

#### **Intended Use**

The Programmer/Recorder/Monitor (PRM) is intended to be used as part of the ZOOM™ LATITUDE™ Programming System to communicate with Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literature for the pulse generator being interrogated.

#### **Contraindications**

The PRM is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator. For contraindications for use related to the pulse generator, refer to the associated product literature for the pulse generator being interrogated.

#### **Warnings**

The use of any cables or accessories with the PRM or Zoom Wireless Transmitter (ZWT) other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the PRM or ZWT. Do not simultaneously touch the patient and any accessible connector contacts on the PRM (e.g., USB, parallel port, external VGA monitor, stimulation input, analog output, and expansion port). Other equipment may interfere with the PRM and ZWT, even if that equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. To avoid the risk of electric shock, only connect the PRM to a grounded/earthed power source. Do not use the PRM or ZWT adjacent to or stacked with other equipment. PRM and ZWT must remain outside sterile field. Operation of the PRM with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. Do not simultaneously touch the patient and the parts inside the printer door. The PRM and ZWT are 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<sup>1</sup>. No modification of this equipment is allowed unless approved by Boston Scientific.

#### **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 effects.*

*Rx only. (Rev. H) 046774 AH*