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Cardiology Checklist for the ImageReady™ Defibrillation System

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

Patient Name: _____

Defibrillator Model: _____ Lead Models: _____

Conditions of Use - Cardiology

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

- ☐ Patient is implanted with an ImageReady MR Conditional Defibrillation 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.
- ☐ 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 Defibrillation System.
- ☐ No evidence of a fractured lead or compromised pulse generator-lead system integrity.

Scanning Procedure

Pre-Scan

1. Ensure patient meets all Cardiology Conditions of Use for MRI scanning (see left column).
2. Exposure to MRI scanning causes 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.

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 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.
7. The Beeper will remain OFF upon 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 Beeper will no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner causes a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper. It is strongly recommended that patients are followed on LATITUDE™ NXT after an MRI scan if they are not already, otherwise an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.
- 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/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 and 3 T

Only specific combinations of pulse generators and leads constitute an ImageReady Defibrillation System that is valid for use with **1.5T or 3T scanners**.

ImageReady™ MR Conditional Defibrillation System Components for 1.5T and 3T

Component	Model Number(s)	MR Status	1.5T	3T
Pulse Generators				
AUTOGEN™ CRT-D	G172, G173, G177, G179	MR Conditional	✔	
AUTOGEN™ ICD	D174, D175, D176, D177	MR Conditional	✔	
AUTOGEN™ MINI ICD	D044, D045, D046, D047	MR Conditional	✔	
CHARISMA™ DF1 ICD	D321, D320	MR Conditional	✔	
CHARISMA™ ICD	D332, D333	MR Conditional	✔	✔
CHARISMA™ IS-1 CRT-D	G348, G324, G325	MR Conditional	✔	
CHARISMA™ X4 CRT-D	G347	MR Conditional	✔	✔
DYNAGEN™ CRT-D	G150, G151, G156, G158	MR Conditional	✔	
DYNAGEN™ ICD	D020, D021, D022, D023, D150, D151, D152, D153	MR Conditional	✔	
INOGEN™ CRT-D	G140, G141, G146, G148	MR Conditional	✔	
INOGEN™ ICD	D010, D011, D012, D013, D140, D141, D142, D143	MR Conditional	✔	
MOMENTUM™ CRT-D	G124, G125, G138	MR Conditional	✔	
MOMENTUM™ ICD	D120, D121	MR Conditional	✔	
ORIGEN™ CRT-D	G050, G051, G056, G058	MR Conditional	✔	
ORIGEN™ ICD	D000, D001, D002, D003, D050, D051, D052, D053	MR Conditional	✔	
PERCIVA DF1 ICD	D400, D401	MR Conditional	✔	
PERCIVA™ ICD	D412, D413	MR Conditional	✔	✔
RESONATE™ DF4 ICD	D432, D433	MR Conditional	✔	✔
RESONATE™ IS-1 CRT-D	G424	MR Conditional	✔	
RESONATE™ X4 CRT-D	G447	MR Conditional	✔	✔
VIGILANT™ ICD	D232, D233	MR Conditional	✔	✔
VIGILANT™ IS-1 CRT-D	G224	MR Conditional	✔	
VIGILANT™ X4 CRT-D	G247	MR Conditional	✔	✔
Leads and Accessories				
ACUITY™ Spiral Pacing lead	4591, 4592, 4593	MR Conditional	✔	
ACUITY™ X4 Pacing leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	✔	✔
EASYTRAK™ 2 Pacing lead	4542,4543,4544	MR Conditional	✔	
ENDOTAK RELIANCE® (DF1) Defibrillation leads	0127, 0128, 0129, 0137, 0138, 0139, 0143, 0147, 0148, 0149, 0153, 0157, 0158, 0159, 0170, 0171, 0172, 0173, 0174, 0175, 0176, 0177, 0180, 0181, 0182, 0183, 0184, 0185, 0186, 0187	MR Conditional	✔	
ENDOTAK RELIANCE® (DF4) Defibrillation leads	0262, 0263, 0265, 0266, 0272, 0273, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional	✔	✔
FINELINE™ II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional	✔	✔
FINELINE™ II Sterox Pacing Leads	4479, 4480	MR Conditional	✔	✔
INGEVITY™ MRI Pacing Leads	7735, 7736, 7740, 7741, 7742	MR Conditional	✔	✔
INGEVITY™+ Pacing Leads	7840, 7841, 7842	MR Conditional	✔	✔
IS-1 Lead Port Plug	7145	MR Conditional	✔	✔
IS4/DF4 Lead Port Plug	7148	MR Conditional	✔	✔
DF1 Lead Port Plug	6996	MR Conditional	✔	✔
RELIANCE 4-FRONT™ Defibrillation leads	0636, 0650, 0651, 0652, 0653, 0654, 0655, 0657, 0658, 0662, 0663, 0665, 0672, 0673, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional	✔	✔
Suture Sleeve for ACUITY™ X4 leads	4603	MR Conditional	✔	✔
Suture Sleeve for FINELINE™ II leads	6220, 6221	MR Conditional	✔	✔
Suture Sleeve for INGEVITY™ MRI leads	6402	MR Conditional	✔	✔
Suture Sleeve for RELIANCE 4-FRONT™ leads	6403	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		

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1. MRI TECHNICAL GUIDE IMAGEREADY™ MR CONDITIONAL DEFIBRILLATION SYSTEM 360205-037 EN Europe
2. Kanal E et al., American Journal of Roetgenology 188:1447-74 2007

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