LATITUDE™ Programming System (3300)
Indications, Safety and Warnings

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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.

Contradictions

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.
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