Boston Scientific
Advancing science for life™

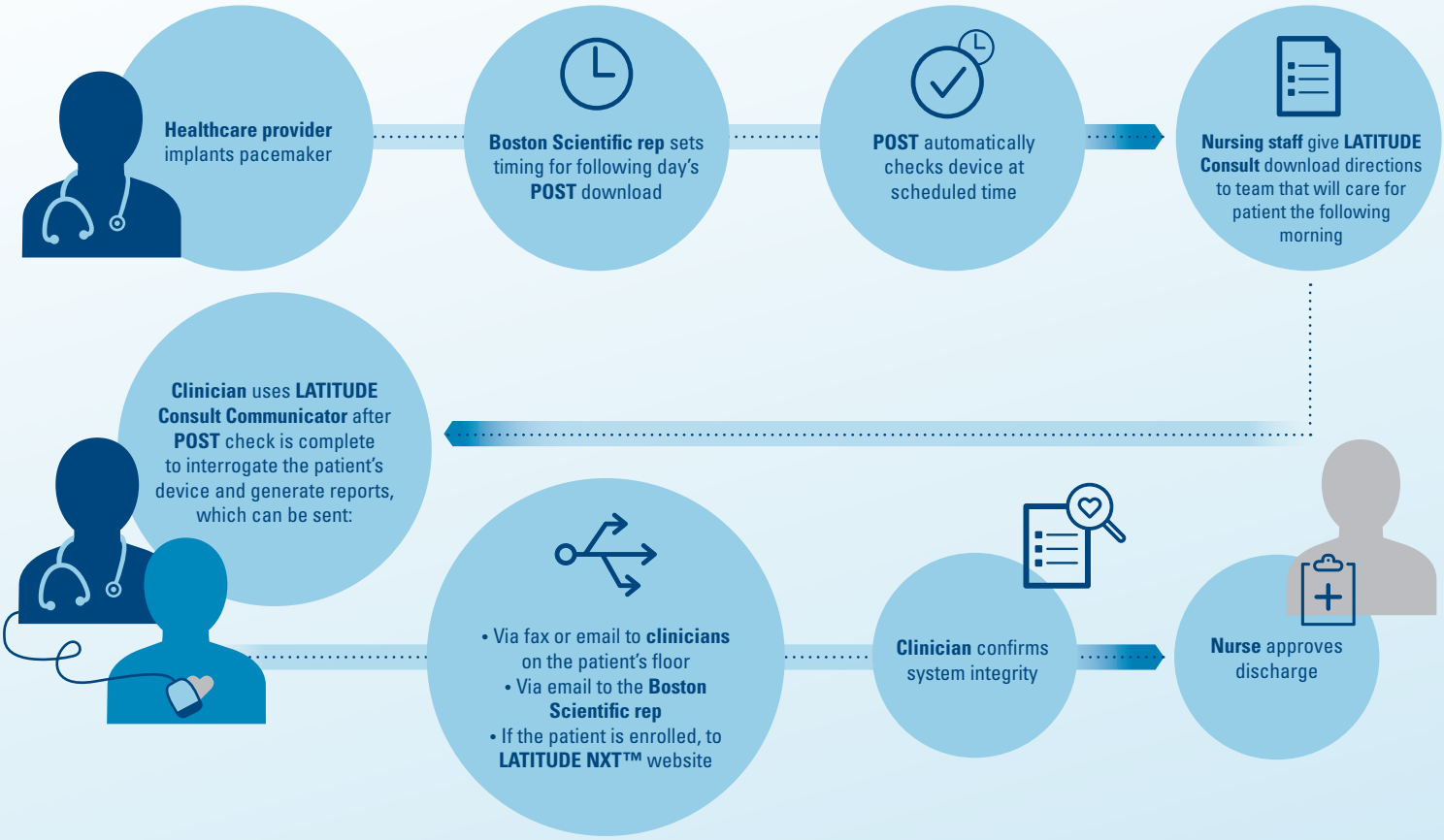
LATITUDE Consult™ System

Streamline pacemaker checks by reducing the need for an in-person pre-discharge check

Automate Pre-Discharge Pacemaker Checks

The morning after a pacemaker procedure, patients and staff have typically had to wait for a trained pacemaker clinician to be at a patient's bedside to gather device data. The combination of the **Post-Operative System Test (POST)** – included in all current Boston Scientific pacemakers – and the **LATITUDE Consult System** eliminates this wait in most cases while providing ***accurate system measurements in an average of 9 minutes.***[1]

Sample Workflow

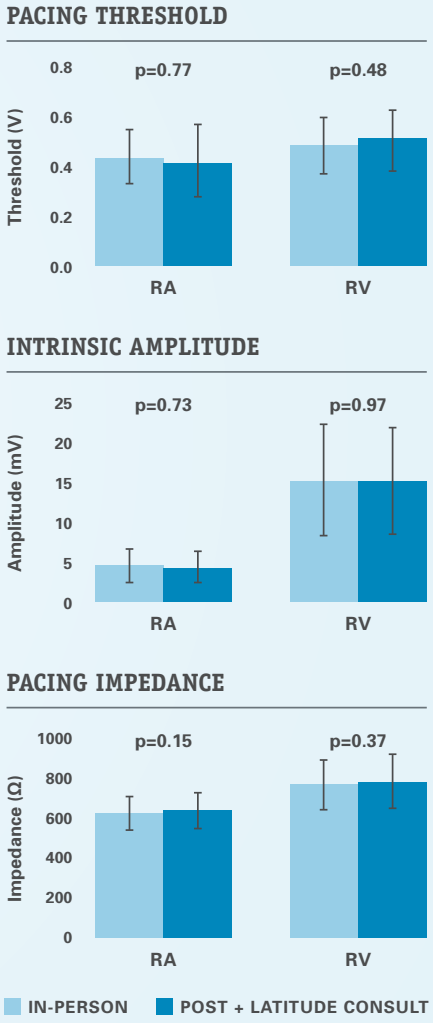


LATITUDE NXT can provide the same data to remotely confirm system integrity. If **LATITUDE Consult** is not available, simply enroll the patient in **LATITUDE NXT** and set up the **LATITUDE Communicator** in the patient's room. After **POST** automatically checks the device, the nursing staff can upload data to **LATITUDE NXT** for the clinician to review by pushing the heart button on the **LATITUDE Communicator.**

Remote Technology Alternative to In-Person Checks

A recent analysis by Ohad Ziv, MD, and Matt Collins, MBA, CCDS, "Combining Remote Cardiac Device Interrogation with a pacemaker-based feature that can schedule full automatic device check the day after implant to replace in-person pre-discharge checks," explored the efficacy of using POST in combination with the LATITUDE Consult System. The results showed comparable pacing threshold, intrinsic amplitude and pacing impedance. Dr. Ziv explains,

"In our practice, we were finding significant delays in patient discharge times due in part to patients waiting for a post-operative device check. We thought the LATITUDE Consult System may be a mechanism to making discharges more efficient. Our first step was to prove that the system functions as well as an in-person check. The data supports this: LATITUDE Consult System checks demonstrated the same post-operative lead function as an in-person device check. Our next step is to apply the system in a device clinic-driven protocol to see if discharge times improve."



Talk to your local Boston Scientific representative to get started using the LATITUDE Consult System.

LATITUDE Consult System **INTENDED USE** The LATITUDE Consult System is intended to read data from a compatible Boston Scientific implanted device and transfer it to a central server. The LATITUDE Consult System can provide implanted device data that may be used as part of the clinical evaluation of the patient. **CONTRAINDICATIONS** The LATITUDE Consult Communicator is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE Consult System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being read. **WARNINGS** The Communicator is MR (Magnetic Resonance) 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.[1] Under no circumstances should the Communicator be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas. **PRECAUTIONS** 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) after sending the data and request a LATITUDE Consult review. **ADVERSE EFFECTS** None known. *Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev B)*

LATITUDE NXT Patient Management System **INTENDED USE** The LATITUDE NXT Patient Management System is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database. The LATITUDE NXT System provides patient data that can be used as part of the clinical evaluation of the patient. **CONTRAINDICATIONS** The LATITUDE NXT Patient Management System is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE NXT System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated. **PRECAUTIONS** Alerts may appear on the LATITUDE NXT website on a daily basis. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NXT website. The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Although secondary notification through email and SMS text messages is available, these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the website. Implanted device data and alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to 14 days may elapse before the LATITUDE NXT server detects these conditions and informs the clinic user that monitoring is not occurring. If both of these conditions occur at the same time, this notification could take up to 28 days. Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following: System limitations; the Communicator is unplugged; the Communicator is not able to connect to the LATITUDE NXT server through the configured phone system; the implanted device and the Communicator cannot establish and complete a telemetry session; the Communicator is damaged or malfunctions; the patient is not compliant with prescribed use or is not using the LATITUDE NXT System as described in the patient manual; if subscribed to the LATITUDE Cellular Data Plan, missing two or more payments discontinues the subscription; the clinic user can identify any patients that are not being monitored as described above by using the Not Monitored filter on the View Patient List. **ADVERSE EFFECTS** None known. **SYSTEM LIMITATIONS** The LATITUDE NXT System does not provide continuous real-time monitoring. As a remote monitoring system, the LATITUDE NXT System provides periodic patient monitoring based on clinician configured settings. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of implanted device, sensor, and patient information as intended by the clinician. These factors include: implanted device clock; patient environment; cellular data service; telephone system; communicator memory capacity; clinic environment; schedule/configuration changes; or data processing. *Refer to the product labeling for specific instructions for use. Rx only. (Rev. D)*

Pacing Systems – ACCOLADE™, ESSENTIO™, VITALIO™, INGENIO™, ADVANTIO™ **INDICATIONS AND USAGE** Boston Scientific pacemakers are indicated for treatment of the following conditions: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block); bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block, VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm, low cardiac output or congestive heart failure secondary to bradycardia. **CONTRAINDICATIONS** These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads. Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed: unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy; Minute Ventilation in patients with both unipolar atrial and ventricular leads; single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing; dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms. **WARNINGS General** Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. **PRECAUTIONS** For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration. **POTENTIAL ADVERSE EVENTS** Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur. *Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. B)*

1. Data on File

Boston Scientific
Advancing science for life™

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

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-517404-AA MAR2018