

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 AI