Boston Scientific
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IMAGEREADY™
MR-Conditional System

Transvenous Defibrillation Systems

Cardiology/Radiology Checklists

Patient name: _____ Date of Birth: _____

Model: _____ RV Lead Model: _____ Atrial Lead Model: _____ LV Lead Model:_____

The following conditions must be met in order for a patient with a Boston Scientific ImageReady MR-Conditional System to undergo an MRI scan:

For Cardiologists ~ MRI Conditions for Use [1]

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

For Radiologists ~ MRI Conditions for Us [1]

- ☐ MRI magnet strength of 1.5T only
- ☐ Radio frequency (RF) field of approximately 64 MHz
- ☐ Maximum spatial gradient no greater than 20T/m (2,000 G/cm)
- ☐ Horizontal, 1H proton, closed bore scanners only
- ☐ Specific Absorption Rate (SAR) limits for the entire active scan:
  - Normal Operating Mode
    - Whole body averaged, 2.0 W/Kg
    - Head, 3.2 W/Kg
- ☐ Maximum specified gradient slew rate: 200 T/m/s per axis
- ☐ There are no restrictions for positioning the transvenous defibrillation system within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted. Local transmit coils may be used, but should not be placed directly over the transvenous 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).

This form may contain patient confidential information.

If you receive this form in error, please do not forward it and contact Boston Scientific Technical Services at (800) 227-3422.

1. Please refer to the MRI Technical Guide: ImageReady™ MRI Defibrillation System as the system is designated as MR-Conditional in accordance with specific conditions.

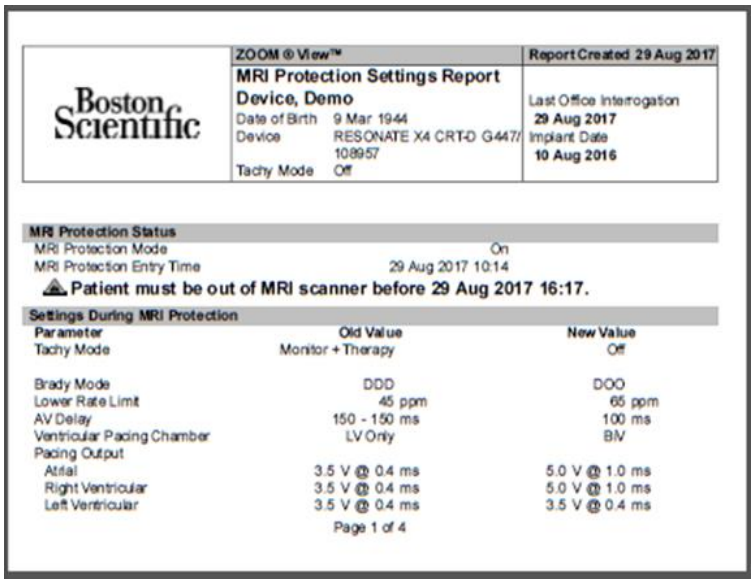
Cardiology/Radiology Checklists for Transvenous Defibrillation Systems

A sample patient flow sequence for an ImageReady™ MR-Conditional System patient who needs an MRI scan is described below. For a more detailed description of the programming and scanning procedure, see the MRI Technical Guide for the ImageReady MR Conditional Defibrillation System, or visit www.BostonScientific.com/imageready.

Sample Patient Flow

1. MRI recommended to patient by specialist (for example, orthopedist or oncologist).
2. Patient or specialist or radiologist contacts the electrophysiologist/cardiologist who manages the patient's MR Conditional System.
3. Electrophysiologist/cardiologist determines patient eligibility for scan per the information in the ImageReady Defibrillator MRI Technical Guide, and ensures communication of patient eligibility to HCP's involved in performing the MRI scan. 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.
4. If the patient is eligible, the programmer is used to put the pulse generator in MRI Protection Mode as close in time to the scan as reasonable. Ensure continuous monitoring of the patient while in MRI Protection Mode. The MRI Protection Settings Report is printed (see Figure 1), placed in the patient's file, and provided to the 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.
5. The radiologist checks the patient file and any communication from the electrophysiologist/cardiologist. If the Time-out feature is used, the radiologist verifies that adequate time remains to complete the scan. Ensure continuous monitoring of the patient before, during, and after the MRI scan.
6. Patient undergoes scan according to the conditions for use described in the ImageReady MR Conditional Defibrillation System MRI Technical Guide
7. The pulse generator is returned to pre-MRI operation, either automatically if the Time-out parameter was set, or manually using the programmer. Perform follow-up testing of the implanted system after exiting MRI Protection Mode and continue patient monitoring until the pulse generator is returned to pre-MRI operation. It is strongly recommend 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.
8. The Beeper will remain OFF upon exiting MRI Protection Mode. If desired, the user can manually attempt to re-enable the Beeper. Refer to the MRI Technical Guide: ImageReady TM MR Conditional Defibrillation System.

Figure 1



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ZOOM ® View™ | Report Created 29 Aug 2017

MRI Protection Settings Report

Device, Demo

Date of Birth 9 Mar 1944
Device RESONATE X4 CRT-D G447/ 108957
Tachy Mode Off

Last Office Interrogation **29 Aug 2017**
Implant Date **10 Aug 2016**

MRI Protection Status

MRI Protection Mode: On
MRI Protection Entry Time: 29 Aug 2017 10:14

⚠ **Patient must be out of MRI scanner before 29 Aug 2017 16:17.**

Settings During MRI Protection

Parameter	Old Value	New Value
Tachy Mode	Monitor + Therapy	Off
Brady Mode	DDD	DOO
Lower Rate Limit	45 ppm	65 ppm
AV Delay	150 - 150 ms	100 ms
Ventricular Pacing Chamber	LV Only	BiV
Pacing Output		
Atrial	3.5 V @ 0.4 ms	5.0 V @ 1.0 ms
Right Ventricular	3.5 V @ 0.4 ms	5.0 V @ 1.0 ms
Left Ventricular	3.5 V @ 0.4 ms	3.5 V @ 0.4 ms

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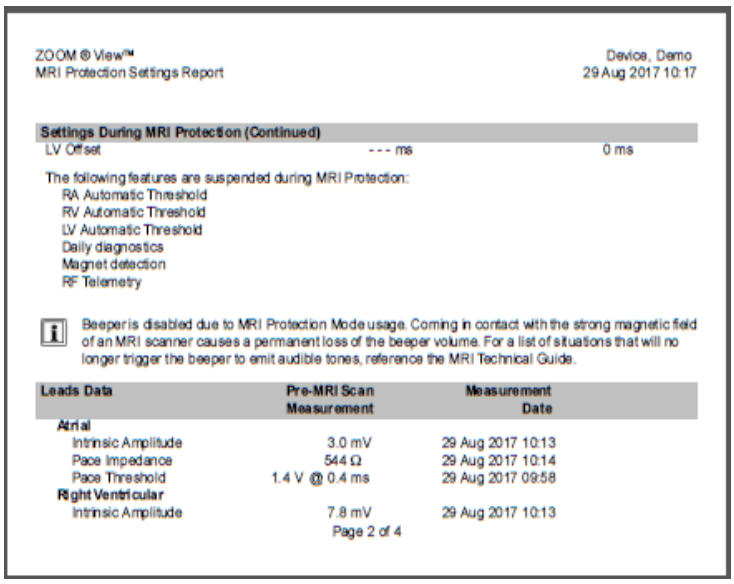

ZOOM ® View™ MRI Protection Settings Report — Device, Demo 29 Aug 2017 10:17

Settings During MRI Protection (Continued)

LV Offset --- ms 0 ms

The following features are suspended during MRI Protection:
- RA Automatic Threshold
- RV Automatic Threshold
- LV Automatic Threshold
- Daily diagnostics
- Magnet detection
- RF Telemetry

Beeper is disabled due to MRI Protection Mode usage. Coming in contact with the strong magnetic field of an MRI scanner causes a permanent loss of the beeper volume. For a list of situations that will no longer trigger the beeper to emit audible tones, reference the MRI Technical Guide.

Leads Data	Pre-MRI Scan Measurement	Measurement Date
Atrial		
Intrinsic Amplitude	3.0 mV	29 Aug 2017 10:13
Pace Impedance	544 Ω	29 Aug 2017 10:14
Pace Threshold	1.4 V @ 0.4 ms	29 Aug 2017 09:58
Right Ventricular		
Intrinsic Amplitude	7.8 mV	29 Aug 2017 10:13

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CRT-D Systems – RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4

INDICATIONS AND USAGE

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

CONTRAINDICATIONS

There are no contraindications for this device.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, and VIGILANT devices with an IS-1/DF4/IS4 lead connection are considered MR Conditional. For these devices, 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. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide.. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev B)

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL

INDICATIONS AND USAGE

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS

Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, and VIGILANT devices with a DF4 right ventricular lead connection are considered MR Conditional. For these devices, 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. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, and supplemental precautionary information.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev B)

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Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

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