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Radiology Checklist for the IMAGEREADY™ MR-Conditional Systems EMBLEM™ MRI S-ICD System

Refer to the Boston Scientific ImageReady MR-Conditional S-ICD System MRI Technical Guide[1] or link: www.bostonscientific.com/imageready for a full list of warnings, precautions and complete instructions for using the ImageReady S-ICD System.

Patient Name: _____

S-ICD Model: _____ Electrode Model: _____

Conditions of Use – Radiology

According to the labeling for the ImageReady S-ICD System, the following Conditions of Use must be met in order for a patient with an ImageReady S-ICD System to undergo an MRI scan.

- ☐ MRI magnet strength = 1.5 T only.
- ☐ RF field = Approximately 64 MHz.
- ☐ Maximum spatial gradient = 30 T/m (3,000 G/cm).
- ☐ MRI equipment specification = Horizontal, 1 H proton, closed bore scanners only.
- ☐ Specific Absorption Rate (SAR) limits for the entire active scan (Normal Operating Mode[a]):
  - Whole body averaged, ≤ 2.0 watts/kilogram (W/Kg)
  - Head, ≤ 3.2 W/Kg
- ☐ Maximum specified gradient slew rate ≤ 200 T/m/s per axis.
- ☐ The use of receive-only coils is not restricted. Local transmit-only coils or local transmit/receive coils may be used, but should not be placed directly over the ImageReady S-ICD 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).

[a]As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.

Scanning Procedure

Pre-Scan

1. Ensure Cardiology has cleared the patient for scanning eligibility based on the Cardiology MRI Conditions of Use ("Cardiology Checklist for the ImageReady S-ICD System").
2. As close to the start of the scan as possible, the patient's pulse generator is programmed into MRI Protection Mode and continuous monitoring of the patient begins.
3. Refer to the MRI Protection Settings Report to confirm that the patient's device is in MRI Protection Mode. If the Time-out feature is used, the report includes the exact time and date when MRI Protection Mode will expire via the Time-out feature. **Verify that adequate time remains to complete the scan.**

During Scan

4. Ensure the patient is continuously monitored by pulse oximetry and electrocardiography (ECG), with backup therapy available (external rescue), while the device is in MRI Protection Mode.

After Scan

5. Ensure the pulse generator is returned to pre-MRI operation, either automatically via the Time-out feature, or manually using the Programmer. Continue patient monitoring until the pulse generator is returned to pre-MRI operation. Follow-up testing of the S-ICD system may be performed after exiting MRI Protection Mode.

Warnings:

- Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.
- The Programmer 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 Practices. Under no circumstances should the Programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

IMAGEREADY™ MR-Conditional Systems *EMBLEM™ MRI S-ICD System Components for 1.5 T*

Only specific combinations of pulse generators and electrodes constitute an ImageReady S-ICD System that is valid for use with **1.5 T scanners**.

ImageReady™ MR-Conditional S-ICD System Components for 1.5 T

Component	Model Number(s)	MR Status	1.5 T
Pulse Generators			
EMBLEM™ S-ICD	A209	MR Conditional	✔
EMBLEM™ MRI S-ICD	A219	MR Conditional	✔
Electrodes and Accessories			
EMBLEM™ S-ICD Electrode	All models	MR Conditional	✔
Q-TRAK S-ICD Electrode	All models	MR Conditional	✔
Suture Sleeves for S-ICD Electrodes	All models	MR Conditional	✔
Programmer			
EMBLEM™ S-ICD Programmer	All models	MR Unsafe*	NA

***Warning:**

- The Programmer/Recorder/Monitor (PRM) 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 Practices. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

1. MRI TECHNICAL GUIDE IMAGEREADY™ MR CONDITIONAL S-ICD SYSTEM 359474-001 EN US 2015-11.

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