Boston Scientific
Advancing science for life™

Radiology Checklist for the ImageReady™ Defibrillation System

Refer to the Boston Scientific ImageReady™ MR Conditional Defibrillation System MRI Technical Guide[1] or link: www.bostonscientific.com/imageready

Patient Name: _____

Defibrillator Model: _____ Lead Models: _____

Conditions of Use – Radiology

The following Conditions of Use must be met in order for a patient with an ImageReady Defibrillation System to undergo an MRI scan.

- ☐ MRI magnet strength = 1.5 T only.
- ☐ RF field = Approximately 64 MHz.
- ☐ Maximum spatial gradient = 50 T/m (5,000 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 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).

[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 Defibrillation 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. **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 if the Time-out parameter was set, or manually using the PRM. Perform 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.

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/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[2]. 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.

ImageReady™ Defibrillation System Components for 1.5 T

Only specific combinations of pulse generators and leads constitute an ImageReady Defibrillation System that is valid for use with **1.5 T scanners**.

ImageReady™ MR Conditional Defibrillation System Components for 1.5 T

Component	Model Number(s)	MR Status	1.5 T
Pulse Generators			
AUTOGEN™ ICD	D044, D046, D174, D176	MR Conditional	✔
AUTOGEN™ X4 CRT-D	G179	MR Conditional	✔
CHARISMA™ ICD	D332, D333	MR Conditional	✔
CHARISMA™ X4 CRT-D	G347	MR Conditional	✔
DYNAGEN™ ICD	D020, D022, D150, D152	MR Conditional	✔
DYNAGEN™ X4 CRT-D	G158	MR Conditional	✔
INOGEN™ ICD	D010, D012, D140, D142	MR Conditional	✔
INOGEN™ X4 CRT-D	G148	MR Conditional	✔
ORIGEN™ ICD	D000, D002	MR Conditional	✔
ORIGEN™ X4 CRT-D	G058	MR Conditional	✔
PERCIVA™ ICD	D412, D413	MR Conditional	✔
RESONATE™ ICD	D432, D433	MR Conditional	✔
RESONATE™ X4 CRT-D	G447	MR Conditional	✔
VIGILANT™ ICD	D232, D233	MR Conditional	✔
VIGILANT™ X4 CRT-D	G247	MR Conditional	✔
Leads and Accessories			
FINELINE™ II Sterox Pacing Leads	4479, 4480	MR Conditional	✔
FINELINE™ II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional	✔
Suture Sleeve for FINELINE™ II leads	6220, 6221	MR Conditional	✔
INGEVITY™ MRI Pacing Leads	7735, 7736, 7740, 7741, 7742	MR Conditional	✔
Suture Sleeve for INGEVITY™ MRI leads	6402	MR Conditional	✔
IS-1 Lead Port Plug	7145	MR Conditional	✔
IS4/DF4 Lead Port Plug	7148	MR Conditional	✔
ENDOTAK RELIANCE® (DF4) Defibrillation leads	0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional	✔
RELIANCE 4-FRONT™ Defibrillation leads	0654, 0655, 0657, 0658, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional	✔
Suture Sleeve for RELIANCE 4-FRONT™ leads	6403	MR Conditional	✔
ACUITY™ X4 Pacing leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	✔
Suture Sleeve for ACUITY™ X4 leads	4603	MR Conditional	✔
ZOOM™ LATITUDE™ Programmer/Recorder/Monitor (PRM) and PRM Software Application			
ZOOM™ LATITUDE™ PRM	3120	MR Unsafe*	
ZOOM™ LATITUDE™ PRM Software App	2869	Not Applicable	

***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 DEFIBRILLATION SYSTEM 360205-001 EN Europe 2016-08
2. Kanal E et al., American Journal of Roetgenology 188:1447-74 2007

CRM-322522-AB MAY2017 Printed in Germany by medicalvision.

Boston Scientific
Advancing science for life™

www.bostonscientific.eu

DINCRM0889EB