Cardiology / Radiology Checklists

IMAGEREADY ™

MR-Conditional Transvenous Defibrillation Systems

PATIENT NAME D.O.B.

MODEL #s	ICD/CRT-D	ATRIAL LEAD	RV LEAD	LV LEAD

Use the following checklists to ensure that patients who have a Boston Scientific Transvenous Defibrillation System labeled MR-Conditional can receive an MR-Conditional scan. Only specific combinations of Boston Scientific MR-Conditional pulse generators and MR-Conditional leads constitute a valid ImageReady™ MR-Conditional Transvenous Defibrillation System for use in a 1.5 or 3 Tesla environment. **To distinguish between combinations that are valid for use with 1.5 T or 3 T scanners, model numbers of the MR Conditional Defibrillation System components are provided in the *Boston Scientific MRI Technical Guide, ImageReady™ MR-Conditional Transvenous Defibrillation System.***

RESOURCES

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

- Boston Scientific MRI Technical Guide, ImageReady™ MR-Conditional Transvenous Defibrillation System
- www.BostonScientific.com/imageready
- Boston Scientific MRI Hotline 1.844.4.BSC.MRI (1.844.427.2674)

CARDIOLOGY CONDITIONS OF USE[1]

- ☐ Patient is implanted with an ImageReady™ MR-Conditional Transvenous Defibrillation System
- ☐ No other active or abandoned implanted devices, components, or accessories present, such as lead adaptors, extenders, leads or pulse generators
- ☐ Pulse generator in MRI Protection Mode during scan
- ☐ 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 is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode
- ☐ Pulse generator implant location restricted to left or right pectoral region
- ☐ At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR-Conditional Transvenous Defibrillation System
- ☐ No evidence of a fractured lead or compromised pulse generator-lead system integrity

RADIOLOGY CONDITIONS OF USE[1]

- ☐ Horizontal, hydrogen proton, closed bore scanners only
- ☐ MRI magnet strength of 1.5 T (64 MHz) or 3 T (128 MHz)
- ☐ Spatial gradient no greater than 20 T/m (2,000 G/cm).
- ☐ RF exposure limits:

  1.5 T
  - Normal Operating Mode[a] must be observed for the entire active scan session (whole body averaged SAR ≤ 2.0 watts/kilogram (W/kg); Head SAR, ≤ 3.2 W/kg)

  3 T (Patient landmark/scan isocenter at or superior to the C7 vertebra)
  - Normal Operating Mode or First Level Controlled Operating Mode must be observed for the entire active scan session

  3 T (Patient landmark/scan isocenter inferior to the C7 vertebra)
  - B_{1+rms} must be ≤ 2.8 microtesla (μT)

  WARNING: If the B_{1+rms} **parameter** value is not displayed on the 3 T MRI scanner system, do not perform 3T scans with a patient landmark (scan isocenter) inferior to the C7 vertebrae. Such scans do not meet the Radiology Conditions of Use.
- ☐ Gradient Field limits – Maximum specified gradient slew rate: ≤ 200 T/m/s per axis
- ☐ There are no restrictions for positioning the defibrillation 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 defibrillation system
- ☐ Patient in supine or prone position only
- ☐ Patient must be continuously monitored by pulse oximetry and electrocardiography (ECG) for the entire duration in which the pulse generator is in MRI Protection Mode. Ensure backup therapy is available (external rescue)

  IMPORTANT: If you are unfamiliar with B_{1+rms}, or are unsure if it is available on your 3 T scanner, either limit scans to 1.5 T and Normal Mode, or contact the MRI scanner manufacturer for more information

[a] As defined in IEC 60601-2-33, 201.3.224, 3rd Edition.

[1] Refer to the MRI Technical Guide: ImageReady™ MRI Defibrillation System as the system is designated as MR-Conditional in accordance with specific conditions.