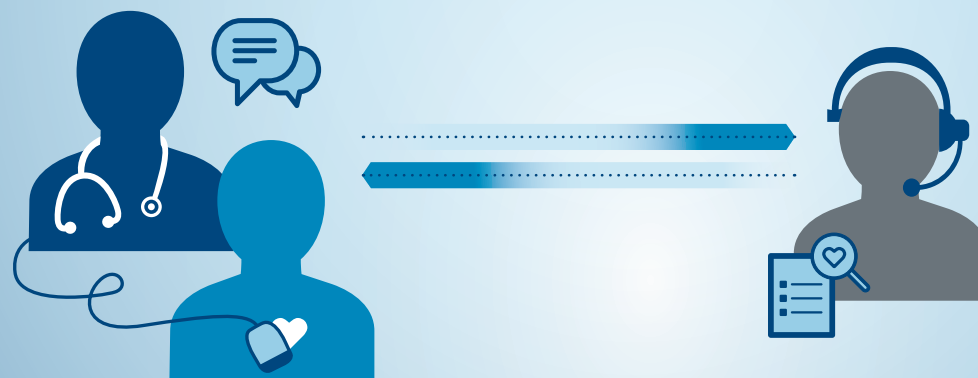




LATITUDE Consult™ System

WHY WAIT FOR A DEVICE EXPERT?



Get convenient access to patient data and diagnostics.

- Comprehensive diagnostics: configurable to point-of-care,* device clinic and heart failure use cases; collects the most recently stored episodes from the last 72 hours or from the last 6 months
- Intuitive screens, portable design – no advanced training required
- Concise and conveniently formatted reports are available via email, fax or LATITUDE NXT™ if patient is enrolled
- Multiple connectivity options: analog telephone line, cellular or internet connection

*Point-of-care configuration is designed for use in locations such as the emergency room (ER) or operating room (OR).

1. Mittal S, et al. Performance of a remote interrogation system for the in-hospital evaluation of cardiac implantable electronic devices. *J Interv Card Electrophysiol*. DOI 10.1007/s10840-015-0091-4, published online. December 22, 2015. In 90% of all device interrogations, it was possible to triage patients as having either normal device function or findings that did not require immediate attention.

2. Atherton C. Management of the device patient outside the arrhythmia center. *EP Lab Digest*. August 2015.

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. The Communicator 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 Practices¹. 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 D) 046774 AH

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 connected medical equipment. The Heart Connect System provides health care providers and Boston Scientific personnel with means to establish an online meeting and share the video display from the connected medical equipment 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 these Instructions For Use.

WARNINGS The use of any cables or accessories with the Heart Connect System, other than those included with the Heart Connect may result in increased emissions or decreased immunity of the system. Do not connect an extension cord or portable multiple socket outlet to the Heart Connect System. The Heart Connect System must be kept outside the patient environment (at least 1.5 m [4.9 ft]) away from the patient or as specified in the instructions for the connected medical equipment. The Heart Connect System is MR unsafe and must remain outside the magnetic resonance imaging (MRI) site Zone III (and higher).The System is non-sterile and cannot be sterilized.

PRECAUTIONS Patient data should only be accessed by authorized healthcare providers and Boston Scientific personnel. Ensure that any changes to the settings of the Heart Connect System are made per guidance from authorized Boston Scientific personnel or authorized health care providers. USB drives should only be connected to the Heart Connect Tablet by authorized personnel. Any USB drives that are to be connected to the Heart Connect Tablet must be controlled to help prevent unauthorized modifications to the Heart Connect System. The Local User should store the Heart Connect System in a secure location when not in use to help prevent theft or unauthorized access. If unexpected behavior is seen with the Heart Connect System, restart the system. If issues continue to be seen or if the system appears to be compromised, discontinue use and contact Boston Scientific Technical Services for assistance, using information from the back cover of this manual.

ADVERSE EFFECTS There are no known adverse effects.

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

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.

Fast. Convenient. Portable.



The **LATITUDE Consult System** gives your team the ability to quickly conduct pacemaker and defibrillator device checks 90% of the time. There's no need to wait for a device expert to arrive on site.

This system creates a convenient way to quickly triage patients during their regularly scheduled follow-up appointments, pre- and post-surgery, and during ER visits. And when advanced troubleshooting is required, the clinician can use **Boston Scientific's Heart Connect™ System** to complete the device check and program as needed.

The LATITUDE Consult System gives you continuous 24/7 support from the experts you know and trust along with real-time technical and clinical support on demand.

This solution empowers your team and improves value.

Talk to your local Boston Scientific representative to get started using the LATITUDE Consult and Heart Connect systems.

Provide faster, more efficient treatment.

