Boston Scientific

MRI TECHNICAL GUIDE

⚠ MR IMAGEREADY™ MR CONDITIONAL PACING SYSTEM

REF J065, J066, J067, J175, J176, J177, J275, J276, J277, J279, L110, L111, L131, L210, L211, L231, L310, L311, L331, 4456, 4457, 4458, 4459, 4469, 4470, 4471, 4472, 4473, 4474, 4479, 4480, 6220, 6221, 6402, 7145, 7731, 7732, 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 Pacing System, as well as radiologists and other HCPs involved in performing magnetic resonance imaging (MRI[1]) scans on such patients.

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

This manual contains:

- Information about ImageReady MR Conditional Pacing Systems
- Information about ImageReady 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 System patients

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

1. 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.

TABLE OF CONTENTS

INTRODUCTION TO MR CONDITIONAL PACING

CHAPTER 1

This chapter contains the following topics:

SYSTEM DESCRIPTION

An ImageReady MR Conditional Pacing System consists of specif c Boston Scientif c model components including pulse generators, leads, accessories, the Programmer/Recorder/Monitor (PRM), and the PRM Software Application. MR Conditional pulse generators may be used with **either** FINELINE II Sterox / FINELINE II Sterox EZ lead(s) and associated accessories (see Table 1-2 on page 1-3) **or** with INGEVITY MRI lead(s) and associated accessories (see Table 1-2 on page 1-3 and Table 1-3 on page 1-3).

The ImageReady MR Conditional Pacing Systems were created specif cally as a system for use with MRI scans performed under the Conditions of Use described in this Technical Guide. The pulse generator design has minimized use of ferromagnetic materials, which can interact with the f elds generated during a typical MRI scan, and the circuits have been designed to tolerate voltages that may be induced during scans. Any part of the body may be imaged. Boston Scientif c 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 modif es the behavior of the pulse generator and has been designed to accommodate the MRI scanner electromagnetic environment. 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 tested to verify the effectiveness of the designs. Other MRI-related risks are further reduced by adherence to the conditions for scanning specif ed in this Technical Guide.

For additional information, see the Boston Scientif c Website at: *http://www.bostonscientific-international.com/MRI*.

Only specif c combinations of pulse generators and leads constitute an ImageReady Pacing System. Consult the following tables to distinguish between combinations that are valid for use with **only 1.5 T scanners** and combinations that are valid for use with **both 1.5 T and 3 T scanners**.

Valid Combinations of Pulse Generators and Leads to Use in 1.5 Tesla and 3 Tesla Environments

Table 1-1. Valid Combinations of Pulse Generators and Leads to Use in 1.5 T and 3 T Environments

	FINELINE II Leads[a]	INGEVITY MRI Leads[b]
ADVANTIO MRI Pulse Generator **INGENIO MRI Pulse Generator** **VITALIO MRI Pulse Generator** **FORMIO MRI Pulse Generator**	1.5 T scanner only. 3 T scanner not allowed.	1.5 T scanner only. 3 T scanner not allowed.
ESSENTIO MRI Pulse Generator **PROPONENT MRI Pulse Generator** **ACCOLADE MRI Pulse Generator**	1.5 T scanner only. 3 T scanner not allowed.	1.5 T or 3 T scanner allowed.

a. For FINELINE II leads, ensure the MRI scanner is operated in Normal Operating Mode (NOT in First Level Controlled Operating Mode).
b. For INGEVITY MRI leads, ensure the MRI scanner is operated in Normal Operating Mode or First Level Controlled Operating Mode.

WARNING: The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System.

WARNING: Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientif c MR Conditional system components must use **only 1.5 T scanners**.

System Configuration for 1.5 T

Table 1-2. System Configuration for 1.5 T

Component	Model Number(s)	MR Status
Pulse Generators		
ADVANTIO MRI Pulse Generator	J065, J066, J067	MR Conditional
INGENIO MRI Pulse Generator	J175, J176, J177	MR Conditional
VITALIO MRI Pulse Generator	J275, J276, J277	MR Conditional
FORMIO MRI Pulse Generator	J279	MR Conditional
ESSENTIO MRI Pulse Generator	L110, L111, L131	MR Conditional
PROPONENT MRI Pulse Generator	L210, L211, L231	MR Conditional
ACCOLADE MRI Pulse Generator	L310, L311, L331	MR Conditional
Leads and Accessories		
WARNING: The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MRI Conditional Pacing System.		
FINELINE II Sterox / Sterox EZ Leads		
FINELINE II Sterox Pacing Lead	4456, 4457, 4458, 4459, 4479, 4480	MR Conditional
FINELINE II Sterox EZ Pacing Lead	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional
Suture Sleeve for FINELINE II leads	6220, 6221	MR Conditional
IS-1 Lead Port Plug	7145	MR Conditional
INGEVITY MRI Leads		
INGEVITY MRI Pacing Lead	7731, 7732, 7735, 7736, 7740, 7741, 7742	MR Conditional
Suture Sleeve for INGEVITY MRI leads	6402	MR Conditional
IS-1 Lead Port Plug	7145	MR Conditional
ZOOM LATITUDE Programmer/Recorder/Monitor (PRM) and PRM Software Application		
ZOOM LATITUDE PRM	3120	MR Unsafe[a]
ZOOM LATITUDE PRM Software App.	2869	N/A

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

System Configuration for 3 T

Table 1-3. System Configuration for 3 T

Component	Model Number(s)	MR Status
Pulse Generators		
ESSENTIO MRI Pulse Generator	L110, L111, L131	MR Conditional
PROPONENT MRI Pulse Generator	L210, L211, L231	MR Conditional
ACCOLADE MRI Pulse Generator	L310, L311, L331	MR Conditional
Leads and Accessories		
INGEVITY MRI Leads		
INGEVITY MRI Pacing Lead	7731, 7732, 7735, 7736, 7740, 7741, 7742	MR Conditional
Suture Sleeve for INGEVITY MRI leads	6402	MR Conditional
IS-1 Lead Port Plug	7145	MR Conditional
ZOOM LATITUDE Programmer/Recorder/Monitor (PRM) and PRM Software Application		
ZOOM LATITUDE PRM	3120	MR Unsafe[a]
ZOOM LATITUDE PRM Software App.	2869	N/A

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

MRI CONDITIONS OF USE

The following Conditions of Use must be met in order for a patient with an ImageReady Pacing System to undergo an MRI scan. Adherence to the Conditions of Use must be verif ed 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 Pacing System (see "System Description" on page 1-2).

   WARNING: Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientif c MR Conditional system components must use **only 1.5 T scanners**.

   WARNING: The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System.

2. Pulse generator in MRI Protection Mode during scan
3. Bipolar pacing operation or pacing off
4. Patient does not have elevated body temperature or compromised thermoregulation at time of scan
5. Pulse generator implant location restricted to left or right pectoral region
6. At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modif cation of the MR Conditional Pacing System
7. No cardiac-related implanted devices, components, or accessories present other than an ImageReady MR Conditional Pacing System (see "System Description" on page 1-2)
8. Pacing threshold ≤ 2.0 V in pace-dependent patients
9. No abandoned leads or pulse generators
10. No evidence of a fractured lead or compromised pulse generator-lead system integrity

Radiology

1. MRI magnet strength of 1.5 T or 3 T

   a. MRI magnet strength of 1.5 T (See Table 1-2 on page 1-3 to determine which pulse generators and leads were tested for use with 1.5 T magnets.)

      • Radio frequency (RF) f eld of approximately 64 MHz
      • Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system

   b. MRI magnet strength of 3 T (See Table 1-3 on page 1-3 to determine which pulse generators and leads were tested for use with 3 T magnets.)

      • RF f eld of approximately 128 MHz
      • Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system

WARNING: Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientif c MR Conditional system components must use **only 1.5 T scanners**.

2. Horizontal, ^{1}H proton, closed bore scanners only

3. Specif c Absorption Rate (SAR) limits:

   a. For an ImageReady Pacing System with **FINELINE II** leads (see Table 1-1 on page 1-2), SAR limits for Normal Operating Mode[1] must be observed for the entire active scan session as follows:

      • Whole body averaged, ≤ 2.0 watts/kilogram (W/Kg)
      • Head, ≤ 3.2 W/Kg

   b. For an ImageReady Pacing System with **INGEVITY MRI** leads (see Table 1-1 on page 1-2), SAR limits for Normal Operating Mode[1] or for First Level Controlled Operating Mode[2] must be observed for the entire active scan session as follows:

      • Whole body averaged, ≤ 4.0 W/Kg
      • Head, ≤ 3.2 W/Kg

   WARNING: The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System.

4. Gradient Field limits: Maximum specif ed gradient slew rate ≤ 200 T/m/s per axis

5. No local transmit-only coils or local transmit/receive coils placed directly over the pacing system; the use of receive-only coils is not restricted

6. Patient in supine or prone position only

7. The patient must be monitored during the MRI scan by pulse oximetry and/or electrocardiography (ECG)

Refer to Table 1-4 on page 1-6 and Table 1-5 on page 1-9 for additional information about the Conditions of Use.

CONDITIONS FOR SCANNING

Table 1-4 on page 1-6 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, 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.

1. As def ned in IEC 60601-2-33, 201.3.224, 3rd Edition.
2. As def ned in IEC 60601-2-33, 201.3.208, 3rd Edition.

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 Pacing System. *For model numbers of MR Conditional components, and to identify an appropriate combination, refer to* "System Description" on page 1-2 *in this Guide, http://www.bostonscientific-international.com/MRI, or Boston Scientific Technical Services.*	• Check patient records. • Interrogate device. (Pulse generator model number is provided on PRM screen and MRI Protection Settings Report.) • Check patient ID card. • Check X-ray identifiers on pulse generator (see Figure 1-1 on page 1-14 and Figure 1-2 on page 1-14). • Check for distinguishing characteristics of the FINELINE II Sterox lead distal tip (see Figure 1-4 on page 1-15) or for INGEVITY MRI lead radiopaque bands (see Figure 1-6 on page 1-16). • Check model numbers in "System Description" on page 1-2 of this Guide, at *http://www.bostonscientific-international.com/MRI*, or by contacting Boston Scientific Technical Services. • Confirm with physician responsible for managing the patient's Pacing System.	• 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 • Inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope • 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
• *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 designed to work together in the MRI environment.* **WARNING:** The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientific MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System. **WARNING:** Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientific MR Conditional system components must use **only 1.5 T scanners**.			
2. Pulse generator 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 designed to mitigate these effects.*	• Program the pulse generator to MRI Protection Mode using the PRM.	• Arrhythmia induction • Inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias

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**
3. Bipolar pacing operation in chamber(s) where pacing will occur in MRI Protection Mode. *Unipolar lead configurations increase the risk of induced voltages in the lead system. Bipolar ventricular pacing operation is required to support Safety Core operation, if Safety Core is entered from MRI Protection Mode.*	• Conf rm that pacing lead conf guration is bipolar. If unipolar, program to bipolar. *Unipolar configuration of the lead used for pacing in MRI Protection Mode will prevent entry into MRI Protection Mode.*	• Arrhythmia induction • Inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope • If Safety Core is entered from MRI Protection Mode, Safety Core pacing will not occur in the absence of a functional bipolar ventricular pacing lead.	• Pacing-dependent patients • Patients prone to sustained arrhythmias
4. Patient does not have an elevated body temperature or compromised thermoregulation at time of MRI scan. *Pre-existing elevated temperature is additive with any scan-induced heating.*	• Check patient's temperature prior to scan.	• Clinically signif cant 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
5. 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 signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Inappropriate pacing or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope • Physical movement of pulse generator in pocket • Pocket discomfort due to pulse generator heating	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
6. At least six weeks have elapsed since implantation and/or any lead revision or surgical modif cation of the MR Conditional Pacing 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 signif cant 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

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. No cardiac-related implanted devices or accessories present other than an ImageReady MR Conditional Pacing System (see "System Description" on page 1-2). *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 Pacing System in reducing risks of MRI scanning.*	• Check patient records. • Conf rm with physician responsible for managing the patient's Pacing System. • Check X-rays. • Check model numbers in this Guide ("System Description" on page 1-2) or at *http://www.bostonscientific-international.com/MRI*. *For model numbers of MR Conditional components, and to identify an appropriate combination, refer to* "System Description" on page 1-2 *in this Guide, http://www.bostonscientific-international.com/MRI, or Boston Scientific Technical Services.*	• Arrhythmia induction • Clinically signif cant 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
8. Pacing threshold ≤ 2.0 V in pace-dependent patients. *Pulse generator pulse amplitude in MRI Protection Mode is set to 5.0 V, providing a minimum two-fold safety margin for patients with a pacing threshold ≤ 2.0 V plus an additional 1.0 V to counteract gradient-induced pace pulse offsets.*	• Check patient records for most recent pacing threshold values or run a pacing threshold test. *The device will check the most recently recorded pacing threshold testing results for each chamber when MRI Protection Mode is programmed and provides an attention message on the PRM screen if > 2.0 V.*	• Inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope	• Pacing-dependent patients

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**
9. No abandoned leads or pulse generators. *The presence of abandoned leads or pulse generators may significantly reduce the effectiveness of the ImageReady MR Conditional Pacing System in reducing risks of MRI scanning.*	• Check patient records. • Conf rm with physician responsible for managing the patient's Pacing System. • Check X-rays.	• Arrhythmia induction • Clinically signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Damage to pulse generator, lead, or connection • Pocket discomfort due to pulse generator heating	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
10. No evidence of a fractured lead or compromised pulse generator-lead system integrity. Lead impedance values within the programmed normal range. No record or evidence of damage to pulse generator seal plug and front lead sealing rings. *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. • Review Daily Measurements on the Leads Status Summary Screen to verify stability over time of pace impedance, pace threshold, and intrinsic amplitude values. • Check patient records from implant procedure. • 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 signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds

Table 1-5 on page 1-9 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, 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.

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 or 3 T (see a and b below).			

Table 1-5. Radiology Conditions (continued)

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
1a. MRI magnet strength of 1.5 T: • RF f eld of approximately 64 MHz • Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system	• Check technical specif cations of MRI scanner. • Refer to "System Description" on page 1-2 to determine which components were tested for use with 1.5 T magnets.	• Arrhythmia induction • Clinically signif cant 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
• *The ImageReady Pacing Systems were designed specifically to mitigate hazards associated with 1.5 T or 3 T magnets. System response to other magnet strengths has not been evaluated. Refer to* "System Description" on page 1-2 *to determine which components were tested for use with 1.5 T magnets.* • *System response to spatial gradients greater than 50 T/m (5,000 G/cm) has not been evaluated.* **WARNING:** Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientif c MR Conditional system components must use **only 1.5 T scanners**.			
1b. MRI magnet strength of 3 T: • RF f eld of approximately 128 MHz • Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system	• Check technical specif cations of MRI scanner. • Refer to "System Description" on page 1-2 to determine which components were tested for use with 3 T magnets.	• Arrhythmia induction • Clinically signif cant 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
• *The ImageReady Pacing Systems were designed specifically to mitigate hazards associated with 1.5 T or 3 T magnets. System response to other magnet strengths has not been evaluated. Refer to* "System Description" on page 1-2 *to determine which components were tested for use with 3 T magnets.* • *System response to spatial gradients greater than 50 T/m (5,000 G/cm) has not been evaluated.* **WARNING:** Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientif c MR Conditional system components must use **only 1.5 T scanners**.			

Table 1-5. Radiology Conditions (continued)

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
2. Horizontal, ^{1}H proton, closed bore scanners only. *The ImageReady Pacing Systems were designed specifically to mitigate hazards associated with horizontal closed bore scanners.*	• Check technical specif cations of MRI scanner.	• Arrhythmia induction • Clinically signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Inappropriate pacing, inhibition of pacing, or irregular intermittent pacing, possibly resulting in pre-syncope or syncope • 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. Specif c Absorption Rate (SAR) limits (see a and b below).			
3a. SAR limits for Normal Operating Mode must be observed for the entire active scan session with an ImageReady Pacing System with **FINELINE II** leads • Whole body averaged, ≤ 2.0 W/Kg • Head, ≤ 3.2 W/Kg **WARNING:** The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System. *An ImageReady Pacing System with FINELINE II leads was designed specifically to mitigate hazards associated with Normal Operating Mode. System response to other scanner settings has not been evaluated.*	• Ensure MRI scanner is operated in Normal Operating Mode (**NOT** in First Level Controlled Operating Mode).	• Clinically signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Inappropriate pacing, inhibition of pacing, or irregular intermittent pacing, possibly resulting in pre-syncope or syncope	• Pacing-dependent patients • 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**
3b. SAR limits for Normal Operating Mode or First Level Controlled Operating Mode must be observed for the entire active scan session with an ImageReady Pacing System with **INGEVITY MRI** leads • Whole body averaged, ≤ 4.0 W/Kg • Head, ≤ 3.2 W/Kg **WARNING:** The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System. *An ImageReady Pacing System with INGEVITY MRI leads was designed specifically to mitigate hazards associated with Normal Operating Mode or First Level Controlled Operating Mode. System response to other scanner settings has not been evaluated.*	• Ensure MRI scanner is operated in Normal Operating Mode or First Level Controlled Operating Mode.	• Clinically signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Inappropriate pacing, inhibition of pacing, or irregular intermittent pacing, possibly resulting in pre-syncope or syncope	• Pacing-dependent patients • Patients with high capture thresholds
4. Gradient Field limits: Maximum specif ed gradient slew rate ≤ 200 T/m/s per axis. *System response to other scanners, and to gradient slew rates higher than 200 T/m/s per axis, has not been evaluated.*	• Check technical specif cations of MRI scanner.	• Arrhythmia induction • Inappropriate pacing, inhibition of pacing, or irregular intermittent pacing, possibly resulting in pre-syncope or syncope • 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

Table 1-5. Radiology Conditions (continued)

Condition for Scanning (Rationale)	Actions	If Condition is Not Met	
		Potential Clinical Consequences	**Risk is Highest for**
5. No local transmit-only coils or local transmit/receive coils placed directly over the pacing system; the use of receive-only coils is not restricted. *System response to local transmit-only or transmit/ receive coils placed directly over the pacing system has not been evaluated.*	• Ensure no local transmit-only or transmit/receive coils are placed directly over the pacing system.	• Arrhythmia induction • Clinically signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Erratic pulse generator behavior • Inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope • Pocket discomfort due to pulse generator heating	• Pacing-dependent patients • Patients prone to sustained arrhythmias • Patients with high capture thresholds
6. The patient must be in a supine or prone position during the scan. *The ImageReady Pacing Systems were designed specifically to mitigate hazards associated with a patient position of supine or prone. System response to other patient positions has not been evaluated.*	• Ensure patient is in the correct position during scan.	• Arrhythmia induction • Clinically signif cant pacing threshold changes and sensing changes as a result of heating at the lead/tissue interface • Inappropriate pacing, inhibition of pacing, or irregular intermittent capture or pacing, possibly resulting in pre-syncope or syncope • 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
7. The patient must be monitored during the MRI scan by pulse oximetry and/or electrocardiography (ECG).	• Ensure patient is being monitored during scan.	• 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 modif es certain pulse generator functions in order to mitigate risks associated with exposing the pacing 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 2-2.

MRI BASIC CONCEPTS

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

- A static magnetic f eld generated by a superconducting electromagnet coil, 1.5 T or 3 T in strength.
- Gradient magnetic f elds of much lower intensity, but with high rates of change over time. Three sets of gradient coils are used to create the gradient f elds.
- A pulsed radio frequency (RF) f eld produced by transmission RF coils (approximately 64 MHz for 1.5 T and 128 MHz for 3 T).

These f elds 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 pacing system designed, optimized, and tested for the ability to function correctly under specif ed 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 1-4), ImageReady MR Conditional Pacing System patients can undergo MRI scans with risks mitigated to the best current standard of care.

X-RAY IDENTIFIER

ImageReady MR Conditional pulse generators have an identif er visible by X-ray or f uoroscopy (Figure 1-1 on page 1-14 and Figure 1-2 on page 1-14). The identif er consists of a f lled triangle, to denote MR Conditional status; the letters BSC, to identify Boston Scientif c as the manufacturer; and either the number 011 or 012, to identify the model 2869 PRM software application needed to communicate with the pulse generator.

- 011 appears on ADVANTIO MRI, INGENIO MRI, VITALIO MRI, and FORMIO MRI pulse generators. These devices can be used with only 1.5 T magnets.

Figure 1-1. X-ray identifier for ADVANTIO MRI, INGENIO MRI, VITALIO MRI, and FORMIO MRI

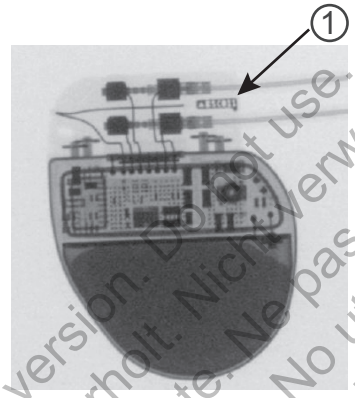
- 012 appears on ESSENTIO MRI, PROPONENT MRI, and ACCOLADE MRI pulse generators. These devices can be used with either 1.5 T or 3 T magnets.

Figure 1-2. X-ray identifier for ESSENTIO MRI, PROPONENT MRI, and ACCOLADE MRI

The identifier is located on the header of the pulse generator (see Figure 1-3 on page 1-15 and Figure 1-5 on page 1-16).

ImageReady Pacing System with FINELINE II Leads

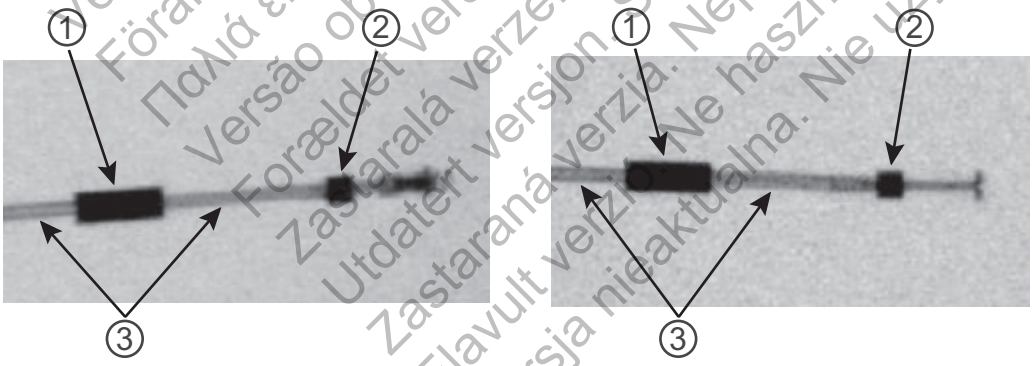
Figure 1-3 on page 1-15 shows a fluoroscopic image of an INGENIO MRI pulse generator with FINELINE II Sterox leads connected. The pulse generator X-ray identifier is visible on the right side of the header.



[1] Location of the pulse generator X-ray identifier

Figure 1-3. INGENIO MRI pulse generator with two FINELINE II Sterox leads

FINELINE II Sterox leads do not include an X-ray identifier. Figure 1-4 on page 1-15 shows fluoroscopic images of the distal tip for the active fixation FINELINE II Sterox EZ leads (Figure 1-4 on page 1-15, left) and passive fixation FINELINE II Sterox leads (Figure 1-4 on page 1-15, right). The arrows indicate the physical features of the lead distal tip region.



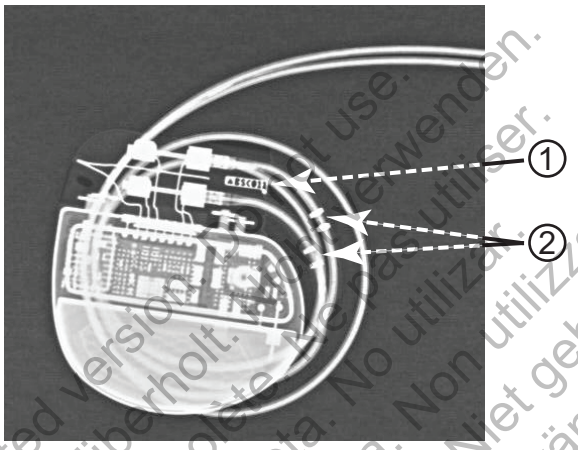
[1] Constant diameter anode ring; [2] Fluoroscopy marker just proximal to distal tip; [3] Constant diameter co-radial coil

Figure 1-4. Fluoroscopic images of the distal tip for the active fixation FINELINE II Sterox EZ (left) and passive fixation FINELINE II Sterox (right) leads

Figure 1-4 on page 1-15 is provided as a reference to aid in the recognition of FINELINE II Sterox leads by fluoroscopy or X-ray. The primary means of lead identification should be the patient's medical files.

ImageReady Pacing System with INGEVITY MRI Leads

Figure 1-5 on page 1-16 shows a fluoroscopic image of a VITALIO MRI pulse generator with INGEVITY MRI leads connected. Two radiopaque bands near the lead terminal (also shown in Figure 1-6 on page 1-16) are designed to aid in identification of INGEVITY MRI leads as components of an MR Conditional Pacing System. The primary means of lead identification should be the patient's medical files. The pulse generator X-ray identifier is visible on the right side of the header.



[1] Pulse generator X-Ray identifier; [2] INGEVITY MRI lead radiopaque bands

Figure 1-5. VITALIO MRI pulse generator with two INGEVITY MRI leads

[1] Radiopaque bands

Figure 1-6. Radiopaque bands near INGEVITY MRI lead terminal

MR CONDITIONAL PACING SYSTEM WARNINGS AND PRECAUTIONS

General

WARNING: Unless all of the MRI Conditions of Use ("MRI Conditions of Use" on page 1-4) 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 1-18.

NOTE: *Table 1-4 on page 1-6 and Table 1-5 on page 1-9 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: The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System.

WARNING: Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientif c MR Conditional system components must use **only 1.5 T scanners**.

WARNING: Ensure that an external def brillator and medical personnel skilled in cardio-pulmonary resuscitation (CPR) are present during the MRI scan should the patient require external rescue.

WARNING: MRI scanning after Explant status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of pacing. 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 1-4).

Programming Considerations

WARNING: If the MRI Protection Time-out value of Off is combined with a Pacing Mode of Off, the patient will not receive pacing until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.

WARNING: Use caution when programming the MRI Protection Mode pacing amplitude for pacing-dependent patients who have high pacing thresholds (> 2.0 V). Programming pacing amplitude below 5.0 V is provided as an option in case of extracardiac stimulation (for example, diaphragmatic stimulation for RV pacing). If pacing amplitude is programmed below 5.0 V, an appropriate safety margin (2X the pacing threshold + 1.0 V) should be maintained. An inadequate safety margin may result in loss of capture.

WARNING: Exit MRI Protection Mode after MRI scanning is completed. If the MRI Protection Time-out value of Off is selected, the pulse generator will remain permanently in the MRI Protection Mode until it is programmed otherwise. Prolonged use of the MRI Protection Mode (such as may occur when the Time-out feature is programmed to Off) may increase the rate of battery depletion. In addition, prolonged exposure of a patient to the XOO mode chosen may be deleterious to the patient's health.

Safety Mode

WARNING: If the pulse generator enters Safety Mode from MRI Protection Mode, backup pacing will not occur in the following scenarios:

- if a functional bipolar ventricular pacing lead is not present
- if the Pacing Mode under MRI Protection Mode settings is programmed to Off; the pulse generator will continue permanently with the Pacing Mode programmed to Off, and the patient will not receive pacing therapy until the pulse generator is replaced

WARNING: Do not perform an MRI scan on a patient whose device has entered Safety Core. Safety Core pacing mode 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 def ned by the American College of Radiology Guidance Document for Safe MR Practices[3]. 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 def ned by the American College of Radiology Guidance Document for Safe MR Practices[4]. 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 pacing parameters required for MR Conditional scanning, in conjunction with the physical conditions required during a scan (for example, prolonged time in a supine position).

CAUTION: If the MR Conditional Pacing System enters Safety Core Operation during MRI Protection Mode and the pacing mode was set to a value other than Off, MRI Protection Mode pacing will be automatically switched to VOO mode, RV bipolar conf guration (sensing and pacing), 5.0 V pace pulse amplitude, 1.0 ms pulse width, and 72.5 min^{-1} pacing rate as the safety mode.

CAUTION: The presence of the implanted Pacing System may cause MRI image artifacts (see "3. Preparing the Patient for the Scan" on page 2-14).

NOTE: *All normal risks associated with an MRI procedure apply to MRI scans with the MR Conditional Pacing 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 Pacing System.*

POTENTIAL ADVERSE EVENTS

Potential adverse events differ depending on whether the MRI Conditions of Use ("MRI Conditions of Use" on page 1-4) 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 MRI Protection Mode pacing at elevated f xed rate and increased output including reduced exercise capacity, acceleration of heart failure, and competitive pacing/arrhythmia induction

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

- Syncope

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
- 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

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 1-4). This verif cation 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 1-4) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and signif cant 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 1-18.

NOTE: *Table 1-4 on page 1-6 and Table 1-5 on page 1-9 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 f ow sequence for an ImageReady Pacing 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 Pacing System.
3. Electrophysiologist/cardiologist determines patient eligibility for scan per the information in this Technical Guide.
4. If the patient is eligible, the PRM is used to put the pulse generator in MRI Protection Mode as close in time to the scan as reasonable. The MRI Protection Settings Report is printed, placed in the patient's f le, and provided to radiology personnel. The report documents MRI 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. Each lead implanted in the patient is identif ed, and this information is communicated to the HCPs involved in performing the MRI scan.
5. The radiologist checks the patient f le and/or printed report. If the Time-out feature is used, the radiologist verif es that adequate time remains to complete the scan.
6. Patient undergoes scan according to the protocol outlined in this chapter.
7. The pulse generator is returned to pre-MRI operation, either automatically if the Time-out parameter was set, or manually using the PRM. Follow-up testing of the pacing system may be performed.

MRI PROTECTION MODE GENERAL INFORMATION

Prior to the patient undergoing an MRI scan, an ImageReady MR Conditional Pacing System must be programmed to the MRI Protection Mode using the PRM (see Table 2-1 on page 2-4). In MRI Protection Mode:

- Pacing mode options include asynchronous pacing or no pacing (DOO, AOO, VOO, or Off). Off should only be used if the patient is judged to be clinically capable of receiving no pacing during the time the pulse generator will be in MRI Protection Mode, including during the scan.

  The programmed pacing mode prior to entry into MRI Protection Mode determines the default MRI Protection pacing mode. For example, if MRI Protection Mode is entered from DDD(R), the pacing mode will be DOO. Any of the other pacing mode options may then be selected.

  WARNING: The Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as def ned 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: If the pulse generator enters Safety Mode from MRI Protection Mode, backup pacing will not occur in the following scenarios:

  – if a functional bipolar ventricular pacing lead is not present

  – if the Pacing Mode under MRI Protection Mode settings is programmed to Off; the pulse generator will continue permanently with the Pacing Mode programmed to Off, and the patient will not receive pacing therapy until the pulse generator is replaced

- The Lower Rate Limit is nominally set to 20 min^{-1} above the starting LRL, and is programmable in normal increments. For both the nominal setting based on the LRL and the programmable setting, the maximum value is 100 min^{-1}.

- Atrial pulse amplitude and ventricular pulse amplitude are nominally set to 5.0 V and are programmable in normal increments between 2.0 V and 5.0 V.

  WARNING: Use caution when programming the MRI Protection Mode pacing amplitude for pacing-dependent patients who have high pacing thresholds (> 2.0 V). Programming pacing amplitude below 5.0 V is provided as an option in case of extracardiac stimulation (for example, diaphragmatic stimulation for RV pacing). If pacing amplitude is programmed below 5.0 V, an appropriate safety margin (2X the pacing threshold + 1.0 V) should be maintained. An inadequate safety margin may result in loss of capture.

- AV Delay is f xed at 100 ms

- Pulse width is f xed at 1.0 ms for both chambers

- A Time-out feature is nominally set to 24 hours, with programmable values of Off, 12, 24, and 48 hours

  WARNING: Exit MRI Protection Mode after MRI scanning is completed. If the MRI Protection Time-out value of Off is selected, the pulse generator will remain permanently in the MRI Protection Mode until it is programmed otherwise. Prolonged use of the MRI Protection Mode (such as may occur when the Time-out feature is programmed to Off) may increase the rate of battery depletion. In addition, prolonged exposure of a patient to the XOO mode chosen may be deleterious to the patient's health.

  NOTE: *Twenty-four hours in MRI Protection Mode (with pacing on) reduces pulse generator longevity by approximately 5 days.*

  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 pacing parameters required for MR Conditional scanning, in conjunction with the physical conditions required during a scan (for example, prolonged time in a supine position).

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

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

- PaceSafe RV automatic capture
- PaceSafe RA automatic threshold
- Cardiac sensing
- 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 pacing. 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 Core. Safety Core pacing mode 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.

Table 2-1. MRI Protection Parameters

Parameter	Programmable Values	Nominal
MRI Brady Mode	Off; VOO; AOO; DOO	DOO for DDD(R), DDI(R), or DOO normal Brady modes; VOO for VDD(R), VVI(R), or VOO normal Brady modes; AOO for AAI(R) or AOO normal Brady Mode; Off for Normal Brady Mode Off
MRI Lower Rate Limit (LRL) (min^{-1})	30; 35; ...; 100	20 min^{-1} above the normal mode LRL
MRI Atrial Amplitude (V)	2.0; 2.1; …; 3.5; 4.0; …; 5.0	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)[a]
MRI Ventricular Amplitude (V)	2.0; 2.1; …; 3.5; 4.0; …; 5.0	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)[a]
MRI Protection Time-out (hours)	Off; 12; 24; 48	24

a. During the transition into the MRI Protection Mode, it may take up to 6 cardiac pacing cycles for the pace amplitude to meet the specif ed tolerance range.

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 2-5)

2. Conf rm the MRI scanner settings and conf gurations ("2. Conf rming MRI Scanner Settings and Conf guration" on page 2-13)

3. Prepare the patient for the scan ("3. Preparing the Patient for the Scan" on page 2-14)

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 Device Mode button to enable MRI Protection Mode.

The user chooses whether to Cancel Changes or Apply Changes to proceed with entry into MRI Protection Mode (Figure 2-1 on page 2-5).

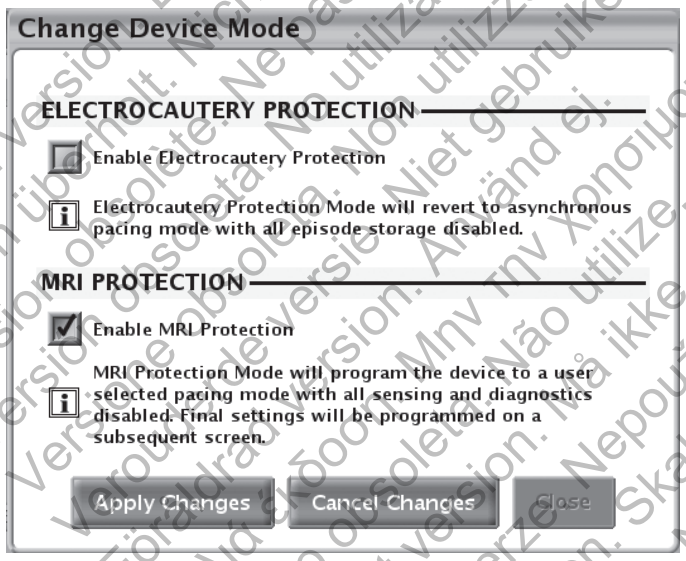


Figure 2-1. Change Device Mode dialog

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 mode
- Unipolar pacing conf guration in chamber(s) where pacing will occur in MRI Protection 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 2-2 on page 2-6.

Figure 2-2. Episode in progress attention message

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. 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 on page 1-6). The dialog provides the option of activating 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 2-3 on page 2-6.

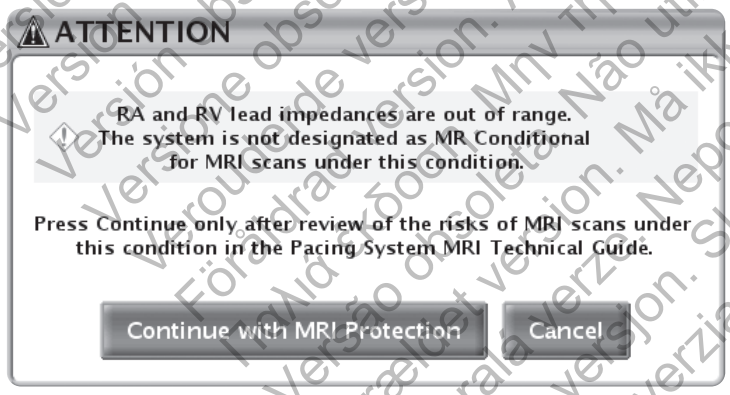


Figure 2-3. Lead impedance out of range attention message

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 on page 1-6). The dialog provides the option of activating MRI Protection Mode in the presence of these conditions, or cancelling entry into MRI Protection Mode.

Upon continuing with entry into MRI Protection Mode, the MRI Protection Checklist screen is displayed (Figure 2-4 on page 2-7). 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-verif cation 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 on page 1-6 and Table 1-5 on page 1-9.

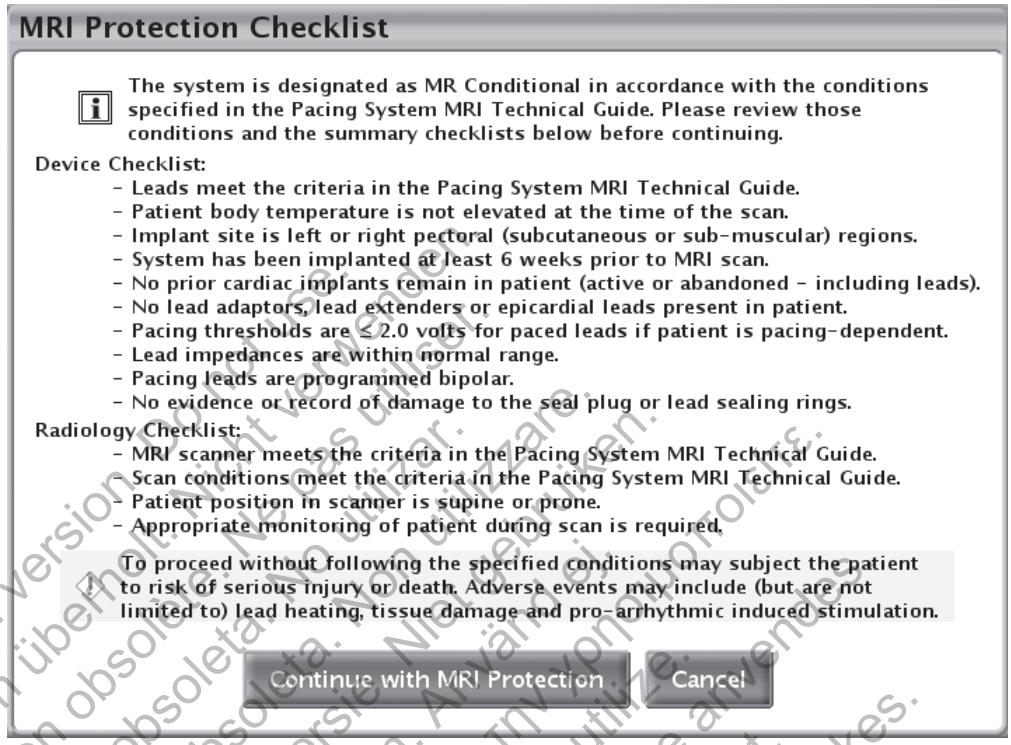


Figure 2-4. MRI Protection Checklist

If the Conditions of Use as summarized in the checklist on the programmer screen are not met, the Cancel button is selected to return to normal system operation, 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 on page 1-6 and Table 1-5 on page 1-9 for additional information about risks), the Continue with MRI Protection button is selected. As a result, the Program MRI Protection screen appears (Figure 2-5 on page 2-9).

Use the dialog boxes to set the:

- Pacing mode (DOO, VOO, AOO, Off)
- Lower rate limit (nominally set 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 amplitude (nominally set to 5.0 V, programmable in normal increments from 2.0 V to 5.0 V)

- Ventricular amplitude (nominally set to 5.0 V, programmable in normal increments from 2.0 V to 5.0 V)

  WARNING: Use caution when programming the MRI Protection Mode pacing amplitude for pacing-dependent patients who have high pacing thresholds (> 2.0 V). Programming pacing amplitude below 5.0 V is provided as an option in case of extracardiac stimulation (for example, diaphragmatic stimulation for RV pacing). If pacing amplitude is programmed below 5.0 V, an appropriate safety margin (2X the pacing threshold + 1.0 V) should be maintained. An inadequate safety margin may result in loss of capture.

- MRI Protection Time-out (nominally set to 24 hours, programmable values of Off, 12, 24, and 48 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 returns 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 1-4).

NOTE: *Any subsequent interrogation by a PRM while the device is still in MRI Protection Mode will reset the Time-out feature to the start of the initially selected time period.*

WARNING: If the MRI Protection Time-out value of Off is combined with a Pacing Mode of Off, the patient will not receive pacing until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.

WARNING: If the pulse generator enters Safety Mode from MRI Protection Mode, backup pacing will not occur in the following scenarios:

- if a functional bipolar ventricular pacing lead is not present
- if the Pacing Mode under MRI Protection Mode settings is programmed to Off; the pulse generator will continue permanently with the Pacing Mode programmed to Off, and the patient will not receive pacing therapy until the pulse generator is replaced

WARNING: Exit MRI Protection Mode after MRI scanning is completed. If the MRI Protection Time-out value of Off is selected, the pulse generator will remain permanently in the MRI Protection Mode until it is programmed otherwise. Prolonged use of the MRI Protection Mode (such as may occur when the Time-out feature is programmed to Off) may increase the rate of battery depletion. In addition, prolonged exposure of a patient to the XOO mode chosen may be deleterious to the patient's health.

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 pacing parameters required for MR Conditional scanning, in conjunction with the physical conditions required during a scan (for example, prolonged time in a supine position).

CAUTION: If the MR Conditional Pacing System enters Safety Core Operation during MRI Protection Mode and the pacing mode was set to a value other than Off, MRI Protection Mode pacing will be automatically switched to VOO mode, RV bipolar conf guration (sensing and pacing), 5.0 V pace pulse amplitude, 1.0 ms pulse width, and 72.5 min^{-1} pacing rate as the safety mode.

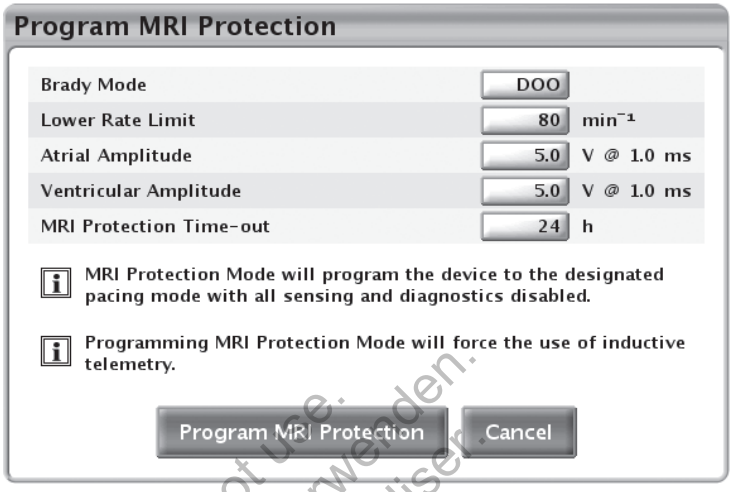


Figure 2-5. Program MRI Protection dialog

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 2-15).*

After the values are chosen, the Program MRI Protection button is selected. Selection of the Program MRI Protection button triggers two additional tests: Previous Pacing Threshold and Pacing Lead Conf guration. If the results indicate that the Previous Pacing Threshold is less than or equal to 2.0 V and the Pacing Lead Conf guration is bipolar, the device enters MRI Protection Mode and the MRI Protection Mode Programmed screen (Figure 2-7 on page 2-10) appears. The two tests are described below.

Previous Pacing Threshold

The most recently recorded pacing threshold test results (whether from a commanded or automatic test) are used by the programmer to determine if pacing thresholds are less than or equal to 2.0 V, a Condition of Use applicable to pace-dependent patients. Thresholds greater than 2.0 V may result in an insuff cient safety margin and failure to capture in MRI Protection Mode (see Table 1-4 on page 1-6). If the threshold is greater than 2.0 V, an attention message appears on the PRM screen advising the user to review the risks of proceeding (Figure 2-6 on page 2-10). Running these tests prior to programming the device to MRI Protection Mode will ensure that the most up-to-date information is used to determine whether this Condition of Use is satisf ed.

NOTE: *Threshold values available for leads that are not enabled for Daily Measurements will only be as current as the date of the last commanded test. Lack of a pace threshold attention message when MRI Protection Mode is programmed does not mean that all leads have threshold values of 2.0 V or lower.*

WARNING: Use caution when programming the MRI Protection Mode pacing amplitude for pacing-dependent patients who have high pacing thresholds (> 2.0 V). Programming pacing amplitude below 5.0 V is provided as an option in case of extracardiac stimulation (for example, diaphragmatic stimulation for RV pacing). If pacing amplitude is programmed below 5.0 V, an appropriate safety margin (2X the pacing threshold + 1.0 V) should be maintained. An inadequate safety margin may result in loss of capture.

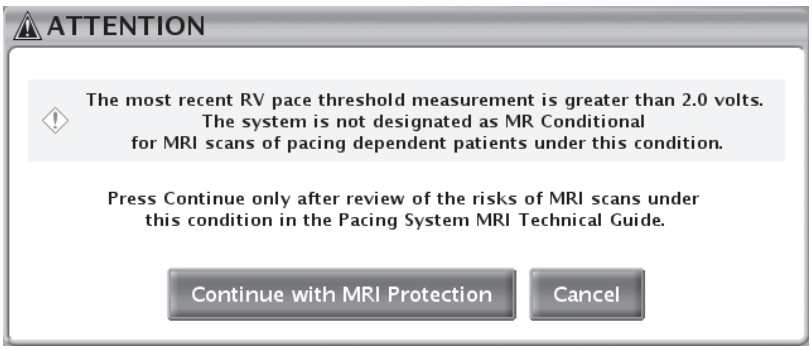


Figure 2-6. Pacing threshold greater than 2.0 V attention message

Pacing Lead Configuration

Upon programming parameters for MRI Protection Mode, the device also checks the pacing lead conf guration to conf rm that it is bipolar in chambers where pacing will occur in MRI Protection Mode. If the lead(s) to be used for pacing while in MRI Protection Mode are programmed to a unipolar pacing conf guration, entry into MRI Protection Mode is denied, since the device does not meet the Condition of Use related to bipolar pacing (see Table 1-4 on page 1-6). In order to proceed, program any lead that will be used to pace in the MRI Protection Mode to bipolar or choose a pacing mode of Off.

If threshold tests are within range and the pacing conf guration is bipolar in chambers where pacing will occur in MRI Protection Mode, or if the user elects to continue with MRI Protection Mode after reviewing the risks of proceeding in the presence of pacing thresholds greater than 2.0 V, the following screen appears, indicating that the device has successfully been programmed into MRI Protection Mode at the settings indicated (Figure 2-7 on page 2-10).

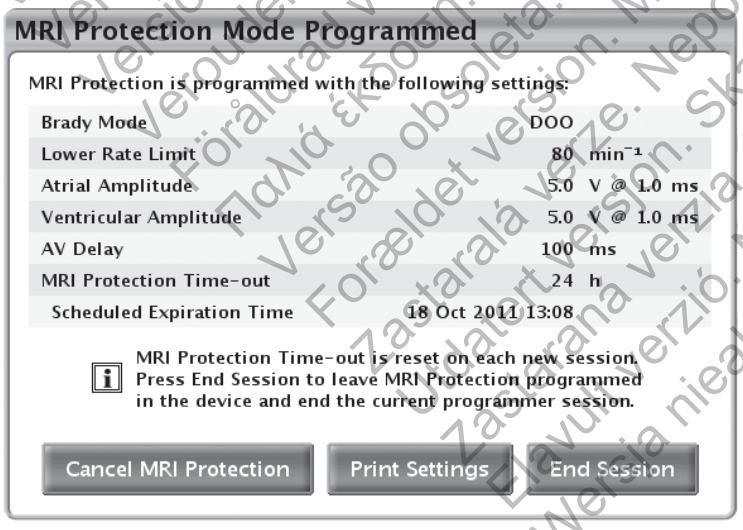


Figure 2-7. MRI Protection Mode Programmed dialog

To exit MRI Protection Mode manually, select the Cancel MRI Protection button (see Manual Exit from MRI Protection Mode in "After the Scan" on page 2-15). If necessary, STAT PACE or DIVERT THERAPY can also be used to exit MRI Protection Mode and return the pulse generator to previously programmed settings (DIVERT THERAPY) or initiate STAT PACE pacing parameters (see the pulse generator Reference Guide for more information about STAT PACE).

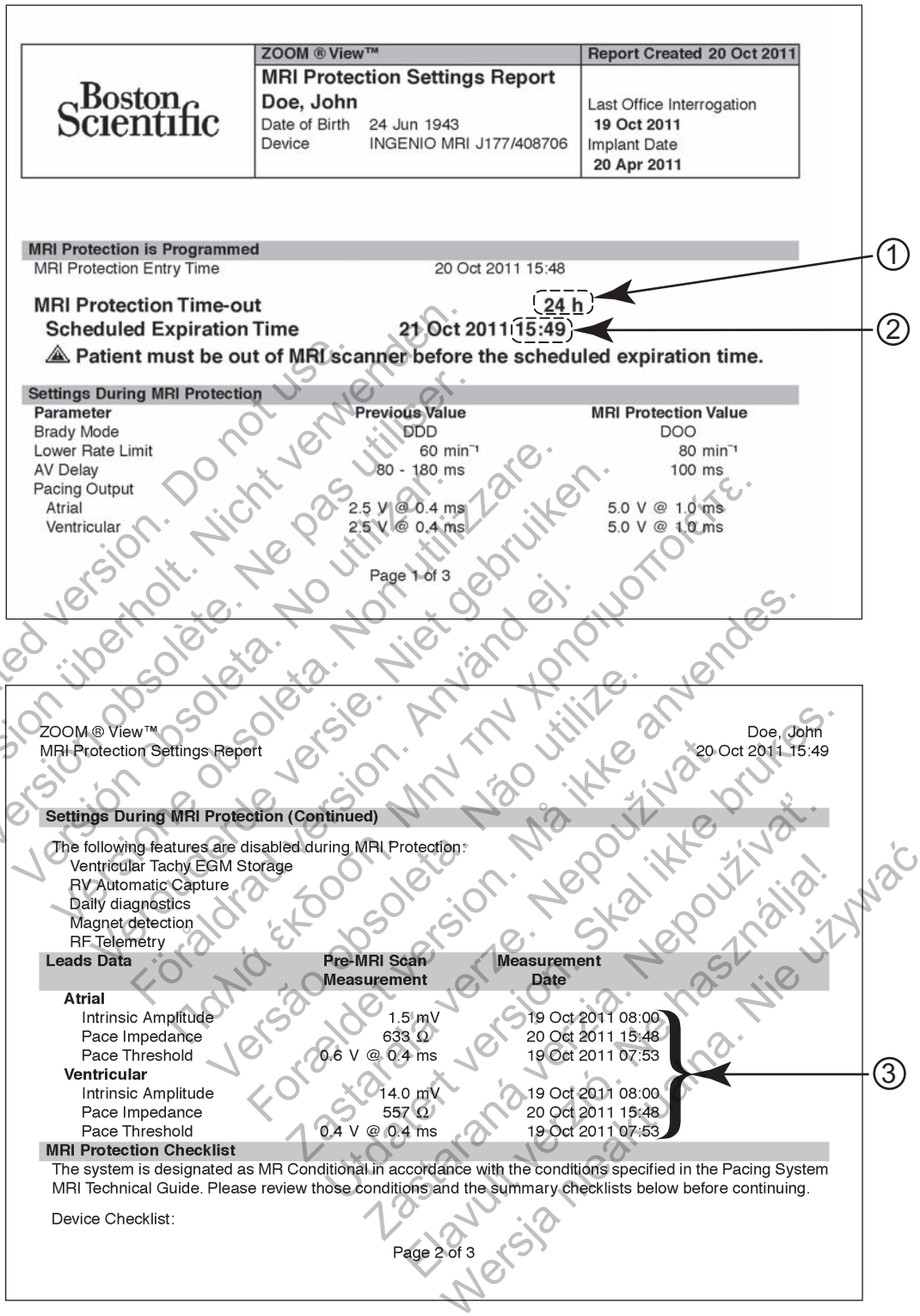
Once MRI Protection Mode has successfully been programmed, print a copy of the MRI Protection Settings Report by selecting the Print Settings button on the MRI Protection Mode Programmed screen. The report lists the settings in operation during MRI Protection Mode. If the

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 f le and used by radiology personnel, for example, to conf rm that suff cient time remains to complete the MRI scan. A sample Settings Report and checklist printout is shown in Figure 2-8 on page 2-12 and Figure 2-9 on page 2-13.

Ensure that the HCPs involved in performing the MRI scan have received the identif cation 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 1-4).



Boston Scientific

ZOOM ® View™ | Report Created 20 Oct 2011

MRI Protection Settings Report
Doe, John
Date of Birth 24 Jun 1943
Device INGENIO MRI J177/408706

Last Office Interrogation
19 Oct 2011
Implant Date
20 Apr 2011

MRI Protection is Programmed
MRI Protection Entry Time 20 Oct 2011 15:48

MRI Protection Time-out **24 h** ①
Scheduled Expiration Time **21 Oct 2011 15:49** ②
⚠ **Patient must be out of MRI scanner before the scheduled expiration time.**

Settings During MRI Protection

Parameter	Previous Value	MRI Protection Value
Brady Mode	DDD	DOO
Lower Rate Limit	60 min⁻¹	80 min⁻¹
AV Delay	80 - 180 ms	100 ms
Pacing Output		
Atrial	2.5 V @ 0.4 ms	5.0 V @ 1.0 ms
Ventricular	2.5 V @ 0.4 ms	5.0 V @ 1.0 ms

Page 1 of 3

ZOOM ® View™ Doe, John
MRI Protection Settings Report 20 Oct 2011 15:49

Settings During MRI Protection (Continued)

The following features are disabled during MRI Protection:
- Ventricular Tachy EGM Storage
- RV Automatic Capture
- Daily diagnostics
- Magnet detection
- RF Telemetry

Leads Data	Pre-MRI Scan Measurement	Measurement Date
Atrial		
Intrinsic Amplitude	1.5 mV	19 Oct 2011 08:00
Pace Impedance	633 Ω	20 Oct 2011 15:48
Pace Threshold	0.6 V @ 0.4 ms	19 Oct 2011 07:53
Ventricular		
Intrinsic Amplitude	14.0 mV	19 Oct 2011 08:00
Pace Impedance	557 Ω	20 Oct 2011 15:48
Pace Threshold	0.4 V @ 0.4 ms	19 Oct 2011 07:53

③

MRI Protection Checklist

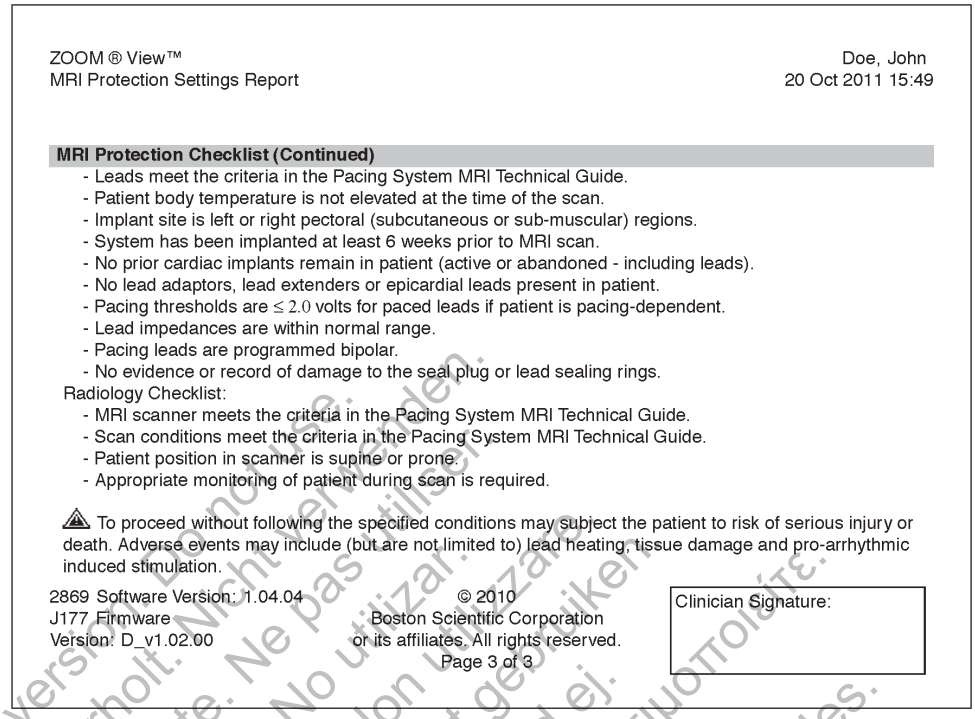
The system is designated as MR Conditional in accordance with the conditions specified in the Pacing System MRI Technical Guide. Please review those conditions and the summary checklists below before continuing.

Device Checklist:

Page 2 of 3

[1] If MRI Protection Time-out is displayed as “Off”, the pulse generator remains in MRI Protection Mode until manually reprogrammed; [2] Twenty-four hour time format is used; [3] Column indicates date measurement was taken

Figure 2-8. Sample settings report and checklist printout



ZOOM ® View™ Doe, John
MRI Protection Settings Report 20 Oct 2011 15:49

MRI Protection Checklist (Continued)

- Leads meet the criteria in the Pacing System MRI Technical Guide.
- Patient body temperature is not elevated at the time of the scan.
- Implant site is left or right pectoral (subcutaneous or sub-muscular) regions.
- System has been implanted at least 6 weeks prior to MRI scan.
- No prior cardiac implants remain in patient (active or abandoned - including leads).
- No lead adaptors, lead extenders or epicardial leads present in patient.
- Pacing thresholds are ≤ 2.0 volts for paced leads if patient is pacing-dependent.
- Lead impedances are within normal range.
- Pacing leads are programmed bipolar.
- No evidence or record of damage to the seal plug or lead sealing rings.

Radiology Checklist:

- MRI scanner meets the criteria in the Pacing System MRI Technical Guide.
- Scan conditions meet the criteria in the Pacing System MRI Technical Guide.
- Patient position in scanner is supine or prone.
- Appropriate monitoring of patient during scan is required.

⚠ 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.

2869 Software Version: 1.04.04
J177 Firmware Version: D_v1.02.00

Page 3 of 3

Clinician Signature:

Figure 2-9. Sample settings report and checklist printout (Cont.)

The End Session button will end the current programmer session with the pulse generator remaining in MRI Protection Mode (Figure 2-10 on page 2-13).

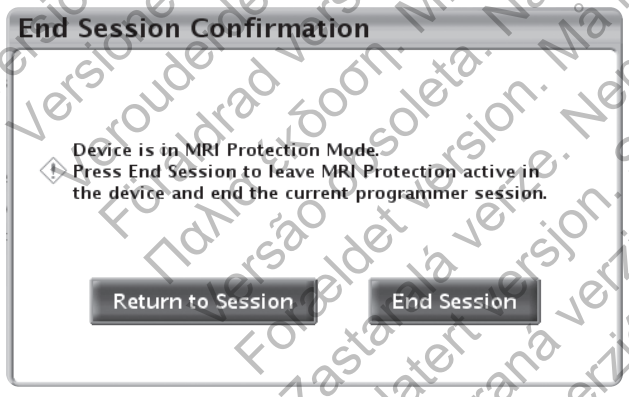


Figure 2-10. End Session Confirmation dialog

2. Confirming MRI Scanner Settings and Configuration

Ensure that the MRI scanner equipment meets the "MRI Conditions of Use" on page 1-4. Only horizontal, closed bore, 1.5 T or 3 T ^{1}H proton MRI scanners can be used, based on the implanted system components.

- For scans with FINELINE II leads, the MRI scanner must be set to Normal Operating Mode.
- For scans with INGEVITY MRI leads, the scanner must be set to Normal Operating Mode or First Level Controlled Operating Mode.

Refer to Table 2-2 on page 2-14 for component combinations.

Valid Combinations of Pulse Generators and Leads to Use in 1.5 T and 3 T Environments

Table 2-2. Valid Combinations of Pulse Generators and Leads to Use in 1.5 T and 3 T Environments

	FINELINE II Leads[a]	INGEVITY MRI Leads[b]
ADVANTIO MRI Pulse Generator **INGENIO MRI Pulse Generator** **VITALIO MRI Pulse Generator** **FORMIO MRI Pulse Generator**	1.5 T scanner only. 3 T scanner not allowed.	1.5 T scanner only. 3 T scanner not allowed.
ESSENTIO MRI Pulse Generator **PROPONENT MRI Pulse Generator** **ACCOLADE MRI Pulse Generator**	1.5 T scanner only. 3 T scanner not allowed.	1.5 T or 3 T scanner allowed.

a. For FINELINE II leads, ensure the MRI scanner is operated in Normal Operating Mode (NOT in First Level Controlled Operating Mode).
b. For INGEVITY MRI leads, ensure the MRI scanner is operated in Normal Operating Mode or First Level Controlled Operating Mode.

WARNING: The combined use of a **FINELINE II** lead and an **INGEVITY MRI** lead with a Boston Scientif c MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady MR Conditional Pacing System.

WARNING: Only the combination of INGEVITY MRI lead(s) with an ESSENTIO MRI, PROPONENT MRI, or ACCOLADE MRI pulse generator is valid to use with **either 1.5 T or 3 T scanners**. All other allowable combinations of Boston Scientif c MR Conditional system components must use **only 1.5 T scanners**.

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/or ECG).

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 2-8 on page 2-12.

NOTE: *If the time remaining is not sufficient for the patient to undergo the MRI scan, re-interrogation of the device will reset the Time-out value to the start of the originally programmed timer setting.*

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 1-4).

Image distortion must be considered when planning an MRI scan, and when interpreting MRI images of f elds 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/or ECG, must be monitored for the duration of the scan.

WARNING: Ensure that an external def brillator and medical personnel skilled in cardio-pulmonary resuscitation (CPR) are present during the MRI scan should the patient require external rescue.

AFTER THE SCAN

WARNING: Exit MRI Protection Mode after MRI scanning is completed. If the MRI Protection Time-out value of Off is selected, the pulse generator will remain permanently in the MRI Protection Mode until it is programmed otherwise. Prolonged use of the MRI Protection Mode (such as may occur when the Time-out feature is programmed to Off) may increase the rate of battery depletion. In addition, prolonged exposure of a patient to the XOO mode chosen may be deleterious to the patient's health.

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, system integrity may be checked by running lead impedance, pacing threshold, and intrinsic amplitude tests.

Upon exit from MRI Protection Mode, all parameters are immediately restored to pre-MRI Protection Mode values with two exceptions. If PaceSafe Automatic Capture (RVAC) was programmed on, this feature enters suspension upon entry of the device into MRI Mode. Upon exit from MRI Protection Mode, RV pace amplitude is set to two times the last capture threshold determined by the RVAC feature before it entered suspension (output limited to between 3.5 V and 5.0 V). After the next scheduled autothreshold test runs (within the next 21 hours) and is successful, the RV pace amplitude is set to the new capture threshold plus 0.5 V. This behavior was designed to provide a safety margin against loss of capture during the transient period between MRI completion and full body recovery from effects of the scanner electromagnetic fields.

For details about the PaceSafe Automatic Capture feature, see the Reference Guide for the pulse generator.

Restoration of function of the Minute Ventilation sensor is also delayed upon exit from MRI Protection Mode. If MV is programmed to On or Passive at the time of entry into MRI 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.

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 (for details about the resumption of PaceSafe Automatic Capture and Minute Ventilation, see "After the Scan" on page 2-15).

Manual Exit from MRI Protection Mode

Alternatively, if the Time-out feature was programmed Off, 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. MRI Protection Mode pacing is performed at a fixed, elevated rate. Some patients may experience side effects during protracted pacing in this mode, including decreased exercise capacity, acceleration of heart failure, and proarrhythmia.

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

- Select the Cancel MRI Protection Mode button from the MRI Protection Mode Programmed screen (Figure 2-11 on page 2-16)

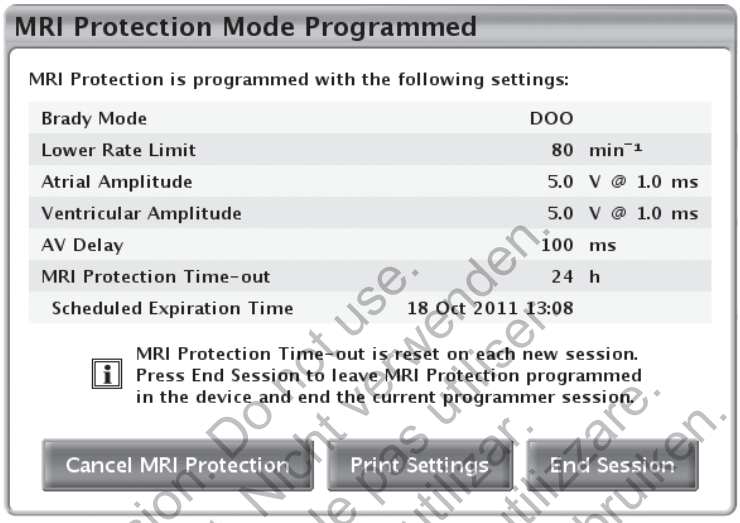


Figure 2-11. MRI Protection Mode Programmed (Cancel MRI Protection)

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 2-12 on page 2-16):

- Lead impedance
- Pacing threshold
- Intrinsic amplitude

These tests may be performed subsequent to automatic (Time-out) exit from MRI Protection Mode as well.

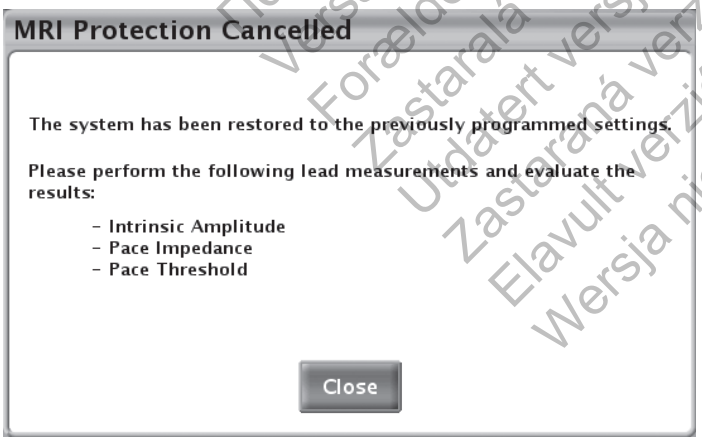


Figure 2-12. MRI Protection Cancelled dialog

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 using the PRM printer. The MRI Protection episode can also be accessed and viewed via the Arrhythmia Logbook. A sample stored event detail printout is shown in Figure 2-13 on page 2-17.

The MRI episode can also be viewed on the Arrhythmia Logbook via remote patient monitoring (if available).

Boston Scientific

ZOOM ® View™

Selected Episodes Report

Doe, John

Date of Birth 24 Jun 1943

Device INGENIO MRI J177/408706

Report Created 20 Oct 2011

Last Office Interrogation
19 Oct 2011
Implant Date
20 Apr 2011

Event MRI-3: 20 Oct 2011 15:48

Settings During MRI Protection		
Brady Mode	DOO	
Lower Rate Limit	80 min^{-1}	
AV Delay	100 ms	
Pacing Output		
Atrial	5.0 V @ 1.0 ms	
Ventricular	5.0 V @ 1.0 ms	
Ventricular Tachy EGM Storage	Off	
MRI Protection Time-out	24 h	
Leads Data (most recent pre-MRI scan measurements)		
Atrial		
Intrinsic Amplitude	1.5 mV	19 Oct 2011 08:00
Pace Impedance	633 Ω	20 Oct 2011 15:48
Pace Threshold	0.6 V @ 0.4 ms	19 Oct 2011 07:53
Ventricular		
Intrinsic Amplitude	14.0 mV	19 Oct 2011 08:00
Pace Impedance	557 Ω	20 Oct 2011 15:48
Pace Threshold	0.4 V @ 0.4 ms	19 Oct 2011 07:53
MRI Protection Exit Status	User Terminated	
MRI Protection Exit Time	20 Oct 2011 15:50	

Event Ended 00:01:22

2869 Software Version: 1.04.04
J177 Firmware Version: D_v1.02.00

Page 1 of 1

Clinician Signature:

Figure 2-13. Sample stored event detail printout

SYMBOLS ON PACKAGING

APPENDIX A

SYMBOLS ON PACKAGING

The following symbols may be used on packaging and labeling.

Table A-1. Symbols on Packaging

Symbol	Description
CE 0086	CE mark of conformity with the identif cation of the notif ed body authorizing use of the mark
EC REP	Authorized Representative in the European Community
	Manufacturer
MR	MR Conditional

INDEX

R

S

T

U

V

Z

Boston Scientific

Boston Scientif c
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

EC REP
Guidant Europe NV/SA; Boston Scientif c
Green Square, Lambroekstraat 5D
1831 Diegem, Belgium

www.bostonscientif c.com

1.800.CARDIAC (227.3422)

+1.651.582.4000

359259-018 EN Europe 2014-02

CE0086