

Cardiology / Radiology Checklists

IMAGEREADY™

MR-Conditional Pacing Systems

PATIENT NAME _____

D.O.B. _____

MODEL #s _____

PACEMAKER/CRT-P _____

ATRIAL LEAD _____

RV LEAD _____

LV 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 constitute a valid ImageReady™ MR-Conditional Pacing System for use in 1.5 Tesla and 3 Tesla environments.

RESOURCES

Confirm that the patient has a valid ImageReady™ MR-Conditional Pacing System by referring to the below resources:

- ▶ Boston Scientific MRI Technical Guide, ImageReady™ MR-Conditional Pacing Systems
- ▶ www.BostonScientific.com/imageready
- ▶ Boston Scientific MRI Hotline 1.844.4.BSC.MRI (1.844.427.2674)

CARDIOLOGY CONDITIONS OF USE¹

- Patient is implanted with an ImageReady™ MR-Conditional Pacing System.
- At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR-Conditional Pacing System.
- Pulse generator implant location restricted to left or right pectoral region.
- No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, extenders, leads, or pulse generators.
- No evidence of fractured lead or compromised pulse generator-lead integrity.
- RA and RV leads programmed to bipolar pacing operation or pacing OFF.
- Pulse generator in MRI Protection Mode during scan.

RADIOLOGY CONDITIONS OF USE¹

- MRI magnet strength
 - 64 MHz for 1.5 T
 - 128 MHz for 3 T
 - Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system for 1.5 T or 3 T
- Horizontal, ¹H proton, closed bore scanners only.
- Specific Absorption Rate (SAR) limits: for all ImageReady™ Pacing Systems – SAR limits for Normal Operating Mode¹ must be observed for the entire active scan session as follows:
 - Whole body averaged, ≤ 2.0 watts/kilogram (W/Kg)
 - Head, ≤ 3.2 W/Kg
- Specific Absorption Rate (SAR) limits: for an ImageReady™ Pacing System utilizing only INGEVITY™ MRI leads – SAR limits up to First Level Controlled Operating Mode² may be applied for the entire active scan as follows:
 - Whole body averaged, ≤ 4.0 W/Kg
 - Head, ≤ 3.2 W/Kg
- Gradient Field limits – Maximum specified gradient slew rate ≤ 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.

¹ As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.

² As defined in IEC 60601-2-33, 201.3.201, 3rd Edition