Boston Scientific

MRI TECHNICAL GUIDE

⚠ MR IMAGEREADY™ MR CONDITIONAL DEFIBRILLATION SYSTEM

REF D000, D002, D010, D012, D020, D022, D044, D046, D050, D052, D140, D142, D150, D152, D174, D176, G058, G148, G158, G179, 0265, 0266, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296, 0636, 0654, 0655, 0657, 0658, 0665, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696, 4469, 4470, 4471, 4472, 4473, 4474, 4479, 4480, 4603, 4671, 4672, 4674, 4675, 4677, 4678, 6220, 6221, 6402, 6403, 7145, 7735, 7736, 7740, 7741, 7742

ABOUT THIS MANUAL

This manual is intended for use by physicians and other health care professionals (HCPs) involved in managing patients with an ImageReady MR Conditional Defibrillation System, as well as radiologists and other HCPs involved in performing magnetic resonance imaging (MRI) scans on such patients.

NOTE: *For the purposes of this Technical Guide, MRI is used as a general term and encompasses all MR-based clinical imaging activities. In addition, information in this guide applies only to ^{1}H MRI (Proton MRI) scanners.*

Read this manual in its entirety before scanning patients who are implanted with an ImageReady MR Conditional Defibrillation System.

This manual contains:

- Information about the ImageReady MR Conditional Defibrillation System (Boston Scientific transvenous ICDs and CRT-Ds)
- Information about ImageReady MR Conditional Defibrillation System patients who can and cannot undergo an MRI scan and the Conditions of Use that must be met in order for an MRI scan to be performed
- Instructions for carrying out an MRI scan on ImageReady MR Conditional Defibrillation System patients

How to use this manual:

1. Refer to the patient's records to locate model numbers for all components of the patient's implanted system.
2. Refer to "System Configuration for 1.5 T" on page 1-2 to determine if *all* components of the patient's implanted system are found within the tables. If not all components of the implanted system can be found within the tables, the system is either a pacing system or it is not MR Conditional.

   NOTE: *Two Boston Scientific MRI Technical Guides are available - one for Defibrillators and one for Pacemakers. If a particular pulse generator model is not represented in this manual, refer to the ImageReady MR Conditional Pacing System Technical Guide. If a particular model is not represented in either manual, it is not an MR Conditional system.*

Refer to the Physician's Technical Manual, Reference Guide, Leads Manual, Clinician Manual, or Programmer Operator's Manual for detailed information about non-MRI aspects of implantation, features, programming, and use of the components of the Defibrillation System.

TABLE OF CONTENTS

INTRODUCTION TO THE MR CONDITIONAL DEFIBRILLATION SYSTEM

CHAPTER 1

This chapter contains the following topics:

SYSTEM DESCRIPTION

An ImageReady MR Conditional Defibrillation System consists of specific Boston Scientific model components including pulse generators, leads, accessories, the Programmer/Recorder/Monitor (PRM), and the PRM Software Application. For the model numbers of MR Conditional Defibrillation System components, see "System Configuration for 1.5 T" on page 1-2.

The ImageReady MR Conditional Defibrillation System was evaluated as a system for use with MRI scans performed under the Conditions of Use described in this Technical Guide. The pulse generator uses minimal ferromagnetic materials, which can interact with the fields generated during a typical MRI scan. The pulse generator's circuits can tolerate voltages that may be induced during scans. Any part of the body may be imaged. Boston Scientific MR Conditional pulse generators and leads, when used together, have mitigated risks associated with MRI scans as compared to conventional pulse generators and leads. The implanted system, as opposed to its constituent parts, is determined to have the status of MR Conditional as described in ASTM F2503:2008. Additionally, an MRI Protection Mode has been created for use during the scan. MRI Protection Mode modifies the behavior of the pulse generator to accommodate the MRI scanner electromagnetic environment ("MRI Protection Mode General Information" on page 2-3). A Time-out feature can be programmed to allow automatic exit from MRI Protection Mode after a set number of hours chosen by the user. These features have been evaluated to verify their effectiveness. Other MRI-related risks are further reduced by adherence to the conditions for scanning specified in this Technical Guide.

For additional information, see the Boston Scientific Website at: *www.bostonscientific.com/imageready*.

Only specific combinations of pulse generators and leads constitute an ImageReady Defibrillation System that is valid for use with **1.5 T scanners** ("System Configuration for 1.5 T" on page 1-2).

System Configuration for 1.5 T

Table 1–1. Pulse Generators – ImageReady MR Conditional Defibrillation System

Component	Model Number(s)	MR Status
AUTOGEN MINI ICD	D044, D046	MR Conditional
AUTOGEN EL ICD	D174, D176	MR Conditional
AUTOGEN X4 CRT-D	G179	MR Conditional
DYNAGEN MINI ICD	D020, D022	MR Conditional
DYNAGEN EL ICD	D150, D152	MR Conditional
DYNAGEN X4 CRT-D	G158	MR Conditional
INOGEN MINI ICD	D010, D012	MR Conditional
INOGEN EL ICD	D140, D142	MR Conditional
INOGEN X4 CRT-D	G148	MR Conditional
ORIGEN MINI ICD	D000, D002	MR Conditional
ORIGEN EL ICD	D050, D052	MR Conditional
ORIGEN X4 CRT-D	G058	MR Conditional

Table 1–2. Leads and Accessories – ImageReady MR Conditional Defibrillation System

Component		Model Number(s)	MR Status
Right Atrial 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 Sleeves for FINELINE II leads	6220, 6221	MR Conditional

Table 1–2. Leads and Accessories – ImageReady MR Conditional Defibrillation System (continued)

Component		Model Number(s)	MR Status
	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
Right Ventricular Leads and Accessories	ENDOTAK RELIANCE (DF4) Defibrillation Leads	0265, 0266, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional
	RELIANCE 4-FRONT (DF4) Defibrillation Leads	0636, 0654, 0655, 0657, 0658, 0665, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional
	Suture Sleeve for RELIANCE 4-FRONT leads	6403	MR Conditional
Left Ventricular Leads and Accessories	ACUITY X4 (IS4) Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional
	Suture Sleeve for ACUITY X4 leads	4603	MR Conditional

Table 1–3. ZOOM LATITUDE Programmer/Recorder/Monitor (PRM) and PRM Software Application

Component	Model Number(s)	MR Status
ZOOM LATITUDE PRM	3120	MR Unsafe[a]
ZOOM LATITUDE PRM Software Application	2868	N/A

a. See PRM is MR Unsafe Warning regarding the PRM.

MRI CONDITIONS OF USE

While any part of the body may be imaged, the following Conditions of Use must be met in order for a patient with an ImageReady Defibrillation System to undergo an MRI scan. Adherence to the Conditions of Use must be verified prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR Conditional scan. For additional details regarding each Condition of Use, refer to "Conditions for Scanning" on page 1-4.

Cardiology

1. Patient is implanted with an ImageReady MR Conditional Defibrillation System[1] (see "System Description" on page 1-2).

2. No other active or abandoned implanted devices, components, or accessories present such as lead adaptors, extenders, leads, or pulse generators.

3. Pulse generator is in MRI Protection Mode during scan.

4. 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).

5. Patient is judged to be clinically capable of tolerating no Tachycardia protection and no Bradycardia support (including CRT) for the entire duration in which the pulse generator is in MRI Protection Mode.

6. Patient does not have elevated body temperature or compromised thermoregulation at time of scan.

1. Defined as a Boston Scientific MR Conditional pulse generator and lead(s), with all ports occupied by a lead or port plug ("System Configuration for 1.5 T" on page 1-2).

7. Pulse generator implant location restricted to left or right pectoral region.

8. At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR Conditional Defibrillation System.

9. No evidence of a fractured lead or compromised pulse generator-lead system integrity.

Radiology

1. 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
2. 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
3. Maximum specified gradient slew rate	≤ 200 T/m/s per axis
4. 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.	
5. Patient in supine or prone position only.	
6. 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, 201.3.224, 3rd Edition.

Refer to Table 1–4 Cardiology Conditions/Patient Conditions on page 1-4 and Table 1–5 Radiology Conditions on page 1-7 for additional information about the Conditions of Use.

CONDITIONS FOR SCANNING

Table 1–4 Cardiology Conditions/Patient Conditions on page 1-4 summarizes the Cardiology Conditions/Patient-related Conditions of Use that must be met in order for an MR Conditional scan to be performed. For each condition or requirement, possible actions to determine eligibility, the potential clinical consequences of failing to meet the condition(s), and the patient population most impacted by failure to meet the condition(s) are listed. This information is intended to assist in performing a risk/benefit analysis to decide whether or not to scan a patient who does not meet all the stated criteria for MR Conditional status.

Table 1–4. Cardiology Conditions/Patient Conditions

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
1. Patient is implanted with an ImageReady MR Conditional Defibrillation System.	• Check patient records. • Interrogate device. (Pulse generator model number is provided on PRM screen and MRI Protection Settings Report.) • Check patient ID card. • Check model numbers in "System Description" on page 1-2 of this Guide or at *www.bostonscientific.com/imageready*. • Contact Boston Scientific Technical Services.	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Damage to pulse generator and/or lead • Erratic pulse generator behavior • Physical movement of pulse generator and/or leads • Pocket discomfort due to pulse generator heating	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds

Table 1–4. Cardiology Conditions/Patient Conditions (continued)

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
	• Confirm with physician responsible for managing the patient's defibrillation system.	• Pre-syncope or syncope	
The appropriate Boston Scientific MR Conditional pulse generator and Boston Scientific MR Conditional lead(s) must be used together to obtain the intended risk reduction needed for MR Conditional scans. *Another manufacturer's MR Conditional pulse generator combined with a Boston Scientific MR Conditional lead (or vice versa) do not constitute an MR Conditional System, because the components were not evaluated together in the MRI environment.*			
2. No other active or abandoned implanted devices, components, or accessories present such as lead adaptors, extenders, leads, or pulse generators. *The presence of other cardiac implants or accessories such as lead adaptors, extenders, or abandoned leads or pulse generators may significantly reduce the effectiveness of an ImageReady MR Conditional Defibrillation System in reducing risks of MRI scanning.*	• Check patient records. • Confirm with physician responsible for managing the patient's defibrillation system. • Check X-rays.	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Damage to pulse generator, lead, or connection • Physical movement of pulse generator and/or leads • Pocket discomfort due to pulse generator heating	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
3. Pulse generator is in MRI Protection Mode during scan. *Effects of RF or gradient fields create the potential for oversensing, and/or induced voltages in the pulse generator. MRI Protection Mode is intended to mitigate these effects.*	• Program the pulse generator to MRI Protection Mode using the PRM. • Verify settings using the MRI Protection Settings report.	• Arrhythmia induction • Pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
4. 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).	• Ensure patient is being monitored while in MRI Protection Mode and backup therapy is available.	• Lack of patient monitoring could result in failure to detect potentially dangerous changes in the patient's cardiac or hemodynamic function.	• All patients
5. Patient is judged to be clinically capable of tolerating no Tachycardia protection and no Bradycardia support (including CRT) for the entire duration in which the pulse generator is in MRI Protection Mode. *To ensure that cross-chamber conduction does not occur and to prevent over-sensing due to various MR scanner fields, Bradycardia pacing, CRT, and Tachycardia therapy must be disabled.*	• Check patient records. • Use Temporary Brady pacing parameters to evaluate patient condition. • Ensure patient is not pacing-dependent and does not require overdrive pacing to prevent tachyarrhythmias.	• Loss of bradycardia therapy • Loss of Cardiac Resynchronization Therapy (CRT) • Loss of defibrillation therapy • Loss of overdrive pacing for long QT syndrome • Pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients who require overdrive pacing
6. Patient does not have elevated body temperature or compromised thermoregulation at time of scan. *Pre-existing elevated temperature is additive with any scan-induced heating.*	• Check patient's temperature prior to scan.	• Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Pocket discomfort due to pulse generator heating	• Patients with high capture thresholds

Table 1–4. Cardiology Conditions/Patient Conditions (continued)

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
7. Pulse generator implant location restricted to left or right pectoral region. *Lead trajectories associated with non-pectoral implant locations pose risks for heating, inappropriate stimulation, and arrhythmia induction.*	• Check patient records. • Check by physical exam or X-ray.	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Physical movement of pulse generator in pocket • Pocket discomfort due to pulse generator heating • Pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
8. At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR Conditional Defibrillation System. *A six-week period of healing allows for formation of scar tissue and capsule maturation, which reduce the impact of heating, vibration, and movement potentially caused by the magnetic fields of the MRI scanner.*	• Check patient records and/or patient ID card. • Check PRM data for the user-entered Implant Date, if available. *Upon user request to enter MRI Protection Mode, the PRM provides an attention message if the calculated time since exit from Storage Mode is less than or equal to six weeks.* (Check that the PRM is set with the correct time and date to ensure accuracy.)	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Increased rate of lead dislodgement due to incomplete capsule maturation • Physical movement of pulse generator in pocket	• Patients prone to sustained arrhythmias • Patients with high capture thresholds
9. No evidence of a fractured lead or compromised pulse generator-lead system integrity. *Abnormal lead impedance values may indicate a short or open circuit in the lead system. This could result in abnormal conductive trajectories and induced voltages. Broken conductors in the lead system could result in increased potential for heating at the lead tip. A damaged seal plug or front lead sealing ring could promote an alternate current flow path during MRI scanning.*	• Check patient records for most recent lead impedance values. • Check patient records to ensure lead impedance values are within the programmed normal range and that there is no record or evidence of damage to pulse generator seal plug and front lead sealing rings. • Review Daily Measurements on the Leads Status Summary Screen to verify stability over time of lead impedance, pace threshold, and intrinsic amplitude values. • Check patient records from implant procedure to verify system integrity. • Check patient records for a history of noise on EGMs. *The device measures lead impedances upon user request to enter MRI Protection Mode and provides an attention message on the PRM screen if the values are out of the programmed normal range.* *A history of noise on EGMs could be indicative of a damaged seal plug or front lead sealing rings.*	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds

Table 1–5 Radiology Conditions on page 1-7 summarizes the Radiology-related Conditions of Use that must be met in order for an MR Conditional MRI scan to be performed. For each condition or requirement, possible actions to determine eligibility, the potential clinical consequences of failing to meet the condition(s), and the patient population most impacted by failure to meet the condition(s) are listed. This information is intended to assist in performing a risk/benefit analysis to decide whether or not to scan a patient who does not meet all the stated criteria for MR Conditional status.

Table 1–5. Radiology Conditions

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
1. MRI magnet strength of 1.5 T only. RF field of approximately 64 MHz Maximum spatial gradient of 50 T/m (5,000 G/cm) Horizontal, ^{1}H proton, closed bore scanners only. *System response to MRI scanners other than 1.5 T, horizontal bore scanners, and to spatial gradients greater than 50 T/m (5,000 G/cm) has not been evaluated.*	• Check technical specifications of MRI scanner.	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/ tissue interface • Damage to pulse generator, lead, or connection • Physical movement of pulse generator and/or leads • Pocket discomfort due to pulse generator heating	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
2. Specific Absorption Rate (SAR) limits for Normal Operating Mode for the entire active scan: • Whole body averaged, ≤ 2.0 W/Kg • Head, ≤ 3.2 W/Kg *System response to scanner settings above Normal Operating Mode has not been evaluated.*	• Ensure MRI scanner is operated in Normal Operating Mode.	• Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/ tissue interface • Pre-syncope or syncope	• Pacing-dependent patients • Patients with high capture thresholds
3. Maximum specified gradient slew rate ≤ 200 T/m/s per axis. *System response to gradient slew rates higher than 200 T/m/s per axis has not been evaluated.*	• Check technical specifications of MRI scanner.	• Arrhythmia induction • Damage to pulse generator, lead, or connection • Pocket discomfort due to pulse generator heating • Pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias
4. 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. *System response to local transmit-only or transmit/ receive coils placed directly over the defibrillation system has not been evaluated.*	• Ensure no local transmit-only or transmit/receive coils are placed directly over the defibrillation system.	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/ tissue interface • Erratic pulse generator behavior • Pocket discomfort due to pulse generator heating • Pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds

Table 1–5. Radiology Conditions (continued)

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
5. Patient in supine or prone position only. *System response to other patient positions has not been evaluated.*	• Ensure patient is in the correct position during scan.	• Arrhythmia induction • Clinically significant pacing threshold changes and sensing changes as a result of heating at the lead/ tissue interface • Physical movement of pulse generator and/or leads • Pocket discomfort due to pulse generator heating • Pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
6. 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).	• Ensure patient is being monitored while in MRI Protection Mode and backup therapy is available.	• Lack of patient monitoring could result in failure to detect potentially dangerous changes in the patient's cardiac or hemodynamic function.	• All patients

MRI PROTECTION MODE

In preparation for an MRI scan, the pulse generator is programmed into MRI Protection Mode using the PRM. MRI Protection Mode modifies certain pulse generator functions in order to mitigate risks associated with exposing the defibrillation system to the MRI environment. For a list of features and functions that are suspended in MRI Protection Mode, see "MRI Protection Mode General Information" on page 2-3.

MRI BASIC CONCEPTS

MRI is a diagnostic tool that uses three types of magnetic and electromagnetic fields to image soft tissue in the body:

- A static magnetic field generated by a superconducting electromagnet coil, 1.5 T in strength.
- Gradient magnetic fields of much lower intensity, but with high rates of change over time. Three sets of gradient coils are used to create the gradient fields.
- A pulsed radio frequency (RF) field produced by transmission RF coils (approximately 64 MHz for 1.5 T).

These fields may create physical forces or electrical currents that can affect the functioning of active implantable medical devices (AIMDs) such as pulse generators and leads. Therefore, only patients implanted with a defibrillation system optimized and evaluated for the ability to function correctly under specified conditions during an MRI scan are eligible to be scanned. Furthermore, by complying with the MRI Conditions of Use, outlined in this Technical Guide ("MRI Conditions of Use" on page 1-3), ImageReady MR Conditional Defibrillation System patients can undergo MRI scans with risks mitigated to the best current standard of care.

MR CONDITIONAL DEFIBRILLATION SYSTEM WARNINGS AND PRECAUTIONS

General

WARNING: Unless all of the MRI Conditions of Use ("MRI Conditions of Use" on page 1-3) 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, see "Potential Adverse Events" on page 1-11.

NOTE: *Table 1–4 Cardiology Conditions/Patient Conditions on page 1-4 and Table 1–5 Radiology Conditions on page 1-7 provide information on the nature of the increased risk(s) associated with the failure to meet each Condition of Use. This information is intended to assist in performing a risk/benefit analysis to decide whether or not to scan a patient who does not meet all the stated criteria for MR Conditional status. Alternatives including other imaging methods may also be considered.*

WARNING: MRI scanning after Explant status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. After performing an MRI scan on a device that has reached Explant status, verify pulse generator function and schedule device replacement.

WARNING: When the Time-out parameter is programmed to a value other than Off, the patient must be out of the scanner before the time programmed elapses. Otherwise, the patient will no longer meet Conditions of Use ("MRI Conditions of Use" on page 1-3).

WARNING: 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.

WARNING: During MRI Protection Mode, the patient will not receive Bradycardia pacing (including backup pacing), Cardiac Resynchronization Therapy, or Tachycardia therapy (including ATP & defibrillation). Therefore the patient needs to be continuously monitored for the entire duration in which the system is in MRI Protection Mode, including during the scan. Continuous monitoring includes maintaining normal voice and visual contact, as well as monitoring pulse oximetry and ECG for the entire duration that the pulse generator is in MRI Protection Mode. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present as long as the pulse generator is in MRI Protection Mode, including during the scan, should the patient require external rescue.

Programming Considerations

WARNING: If the MRI Protection Time-out value is programmed to Off, the patient will not receive Bradycardia pacing, Cardiac Resynchronization Therapy, or Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.

WARNING: During MRI Protection Mode the Bradycardia therapy and Cardiac Resynchronization Therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Defibrillation System must be programmed to MRI Protection Mode using the PRM. MRI Protection Mode disables Bradycardia and CRT pacing. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only scan the patient if judged to be clinically capable of tolerating no Bradycardia therapy (including pacing-

dependence or need for overdrive pacing) and no CRT for the entire duration in which the pulse generator is in MRI Protection Mode.

WARNING: During MRI Protection Mode the Tachycardia therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Defibrillation System must be programmed to MRI Protection Mode using the PRM. MRI Protection Mode disables Tachycardia therapy. The system will not detect ventricular arrhythmias and the patient will not receive ATP or shock defibrillation therapy until the pulse generator is programmed back to normal operation. Only scan the patient if judged to be to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

WARNING: If Bradycardia, CRT, and/or Tachycardia therapy are programmed Off prior to entering MRI Protection Mode, the therapy will remain Off when the MRI Protection Time-out elapses after the programmed time period.

Safety Mode

WARNING: If the device enters Safety Mode Operation during the MRI scan, the Bradycardia Pacing Mode will be switched to VVI unipolar from OOO mode and Tachycardia therapy will be reenabled. This subjects the patient to increased risk of arrhythmia induction, inappropriate therapy, inappropriate pacing, inhibition of pacing, or irregular/intermittent capture or pacing.

WARNING: Do not perform an MRI scan on a patient whose device has entered Safety Mode. Safety Mode pacing is VVI unipolar, which, in the MRI environment, subjects the patient to increased risk of arrhythmia induction, inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing.

MRI Site Zone III Exclusions

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[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.

WARNING: Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[3]. Some of the accessories packaged with pulse generators and leads, including the torque wrench and stylet wires, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

Precautions

CAUTION: The physician choosing MRI Protection Mode parameter values will need to exercise professional judgment to determine an individual patient's ability to tolerate the device settings required for MR Conditional scanning, in conjunction with the physical conditions required during a scan (for example, prolonged time in a supine position).

CAUTION: The presence of the implanted defibrillation system may cause MRI image artifacts (see "3. Preparing the Patient for the Scan" on page 2-8).

NOTE: *All normal risks associated with an MRI procedure apply to MRI scans with the MR Conditional Defibrillation System. Consult MRI scanner documentation for a complete list of risks associated with MRI scanning.*

2. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.
3. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.

NOTE: *Other implanted devices or patient conditions (e.g., pacing-dependence or need for overdrive pacing to prevent tachyarrhythmias) may cause a patient to be ineligible for an MRI scan, independent of the status of the patient's ImageReady MR Conditional Defibrillation System.*

POTENTIAL ADVERSE EVENTS

Potential adverse events differ depending on whether the MRI Conditions of Use ("MRI Conditions of Use" on page 1-3) are met. For a complete list of potential adverse events, refer to the Physician's Technical Manual for the pulse generator.

MRI scanning of patients when the Conditions of Use are met could result in the following potential adverse events:

- Arrhythmia induction
- Bradycardia
- Patient death
- Patient discomfort due to slight movement or heating of the device
- Syncope
- Worsening heart failure

MRI scanning of patients when the Conditions of Use are **NOT** met could result in the following potential adverse events:

- Arrhythmia induction
- Bradycardia
- Damage to the pulse generator and/or leads
- Erratic pulse generator behavior
- Inappropriate pacing, inhibition of pacing, failure to pace
- Increased rate of lead dislodgement (within six weeks of implant or revision of system)
- Irregular or intermittent capture or pacing
- Loss of defibrillation therapy
- Pacing threshold changes
- Patient death
- Patient discomfort due to movement or heating of the device
- Physical movement of pulse generator and/or leads
- Sensing changes
- Syncope

- Side effects of pacing at a fixed high rate such as competition with intrinsic rhythms and arrhythmias. Competitive pacing may increase the rate of pacing induced arrhythmia until the device is reprogrammed.

- Worsening heart failure

MRI SCAN PROCEDURE PROTOCOL

CHAPTER 2

This chapter contains the following topics:

Before proceeding with this MRI scan procedure protocol, verify that the patient and the MRI scanner meet the MRI Conditions of Use ("MRI Conditions of Use" on page 1-3). This verification must be performed prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR Conditional scan.

WARNING: Unless all of the MRI Conditions of Use ("MRI Conditions of Use" on page 1-3) 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, see "Potential Adverse Events" on page 1-11.

NOTE: *Table 1–4 Cardiology Conditions/Patient Conditions on page 1-4 and Table 1–5 Radiology Conditions on page 1-7 provide information on the nature of the increased risk(s) associated with the failure to meet each Condition of Use. This information is intended to assist in performing a risk/benefit analysis to decide whether or not to scan a patient who does not meet all the stated criteria for MR Conditional status. Alternatives including other imaging methods may also be considered.*

PATIENT FLOW

A sample patient flow sequence for an ImageReady Defibrillation System patient who needs an MRI scan is described below. For a more detailed description of the programming and scanning procedure, see this chapter.

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 Defibrillation System.

3. Electrophysiologist/cardiologist determines patient eligibility for scan per the information in this Technical Guide, and ensures communication of patient eligibility to HCPs 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 ("Beeper volume after MRI Warning" on page 2-6).

4. If the patient is eligible, the PRM is used to put the pulse generator into 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, placed in the patient's file, and provided 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.

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.

   NOTE: *The patient must be continuously monitored for the entire duration in which the system is in MRI Protection Mode. Continuous monitoring includes maintaining normal voice and visual contact, as well as monitoring pulse oximetry and ECG for the entire duration that the pulse generator is in MRI Protection Mode. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present when the patient is put into MRI Protection Mode.*

6. Patient undergoes scan according to the protocol outlined in this 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 PRM. Perform follow-up testing of the implanted system. 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.

MRI PROTECTION MODE GENERAL INFORMATION

Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Defibrillation System must be programmed to the MRI Protection Mode using the PRM. In MRI Protection Mode:

- Bradycardia pacing is suspended
- Cardiac Resynchronization Therapy is suspended
- Tachycardia therapy is suspended
- A Time-out feature is nominally set to 6 hours, with programmable values of Off, 3, 6, 9, and 12 hours
- Beeper is disabled

NOTE: *Six hours in MRI Protection Mode reduces pulse generator longevity by approximately 2 days (CRT-D) or 3 days (ICD).*

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[1]. 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.

WARNING: During MRI Protection Mode the Bradycardia therapy and Cardiac Resynchronization Therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Defibrillation System must be programmed to MRI Protection Mode using the PRM. MRI Protection Mode disables Bradycardia and CRT pacing. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only scan the patient if judged to be clinically capable of tolerating no Bradycardia therapy (including pacing-dependence or need for overdrive pacing) and no CRT for the entire duration in which the pulse generator is in MRI Protection Mode.

WARNING: During MRI Protection Mode the Tachycardia therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Defibrillation System must be programmed to MRI Protection Mode using the PRM. MRI Protection Mode disables Tachycardia therapy. The system will not detect ventricular arrhythmias and the patient will not receive ATP or shock defibrillation therapy until the pulse generator is programmed back to normal operation. Only scan the patient if judged to be to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

WARNING: If the MRI Protection Time-out value is programmed to Off, the patient will not receive Bradycardia pacing, Cardiac Resynchronization Therapy, or Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.

WARNING: 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

1. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.

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.

The following features and functions are suspended in MRI Protection Mode:

- Bradycardia sensing/pacing
- Cardiac Resynchronization Therapy
- Tachycardia detection and therapy
- PaceSafe automatic threshold(s)
- Daily diagnostics (Lead Impedance, Intrinsic Amplitude, Pace Threshold)
- Motion and respiratory sensors
- Magnet detection
- RF telemetry
- Battery voltage monitoring

The following device conditions will preclude the user from having the option to enter MRI Protection Mode (see the Reference Guide for the pulse generator for additional information about these conditions):

- Battery capacity status is Depleted
- Pulse generator is in Storage Mode
- Pulse generator is in Electrocautery Mode
- Pulse generator is in Safety Core operation (Safety Mode)
- Diagnostic test is in progress
- EP test is in progress

WARNING: MRI scanning after Explant status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. After performing an MRI scan on a device that has reached Explant status, verify pulse generator function and schedule device replacement.

WARNING: Do not perform an MRI scan on a patient whose device has entered Safety Mode. Safety Mode pacing is VVI unipolar, which, in the MRI environment, subjects the patient to increased risk of arrhythmia induction, inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing.

PRE-SCAN ACTIVITIES

Three activities are required before the MRI scan takes place:

1. Prepare the pulse generator for the scan by programming into MRI Protection Mode ("1. Programming the Pulse Generator for a Scan" on page 2-4)

2. Confirm the MRI scanner settings and configuration ("2. Confirming MRI Scanner Settings and Configuration" on page 2-8)

3. Prepare the patient for the scan ("3. Preparing the Patient for the Scan" on page 2-8)

1. Programming the Pulse Generator for a Scan

Use the PRM to program pulse generator entry into MRI Protection Mode.

NOTE: *Maintain access to the programmer wand, as RF telemetry becomes unavailable during the process of entering MRI Protection Mode.*

From the Main screen, use the Tachy Mode button to enable MRI Protection Mode.

The user chooses whether to Cancel Changes or Continue to proceed with entry into MRI Protection Mode (Figure D–1 Change Device Mode dialog on page D-1).

Certain conditions in the pulse generator and/or system will cause a user request to enter MRI Protection Mode to be rejected. These include:

- A ventricular episode as detected and recognized by the pulse generator is in progress
- Magnet presence is detected by magnet sensor
- Pulse generator is in STAT PACE or STAT SHOCK mode

If one or more of these conditions are present, a dialog box will appear describing the condition, and MRI Protection Mode cannot be entered. For example, see Figure D–7 Episode in progress attention message on page D-3.

In addition to the above-listed conditions that prevent entry into MRI Protection Mode, two other conditions of use are assessed by the PRM upon a request to enter MRI Protection Mode: lead impedance and time since implant.

- **Lead Impedance**

  A user request to enter the MRI Protection Mode triggers a lead impedance test in all chambers and a shock lead impedance test. If the lead impedance values obtained from this testing are outside the programmed normal range, the PRM provides a dialog box recommending a review of the associated risks if the user chooses to proceed (see Table 1–4 Cardiology Conditions/Patient Conditions on page 1-4). The dialog provides the option of continuing with MRI Protection Mode in the presence of these conditions, or cancelling entry into MRI Protection Mode. The dialog box that appears in the case of an out-of-range lead impedance value is shown in Figure D–8 Lead impedance out of range attention message on page D-3.

- **Time Since Implant**

  The PRM also determines the time since implant, calculated based on the date at which the pulse generator was taken out of Storage Mode.

  NOTE: *If the PRM clock is not set to the correct time and date, this determination may not be accurate.*

  If the calculated time since exit from Storage Mode is less than 6 weeks, the PRM provides a dialog box recommending a review of the associated risks if the user chooses to proceed (see Table 1–4 Cardiology Conditions/Patient Conditions on page 1-4). The dialog provides the option of continuing with MRI Protection Mode in the presence of these conditions, or cancelling entry into MRI Protection Mode.

Beeper

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. The system proactively disables the programmable and non-programmable Beeper options when MRI Protection Mode is programmed. The Beeper will remain Off upon exiting MRI Protection Mode.

Upon subsequent interrogations, a notification that the Beeper is disabled and the date MRI Protection Mode was last programmed will be provided on the initial Summary dialog (Figure D–9 Beeper disabled Summary dialog on page D-4).

WARNING: 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.

The following are situations that will no longer trigger the Beeper to emit audible tones once the device is programmed into MRI Protection Mode.

Table 2–1. Situations that will no longer trigger audible Beeper tones once the device is programmed into MRI Protection Mode

Programmable Beeper options	• Beep During Capacitor Charge • Beep When Out-of-Range • Beep when Explant is Indicated
Non-Programmable Beeper options	• Application of the patient magnet over the pulse generator in certain situations (e.g. confirming Tachycardia Mode) • Battery capacity depleted (End of Life (EOL)) • Battery fault alert • High voltage fault alert

The Beeper will emit tones following reversion of the pulse generator to Safety Mode Operation or device reset even after the device is programmed into MRI Protection Mode. But the Beeper volume in the device will be decreased and may be inaudible.

NOTE: *In situations where the MRI scan did not occur, the Beeper can be re-enabled after exiting MRI Protection Mode ("After the Scan" on page 2-9).*

Upon continuing with entry into MRI Protection Mode, the MRI Protection Checklist screen is displayed (Figure D–2 MRI Protection Checklist on page D-1). The Checklist summarizes the conditions that must be met at the time of scanning in order for a patient to be eligible for an MR Conditional scan. Re-verification is required before every scan to guard against the possibility that changes in the system or patient occurred subsequent to the original pulse generator/system implant. These conditions are described in greater detail in Table 1–4 Cardiology Conditions/ Patient Conditions on page 1-4.

If the Conditions of Use as described in this manual are not met, the Cancel button is selected to return to normal system operation (Beeper has not been disabled), and the patient does not undergo an MRI scan.

If the Conditions of Use are met, or if the Conditions of Use are not met but the user elects to continue with MRI Protection Mode after reviewing the risks of proceeding (see Table 1–4 Cardiology Conditions/Patient Conditions on page 1-4 for additional information about risks), the Continue with MRI Protection button is selected. As a result, the Program MRI Protection screen appears (Figure D–3 Program MRI Protection dialog on page D-2).

Use the dialog boxes to set the MRI Protection Time-out (nominally set to 6 hours; programmable values of Off, 3, 6, 9, 12 hours).

The MRI Protection Mode Time-out function allows the user to choose the length of time the pulse generator remains in MRI Protection Mode. Check that the programmer clock is set to the correct time and date to ensure the accuracy of the projected expiration time (displayed on the screen and on the printed MRI Protection Settings Report). When the programmed time has elapsed, the pulse generator automatically exits MRI Protection Mode and all parameters (except for the Beeper) return to the previously programmed settings.

WARNING: When the Time-out parameter is programmed to a value other than Off, the patient must be out of the scanner before the time programmed elapses. Otherwise, the patient will no longer meet Conditions of Use ("MRI Conditions of Use" on page 1-3).

WARNING: If the MRI Protection Time-out value is programmed to Off, the patient will not receive Bradycardia pacing, Cardiac Resynchronization Therapy, or Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.

WARNING: During MRI Protection Mode the Bradycardia therapy and Cardiac Resynchronization Therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Defibrillation System must be programmed to MRI Protection Mode using the PRM. MRI Protection Mode disables Bradycardia and CRT pacing. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only scan the patient if judged to be clinically capable of tolerating no Bradycardia therapy (including pacing-dependence or need for overdrive pacing) and no CRT for the entire duration in which the pulse generator is in MRI Protection Mode.

WARNING: During MRI Protection Mode the Tachycardia therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Defibrillation System must be programmed to MRI Protection Mode using the PRM. MRI Protection Mode disables Tachycardia therapy. The system will not detect ventricular arrhythmias and the patient will not receive ATP or shock defibrillation therapy until the pulse generator is programmed back to normal operation. Only scan the patient if judged to be to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

CAUTION: The physician choosing MRI Protection Mode parameter values will need to exercise professional judgment to determine an individual patient's ability to tolerate the device settings required for MR Conditional scanning, in conjunction with the physical conditions required during a scan (for example, prolonged time in a supine position).

NOTE: *Use of the wand is necessary to complete entry into MRI Protection Mode. Keep the wand in place until receiving confirmation that MRI Protection Mode is programmed. Wanded communication is also required for manual cancellation of MRI Protection Mode (see Manual Exit from MRI Protection Mode in "After the Scan" on page 2-9).*

After the MRI Protection Time-out value is chosen, the Program MRI Protection button is selected and the device enters MRI Protection Mode. The MRI Protection Mode Programmed screen appears indicating that the device has successfully been programmed into MRI Protection Mode at the settings indicated (Figure D–4 MRI Protection Programmed dialog with Exit MRI Protection button on page D-2).

WARNING: If the MRI Protection Time-out value is programmed to Off, the patient will not receive Bradycardia pacing, Cardiac Resynchronization Therapy, or Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.

WARNING: During MRI Protection Mode, the patient will not receive Bradycardia pacing (including backup pacing), Cardiac Resynchronization Therapy, or Tachycardia therapy (including ATP & defibrillation).Therefore the patient needs to be continuously monitored for the entire duration in which the system is in MRI Protection Mode, including during the scan. Continuous monitoring includes maintaining normal voice and visual contact, as well as monitoring pulse oximetry and ECG for the entire duration that the pulse generator is in MRI Protection Mode. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present as long as the pulse generator is in MRI Protection Mode, including during the scan, should the patient require external rescue.

To exit MRI Protection Mode manually, select the Exit MRI Protection button (see Manual Exit from MRI Protection Mode in "After the Scan" on page 2-9).

NOTE: *In situations where the MRI scan does not occur, the Beeper can be re-enabled after exiting MRI Protection Mode ("After the Scan" on page 2-9).*

Once MRI Protection Mode has successfully been programmed, print a copy of the MRI Protection Settings Report by selecting the Print Settings button on the MRI Protection Mode Programmed screen. The report lists the settings in operation during MRI Protection Mode. If the Time-out feature is used, the report includes the time and date when MRI Protection Mode will expire, returning the pulse generator to the pre-MRI Protection Mode settings.

The printed report can be placed in the patient's file and used by radiology personnel, for example, to confirm that sufficient time remains to complete the MRI scan. A sample Settings Report and checklist printout is shown with the Time-out set to 6 hours (Figure D–11 Sample settings report and checklist printout (Time-out set to 6 hours) on page D-5 and Figure D–12 Sample settings report and checklist printout (Cont.) on page D-6) and with the Time-out set to Off (Figure D–13 Sample settings report Page 1 (Time-out set to Off) on page D-7).

Ensure that the HCPs involved in performing the MRI scan have received the identification of the pulse generator and lead(s) implanted in the patient.

WARNING: When the Time-out parameter is programmed to a value other than Off, the patient must be out of the scanner before the time programmed elapses. Otherwise, the patient will no longer meet Conditions of Use ("MRI Conditions of Use" on page 1-3).

The End Session button will end the current programmer session with the pulse generator remaining in MRI Protection Mode (Figure D–5 End Session Confirmation dialog on page D-2).

2. Confirming MRI Scanner Settings and Configuration

Ensure that the MRI scanner equipment meets the "MRI Conditions of Use" on page 1-3.

3. Preparing the Patient for the Scan

The patient must not have an elevated temperature or compromised thermoregulation. Patient position within the bore must be prone or supine, and the appropriate monitoring system must be put in place (pulse oximetry and ECG). See "MRI Conditions of Use" on page 1-3.

If the MRI Protection Mode Time-out feature is being used, be sure to note the time at which the pulse generator is scheduled to exit MRI Protection Mode. Refer to Figure D–4 MRI Protection Programmed dialog with Exit MRI Protection button on page D-2.

NOTE: *If the time remaining is not sufficient for the patient to undergo the MRI scan, re-interrogate the device and reprogram the Time-out value as desired (see "1. Programming the Pulse Generator for a Scan" on page 2-4)*

WARNING: During MRI Protection Mode, the patient will not receive Bradycardia pacing (including backup pacing), Cardiac Resynchronization Therapy, or Tachycardia therapy (including ATP & defibrillation).Therefore the patient needs to be continuously monitored for the entire duration in which the system is in MRI Protection Mode, including during the scan. Continuous monitoring includes maintaining normal voice and visual contact, as well as monitoring pulse oximetry and ECG for the entire duration that the pulse generator is in MRI Protection Mode. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present as long as the pulse generator is in MRI Protection Mode, including during the scan, should the patient require external rescue.

WARNING: When the Time-out parameter is programmed to a value other than Off, the patient must be out of the scanner before the time programmed elapses. Otherwise, the patient will no longer meet Conditions of Use ("MRI Conditions of Use" on page 1-3).

Image distortion must be considered when planning an MRI scan, and when interpreting MRI images of fields containing the pulse generator and/or leads. Pulse generator artifacts extend beyond the margin of the device in all directions. Lead artifacts are present around the lead, including cardiac electrodes. Some artifacts include moderate spatial distortion beyond the boundaries of the visible pulse generator artifact. Gradient Recalled Echo artifacts are generally larger and more prone to have accompanying spatial distortion than Spin Echo artifacts.

DURING THE SCAN

Patient Monitoring

Normal voice and visual contact, as well as pulse oximetry and ECG, must be monitored for the duration of the scan.

WARNING: During MRI Protection Mode, the patient will not receive Bradycardia pacing (including backup pacing), Cardiac Resynchronization Therapy, or Tachycardia therapy (including ATP & defibrillation). Therefore the patient needs to be continuously monitored for the entire duration in which the system is in MRI Protection Mode, including during the scan. Continuous monitoring includes maintaining normal voice and visual contact, as well as monitoring pulse oximetry and ECG for the entire duration that the pulse generator is in MRI Protection Mode. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present as long as the pulse generator is in MRI Protection Mode, including during the scan, should the patient require external rescue.

AFTER THE SCAN

1. Exit MRI Protection

   MRI Protection Mode can be exited either automatically or manually. Exit occurs automatically if the Time-out feature is set to a numerical value. If the Timer is programmed to Off, exit is performed manually using the PRM (see Manual Exit from MRI Protection Mode). After exit from MRI Protection Mode, check system integrity by running lead impedance, pacing threshold, and intrinsic amplitude tests.

   Time-out (automatic) Exit from MRI Protection Mode

   If the MRI Protection Mode Time-out parameter was programmed to a value other than Off, the pulse generator will exit MRI Protection Mode automatically after the selected number of hours, and the system will return to previously programmed settings (except for the Beeper and Minute Ventilation as described below).

   Manual Exit from MRI Protection Mode

   Alternatively, if the Time-out feature was programmed Off, or any time manual cancellation of MRI Protection Mode is desired, the PRM is used to take the pulse generator out of MRI Protection Mode.

   Do not leave the pulse generator in MRI Protection Mode any longer than necessary following the scan. To manually exit MRI Protection Mode, perform the following steps:

   a. Interrogate the pulse generator using the wand (RF telemetry is disabled in MRI Protection Mode).

   b. Select the Exit MRI Protection Mode button from the MRI Protection Programmed screen (Figure D–4 MRI Protection Programmed dialog with Exit MRI Protection button on page D-2).

NOTE: *If necessary, STAT PACE, STAT SHOCK, or DIVERT THERAPY can also be used to exit MRI Protection Mode. STAT PACE will initiate STAT PACE pacing parameters (see the pulse generator's Reference Guide for more information about STAT PACE).*

2. Evaluate Device

Following user-initiated cancellation of MRI Protection Mode, the PRM will automatically navigate to the Lead Tests screen and prompt the user to perform the following lead tests (Figure D–6 MRI Protection Exited dialog on page D-3). Perform the following lead measurements and evaluate the results:

- Intrinsic Amplitude
- Lead Impedance
- Pace Threshold

Perform these tests subsequent to automatic (Time-out) exit from MRI Protection Mode as well. When testing is complete, it is recommended that the PRM be used to save all patient data.

Upon exit from MRI Protection Mode, all parameters are immediately restored to pre-MRI Protection Mode values with two exceptions:

a. Restoration of function of the Minute Ventilation sensor is delayed upon exit from MRI Protection Mode. If MV is programmed to On or Passive at the time of entry into MRI Protection Mode, upon exit from the mode, an automatic six-hour calibration of the sensor will begin. MV-driven rate response is not available during this calibration period. If MV-driven rate response is desired sooner, a manual calibration can be performed. Manual calibration is completed in five minutes or less. For additional information about MV calibration, see the Reference Guide for the pulse generator.

b. The Beeper will remain Off upon exiting MRI Protection Mode. If desired, the user can manually attempt to reenable the Beeper (Figure D–10 Configure Beeper Settings screen on page D-4).

   The Configure Beeper Settings option will only be available after the device is programed into MRI Protection Mode. When the Beeper is programmed back On, all programmable and non-programmable Beeper features will be reverted to their nominal values.

   Perform the following steps to program the Beeper:

   i. Select the Settings tab.

   ii. Select the Beeper tab.

   iii. Select the desired value for the Beeper.

   Coming into contact with the strong magnetic field of an MRI scanner causes a permanent loss of the Beeper volume. After reenabling the Beeper, ensure it is still audible by placing a magnet over the device and listening for beeps. If the Beeper is audible, leave the Beeper On. If the Beeper is not audible, program the Beeper to Off.

CARDIOLOGY CHECKLIST FOR THE IMAGEREADY DEFIBRILLATION SYSTEM

APPENDIX A

This appendix is provided for convenience. Refer to the remainder of this Technical Guide for the full list of Warnings and Precautions and complete instructions for using the ImageReady Defibrillation System.

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 ("ImageReady MR Conditional Defibrillation System – Quick Reference Guide" on page C-1).

☐ 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 and no Bradycardia support (including CRT) 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.

WARNING: 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.

WARNING: 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.

WARNING: If the MRI Protection Time-out value is programmed to Off, the patient will not receive Bradycardia pacing, Cardiac Resynchronization Therapy, or Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.

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[1]. 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. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.

RADIOLOGY CHECKLIST FOR THE IMAGEREADY DEFIBRILLATION SYSTEM

APPENDIX B

This appendix is provided for convenience. Refer to the remainder of this Technical Guide for the full list of Warnings and Precautions and complete instructions for using the ImageReady Defibrillation System.

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, 201.3.224, 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" on page A-1)

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.

WARNING: 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.

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[1]. 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.

CAUTION: The presence of the implanted defibrillation system may cause MRI image artifacts.

1. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.

IMAGEREADY DEFIBRILLATION SYSTEM COMPONENTS FOR 1.5 T

APPENDIX C

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 MINI ICD	D044, D046	MR Conditional	X
AUTOGEN EL ICD	D174, D176	MR Conditional	X
AUTOGEN X4 CRT-D	G179	MR Conditional	X
DYNAGEN MINI ICD	D020, D022	MR Conditional	X
DYNAGEN EL ICD	D150, D152	MR Conditional	X
DYNAGEN X4 CRT-D	G158	MR Conditional	X
INOGEN MINI ICD	D010, D012	MR Conditional	X
INOGEN EL ICD	D140, D142	MR Conditional	X
INOGEN X4 CRT-D	G148	MR Conditional	X
ORIGEN MINI ICD	D000, D002	MR Conditional	X
ORIGEN EL ICD	D050, D052	MR Conditional	X
ORIGEN X4 CRT-D	G058	MR Conditional	X
Leads and Accessories			
FINELINE II Sterox Pacing Leads	4479, 4480	MR Conditional	X
FINELINE II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional	X
Suture Sleeves for FINELINE II leads	6220, 6221	MR Conditional	X
INGEVITY MRI Pacing Leads	7735, 7736, 7740, 7741, 7742	MR Conditional	X
Suture Sleeve for INGEVITY MRI leads	6402	MR Conditional	X
IS-1 Lead Port Plug	7145	MR Conditional	X
ENDOTAK RELIANCE (DF4) Defibrillation Leads	0265, 0266, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional	X
RELIANCE 4-FRONT (DF4) Defibrillation Leads	0636, 0654, 0655, 0657, 0658, 0665, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional	X
Suture Sleeve for RELIANCE 4-FRONT leads	6403	MR Conditional	X
ACUITY X4 (IS4) Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	X
Suture Sleeve for ACUITY X4 leads	4603	MR Conditional	X
ZOOM LATITUDE Programmer/Recorder/Monitor (PRM) and PRM Software Application			
ZOOM LATITUDE PRM	3120	MR Unsafe[a]	N/A
ZOOM LATITUDE PRM Software Application	2868	N/A	N/A

a. See PRM is MR Unsafe Warning regarding the PRM.

MR CONDITIONAL DEFIBRILLATOR PROGRAMMER SCREENS AND REPORTS

APPENDIX D

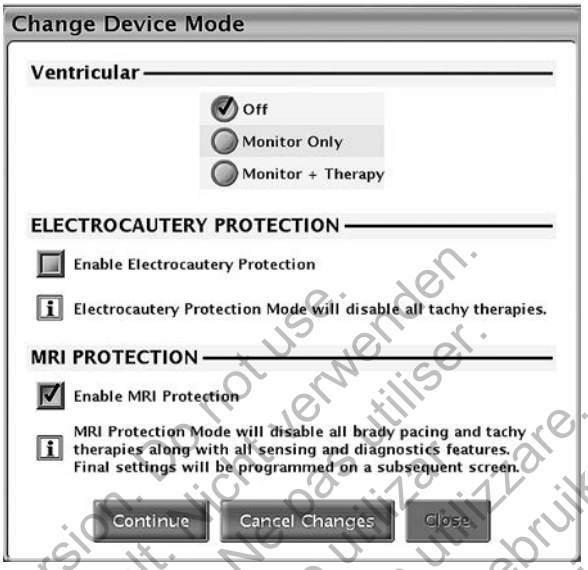

Figure D–1. Change Device Mode dialog

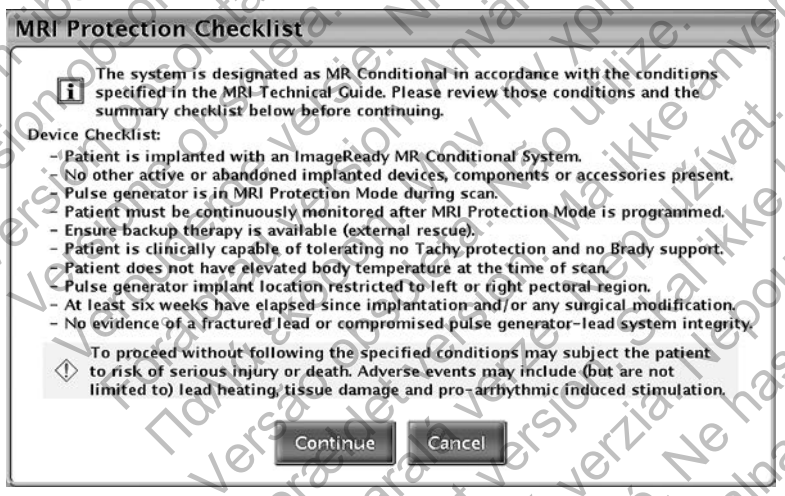

Figure D–2. MRI Protection Checklist

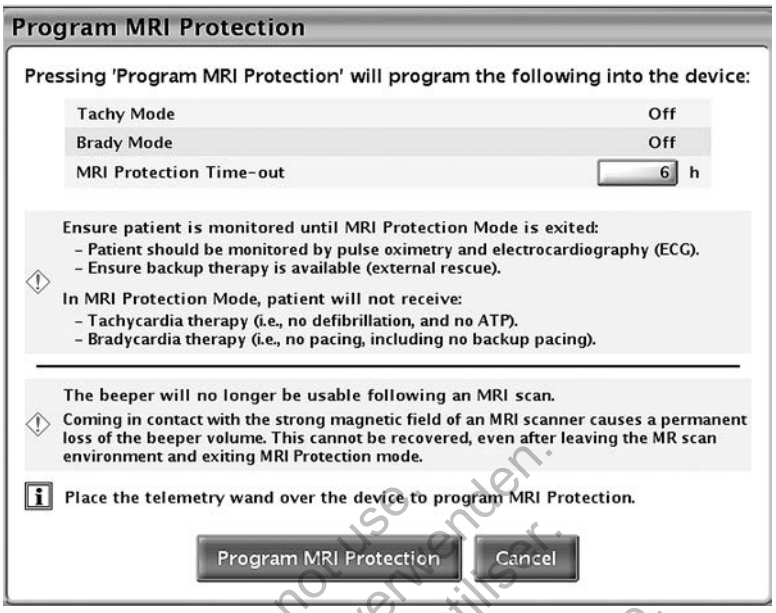

Figure D–3. Program MRI Protection dialog

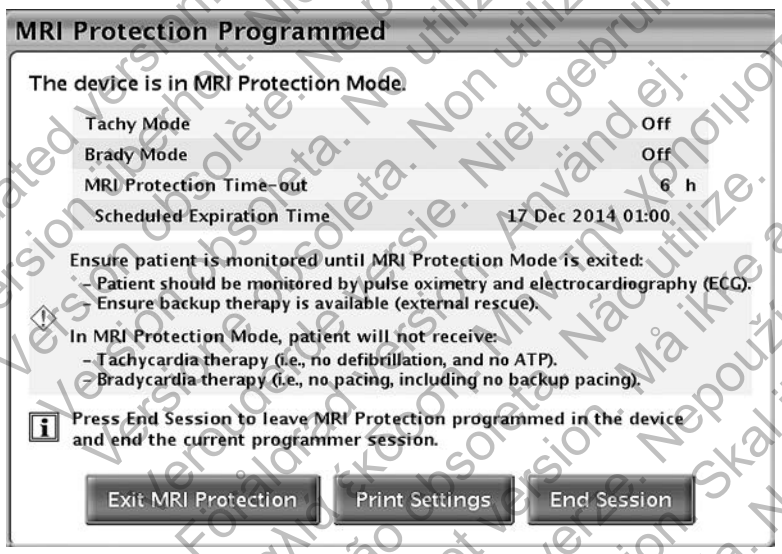

Figure D–4. MRI Protection Programmed dialog with Exit MRI Protection button

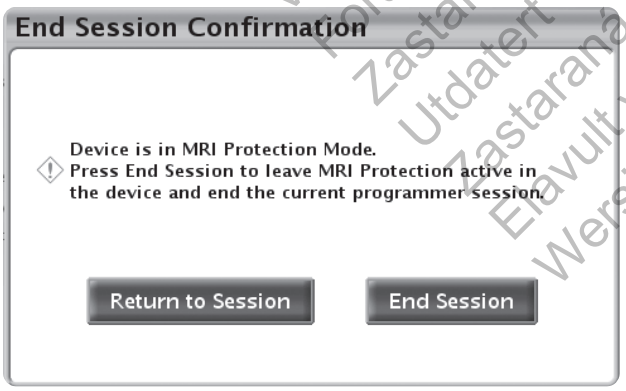

Figure D–5. End Session Confirmation dialog

Figure D–6. MRI Protection Exited dialog

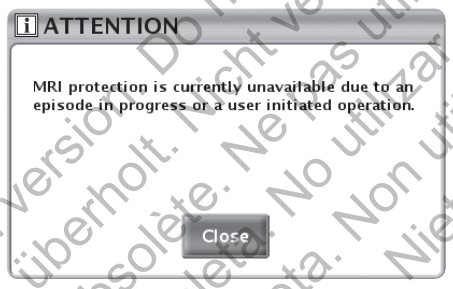

Figure D–7. Episode in progress attention message

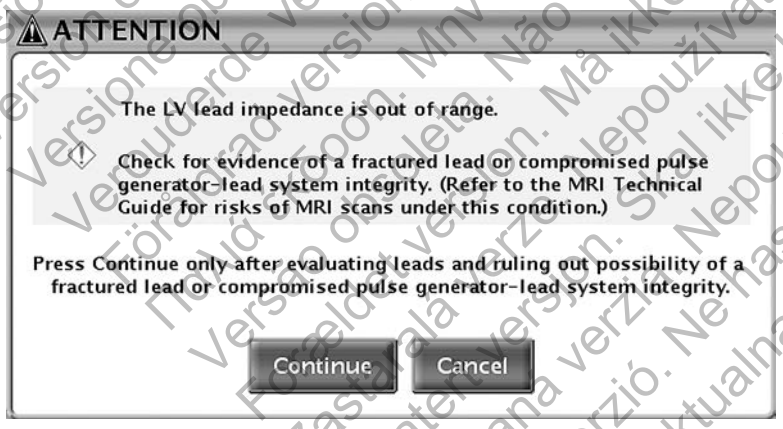

Figure D–8. Lead impedance out of range attention message

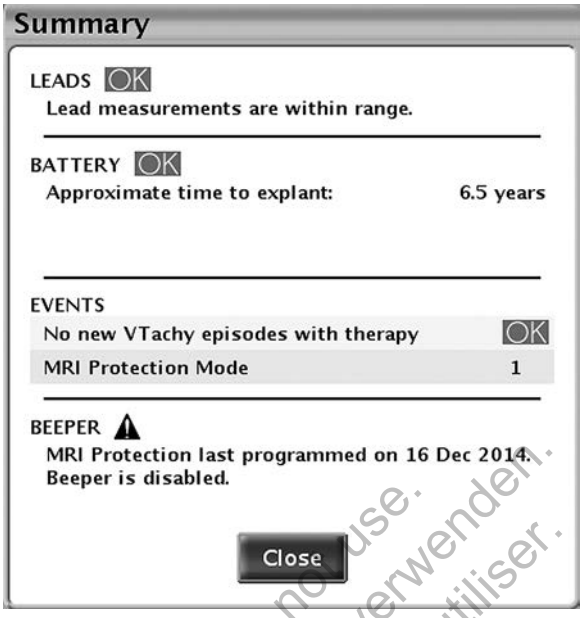

Figure D–9. Beeper disabled Summary dialog

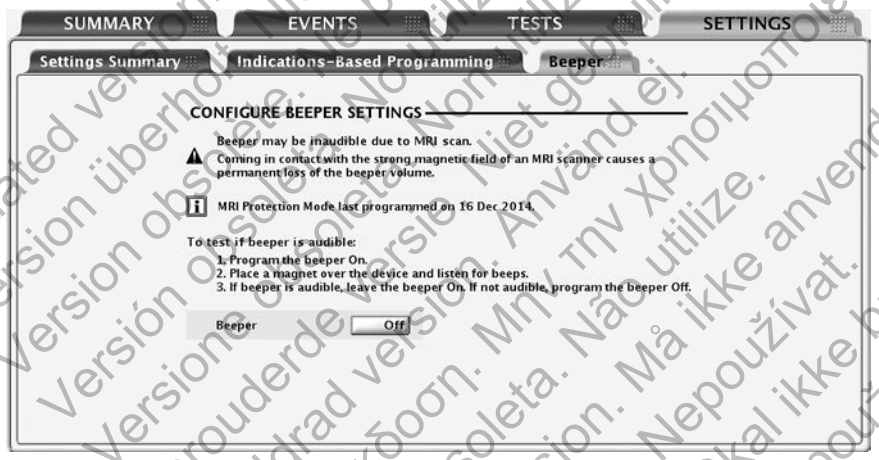

Figure D–10. Configure Beeper Settings screen

Boston Scientific

ZOOM ® View™	Report Created 16 Dec 2014
MRI Protection Settings Report	
Doe, John	Last Office Interrogation
Date of Birth 1 Jan 1940	**16 Dec 2014**
Device AUTOGEN X4 CRT-D G179/ 10101010	Implant Date
Tachy Mode Off	**1 Mar 2010**

MRI Protection Status

MRI Protection Mode	On
MRI Protection Entry Time	16 Dec 2014 15:32

Patient must be out of MRI scanner before 16 Dec 2014 22:32. ①

Settings During MRI Protection

Parameter	Old Value	New Value
Brady Mode	DDD	Off
Tachy Mode	Monitor Only	Off

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

Page 1 of 4

ZOOM ® View™ Doe, John
MRI Protection Settings Report 16 Dec 2014 21:32

Settings During MRI Protection (Continued)

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	5.7 mV	16 Dec 2014 07:22
Pace Impedance	518 Ω	16 Dec 2014 15:32
Pace Threshold	1.5 V @ 0.4 ms	16 Dec 2014 12:56
Right Ventricular		
Intrinsic Amplitude	5.5 mV	16 Dec 2014 00:00
Pace Impedance	557 Ω	16 Dec 2014 15:32
Pace Threshold	2.3 V @ 0.4 ms	01 Dec 2014 08:00
Left Ventricular		
Intrinsic Amplitude	2.9 mV	16 Dec 2014 00:00
Pace Impedance	650 Ω	16 Dec 2014 15:32
Pace Threshold	2.5 V @ 0.4 ms	16 Dec 2014 08:00
Shock		
Impedance	42 Ω	16 Dec 2014 15:32

② [2]

Page 2 of 4

[1] Twenty-four hour time format is used; [2] Column indicates date measurement was taken

Figure D–11. Sample settings report and checklist printout (Time-out set to 6 hours)

ZOOM ® View™ Doe, John
MRI Protection Settings Report 16 Dec 2014 21:32

MRI Protection Checklist

The system is designated as MR Conditional in accordance with the conditions specified in the MRI Technical Guide. Please review those conditions and the summary checklist below before continuing.

Cardiology Checklist:
- Patient is implanted with an ImageReady MR Conditional System.
- No other active or abandoned implanted devices, components or accessories present.
- Pulse generator is in MRI Protection Mode during scan.
- Patient must be continuously monitored after MRI Protection Mode is programmed.
- Ensure backup therapy is available (external rescue).
- Patient is clinically capable of tolerating no Tachy protection and no Brady support.
- Patient does not have elevated body temperature at the time of scan.
- Pulse generator implant location restricted to left or right pectoral region.
- At least six weeks have elapsed since implantation and/or any surgical modification.
- No evidence of a fractured lead or compromised pulse generator-lead system integrity.

Radiology Checklist:
- MRI scanner meets the criteria in the MRI Technical Guide.
- Scan conditions meet the criteria in the MRI Technical Guide.
- Patient position in scanner is supine or prone.
- Appropriate monitoring of patient is required.

Page 3 of 4

ZOOM ® View™ Doe, John
MRI Protection Settings Report 16 Dec 2014 21:32

MRI Protection Checklist (Continued)

⚠ To proceed without following the specified conditions may subject the patient to risk of serious injury or death. Adverse events may include (but are not limited to) lead heating, tissue damage and pro-arrhythmic induced stimulation.

2868 Software Version: 3.05.18
G179 Firmware Version:

Page 4 of 4

Clinician Signature:

Figure D–12. Sample settings report and checklist printout (Cont.)

Boston Scientific	ZOOM ® View™	Report Created 16 Dec 2014
	MRI Protection Settings Report	
	Doe, John	Last Office Interrogation
	Date of Birth 1 Jan 1940	**16 Dec 2014**
	Device AUTOGEN X4 CRT-D G179/ 10101010	Implant Date
	Tachy Mode Off	**1 Mar 2010**

MRI Protection Status

MRI Protection Mode	On
MRI Protection Entry Time	16 Dec 2014 15:34

⚠ **MRI Protection will stay "On" until reprogrammed by a trained professional.**

Settings During MRI Protection

Parameter	Old Value	New Value
Brady Mode	DDD	Off
Tachy Mode	Monitor Only	Off

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

Page 1 of 4

Figure D–13. Sample settings report Page 1 (Time-out set to Off)

SYMBOLS ON PACKAGING

APPENDIX E

The following symbols may be used on packaging and labeling.

Table E–1. Symbols on Packaging

Symbol	Description
CE 0086	CE mark of conformity with the identification of the notified body authorizing use of the mark
EC REP	Authorized Representative in the European Community
	Manufacturer
AUS	Australian Sponsor Address
	MR Conditional

INDEX

Q

R

S

T

V

Z

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St. Paul, MN 55112-5798 USA

EC REP

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359447-001 EN Europe 2015-04

CE 0086