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Using the LATITUDE Consult™ Application on the LATITUDE™ Programming System, Model 3300

Steps to interrogate a device with LATITUDE Consult:

1. **POWER ON** Programmer
2. **PRESS** Start READ-ONLY Mode **or**
   PRESS LATITUDE Consult System button if already in programming mode

3. **FOLLOW** onscreen instructions to interrogate and send data
4. **CALL** LATITUDE Consult Technical Services at **1.800.227.3422** to request a review and/or reports

Note: Use of LATITUDE Consult from the Programmer + Consult configuration is intended for users trained in device-based testing and reprogramming.

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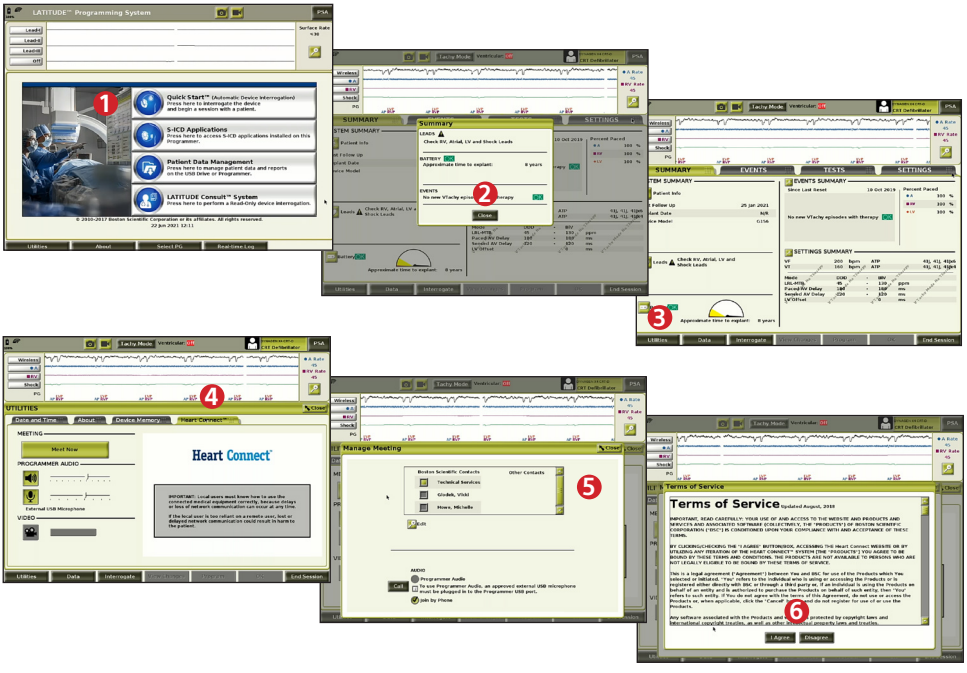
Using the Heart Connect™ System on the LATITUDE™ Programming System, Model 3300

Steps to make a Heart Connect call:

1. **SELECT** Quick Start
2. **SELECT** Close on Summary page
3. **SELECT** Utilities tab
4. **SELECT** Heart Connect tab then **PRESS** Meet Now
5. **PRESS** Intended Contacts and **PRESS** Call
6. **READ** Terms of Service and **PRESS** I Agree



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 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

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 with the appropriate power cord 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, Maintenance and Handling, and Radio Frequency (RF) Performance.

ADVERSE EFFECTS The following list includes the possible adverse effects associated with programming pulse generators described in this manual (refer to the operator's manual): • Asystole • Atrial arrhythmia • Bradycardia • Tachycardia • Ventricular arrhythmia
92436264 (Rev. B)

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.

LATITUDE Consult™ System

INTENDED USE The Programmer is intended for use in hospital and clinical environments to communicate with Boston Scientific implantable systems. LATITUDE Consult is intended to read data from a compatible Boston Scientific implanted device and transfer data to a central server. LATITUDE Consult can provide implanted device data that may be used as part of the clinical evaluation of the patient.

CONTRAINDICATIONS There are no known contraindications for LATITUDE Consult.

WARNINGS Refer to the LATITUDE Programming System Operator's Manual, Model 3300 for warnings.

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

- Ensuring a review. In order to ensure a review by Boston Scientific of the patient's implanted device data, the clinician must call Boston Scientific at 1-800-CARDIAC (227-3422) or contact a local Boston Scientific representative after sending the data to request a LATITUDE Consult review.
    - o At all times the institution (clinic) is responsible for the clinical and technical interpretation of LATITUDE Consult reports. The institution acknowledges that if a technical consultation on the data is desired, an institution employee may call 1-800-CARDIAC (227-342a2) or contact a local Boston Scientific representative to request a technical review by Boston Scientific. A local Boston Scientific representative may also be notified to assist with technical support of the device. If the institution requests reports to be sent automatically and does not receive a report within 15 minutes of a LATITUDE Consult transmission to Boston Scientific, the institution should call 1-800-CARDIAC (227-3422) or contact a local Boston Scientific representative to receive LATITUDE Consult System status; it is the institution's responsibility, and not Boston Scientific's, to ensure that the report is received by the institution.

ADVERSE EFFECTS None known. 92793836 (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.

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.

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1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

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