Boston Scientific

MRI TECHNICAL GUIDE

⚠ IMAGEREADY™ MR Conditional Defibrillation System

REF D000, D001, D002, D003, D010, D011, D012, D013, D020, D021, D022, D023, D044, D045, D046, D047, D050, D051, D052, D053, D120, D121, D140, D141, D142, D143, D150, D151, D152, D153, D174, D175, D176, D177, D220, D221, D232, D233, D320, D321, D332, D333, D400, D401, D412, D413, D420, D421, D432, D433, D500, D501, D512, D513, D520, D521, D532, D533, G050, G051, G056, G058, G124, G125, G128, G138, G140, G141, G146, G148, G150, G151, G156, G158, G172, G173, G177, G179, G224, G225, G228, G237, G247, G248, G324, G325, G328, G337, G347, G348, G424, G425, G428, G437, G447, G448, G524, G525, G528, G537, G547, G548, 0127, 0128, 0129, 0137, 0138, 0139, 0143, 0147, 0148, 0149, 0153, 0157, 0158, 0159, 0170, 0171, 0172, 0173, 0174, 0175, 0176, 0177, 0180, 0181, 0182, 0183, 0184, 0185, 0186, 0187, 0262, 0263, 0265, 0266, 0272, 0273, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296, 0636, 0650, 0651, 0652, 0653, 0654, 0655, 0657, 0658, 0662, 0663, 0665, 0672, 0673, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696, 4469, 4470, 4471, 4472, 4473, 4474, 4479, 4480, 4542, 4543, 4544, 4591, 4592, 4593, 4603, 4671, 4672, 4674, 4675, 4677, 4678, 6100, 6220, 6221, 6402, 6403, 6773, 6996, 7145, 7148, 7735, 7736, 7740, 7741, 7742, 7840, 7841, 7842

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 hydrogen 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 Tesla (T) and 3 Tesla (T)" on page 1-2 to determine if *all* components of the patient's implanted system are found within the tables. If any of the components cannot be found within the tables, the system is not an ImageReady MR Conditional Defibrillation System.

   NOTE: *Multiple Boston Scientific ImageReady MRI Technical Guides are available based on therapy type, for example, a pacing system versus a defibrillation system. If a particular pulse generator model is not represented in this manual, refer to the other Boston Scientific ImageReady MRI Technical Guides. If a particular model is not represented in any Boston Scientific ImageReady MRI Technical Guide, the patient's implanted system is not an ImageReady 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.

NOTE: *These pulse generators can be used only with the Model 3300 LATITUDE Programming System. The LATITUDE Programming System is the external portion of the pulse generator system.*
NOTE: *The 2868 software application on the model 3120 LATITUDE programming system is outdated and should not be used with the pulse generators. For assistance, call +1.651.582.4000 (worldwide) or contact your local Boston Scientific representative.*

The following are trademarks of Boston Scientific Corporation or its affiliates (all other trademarks are the property of their respective owners):

ACUITY, AUTOGEN, CHARISMA, DYNAGEN, EASYTRAK, ENDOTAK RELIANCE, FINELINE, IMAGEREADY, INGEVITY, INOGEN, LATITUDE, MOMENTUM, ORIGEN, PaceSafe, PERCIVA, RELIANCE 4-FRONT, RESONATE, VIGILANT.

TABLE OF CONTENTS

INTRODUCTION TO THE MR CONDITIONAL DEFIBRILLATION SYSTEM 1-1
CHAPTER 1

System Description 1-2
System Configuration for 1.5 Tesla (T) and 3 Tesla (T) 1-2

MRI Conditions of Use 1-5
Cardiology 1-5
Radiology 1-5

MRI Protection Mode 1-7

MRI Basic Concepts 1-7

MR Conditional Defibrillation System Warnings and Precautions 1-8
General 1-8
Programming Considerations 1-8
Safety Mode 1-9
MRI Site Zone III Exclusions 1-9
Precautions 1-10

Potential Adverse Events 1-10

MRI SCAN PROCEDURE 2-1
CHAPTER 2

Patient Flow 2-2

MRI Protection Mode General Information 2-3

Pre-Scan Activities 2-4
Programming the Pulse Generator for a Scan 2-4
Confirming MRI Scanner Settings and Configuration 2-11
Preparing the Patient for the Scan 2-12

After the Scan 2-12

CARDIOLOGY CHECKLIST FOR THE IMAGEREADY DEFIBRILLATION SYSTEM A-1
APPENDIX A

RADIOLOGY CHECKLIST FOR THE IMAGEREADY DEFIBRILLATION SYSTEM B-1
APPENDIX B

DETERMINE BEEPER TYPE C-1
APPENDIX C

IMAGEREADY DEFIBRILLATION SYSTEM COMPONENTS FOR 1.5 T AND 3 T D-1
APPENDIX D

MR CONDITIONAL DEFIBRILLATOR PROGRAMMER REPORTS E-1
APPENDIX E

SYMBOLS ON PACKAGING F-1
APPENDIX F

INTRODUCTION TO THE MR CONDITIONAL DEFIBRILLATION SYSTEM

CHAPTER 1

This chapter contains the following topics:

- "System Description" on page 1-2
- "MRI Conditions of Use" on page 1-5
- "MRI Protection Mode" on page 1-7
- "MRI Basic Concepts" on page 1-7
- "MR Conditional Defibrillation System Warnings and Precautions" on page 1-8
- "Potential Adverse Events" on page 1-10

SYSTEM DESCRIPTION

An ImageReady MR Conditional Defibrillation System consists of specific Boston Scientific model components including pulse generators, leads, accessories, the Programmer, and the Programmer Software Application. 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 F2503:2020. Prior to the patient undergoing an MRI scan, the ImageReady MR Conditional Defibrillation System must be programmed to MRI Protection Mode. 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.

Only specific combinations of pulse generators and leads constitute an ImageReady Defibrillation System. Consult the following tables to distinguish between combinations that are valid for use with **1.5 T** or **3 T** scanners. For the model numbers of MR Conditional Defibrillation System components, see "System Configuration for 1.5 Tesla (T) and 3 Tesla (T)" on page 1-2.

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

For additional technical reference guides, go to *www.bostonscientific-elabeling.com*.

System Configuration for 1.5 Tesla (T) and 3 Tesla (T)

Gray shading of model rows indicates components compatible with both 1.5 T and 3 T scanners. An ‘x’ indicates MR Conditional status at the magnet strength indicated.

Table 1–1. CRT-D Pulse Generators — ImageReady MR Conditional Defibrillation System

Component	Model Number(s)	MR Status	1.5 T	3 T
CRT-D Pulse Generators				
AUTOGEN X4 CRT-D	G177, G179	MR Conditional	X	
AUTOGEN CRT-D	G172, G173	MR Conditional	X	
CHARISMA X4 CRT-D	G328, G348	MR Conditional	X	
	G337, G347	MR Conditional	X	X
CHARISMA CRT-D	G324, G325	MR Conditional	X	
DYNAGEN X4 CRT-D	G156, G158	MR Conditional	X	
DYNAGEN CRT-D	G150, G151	MR Conditional	X	
INOGEN X4 CRT-D	G146, G148	MR Conditional	X	
INOGEN CRT-D	G140, G141	MR Conditional	X	
MOMENTUM CRT-D X4	G128, G138	MR Conditional	X	
MOMENTUM CRT-D	G124, G125	MR Conditional	X	
ORIGEN X4 CRT-D	G056, G058	MR Conditional	X	
ORIGEN CRT-D	G050, G051	MR Conditional	X	
RESONATE HF CRT-D	G524, G525, G528, G548	MR Conditional	X	
	G537, G547	MR Conditional	X	X
RESONATE X4 CRT-D	G428, G448	MR Conditional	X	
	G437, G447	MR Conditional	X	X

Table 1–1. CRT-D Pulse Generators — ImageReady MR Conditional Defibrillation System (continued)

Component	Model Number(s)	MR Status	1.5 T	3 T
RESONATE CRT-D	G424, G425	MR Conditional	X	
VIGILANT X4 CRT-D	G228, G248	MR Conditional	X	
	G237, G247	MR Conditional	X	X
VIGILANT CRT-D	G224, G225	MR Conditional	X	

Table 1–2. ICD Pulse Generators — ImageReady MR Conditional Defibrillation System

Component	Model Number(s)	MR Status	1.5 T	3 T
ICD Pulse Generators				
AUTOGEN EL ICD	D174, D175, D176, D177	MR Conditional	X	
AUTOGEN MINI ICD	D044, D045, D046, D047	MR Conditional	X	
CHARISMA EL ICD	D320, D321	MR Conditional	X	
	D332, D333	MR Conditional	X	X
DYNAGEN EL ICD	D150, D151, D152, D153	MR Conditional	X	
DYNAGEN MINI ICD	D020, D021, D022, D023	MR Conditional	X	
INOGEN EL ICD	D140, D141, D142, D143	MR Conditional	X	
INOGEN MINI ICD	D010, D011, D012, D013	MR Conditional	X	
MOMENTUM EL ICD	D120, D121	MR Conditional	X	
ORIGEN EL ICD	D050, D051, D052, D053	MR Conditional	X	
ORIGEN MINI ICD	D000, D001, D002, D003	MR Conditional	X	
PERCIVA HF ICD	D500, D501	MR Conditional	X	
	D512, D513	MR Conditional	X	X
PERCIVA ICD	D400, D401	MR Conditional	X	
	D412, D413	MR Conditional	X	X
RESONATE HF ICD	D520, D521	MR Conditional	X	
	D532, D533	MR Conditional	X	X
RESONATE EL ICD	D420, D421	MR Conditional	X	
	D432, D433	MR Conditional	X	X
VIGILANT EL ICD	D220, D221	MR Conditional	X	
	D232, D233	MR Conditional	X	X

Table 1–3. Leads and Accessories — ImageReady MR Conditional Defibrillation System

Component	Model Number(s)	MR Status	1.5 T	3 T
Leads and Accessories				
Right Atrial Leads and Accessories				
FINELINE II Sterox Pacing Leads	4479, 4480	MR Conditional	X	X
FINELINE II Sterox EZ Pacing Leads	4469, 4470, 4471	MR Conditional	X	X
FINELINE II Sterox EZ Pacing Leads[a]	4472, 4473, 4474	MR Conditional	X	X

Table 1–3. Leads and Accessories — ImageReady MR Conditional Defibrillation System (continued)

Component	Model Number(s)	MR Status	1.5 T	3 T
Suture Sleeve for FINELINE II Leads	6220	MR Conditional	X	X
Suture Sleeve for FINELINE II Leads[a]	6221	MR Conditional	X	X
INGEVITY MRI Pacing Leads (Tined Fixation)	7735, 7736	MR Conditional	X	X
INGEVITY MRI Pacing Leads (Extendable/ Retractable Fixation)	7740, 7741, 7742	MR Conditional	X	X
INGEVITY+ Pacing Leads (Extendable/ Retractable Fixation)	7840, 7841, 7842	MR Conditional	X	X
Suture Sleeve for INGEVITY MRI / INGEVITY+ Leads	6402	MR Conditional	X	X
IS-1 Lead Port Plug	7145	MR Conditional	X	X
Right Ventricular Leads and Accessories				
ENDOTAK RELIANCE (IS-1) Leads – Single Coil	0128, 0138, 0170, 0171, 0180, 0181, 0182, 0183	MR Conditional	X	
ENDOTAK RELIANCE (IS-1) Leads – Single Coil[a]	0127, 0129, 0137, 0139, 0172, 0173	MR Conditional	X	
DF-1 Lead Port Plug for ENDOTAK RELIANCE (IS-1) Leads – Single Coil	6996	MR Conditional	X	
ENDOTAK RELIANCE (IS-1) Leads – Dual Coil	0148, 0157, 0158, 0174, 0175, 0176, 0177, 0184, 0185, 0186, 0187	MR Conditional	X	
ENDOTAK RELIANCE (IS-1) Leads – Dual Coil[a]	0143, 0147, 0149, 0153, 0159	MR Conditional	X	
ENDOTAK RELIANCE (DF4) Defibrillation Leads	0262, 0263, 0265, 0266, 0272, 0273, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional	X	X
RELIANCE 4-FRONT (DF4) Defibrillation Leads	0636, 0650, 0651, 0652, 0653, 0654, 0655, 0657, 0658, 0662, 0663, 0665, 0672, 0673, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional	X	X
Suture Sleeve for RELIANCE 4-FRONT Leads	6403	MR Conditional	X	X
Left Ventricular Leads and Accessories				
ACUITY Spiral Leads[a]	4591, 4593	MR Conditional	X	
ACUITY Spiral Lead	4592	MR Conditional	X	
Suture Sleeve for ACUITY Spiral Leads[a]	6100	MR Conditional	X	
ACUITY X4 (IS4) Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	X	X
Suture Sleeve for ACUITY X4 Leads	4603	MR Conditional	X	X
EASYTRAK 2 (IS-1) Leads[a]	4542, 4543, 4544	MR Conditional	X	
Suture Sleeve for EASYTRAK 2 Leads[a]	6773	MR Conditional	X	
IS4/DF4 Lead Port Plug	7148	MR Conditional	X	X
IS-1 Lead Port Plug	7145	MR Conditional	X	

a. These devices are no longer placed on the EU market, and no longer carry an active CE Mark. These devices and the MR Conditional systems they are a part of continue to be supported by Boston Scientific.

MRI CONDITIONS OF USE

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.

Cardiology

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

   Only a Boston Scientific MR Conditional pulse generator and lead(s), with all ports occupied by a lead or port plug, constitute an ImageReady MR Conditional Defibrillation System. Another manufacturer's MR Conditional pulse generator combined with a Boston Scientific MR Conditional lead (or vice versa) does not constitute an MR Conditional System.

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

   Mitigation of risks associated with MRI scans has not been demonstrated when other cardiac implants or accessories such as lead adaptors, extenders, or abandoned leads or pulse generators are present.

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 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.

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.

   A six-week period allows for healing and scar tissue formation, which reduce the impact of potential risks associated with MRI scans such as heating or movement.

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

   Mitigation of risks associated with MRI scans has not been demonstrated if the lead and/or the pulse generator-lead system integrity are compromised.

Radiology

This manual introduces use of a new parameter for limiting RF exposure during certain 3 T scans. B_{1+rms} is a measure of RF exposure that is different from SAR. It is used instead of SAR for limiting 3 T scans with a patient landmark (scan isocenter) inferior to the C7 vertebra. B_{1+rms} is not displayed on all 3 T scanners.

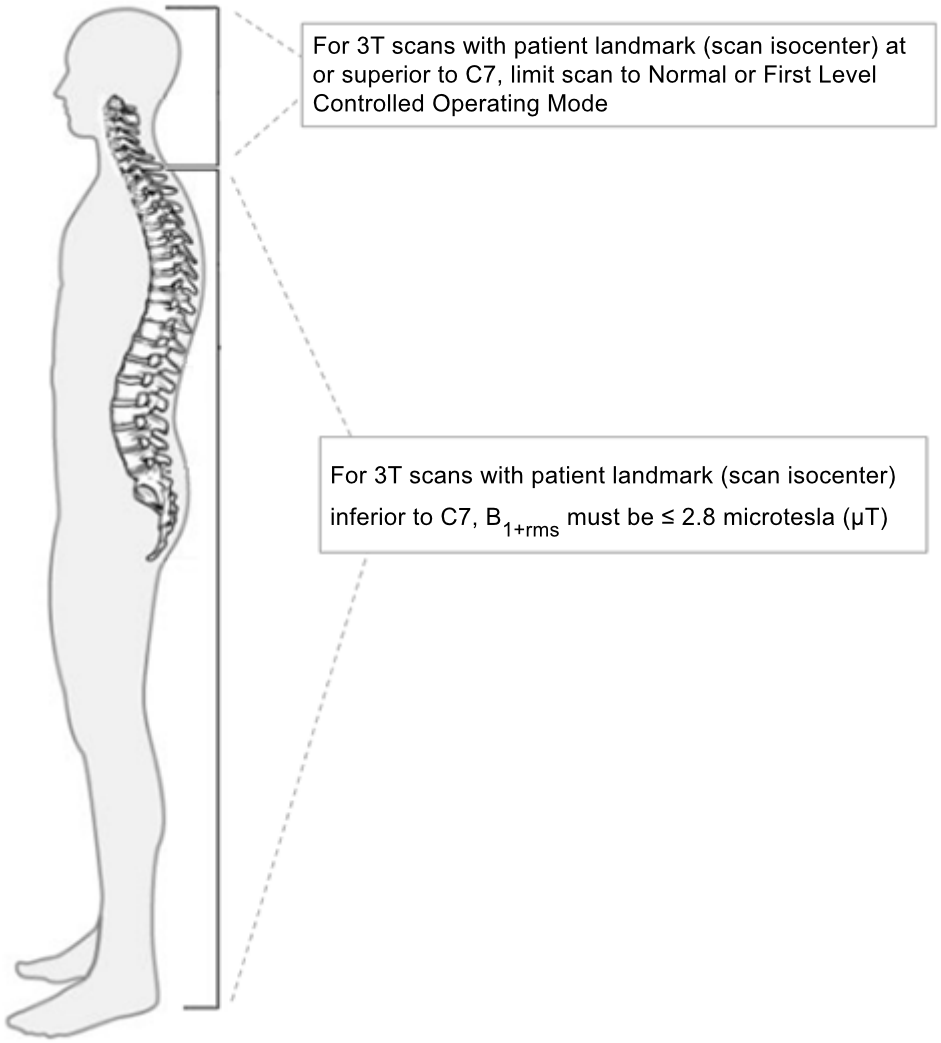
Important: If you are unfamiliar with B_{1+rms}, or are unsure if it is available on your 3 T scanner, either limit scans to 1.5 T and Normal Mode, or contact the MRI scanner manufacturer for more information.

1. Horizontal, hydrogen proton, closed bore scanners only
2. MRI magnet strength of 1.5 T (64 MHz) or 3 T (128 MHz)
3. Spatial gradient no greater than 50 T/m (5,000 G/cm)
4. RF exposure limits:

1.5 T • Normal Operating Mode[a] must be observed for the entire active scan session (whole body averaged SAR, ≤ 2.0 watts/kilogram (W/kg); Head SAR, ≤ 3.2 W/kg) 3 T (Patient landmark/scan isocenter at or superior to the C7 vertebra) • Normal Operating Mode or First Level Controlled Operating Mode must be observed for the entire active scan session 3 T (Patient landmark/scan isocenter inferior to the C7 vertebra) • B_{1+rms} must be ≤ 2.8 microtesla (μT)
WARNING: If the B_{1+rms} parameter value is not displayed on the 3 T MRI scanner system, do not perform 3 T scans with a patient landmark (scan isocenter) inferior to the C7 vertebra. Such scans do not meet the Radiology Conditions of Use.
5. Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis
6. There are no restrictions for positioning the defibrillation system within the integrated body coil of the MRI scanner. 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.
7. Patient in supine or prone position only.
8. 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.

The system response to conditions other than those listed above for the radiology conditions has not been evaluated.



For 3 T scans, when the patient landmark (scan isocenter) is at or superior to the C7 vertebra, the scan must be limited to Normal Operating Mode or First Level Controlled Operating Mode. When the patient landmark (scan isocenter) is inferior to C7, the B_{1+rms} parameter must be limited to ≤ 2.8 microtesla (µT). If using a scanner that does not display B_{1+rms}, do not scan at 3 T when the patient landmark (scan isocenter) is inferior to C7.

Figure 1–1. Limiting Parameters for 3 T MRI Scanning

MRI PROTECTION MODE

In preparation for an MRI scan, the pulse generator must be programmed into MRI Protection Mode using the Programmer. MRI Protection Mode modifies certain pulse generator functions in order to mitigate risks associated with exposing the ImageReady MR Conditional 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 or 3 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 and 128 MHz for 3 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 an MR Conditional system 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 1-5), ImageReady MR Conditional 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 1-5) 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 1-10.

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 1-5).

WARNING: Determine the beeper type before an MRI scan. The Armature Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Armature Beeper volume. This cannot be recovered, even after leaving the MRI scan environment and exiting MRI Protection Mode. For the Armature Beeper, before an MRI scan is performed, a physician and patient should weigh the benefit of the MRI scan against the risk of losing the Beeper; after the MRI scan, perform Beeper evaluation test to determine if the Beeper is usable. If the Beeper is not usable, 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.

NOTE: *For instructions on how to determine the beeper type, see the "Determine Beeper Type" appendix of this manual. For instructions on performing the Beeper evaluation test, see the Evaluate Device step in "After the Scan" on page 2-12.*

WARNING: During MRI Protection Mode, the patient will not receive Tachycardia therapy (including ATP and defibrillation), and, if Brady Mode is programmed to Off, will not receive Bradycardia pacing (including backup pacing) and Cardiac Resynchronization Therapy. Therefore the patient must be continuously monitored for the entire duration in which the system is in MRI Protection Mode, including during the scan.

WARNING: If the B_{1+rms} parameter value is not displayed on the 3 T MRI scanner system, do not perform 3 T scans with a patient landmark (scan isocenter) inferior to the C7 vertebra. Such scans do not meet the Radiology Conditions of Use.

Programming Considerations

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

WARNING: Use caution when programming MRI Protection Mode in pacing-dependent patients who have high right atrial and right ventricular pacing thresholds on the paced lead(s) (> 2.0 V). The maximum pacing

amplitude in MRI Protection Mode is 5.0 V, which may limit the available pacing amplitude safety margin for patients with high pacing thresholds. Failure to maintain sufficient pacing amplitude safety margin may result in loss of capture.

WARNING: During MRI Protection Mode, Tachycardia therapy is suspended. 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 clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

WARNING: During MRI Protection Mode, if Brady Mode is programmed to Off, Bradycardia therapy and Cardiac Resynchronization Therapy (CRT) are suspended. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only program Brady Mode to Off during MRI Protection Mode and 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. It is recommended to have a programmer powered On near the MRI room in case the patient develops the urgent need for pacing. Patients with the following conditions may have increased risk of developing transient pacing-dependence:

- At risk for intermittent AV block (for example, those with progressive AV block, or a history of unexplained syncope)
- At risk for trifascicular block (alternating bundle branch block or PR interval > 200 ms with LBBB or other bifascicular block)

WARNING: The risk of arrhythmia may be increased with asynchronous pacing (AOO, VOO, DOO). When programming asynchronous pacing during MRI Protection Mode, select a pacing rate that avoids competitive pacing and minimize the time 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: 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.

WARNING: In the rare event that non-recoverable or repeat fault conditions occur while the device is programmed in MRI Protection Mode, the subsequent device behavior will be determined by the MRI Protection Brady Mode setting.

- If MRI Brady Mode is set to Off, the device will enter Safety Mode (permanent VVI unipolar pacing and tachycardia therapy enabled).
- If MRI Brady Mode is set to asynchronous pacing (AOO, VOO, DOO), both bradycardia therapy and tachycardia therapy will be permanently disabled.

MRI Site Zone III Exclusions

WARNING: The Programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices[1]. Under no circumstances should the Programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

1. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.

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 on MR Safe Practices[2]. 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 "Preparing the Patient for the Scan" on page 2-12).

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.*

NOTE: *Other implanted devices or patient conditions 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 1-5) 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
- 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.
- 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

2. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.

- 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
- Worsening heart failure

MRI SCAN PROCEDURE

CHAPTER 2

This chapter contains the following topics:

- "Patient Flow" on page 2-2
- "MRI Protection Mode General Information" on page 2-3
- "Pre-Scan Activities" on page 2-4
- "After the Scan" on page 2-12

Before proceeding with an MRI scan, verify that the patient and the MRI scanner meet the MRI Conditions of Use ("MRI Conditions of Use" on page 1-5). 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 1-5) 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 1-10.

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. Use the programmer to determine the beeper type (for information on determining the beeper type, see the "Determine Beeper Type" appendix of this manual). For the Armature Beeper, 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 (Figure 2–9 Beeper Off Summary dialog on page 2-11).

4. If the patient is eligible, the Programmer 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 conditions of use described 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 Programmer. Perform follow-up testing of the implanted system. For the Armature Beeper, perform the Beeper evaluation test to determine if the Beeper is usable (see the Evaluate Device step in "After the Scan" on page 2-12). If the Beeper is not usable, 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 Programmer. See "Programming the Pulse Generator for a Scan" on page 2-4 for details about programming the pulse generator into MRI Protection Mode.

Tachycardia therapy is suspended in MRI Protection Mode.

Pacing mode options include asynchronous pacing (DOO, AOO, VOO) or no pacing (Off). Asynchronous pacing should only be used if the patient is pacing-dependent. If MRI Protection Brady Mode is programmed to Off, the patient will not receive therapy until MRI Protection Mode is exited. Off should only be used if the patient is judged to be clinically capable of receiving no pacing during the time the pulse generator is in MRI Protection Mode, including during the scan.

Considerations prior to choosing asynchronous pacing include:

- Determine whether the patient is pacing-dependent.
- Determine which chamber(s) need to be paced.
- Consider the possibility of arrhythmia induction with asynchronous pacing.
- Patients with the following conditions may have increased risk of developing transient pacing-dependence:
    1. At risk for intermittent AV block (for example, those with progressive AV block, or a history of unexplained syncope)
    2. At risk for trifascicular block (alternating bundle branch block or PR interval > 200 ms with LBBB or other bifascicular block)

The Beeper is Off in MRI Protection Mode. The Armature Beeper will stay Off after exiting MRI Protection Mode (Figure 2–9 Beeper Off Summary dialog on page 2-11). For the Armature Beeper, perform Beeper evaluation (see the Evaluate Device step in "After the Scan" on page 2-12) and determine if the Beeper is usable following an MRI scan ("After the Scan" on page 2-12). If the Beeper is not usable, 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 features and functions are suspended in MRI Protection Mode:

- Bradycardia sensing
- 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
- Left Ventricular MultiSite Pacing (RESONATE HF G547, RESONATE X4 G447, CHARISMA X4 G347, VIGILANT X4 G247)

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

NOTE: *Six hours in MRI Protection Mode reduces pulse generator longevity by approximately 3 days (CRT-D) or 4 days (ICD).*

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.

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 ("Programming the Pulse Generator for a Scan" on page 2-4)
2. Confirm the MRI scanner settings and configurations ("Confirming MRI Scanner Settings and Configuration" on page 2-11)
3. Prepare the patient for the scan ("Preparing the Patient for the Scan" on page 2-12)

Programming the Pulse Generator for a Scan

Use the Programmer to program the pulse generator into MRI Protection Mode.

NOTE: *See "MR Conditional Defibrillation System Warnings and Precautions" on page 1-8 for a complete list of Warnings and Precautions.*

NOTE: *Maintain access to the programmer wand as wanded telemetry is required to enter 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).

Prior to starting programming, print the Device Settings Report as a reference for choosing Brady settings in MRI Protection Mode.

From the Main screen, use the Tachy Mode button to enable MRI Protection Mode. The Change Device Mode screen is displayed (Figure 2–1 Change Device Mode dialog on page 2-5).
NOTE: *Screens may differ depending on beeper type and device type.*

Figure 2–1. Change Device Mode dialog

Select the Enable MRI Protection button and then choose Continue to proceed with entry into MRI Protection Mode.

The MRI Protection Checklist screen is displayed (Figure 2–2 MRI Protection Checklist on page 2-5). 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.

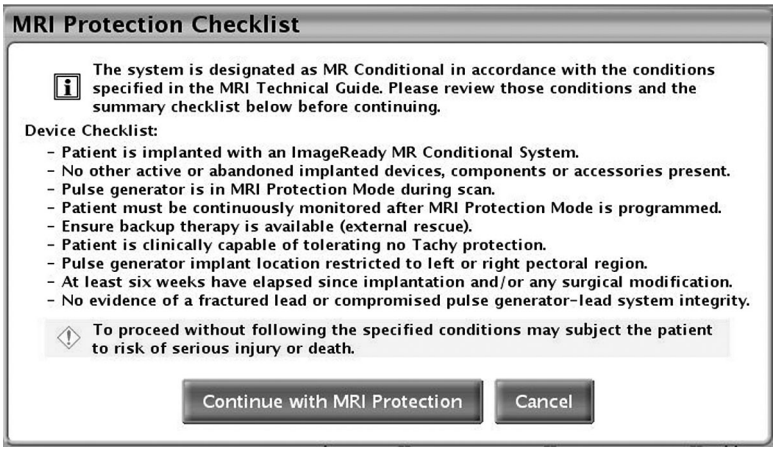


Figure 2–2. MRI Protection Checklist

If the Conditions of Use as described in this manual are met, select the Continue with MRI Protection button. As a result, the Program MRI Protection screen appears (Figure 2–3 Program MRI Protection dialog on page 2-6).

If the Conditions of Use are not met, select the Cancel button to return to normal system operation and do not proceed with the MRI scan (the patient shall not undergo an MRI scan).

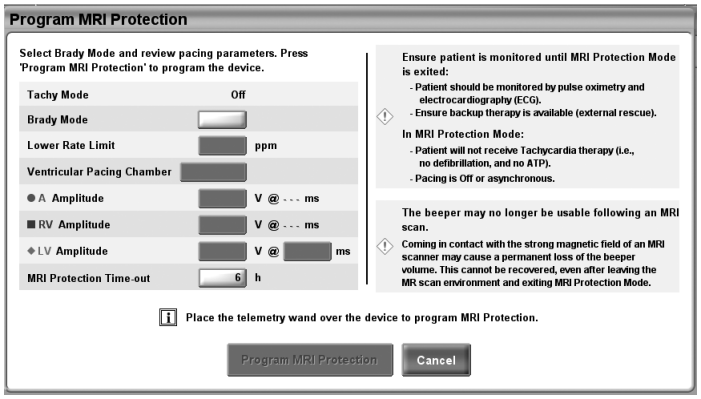


Figure 2–3. Program MRI Protection dialog

Select a Brady Mode (Figure 2–3 Program MRI Protection dialog on page 2-6). Pacing mode options include asynchronous pacing (DOO, AOO, VOO) or no pacing (Off). Asynchronous pacing should only be used if the patient is pacing-dependent.

WARNING: During MRI Protection Mode, if Brady Mode is programmed to Off, Bradycardia therapy and Cardiac Resynchronization Therapy (CRT) are suspended. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only program Brady Mode to Off during MRI Protection Mode and 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. It is recommended to have a programmer powered On near the MRI room in case the patient develops the urgent need for pacing. Patients with the following conditions may have increased risk of developing transient pacing-dependence:

- At risk for intermittent AV block (for example, those with progressive AV block, or a history of unexplained syncope)
- At risk for trifascicular block (alternating bundle branch block or PR interval > 200 ms with LBBB or other bifascicular block)

If asynchronous pacing is required, program the following additional pacing parameters (Figure 2–4 Program MRI Protection dialog with parameters on page 2-7).

- Lower rate limit defaults to 20 min^{-1} above normal mode LRL (programmable in normal increments to a maximum value 100 min^{-1})

  NOTE: *Because MRI Protection Mode pacing is asynchronous, when setting the lower rate limit, consider the patient's intrinsic rate to avoid competitive pacing.*

- Atrial and right ventricular amplitude default to 5.0 V (programmable in normal increments from 2.0 V to 5.0 V) and pulse width fixed at 1.0 ms

  NOTE: *Programming pacing amplitude below 5.0 V is provided as an option in case of extracardiac stimulation (for example, diaphragmatic stimulation).*

  WARNING: Use caution when programming MRI Protection Mode in pacing-dependent patients who have high right atrial and right ventricular pacing thresholds on the paced lead(s) (> 2.0 V). The maximum pacing amplitude in MRI Protection Mode is 5.0 V, which may limit the available pacing amplitude safety margin for patients with high pacing thresholds. Failure to maintain sufficient pacing amplitude safety margin may result in loss of capture.

- Left ventricular amplitude defaults to the normal Brady value when within the range of 2.0 V to 5.0 V (inclusive) (programmable in normal increments from 2.0 V to 5.0 V) and pulse width defaults to the normal Brady setting (programmable in normal increments from 0.1 ms to 2.0 ms)

NOTE: *If the normal Brady value is outside of the 2.0 V to 5.0 V range, the MRI amplitude value will be set to the nearest end of the value range. For example, if the normal Brady value is 1.0 V, the MRI value will be set to 2.0 V.*

NOTE: *In MRI Protection Mode, the minimum allowed pacing amplitude is 2.0 V. Patients whose devices are nominally programmed with LV pacing amplitude less than 2.0 V may experience extracardiac stimulation or phrenic nerve stimulation (PNS) in MRI Protection Mode as the result of the increased LV pacing amplitude. If the patient does not require LV pacing, consider programming the MRI Protection Ventricular Pacing Chamber to RV Only and minimize the time in MRI Protection Mode.*

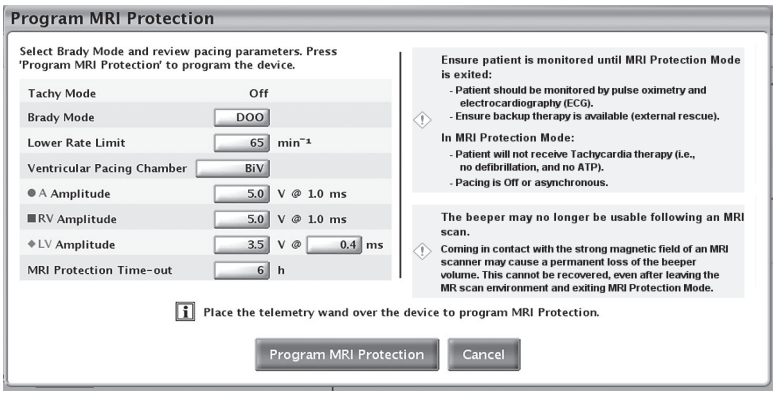


Figure 2–4. Program MRI Protection dialog with parameters

Set 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 Armature Beeper settings) 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 1-5).

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

Select the Program MRI Protection button. The MRI Protection Programmed screen appears when the device has successfully been programmed into MRI Protection Mode at the settings indicated (Figure 2–5 MRI Protection Programmed dialog on page 2-8). Do not proceed with the scan until the MRI Protection Programmed screen is seen to confirm that the device is in MRI Protection Mode.

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.*

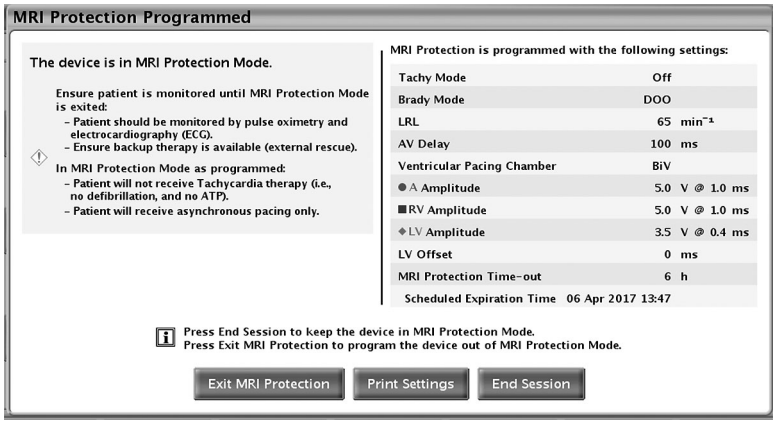


Figure 2–5. MRI Protection Programmed dialog

WARNING: During MRI Protection Mode, the patient will not receive Tachycardia therapy (including ATP and defibrillation), and, if Brady Mode is programmed to Off, will not receive Bradycardia pacing (including backup pacing) and Cardiac Resynchronization Therapy. Therefore the patient must be continuously monitored for the entire duration in which the system is in MRI Protection Mode, including during the scan.

Continuously monitor the patient 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 as long as the pulse generator is in MRI Protection Mode, including during the scan, should the patient require external rescue.

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. Sample MRI Protection Settings Report printouts are shown with the Time-out set to 6 hours (Figure E–1 Sample MRI Protection Settings Report printout with Time-out set to 6 hours on page E-1) and with the Time-out set to Off (Figure E–2 Sample MRI Protection Settings Report printout with Time-out set to Off (Page 1) on page E-2).

Select the End Session button to end the current programmer session with MRI Protection Mode active in the pulse generator (Figure 2–6 End Session Confirmation dialog on page 2-8).

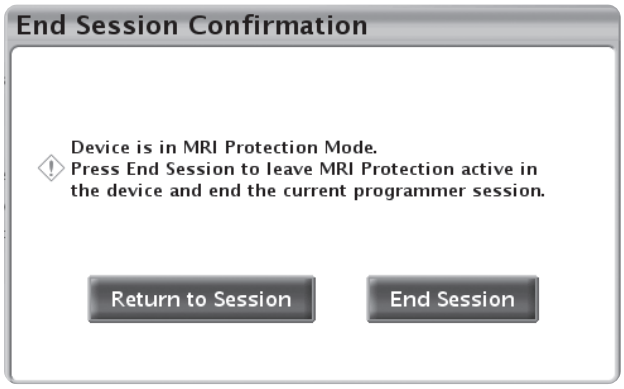


Figure 2–6. End Session Confirmation dialog

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

Conditions Assessed During Programming

Certain conditions will prevent entry into MRI Protection Mode. 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 2–7 Episode in progress attention message on page 2-9.

Figure 2–7. Episode in progress attention message

In addition to the conditions listed above that prevent entry into MRI Protection Mode, three other conditions are assessed by the Programmer during programming: lead impedance, time since implant, and pacing threshold.

1. **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 Programmer provides a dialog box recommending a review of the associated risks if the user chooses to proceed. 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 2–8 Lead impedance out of range attention message on page 2-9.

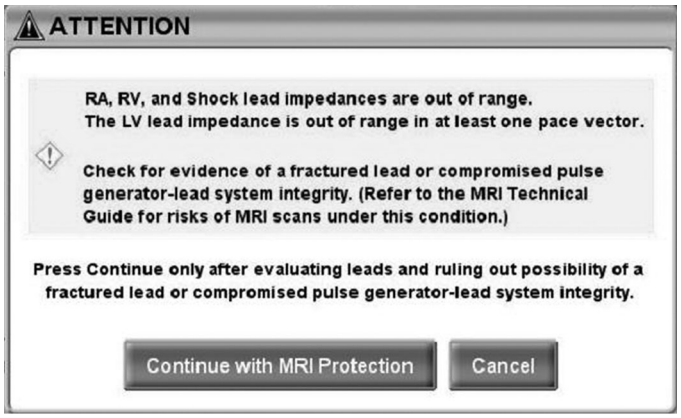


Figure 2–8. Lead impedance out of range attention message

2. **Time Since Implant**

   The Programmer also determines the time since implant, based on the date and time when the pulse generator was taken out of Storage Mode.

   NOTE: *If the Programmer 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 Programmer provides a dialog box recommending a review of the associated risks if the user chooses to proceed. The dialog provides the option of continuing with MRI Protection Mode in the presence of these conditions, or cancelling entry into MRI Protection Mode.

3. **Pacing Threshold**

   If the most recently recorded RA and RV pacing threshold measurements are greater than 2.0 V, the Programmer provides a dialog box recommending the use of caution for pacing-dependent patients. The dialog provides the option of continuing with MRI Protection Mode in the presence of these conditions, or cancelling entry into MRI Protection Mode.

   WARNING: Use caution when programming MRI Protection Mode in pacing-dependent patients who have high right atrial and right ventricular pacing thresholds on the paced lead(s) (> 2.0 V). The maximum pacing amplitude in MRI Protection Mode is 5.0 V, which may limit the available pacing amplitude safety margin for patients with high pacing thresholds. Failure to maintain sufficient pacing amplitude safety margin may result in loss of capture.

Armature Beeper

The Armature Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Armature Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. The system proactively turns off the programmable and non-programmable Armature Beeper options when MRI Protection Mode is programmed. The Armature Beeper will remain Off upon exiting MRI Protection Mode.

Upon subsequent interrogations, a notification that the Beeper is Off and the date MRI Protection Mode was last programmed will be provided on the initial Summary dialog (Figure 2–9 Beeper Off Summary dialog on page 2-11).

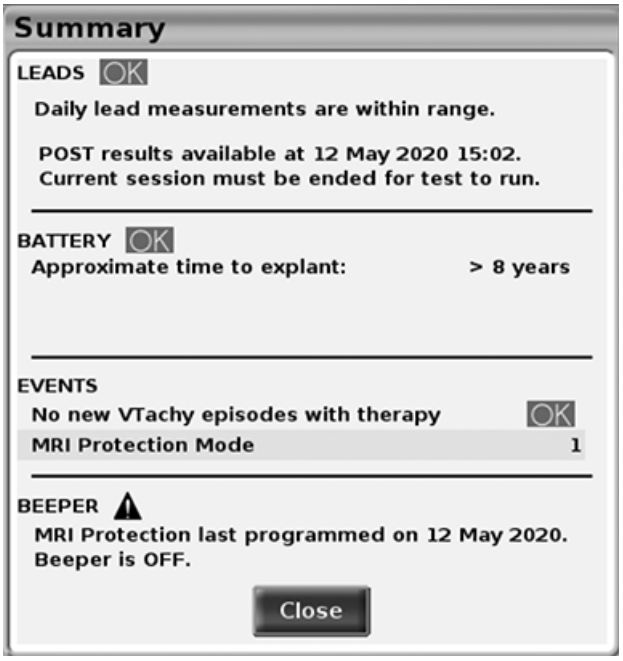


Figure 2–9. Beeper Off Summary dialog

The following are situations that will no longer trigger the Armature 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 Armature Beeper volume in the device may be decreased and may be inaudible.

NOTE: *After an MRI scan, perform Beeper evaluation test to determine if the Armature Beeper is usable (see the Evaluate Device step in "After the Scan" on page 2-12). If the Beeper is not usable, 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 ("After the Scan" on page 2-12). In situations where the MRI scan did not occur, the Armature Beeper can be programmed back On after exiting MRI Protection Mode.*

Confirming MRI Scanner Settings and Configuration

Ensure that the MRI scanner equipment meets the "MRI Conditions of Use" on page 1-5.

Preparing the Patient for the Scan

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 2–5 MRI Protection Programmed dialog on page 2-8.

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 "Programming the Pulse Generator for a Scan" on page 2-4).*

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 1-5).

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 1-5.

WARNING: During MRI Protection Mode, the patient will not receive Tachycardia therapy (including ATP and defibrillation), and, if Brady Mode is programmed to Off, will not receive Bradycardia pacing (including backup pacing) and Cardiac Resynchronization Therapy. Therefore the patient must be continuously monitored for the entire duration in which the system is in MRI Protection Mode, including during the scan.

Image distortion must be considered when planning an MRI scan and when interpreting MRI images in proximity to the pulse generator and/or leads. Artifacts may include moderate spatial distortion beyond the boundaries of the visible artifact. In non-clinical 1.5 T and 3 T testing, the maximum image artifact associated with any ImageReady Defibrillation System pulse generator extended approximately 18.6 cm radially from the device when testing with spin-echo sequencing in a 3 T MRI system and the maximum image artifact associated with any ImageReady Defibrillation System lead extended 2.1 cm from the device when testing with spin-echo sequencing in a 3 T MRI system.

AFTER THE SCAN

1. Exit MRI Protection

   MRI Protection Mode can be exited either automatically or manually. Exit occurs automatically after the programmed number of hours has elapsed if the Time-out feature is set to a numerical value. If the Timer is programmed to Off, exit is performed manually using the Programmer (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.

   For RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, CHARISMA, VIGILANT, and MOMENTUM devices, on exit from MRI Protection Mode, a summary report of the MRI is stored as an MRI episode and can be printed as an episode report. A sample report printout is shown in Figure E–3 Sample stored event detail printout on page E-2. The MRI Protection episode can also be accessed and viewed via the Arrhythmia Logbook. The MRI episode can also be viewed on the Arrhythmia Logbook via remote patient monitoring (if available).

   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 Armature 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 Programmer 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 2–10 MRI Protection Programmed dialog on page 2-13).

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).*

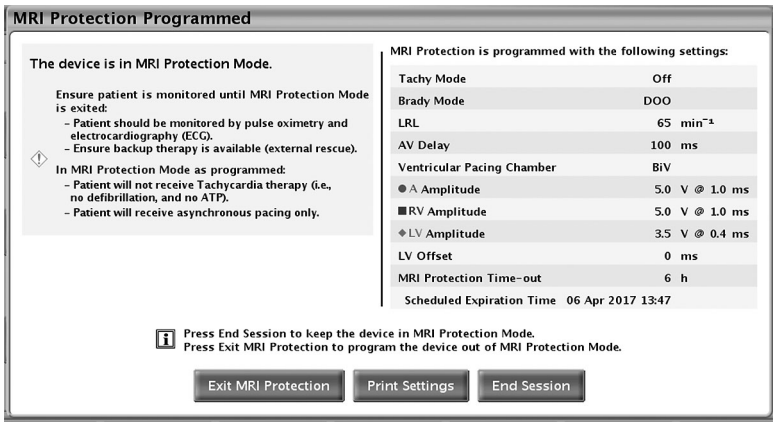


Figure 2–10. MRI Protection Programmed dialog

2. Evaluate Device

Following user-initiated cancellation of MRI Protection Mode, the Programmer will automatically navigate to the Lead Tests screen and prompt the user to perform lead tests (Figure 2–11 MRI Protection Exited dialog on page 2-13).

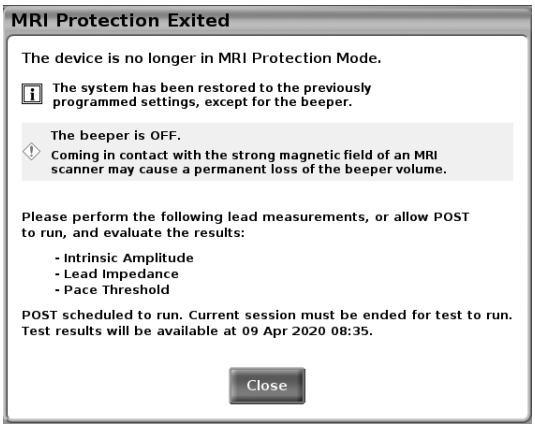


Figure 2–11. MRI Protection Exited dialog

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 Programmer be used to save all patient data.

For RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, CHARISMA, VIGILANT, and MOMENTUM devices, the pulse generator will automatically initiate Post-Operative System Test (POST) upon exit from MRI Protection mode. Automatic Intrinsic Amplitude, Lead Impedance, and Pace Threshold testing (if enabled) will be attempted with results available in one hour. For additional information about POST, see the Reference Guide for the pulse generator.

Upon exit from MRI Protection Mode, whether automatically or manually, all parameters are immediately restored to pre-MRI Protection Mode values with the following exception(s):

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 Armature Beeper will remain Off upon exiting MRI Protection Mode. After exiting MRI Protection Mode, perform the Beeper evaluation test (Figure 2–12 Configure Beeper Settings screen on page 2-14).

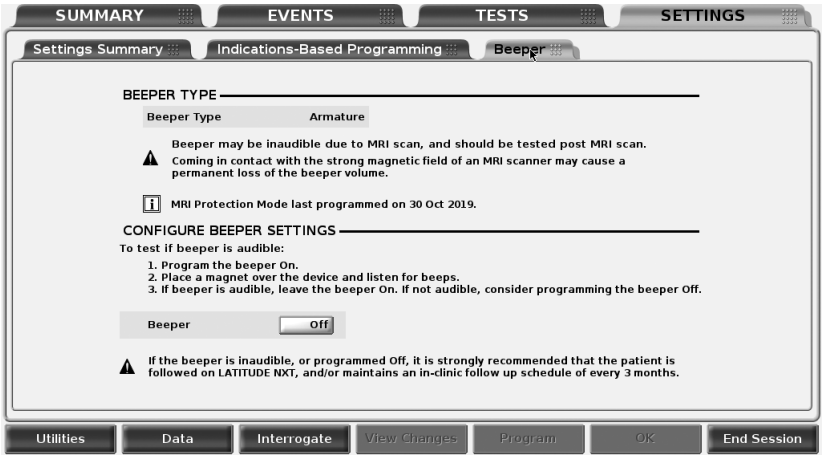


Figure 2–12. Configure Beeper Settings screen

Perform the following steps to perform the Beeper evaluation test:

i. Select the Settings tab.

ii. Select the Beeper tab.

iii. Select the desired value for the Beeper.

iv. After turning on 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, consider programing the Beeper to Off. If the Beeper is not audible, 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.

When the Beeper is programmed back On, all programmable and non-programmable Beeper features will be reverted to their nominal values.

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 Defibrillation System Components for 1.5 T and 3 T" on page D-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 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. Determine the Beeper Type. Exposure to MRI scanning may cause a permanent loss of the Armature Beeper volume. For the Armature Beeper, the physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper.

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

4. 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.

5. 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

6. 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

7. Ensure 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 defibrillation system after exiting MRI Protection Mode, and continue patient monitoring until the pulse generator is returned to pre-MRI operation.

8. The Armature Beeper will remain OFF upon exiting MRI Protection Mode. Perform the Beeper evaluation test after 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: Use caution when programming MRI Protection Mode in pacing-dependent patients who have high right atrial and right ventricular pacing thresholds on the paced lead(s) (> 2.0 V). The maximum pacing amplitude in MRI Protection Mode is 5.0 V, which may limit the available pacing amplitude safety margin for patients with high pacing thresholds. Failure to maintain sufficient pacing amplitude safety margin may result in loss of capture.

WARNING: The risk of arrhythmia may be increased with asynchronous pacing (AOO, VOO, DOO). When programming asynchronous pacing during MRI Protection Mode, select a pacing rate that avoids competitive pacing and minimize the time in MRI Protection Mode.

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

WARNING: The Programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices[1]. Under no circumstances should the Programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

WARNING: Determine the beeper type before an MRI scan. The Armature Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Armature Beeper volume. This cannot be recovered, even after leaving the MRI scan environment and exiting MRI Protection Mode. For the Armature Beeper, before an MRI scan is performed, a physician and patient should weigh the benefit of the MRI scan against the risk of losing the Beeper; after the MRI scan, perform Beeper evaluation test to determine if the Beeper is usable. If the Beeper is not usable, 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.

NOTE: *For instructions on how to determine the beeper type, see the "Determine Beeper Type" appendix of this manual. For instructions on performing the Beeper evaluation test, see the Evaluate Device step in "After the Scan" on page 2-12.*

1. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.

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.

This manual introduces use of a new parameter for limiting RF exposure during certain 3 T scans. B_{1+rms} is a measure of RF exposure that is different from SAR. It is used instead of SAR for limiting 3 T scans with a patient landmark (scan isocenter) inferior to the C7 vertebra. B_{1+rms} is not displayed on all 3 T scanners.

Important: If you are unfamiliar with B_{1+rms}, or are unsure if it is available on your 3 T scanner, either limit scans to 1.5 T and Normal Mode, or contact the MRI scanner manufacturer for more information.

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.

☐Horizontal, hydrogen proton, closed bore scanners only.

☐ MRI magnet strength of 1.5 T (64 MHz) or 3 T (128 MHz). See "ImageReady Defibrillation System Components for 1.5 T and 3 T" on page D-1.

☐ Spatial gradient no greater than 50 T/m (5,000 G/cm).

☐ RF exposure limits:

1.5 T

- Normal Operating Mode[a] must be observed for the entire active scan session (whole body averaged SAR, ≤ 2.0 watts/kilogram (W/kg); Head SAR, ≤ 3.2 W/kg)

3 T (Patient landmark/scan isocenter at or superior to the C7 vertebra)

- Normal Operating Mode or First Level Controlled Operating Mode must be observed for the entire active scan session

3 T (Patient landmark/scan isocenter inferior to the C7 vertebra)

- B_{1+rms} must be ≤ 2.8 microtesla (µT)

WARNING: If the B_{1+rms} parameter value is not displayed on the 3 T MRI scanner system, do not perform 3 T scans with a patient landmark (scan isocenter) inferior to the C7 vertebra. Such scans do not meet the Radiology Conditions of Use.

☐ Maximum specified gradient slew rate ≤ 200 T/m/s per axis.

☐ There are no restrictions for positioning the defibrillation system within the integrated body coil of the MRI scanner. 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.

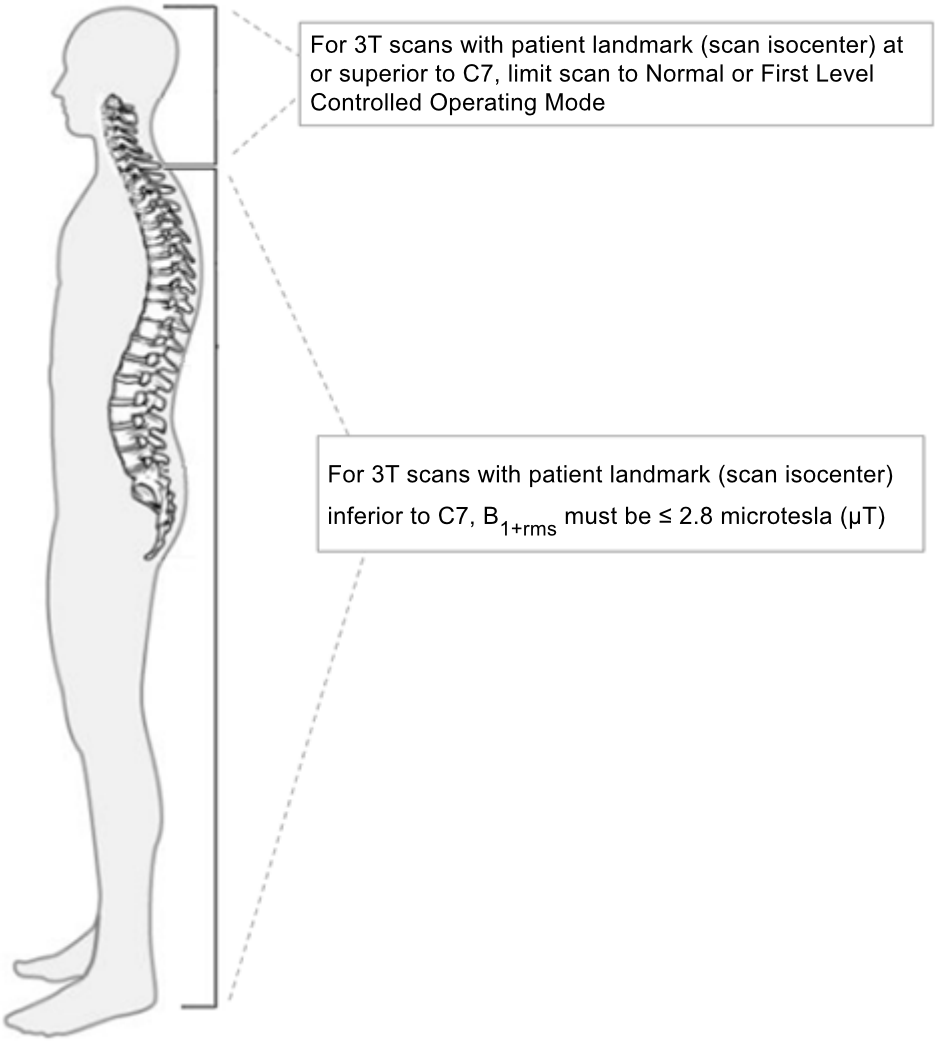
After scan

5. Ensure the pulse generator is returned to pre-MRI operation, either automatically if the Time-out parameter was set, or manually using the Programmer. 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 is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices[1]. Under no circumstances should the Programmer 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.



For 3 T scans, when the patient landmark (scan isocenter) is at or superior to the C7 vertebra, the scan must be limited to Normal Operating Mode or First Level Controlled Operating Mode. When the patient landmark (scan isocenter) is inferior to C7, the B_{1+rms} parameter must be limited to ≤ 2.8 microtesla (μT). If using a scanner that does not display B_{1+rms}, do not scan at 3 T when the patient landmark (scan isocenter) is inferior to C7.

Figure B–1. Limiting Parameters for 3 T MRI Scanning

1. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.

DETERMINE BEEPER TYPE

APPENDIX C

The pulse generator contains either an Armature or Piezo beeper.

- The Armature Beeper contains a magnetic component and may be damaged by the strong magnetic fields associated with MRI scanners. Before undergoing an MRI scan, the patient and physician should weigh the benefit of the MRI scan against the risk of losing beeper function. The Beeper may be inaudible due to MRI scan, and should be tested post MRI scan.

- The Piezo Beeper does not contain any magnetic components, and is designed to withstand the strong magnetic fields associated with MRI scanners without being damaged.

To determine the Beeper type, ensure the Model 3868 Programmer Software Application is version 1.08 or above and interrogate the device using the Model 3300 Programmer.

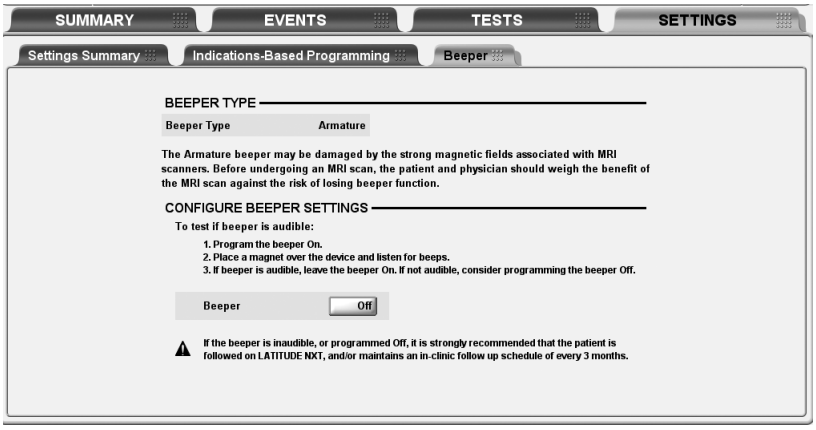


Figure C–1. Beeper Tab Armature

NOTE: *Screens will differ depending on beeper type and MRI Protection Mode availability.*

IMAGEREADY DEFIBRILLATION SYSTEM COMPONENTS FOR 1.5 T AND 3 T

APPENDIX D

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

Gray shading of model rows indicates components compatible with both 1.5 T and 3 T scanners. An 'x' indicates MR Conditional status at the magnet strength indicated.

CRT-D Pulse Generators — ImageReady MR Conditional Defibrillation System Components

Component	Model Number(s)	MR Status	1.5 T	3 T
CRT-D Pulse Generators				
AUTOGEN X4 CRT-D	G177, G179	MR Conditional	X	
AUTOGEN CRT-D	G172, G173	MR Conditional	X	
CHARISMA X4 CRT-D	G328, G348	MR Conditional	X	
	G337, G347	MR Conditional	X	X
CHARISMA CRT-D	G324, G325	MR Conditional	X	
DYNAGEN X4 CRT-D	G156, G158	MR Conditional	X	
DYNAGEN CRT-D	G150, G151	MR Conditional	X	
INOGEN X4 CRT-D	G146, G148	MR Conditional	X	
INOGEN CRT-D	G140, G141	MR Conditional	X	
MOMENTUM CRT-D X4	G128, G138	MR Conditional	X	
MOMENTUM CRT-D	G124, G125	MR Conditional	X	
ORIGEN X4 CRT-D	G056, G058	MR Conditional	X	
ORIGEN CRT-D	G050, G051	MR Conditional	X	
RESONATE HF CRT-D	G524, G525, G528, G548	MR Conditional	X	
	G537, G547	MR Conditional	X	X
RESONATE X4 CRT-D	G428, G448	MR Conditional	X	
	G437, G447	MR Conditional	X	X
RESONATE CRT-D	G424, G425	MR Conditional	X	
VIGILANT X4 CRT-D	G228, G248	MR Conditional	X	
	G237, G247	MR Conditional	X	X
VIGILANT CRT-D	G224, G225	MR Conditional	X	

ICD Pulse Generators — ImageReady MR Conditional Defibrillation System Components

Component	Model Number(s)	MR Status	1.5 T	3 T
ICD Pulse Generators				
AUTOGEN EL ICD	D174, D175, D176, D177	MR Conditional	X	
AUTOGEN MINI ICD	D044, D045, D046, D047	MR Conditional	X	
CHARISMA EL ICD	D320, D321	MR Conditional	X	
	D332, D333	MR Conditional	X	X
DYNAGEN EL ICD	D150, D151, D152, D153	MR Conditional	X	

Component	Model Number(s)	MR Status	1.5 T	3 T
DYNAGEN MINI ICD	D020, D021, D022, D023	MR Conditional	X	
INOGEN EL ICD	D140, D141, D142, D143	MR Conditional	X	
INOGEN MINI ICD	D010, D011, D012, D013	MR Conditional	X	
MOMENTUM EL ICD	D120, D121	MR Conditional	X	
ORIGEN EL ICD	D050, D051, D052, D053	MR Conditional	X	
ORIGEN MINI ICD	D000, D001, D002, D003	MR Conditional	X	
PERCIVA HF ICD	D500, D501	MR Conditional	X	
	D512, D513	MR Conditional	X	X
PERCIVA ICD	D400, D401	MR Conditional	X	
	D412, D413	MR Conditional	X	X
RESONATE HF ICD	D520, D521	MR Conditional	X	
	D532, D533	MR Conditional	X	X
RESONATE EL ICD	D420, D421	MR Conditional	X	
	D432, D433	MR Conditional	X	X
VIGILANT EL ICD	D220, D221	MR Conditional	X	
	D232, D233	MR Conditional	X	X

Leads and Accessories — ImageReady MR Conditional Defibrillation System Components

Component	Model Number(s)	MR Status	1.5 T	3 T
Leads and Accessories				
Right Atrial Leads and Accessories				
FINELINE II Sterox Pacing Leads	4479, 4480	MR Conditional	X	X
FINELINE II Sterox EZ Pacing Leads	4469, 4470, 4471	MR Conditional	X	X
FINELINE II Sterox EZ Pacing Leads[a]	4472, 4473, 4474	MR Conditional	X	X
Suture Sleeve for FINELINE II Leads	6220	MR Conditional	X	X
Suture Sleeve for FINELINE II Leads[a]	6221	MR Conditional	X	X
INGEVITY MRI Pacing Leads (Tined Fixation)	7735, 7736	MR Conditional	X	X
INGEVITY MRI Pacing Leads (Extendable/ Retractable Fixation)	7740, 7741, 7742	MR Conditional	X	X
INGEVITY+ Pacing Leads (Extendable/ Retractable Fixation)	7840, 7841, 7842	MR Conditional	X	X
Suture Sleeve for INGEVITY MRI / INGEVITY+ Leads	6402	MR Conditional	X	X
IS-1 Lead Port Plug	7145	MR Conditional	X	X
Right Ventricular Leads and Accessories				
ENDOTAK RELIANCE (IS-1) Leads – Single Coil	0128, 0138, 0170, 0171, 0180, 0181, 0182, 0183	MR Conditional	X	
ENDOTAK RELIANCE (IS-1) Leads – Single Coil[a]	0127, 0129, 0137, 0139, 0172, 0173	MR Conditional	X	
DF-1 Lead Port Plug for ENDOTAK RELIANCE (IS-1) Leads – Single Coil	6996	MR Conditional	X	

Component	Model Number(s)	MR Status	1.5 T	3 T
ENDOTAK RELIANCE (IS-1) Leads – Dual Coil	0148, 0157, 0158, 0174, 0175, 0176, 0177, 0184, 0185, 0186, 0187	MR Conditional	X	
ENDOTAK RELIANCE (IS-1) Leads – Dual Coil[a]	0143, 0147, 0149, 0153, 0159	MR Conditional	X	
ENDOTAK RELIANCE (DF4) Defibrillation Leads	0262, 0263, 0265, 0266, 0272, 0273, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional	X	X
RELIANCE 4-FRONT (DF4) Defibrillation Leads	0636, 0650, 0651, 0652, 0653, 0654, 0655, 0657, 0658, 0662, 0663, 0665, 0672, 0673, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional	X	X
Suture Sleeve for RELIANCE 4-FRONT Leads	6403	MR Conditional	X	X
Left Ventricular Leads and Accessories				
ACUITY Spiral Leads[a]	4591, 4593	MR Conditional	X	
ACUITY Spiral Lead	4592	MR Conditional	X	
Suture Sleeve for ACUITY Spiral Leads[a]	6100	MR Conditional	X	
ACUITY X4 (IS4) Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	X	X
Suture Sleeve for ACUITY X4 Leads	4603	MR Conditional	X	X
EASYTRAK 2 (IS-1) Leads[a]	4542, 4543, 4544	MR Conditional	X	
Suture Sleeve for EASYTRAK 2 Leads[a]	6773	MR Conditional	X	
IS4/DF4 Lead Port Plug	7148	MR Conditional	X	X
IS-1 Lead Port Plug	7145	MR Conditional	X	

a. These devices are no longer placed on the EU market, and no longer carry an active CE Mark. These devices and the MR Conditional systems they are a part of continue to be supported by Boston Scientific.

MR CONDITIONAL DEFIBRILLATOR PROGRAMMER REPORTS

APPENDIX E

MRI Protection Status

MRI Protection Mode	On
MRI Protection Entry Time	13 Apr 2020 19:37

⚠ Patient must be out of MRI scanner before 14 Apr 2020 01:41 ①

Settings During MRI Protection

Parameter	Old Value	New Value
Tachy Mode	Off	Off
Brady Mode	DDD	DOO
Lower Rate Limit	45 min^{-1}	65 min^{-1}
AV Delay	180 - 200 ms	100 ms
Ventricular Pacing Chamber	BiV	BiV
Pacing Output		
Atrial	3.5 V @ 0.4ms	5.0 V @ 1.0ms
Right Ventricular	3.5 V @ 0.4ms	5.0 V @ 1.0ms
Left Ventricular	3.5 V @ 0.4ms	3.5 V @ 0.4ms
LV Offset	0 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 OFF due to MRI Protection Mode usage. Coming in contact with the strong magnetic field of an MRI scanner may cause 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.

ⓘ Post-Operative System Test will automatically run immediately upon exiting MRI Protection Mode.

Leads Data	Pre-MRI Scan Measurement	Measurement Date
Atrial		
Intrinsic Amplitude	2.3 mV	13 Apr 2020 19:37
Pace Impedance	547Ω	13 Apr 2020 19:37
Pace Threshold	1.8 V @ 0.4ms	13 Apr 2020 19:37
Right Ventricular		
Intrinsic Amplitude	4.3 mV	13 Apr 2020 19:37
Pace Impedance	547Ω	13 Apr 2020 19:37
Pace Threshold	0.1 V @ 2.0ms	13 Apr 2020 19:37
Left Ventricular		
Intrinsic Amplitude	2.3 mV	13 Apr 2020 19:37
Pace Impedance	547Ω	13 Apr 2020 19:37
Pace Threshold	0.1 V @ 2.0ms	13 Apr 2020 19:37
Shock		
Impedance	0Ω	13 Apr 2020 19:37

②

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.

[1] Twenty-four hour time format is used. [2] Measurement Date column indicates the date the Leads Data were collected, which may be prior to the date of the MRI Protection Settings Report itself.

Figure E–1. Sample MRI Protection Settings Report printout with Time-out set to 6 hours

Boston Scientific	ZOOM ® View™	Report Created 10 Apr 2017
	MRI Protection Settings Report	
	Date of Birth N/R N/R N/R Device RESONATE HF CRT-D G547/ 268019AC7812624EFFFFFFF1 Tachy Mode Off	Last Office Interrogation **10 Apr 2017** Implant Date **N/R**

MRI Protection Status

MRI Protection Mode	On
MRI Protection Entry Time	10 Apr 2017 12:36

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

Settings During MRI Protection

Parameter	Old Value	New Value
Tachy Mode	Monitor + Therapy	Off
Brady Mode	DDD	DOO
Lower Rate Limit	45 min^{-1}	65 min^{-1}
AV Delay	180 - 180 ms	100 ms
Ventricular Pacing Chamber	BiV	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

Page 1 of 4

Figure E–2. Sample MRI Protection Settings Report printout with Time-out set to Off (Page 1)

Event MRI-5: 10 Apr 2017 12:34

Settings During MRI Protection

Tachy Mode	Off	
Brady Mode	DOO	
Lower Rate Limit	65 min^{-1}	
AV Delay	100 ms	
Ventricular Pacing Chamber	BiV	
Pacing Output		
Atrial	5.0 V @ 1.0 ms	
Right Ventricular	5.0 V @ 1.0 ms	
Left Ventricular	3.5 V @ 0.4 ms	
LV Offset	0 ms	
MRI Protection Time-out	6 h	

Leads Data (most recent pre-MRI scan measurements)

Atrial		
Intrinsic Amplitude	2.3 mV	10 Apr 2017 11:02
Pace Impedance	548 Ω	10 Apr 2017 12:34
Pace Threshold	1.8 V @ 0.4 ms	10 Apr 2017 11:03
Right Ventricular		
Intrinsic Amplitude	4.3 mV	10 Apr 2017 11:02
Pace Impedance	549 Ω	10 Apr 2017 12:34
Pace Threshold	1.4 V @ 0.4 ms	10 Apr 2017 11:03
Left Ventricular		
Intrinsic Amplitude	4.2 mV	10 Apr 2017 11:02
Pace Impedance	311 Ω	10 Apr 2017 12:34
Pace Threshold	1.5 V @ 0.4 ms	10 Apr 2017 11:04
Shock		
Impedance	47 Ω	10 Apr 2017 12:34
MRI Protection Exit Status	User Terminated	
MRI Protection Exit Time	10 Apr 2017 12:35	

Event Ended 00:00:52

For RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, CHARISMA, VIGILANT, and MOMENTUM devices

Figure E–3. Sample stored event detail printout

SYMBOLS ON PACKAGING

APPENDIX F

The following symbols may be used on packaging and labeling.

Table F–1. Symbols on Packaging

Symbol	Description
EC REP	Authorized Representative in the European Community
	Manufacturer
MR	MR Conditional
REF	Reference Number

INDEX

A

Abandoned leads or pulse generators 1-5
Active implantable medical devices (AIMDs) 1-7
ACUITY Spiral 1-2
ACUITY X4 1-2
Armature Beeper 2-10
Arrhythmia Logbook 2-12
AUTOGEN 1-2

B

Battery capacity status 2-4
Beeper 2-14

C

Cardiology Checklist A-1
CHARISMA 1-2
Closed bore 1-5
Coils 1-7
  receive-only 1-5
  transmit-only 1-5
  transmit/receive 1-5
Configure Beeper Settings 2-14

D

DIVERT THERAPY 2-13
DYNAGEN 1-2

E

EASYTRAK 2 1-2
Electrocautery Mode 2-4
ENDOTAK RELIANCE 1-2

F

FINELINE II 1-2
Fractured lead 1-5

I

Image distortion 2-12
ImageReady MR Conditional Defibrillation System 1-2, 1-5
INGEVITY MRI 1-2
INGEVITY+ 1-2
INOGEN 1-2
Intrinsic amplitude 2-3, 2-12–2-13

L

Lead impedance 2-3, 2-9, 2-12–2-13
Leads
  ACUITY Spiral 1-2
  ACUITY X4 1-2
  EASYTRAK 2 1-2
  ENDOTAK RELIANCE 1-2
  FINELINE II 1-2
  INGEVITY MRI 1-2
  INGEVITY+ 1-2
  RELIANCE 4–FRONT 1-2

M

Magnet sensor 2-9
Minute Ventilation 2-14
Models for use with 1.5 T 1-2
Models for use with 3 T 1-2
MOMENTUM 1-2
Monitoring patient 1-5, 2-8
MRI magnet strength
  1.5 T 1-2
  1.5 Tesla 1-2, 1-5, 1-7
  3 T 1-2
  3 Tesla 1-2, 1-5, 1-7
MRI Protection Checklist 2-5
MRI Protection episode 2-12
MRI Protection Mode 1-5, 1-7, 2-4
  automatic exit 2-12
  conditions preventing entry 2-4, 2-9
  entry into 2-4
  manual exit 2-7–2-8, 2-12
  suspended features and functions 2-3
  Time-out feature 1-2, 2-2–2-3, 2-7–2-8, 2-12–2-13
MRI Protection Settings Report 2-2, 2-8

N

Normal operating mode 1-5

O

Operating mode
  normal 1-5
ORIGEN 1-2

P

Pacing threshold 2-12–2-13
Pacing threshold changes 1-10
Patient position 1-5, 2-12
PERCIVA 1-2
PERCIVA HF 1-2
Programmer 1-2
Programmer wand 2-4, 2-7, 2-13
Pulse generators
  AUTOGEN 1-2
  CHARISMA 1-2
  DYNAGEN 1-2
  INOGEN 1-2
  MOMENTUM 1-2
  ORIGEN 1-2
  PERCIVA 1-2
  PERCIVA HF 1-2
  RESONATE 1-2
  RESONATE HF 1-2
  VIGILANT 1-2
Pulse oximetry 1-5, 2-12

Q

Quick Reference Guide D-1

R

Radiology Checklist B-1
Receive-only coils 1-5
RELIANCE 4–FRONT 1-2
Reports E-1
RESONATE 1-2
RESONATE HF 1-2
RF telemetry 2-3–2-4, 2-13

S

Safety Core operation 2-4
SAR limits 1-5
Six weeks since implant 1-5, 1-10
Specific Absorption Rate (SAR) limits 1-5
STAT PACE 2-13
STAT PACE mode 2-9
STAT SHOCK 2-13
STAT SHOCK mode 2-9
Storage Mode 2-4, 2-10
System integrity 2-12
  compromised 1-5

T

Tachycardia protection 1-5
Tesla
  1.5 T 1-2, 1-5, 1-7
  3 T 1-2, 1-5, 1-7
Time since implant 2-10
Transmit-only coils 1-5
Transmit/receive coils 1-5

V

Ventricular episode 2-9
VIGILANT 1-2

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

EC REP

Guidant Europe NV/SA; Boston Scientific
Green Square, Lambroekstraat 5D
1831 Diegem, Belgium

www.bostonscientific.com

1.800.CARDIAC (227.3422)

+1.651.582.4000

© 2022 Boston Scientific Corporation or its affiliates.

All rights reserved.
51308710-027 EN Europe 2022-02

CE 2797

The following devices are no longer placed on the EU market, and no longer carry an active CE Mark: 0127, 0129, 0137, 0139, 0143, 0147, 0149, 0153, 0159, 0172, 0173, 4472, 4473, 4474, 4542, 4543, 4544, 4591, 4593, 6100, 6221, 6773.