

Cardiology Checklist for the **IMAGEREADY™**

MR-Conditional Systems

EMBLEM™ MRI S-ICD System

This form contains confidential patient information, and should be treated with proper care and precaution and not shared except as needed. Refer to the Boston Scientific ImageReady MR Conditional S-ICD System MRI Technical Guide¹ 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 - Cardiology

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

- Patient is implanted with an ImageReady MR Conditional S-ICD System (see reverse).
- 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.
- 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 S-ICD System.
- No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.

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.
- If the MRI Protection Time-out value is programmed to Off, the patient will not receive Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.
- The Programmer (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 Programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

Scanning Procedure

The following Scanning Procedure information is being provided for your information.

Pre-Scan

1. Ensure patient meets all Cardiology Conditions of Use for MRI scanning (see left column).
2. Exposure to MRI scanning can cause a permanent loss of the Beeper volume. The physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper.
3. As close to the start of the scan as possible, program the pulse generator into MRI Protection Mode and begin continuous monitoring of the patient.
4. Print the MRI Protection Settings Report, place it in the patient's file, and provide to radiology personnel.
 - The report documents MRI Protection Mode settings and details. 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.

During Scan

5. 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

6. Ensure the pulse generator is returned to pre-MRI operation, either automatically if the Time-out feature was set, or manually using the programmer. Follow-up testing of the defibrillation system after exiting MRI Protection Mode, and 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.
7. The Beeper will remain disabled upon exiting MRI Protection Mode.

IMAGEREADY™ EMBLEM™ MRI S-ICD Components for 1.5T

MR-Conditional Systems

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

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

Component	Model Number(s)	MR Status	1.5T
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.

All trademarks are the property of their respective owners. CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Not intended for use or distribution in France.

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