of electric shock, only connect the Programmer's Model 6689 Power Adapter to a grounded/earthed power source. When accessing the battery, ensure that power to the Programmer is turned off. Do not touch the metal clips on the patient cable or the pacing lead. Discharge any electrical static charge on your person by touching a grounded metal surface before touching the patient, the patient cables, or the device. Unused PSA cable connections contacting conductive surfaces can induce electrical currents into the patient's heart. Electrocautery can induce electrical currents in the PSA cables that can be conducted into the patient's heart. Never stack the Programmer on top of an electrocautery system or associated components. 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. Use of the Model 3300 Programmer adjacent or stacked with other equipment should be avoided because it could result in improper operation. The Programmer is non-sterile and cannot be sterilized. Operation of the LATITUDE Programming System with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. 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 for Safe MR Practices. When activating PSA Burst Pacing, which may cause unpredictable arrhythmias, always have cardiac emergency equipment in an operational status available for immediate life support. The LATITUDE Programming System is designed and tested to be defibrillation safe. The PSA cable must be disconnected from the lead(s) before using external defibrillation. If the patient is pacer dependent and the Programmer encounters a fault condition, pacing operation continues unless the fault was in the PSA component itself. For this reason, always have external pacing equipment available for patient back-up. Operating the Programmer with a depleted internal battery or no battery can suspend Programmer function if AC power is temporarily interrupted. Always have external cardiac pacing equipment in an operational status available for immediate life support. Single chamber atrial modes are contraindicated for patients with impaired AV conduction. Abruptly terminating pacing may result in extended periods of asystole in some patients. Pacing threshold testing implies loss of capture. Incorrect positioning of the protective silicone rubber sleeves over the PSA cable clip(s) can cause unintended electrical connections that can impair cable function endanger the patient. Moisture or wet cables can impair cable function and endanger the patient. Before cleaning and disinfecting the Programmer surfaces, power down the device and disconnect the external power supply. If this equipment is used in a residential environment, the equipment might not offer adequate protection to radio-frequency communication services. The Model 6753 Battery is a Lithium-ion battery and as such, is deemed a Dangerous Good in regards to shipping.

Precautions For specific information on precautions, read the following sections of the product labeling: General, Preparations for Use, Maintenance and Handling.

Adverse Effects None known.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev C) 046774 AH

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