

# Cardiology and Radiology Checklists

## IMAGEREADY™

### MR-Conditional Pacing Systems

PATIENT NAME

D.O.B.

PG MODEL #

ATRIAL LEAD

RV LEAD

Use the following checklists to ensure that patients who have a Boston Scientific Pacing System labeled MR-Conditional can receive a MR-Conditional scan. Only specific combinations of Boston Scientific MR-Conditional pulse generators and MR-Conditional leads/electrodes constitute a valid ImageReady™ MR-Conditional Pacing System for use in 1.5 Tesla or 3 Tesla environments.

**RESOURCES** Confirm that patient has a complete ImageReady™ MR-Conditional System by referring to the below resources:  
 ▶ Boston Scientific MRI Technical Guide [www.bostonscientific.com/manuals/](http://www.bostonscientific.com/manuals/)  
 ▶ Boston Scientific ImageReady [www.BostonScientific.com/imageready](http://www.BostonScientific.com/imageready)  
 ▶ Boston Scientific Technical Services Hotline 1800 245 559 (Australia), 0800 742 678 (New Zealand)

**OFF-LABEL MRI SCAN**  My patient **DOES NOT HAVE** a complete ImageReady™ MR-Conditional Pacing System and/or **DOES NOT MEET** the Conditions of Use listed below. Because not all Conditions of Use have been met, the scan is off-label. Boston Scientific labeling warns of potential risks for off-label MRI scans and does not promote nor encourage this use. Use the Cardiology Order Form *Off-Label MRI Scan* to specify programming parameters during off-label MRI scans.

**CARDIOLOGY CONDITIONS OF USE**

- Patient is implanted with an ImageReady™ MR-Conditional Pacing System with all ports occupied by a lead or port plug.
- Pulse generator in MRI Protection Mode during scan.
- Bipolar pacing operation or pacing off.
- No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, extenders, leads, or pulse generators.
- As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and electrocardiography (ECG). Ensure backup therapy is available (external rescue).
- Patient does not have elevated body temperature or compromised thermoregulation at time of scan.
- At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady™ MR-Conditional Pacing System.
- No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.
- Pacing threshold  $\leq 2.0$  V in pace-dependent patients.

**RADIOLOGY CONDITIONS OF USE**

- MRI magnet strength
  - 64 MHz for 1.5T
  - 128 MHz for 3T
  - Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system for 1.5T or 3T
- Horizontal, <sup>1</sup>H proton, closed bore scanners only.
- Specific Absorption Rate (SAR) limits for the entire active scan – Normal Operating Mode<sup>1</sup>
  - Whole body averaged,  $\leq 4.0$  W/Kg
  - Head,  $\leq 3.2$  W/Kg
- Gradient Field limits – Maximum specified gradient slew rate  $\leq 200$  T/m/s per axis.
- There are no restrictions for positioning the pacing system within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted; local transmit coils may be used but should not be placed directly over the pacing system.
- Patient in supine or prone position only.
- Patient must be continuously monitored during the MRI scan by pulse oximetry and/or electrocardiography.

**NOTE** Ensure that external defibrillator and medical personnel skilled in CPR are present during the MRI scan should the patient require external rescue.

<sup>1</sup> As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.