

Cardiology / Radiology Checklists

IMAGEREADY™

EMBLEM™ MRI S-ICD System

PATIENT NAME _____

D.O.B. _____

MODEL #s

S-ICD _____

ELECTRODE _____

Use the following checklists to ensure that patients who have a Boston Scientific EMBLEM™ MRI S-ICD System labeled MR-Conditional can receive a MR-Conditional scan. Only specific combinations of Boston Scientific MR-Conditional pulse generators and MR-Conditional electrodes constitute an ImageReady™ MR-Conditional S-ICD System that is valid for use in a 1.5 Tesla environment.

RESOURCES

Confirm that patient has a valid ImageReady™ MR-Conditional S-ICD system by referring to the below resources:

- ▶ Boston Scientific MRI Technical Guide, <https://www.bostonscientific.com/manuals>
- ▶ Boston Scientific Technical Services 1800.245.559 (Australia), 0800.742.678 (New Zealand)

CARDIOLOGY

CONDITIONS OF USE

- Patient is implanted with an ImageReady™ MR-Conditional S-ICD System.
- No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, 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™ MR-Conditional S-ICD System.
- No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.

RADIOLOGY

CONDITIONS OF USE

- MRI magnet strength of 1.5 T, only.
- Radio Frequency (RF) field of approximately 64 MHz.
- Maximum spatial gradient of 30 T/m (3,000 G/cm).
- Horizontal, ¹H proton, closed bore scanner 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
- Gradient Field limits – Maximum specified gradient slew rate: ≤ 200 T/m/s per axis.
- The use of local 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™ MR-Conditional 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