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LATITUDE™

PROGRAMMING SYSTEM, MODEL 3300

Spec Sheet

The Model 3300 Programmer 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 (PGs).

Portable

- Small and lightweight tablet design, which weighs less than 9 lbs (5 kg).
- Easy grip handle and integrated wand holster for convenient transport.
- Rechargeable Lithium-ion battery that provides up to two hours of power at typical use.

Connected

- Internet download of software updates via Wi-Fi or Ethernet connection.
- Transfer of data and reports to an electronic medical record system via LATITUDE Link™ using Bluetooth™ or a USB flash drive.
- Report printing using either a Bluetooth connection or USB cable to an external printer.
- DisplayPort video output allows for high-resolution display of the programmer screen on an external monitor.

Flexible

- Integrated Pacing System Analyzer (PSA) application to assess electrical performance and placement of cardiac lead systems during implant of cardiac rhythm management devices. The PSA application displays real-time EGM traces and event markers for each enabled channel. Real-time EGMs display on the same screen as the surface ECG, which includes a heart-rate indicator.
- Real-time Log Event display for ECG and EGM events. Enhanced Snapshot and Real-time Recorder provide electronic capture of real-time events from ECG, PG and PSA applications, offering customizable Real-time Log Tool to crop, annotate, add notes, and use Electronic Calipers.
- Optimize lead placement using RV-LV timing on screen.

Emergency Function Capabilities

- Provides emergency access to STAT SHOCK, STAT PACE, and DIVERT THERAPY functionality as applicable to PG and PSA applications.

Stand Model 6755	Telemetry Wand Model 6395	Power Supply Model 6689 plus Power Cord Model 6175	Battery Model 6753
			
Provides two convenient viewing angles	Green light illuminates to indicate telemetry	Model 6689 Dimensions: 5.88 in x 2.46 in x 1.32 in (14.94 cm x 6.26 cm x 3.35 cm)	Full charge provides approximately two hours of normal operation
Integrated compartment in the back for convenient storage of programmer cables and wands	Length: 117 in (2.98 m)	Model 6689 and 6175 combined length: 134 in (3.41 m)	Charge time is 1-2 hours (approx.)

PSA Cables Model 6763	ECG Cables Model 3153	BNC Slave Cable Model 6629
		
Resterilizable (Details in Manual) Length: 112 in (2.84 m)	Length: 110 in (2.79 m)	Length: 110 in (2.79 m)

Specifications

LATITUDE Programming System Nominal Specifications

Characteristics	Nominal
Safety classification	LATITUDE Programming System: Class I • ECG connection: Type BF, defibrillation-protected • Model 6395 Telemetry Wand connection: Type BF, defibrillation-protected • Model 3203 S-ICD Telemetry Wand connection: Type BF, defibrillation-protected • Connection port for future use: Type BF, defibrillation-protected • PSA cable connections: Type CF, defibrillation-protected • Ingress protection rating: IPX0
Dimensions	Programmer without Stand: 30.7 cm (12.1 in) deep, 34 cm (13.4 in) wide, 12.5 cm (4.9 in) high With Stand (in handle up position): 24.9 cm (9.8 in) deep, 35.1 cm (13.8 in) wide, 31.8 cm (12.5 in) high
Weight Approximate	Programmer (without battery or stand): 3.58 kg (7.9 lbs) Battery: 0.45 kg (1.0 lb) Stand: 1.28 kg (2.75 lb)
Model 6689 power adapter power rating	100-120V, 50-60 Hz, 3.8A 220-240 V, 50 Hz, 1.9 A
Maximum Output **DC cord length** **Dimensions**	15 V @ 6 A, 90 W 1.53 m (5 ft) 14.94 cm x 6.26 cm x 3.35 cm, (5.88 in x 2.46 in x 1.32 in)
AC power cord (3 prong)	1.88 m (6.17 ft) 100-240 V
Duty cycle	Continuous
Operating temperature	10 °C to 32 °C (50 °F to 90 °F)
Transport and storage temperature	-20 °C to 60 °C (-4 °F to 140 °F)
Operating humidity	25% to 85% non-condensing
Transport and storage humidity	25% to 85% non-condensing
Operating altitude	≤ 3,000 m (≤ 9,843 ft)
Transport and storage atmospheric pressure	50 kPa to 106 kPa (7.252 psi to 15.374 psi)
External support; pen drives, printer	(3) USB 2.0 ports; (1) USB 3.0 port
External digital monitor support	DisplayPort digital connector; Monitor must comply with emissions standard CISPR 32.
Battery type	Lithium-ion, IEC62133:2012 and UN38.3 compliant
Ethernet: Data Interface	Data Interface RJ-45 Ethernet Connector
Data Modulation	IEEE 802.3u, 100 Mbps full duplex and half duplex on 100BASE-T IEEE 802.3ab, 1 Gbps full duplex and half duplex on 1000BASE-T
Wi-Fi	IEEE 802.11g, 802.11n, and 802.11ac
ECG cable, Model 3153	3.9 m to 4.3 m (12.7 ft to 14.0 ft)
ECG performance: **Minimum amplitude detected**	 6.54 µV
Lead selection	I, II, III, aVR, aVL, aVF, V
Intrinsic and paced ventricular rate display	30 bpm to 120 bpm ± 4 bpm on a three-beat average basis; 120 bpm to 240 bpm ± 8 bpm on a three-beat average basis
Input impedance	≥ 1.5 MΩ
Electrode offset tolerance	300 mV
Storage resolution	500 samples/sec, 6.54 µV
Filter settings for storage resolution	ON: 0.5 Hz to 40 Hz, ± 10% or ± 0.1 Hz, whichever is greater OFF: 0.05 Hz to 100 Hz, ± 20% or ± 0.02 Hz, whichever is greater
Gain settings	0.5, 1, 2, 5, 10, 20 mm/mV ± 25%

LATITUDE Programming System Nominal Specifications (continued)

Characteristics	Nominal
Electrical Safety Testing-Reference for testing according to the IEC 62353 (Installation, Maintenance, Repair)	
Earthbond testing (Groundbond testing)	≤ 300 mΩ including power cable not exceeding 3 meters
Equipment leakage, direct method (accessible parts)	≤ 500 µA
Patient leakage current, direct method	Model 6395 Telemetry Wand (BF) ≤ 5000 µA, ECG (BF) ≤ 5000 µA, PSA (CF) ≤ 50 µA
Safety Feature: Defibrillator protection	Up to 5000 V

Radio Nominal Specifications

Characteristics	Nominal
ZIP MICS Telemetry (MICS/MedRadio)	
Frequency band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	< 145 kHz
Modulation	FSK
Radiated Power	< 25 µW E.I.R.P.
ZIP Telemetry (ISM)	
Frequency band	916.5 MHz Industrial, Scientific, and Medical radio band (ISM)
Bandwidth	< 650 kHz
Modulation	ASK
Radiated Power	< 0.75 mW E.I.R.P.
Model 6395 Wand Telemetry (Inductive)	
Frequency band	Transmit: 20 kHz Receive: 0 – 100 kHZ
Bandwidth	< 125 kHz
Modulation	OOK/QPSK
Radiated Power	< 13.7 dBµV/m @ 3 m
Bluetooth™	
Frequency band	2400.0 – 2483.5 MHz
Bandwidth	< 1.4 MHz
Modulation	GFSK, π/4–DQPSK, 8DPSK
Radiated Power	< 9.6 mW E.I.R.P.
Receiver Category	2
Wi-Fi 2.4 GHz	
Frequency band	2400.0 – 2483.5 MHz
Bandwidth	20/40 MHz
Modulation	IEEE 802.11b/g/n
Radiated Power	< 80 mW E.I.R.P.
Wi-Fi 5.0 GHz	
Frequency band	5150 – 5350 MHz 5470 – 5725 MHz
Bandwidth	20/40/80 MHz
Modulation	IEEE 802.11a/n/ac
Radiated Power	< 50 mW E.I.R.P.

Network and Connectivity Specifications

Characteristics	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 100BASE-T
Wi-Fi	IEEE 802.11g, 802.11n, 802.11ac
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
Internet protocol	IPv4
Dynanic Host Configuration Protocol (DHCP) mode	Both manual and automatic DHCP modes are supported
Wi-Fi MAC address	Displayable

LATITUDE™ PROGRAMMER

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

Adverse Effects The following list includes the possible adverse effects associated with programming pulse generators described in this information: Asystole, Atrial arrhythmia, Bradycardia, Tachycardia and Ventricular arrhythmia.

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This document describes at a high level the specifications 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.

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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

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