Boston Scientific

MRI TECHNICAL GUIDE

⚠ 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, U128, U228, 4456, 4457, 4458, 4459, 4469, 4470, 4471, 4472, 4473, 4474, 4479, 4480, 4603, 4671, 4672, 4674, 4675, 4677, 4678, 6220, 6221, 6402, 7145, 7148, 7731, 7732, 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 Pacing System, as well as radiologists and other HCPs involved in performing magnetic resonance imaging (MRI) scans on such patients.

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

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

This manual contains:

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

How to use this manual:

1. Refer to the patient's records to locate model numbers for all components of the patient's implanted system.
2. Refer to "System Configuration for 1.5 T" on page 1-3 and "System Configuration for 3 T" on page 1-3 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 Pacing 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 Pacing System.

NOTE: *Multiple Programming Systems are available for use based on software and regional availability, and they include different programming devices such as the Model 3120 Programmer/Recorder/Monitor (PRM) and the Model 3300 Programmer. Hereafter in this manual, Programmer refers to the applicable programming device associated with the Programming System available for the patient. Consult the appropriate Physician's Technical Manual and Operator's Manual for details.*

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INTRODUCTION TO MR CONDITIONAL PACING

CHAPTER 1

This chapter contains the following topics:

SYSTEM DESCRIPTION

An ImageReady MR Conditional Pacing System consists of specific Boston Scientific model components including pacemaker or cardiac resynchronization therapy pacemaker (CRT-P) 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. Additionally, an MRI Protection Mode has been created for use during the scan. MRI Protection Mode modifies 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 specified in this Technical Guide.

Only specific 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 **1.5 T** or **3 T** scanners. For the model numbers of MR Conditional Pacing System components, see Table 1–3 System Configuration for 1.5 T on page 1-3 and Table 1–4 System Configuration for 3 T on page 1-3.

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

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

The following devices are no longer placed on the EU market, and no longer carry an active CE Mark: FORMIO MRI, VITALIO MRI, INGENIO MRI, and ADVANTIO MRI. These devices and the MR Conditional systems they are a part of continue to be supported by Boston Scientific. In the following table, the systems that contain these devices are highlighted in gray.

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

	INGEVITY MRI / INGEVITY+ Leads only	FINELINE II Leads only	Combination of one INGEVITY MRI / INGEVITY+ Lead and one FINELINE II Lead
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. *Normal Operating Mode or First Level Controlled Operating Mode.*	1.5 T scanner only. 3 T scanner not allowed. *Normal Operating Mode only.*	1.5 T scanner only. 3 T scanner not allowed. *Normal Operating Mode only.*
ESSENTIO MRI Pulse Generator **PROPONENT MRI Pulse Generator** **ACCOLADE MRI Pulse Generator**	1.5 T or 3 T scanner allowed. *Normal Operating Mode or First Level Controlled Operating Mode.*	1.5 T or 3 T scanner allowed. *Normal Operating Mode only.*	1.5 T or 3 T scanner allowed. *Normal Operating Mode only.*

Table 1–2. Valid Combinations of CRT-P Pulse Generators and Leads to Use in 1.5 T and 3 T Environments

	Combination of an ACUITY X4 Lead with INGEVITY MRI / INGEVITY+ Lead(s)	Combination of an ACUITY X4 Lead with FINELINE II Lead(s)	Combination of an ACUITY X4 Lead with one INGEVITY MRI / INGEVITY+ Lead and one FINELINE II Lead
VALITUDE X4 Pulse Generator **VISIONIST X4 Pulse Generator**	1.5 T or 3 T scanner allowed. *Normal Operating Mode only.*		

Refer to Table 1–3 System Configuration for 1.5 T on page 1-3 and Table 1–4 System Configuration for 3 T on page 1-3 for a complete list of the model numbers of MR Conditional Pacing System components.

Refer to "MRI Conditions of Use" on page 1-4 for the entire set of MRI Conditions of Use.

System Configuration for 1.5 T

The following devices are no longer placed on the EU market, and no longer carry an active CE Mark: FORMIO MRI, VITALIO MRI, INGENIO MRI, and ADVANTIO MRI. These devices and the MR Conditional systems they are a part of continue to be supported by Boston Scientific. In the following table, these devices are highlighted in gray.

Table 1–3. System Configuration for 1.5 T

Component	Model Number(s)	MR Status
Pacemaker 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
CRT-P Pulse Generators		
VALITUDE X4 Pulse Generator	U128	MR Conditional
VISIONIST X4 Pulse Generator	U228	MR Conditional
Leads and Accessories		
Right Atrial and Right Ventricular Leads and Accessories		
FINELINE II Sterox Pacing Leads	4456, 4457, 4458, 4459, 4479, 4480	MR Conditional
FINELINE II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional
Suture Sleeve for FINELINE II leads	6220, 6221	MR Conditional
INGEVITY MRI Pacing Leads (Tined Fixation)	7731, 7732, 7735, 7736	MR Conditional
INGEVITY MRI Pacing Leads (Extendable/Retractable Fixation)	7740, 7741, 7742	MR Conditional
INGEVITY+ Pacing Leads (Extendable/Retractable Fixation)	7840, 7841, 7842	MR Conditional
Suture Sleeve for INGEVITY MRI / INGEVITY+ leads	6402	MR Conditional
IS-1 Lead Port Plug	7145	MR Conditional
Left Ventricular Leads and Accessories		
ACUITY X4 (IS4) Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional
Suture Sleeve for ACUITY X4 leads	4603	MR Conditional
IS4 Lead Port Plug	7148	MR Conditional

System Configuration for 3 T

Table 1–4. System Configuration for 3 T

Component	Model Number(s)	MR Status
Pacemaker 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

Table 1–4. System Configuration for 3 T (continued)

Component	Model Number(s)	MR Status
CRT-P Pulse Generators		
VALITUDE X4 Pulse Generator	U128	MR Conditional
VISIONIST X4 Pulse Generator	U228	MR Conditional
Leads and Accessories		
Right Atrial and Right Ventricular Leads and Accessories		
FINELINE II Sterox Pacing Leads	4456, 4457, 4458, 4459, 4479, 4480	MR Conditional
FINELINE II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional
Suture Sleeve for FINELINE II leads	6220, 6221	MR Conditional
INGEVITY MRI Pacing Leads (Tined Fixation)	7731, 7732, 7735, 7736	MR Conditional
INGEVITY MRI Pacing Leads (Extendable/Retractable Fixation)	7740, 7741, 7742	MR Conditional
INGEVITY+ Pacing Leads (Extendable/Retractable Fixation)	7840, 7841, 7842	MR Conditional
Suture Sleeve for INGEVITY MRI / INGEVITY+ leads	6402	MR Conditional
IS-1 Lead Port Plug	7145	MR Conditional
Left Ventricular Leads and Accessories		
ACUITY X4 (IS4) Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional
Suture Sleeve for ACUITY X4 leads	4603	MR Conditional
IS4 Lead Port Plug	7148	MR Conditional

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 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 Pacing 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 Pacing 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. Pulse generator in MRI Protection Mode during scan

3. RA and RV leads programmed to 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 modification of the MR Conditional Pacing System

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

7. 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.

8. RA and RV pacing threshold ≤ 2.0 V in paced leads for pacing-dependent patients

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

1. Horizontal, ^{1}H 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. Specific Absorption Rate (SAR) limits:

   a. For all ImageReady Pacing Systems, 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 ImageReady Pacing Systems utilizing only **INGEVITY MRI** and/or **INGEVITY+** leads (see "Valid Combinations of Pulse Generators and Leads to Use in 1.5 Tesla and 3 Tesla Environments" on page 1-2), SAR limits up to First Level Controlled Operating Mode[2] may be applied for the entire active scan session as follows:

      • Whole body averaged, ≤ 4.0 W/kg

      • Head, ≤ 3.2 W/kg

5. Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis
6. There are no restrictions for positioning the pacing 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 pacing system.
7. Patient in supine or prone position only
8. The patient must be monitored during the MRI scan by pulse oximetry and/or electrocardiography (ECG)

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

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 2-2.

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

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 1-4), ImageReady MR Conditional System patients can undergo MRI scans with risks mitigated to the best current standard of care.

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 1-8.

WARNING: Ensure that an external defibrillator 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: 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 if the patient is judged to be clinically capable of tolerating no Bradycardia therapy and/or no CRT for the entire duration in which the pulse generator is in MRI Protection Mode. It is recommended to have the Programmer powered On near the MRI room in case the patient develops the urgent need for pacing. Certain conditions, including but not limited to the following, may indicate increased risk of developing transient pacing-dependence:

- Intermittent AV block
- Progressive AV block
- Trifascicular block (alternating bundle branch block or PR interval > 200 ms with left bundle branch block [LBBB] or other bifascicular block)

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 an appropriate pacing amplitude 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.

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

- if a functional bipolar right 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

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[3]. 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: 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[3]. Some of the accessories packaged with pulse generators and leads, including the torque wrench and stylet wires, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

Precautions

CAUTION: The physician choosing MRI Protection Mode parameter values will need to exercise professional judgment to determine an individual patient's ability to tolerate the 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, pacing chamber RV only, RV bipolar configuration (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 "Preparing the Patient for the Scan" on page 2-9).

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

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 fixed rate and increased output including reduced exercise capacity, acceleration of heart failure, and competitive pacing/arrhythmia induction
- Syncope
- Worsening heart failure

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

- Arrhythmia induction
- Bradycardia
- Damage to the pulse generator and/or leads
- Erratic pulse generator behavior
- Inappropriate pacing, inhibition of pacing, failure to pace
- Increased rate of lead dislodgement (within six weeks of implant or revision of system)
- Irregular or intermittent capture or pacing
- 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:

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 1-4). 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 1-4) 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 1-8.

PATIENT FLOW

A sample patient flow sequence for an ImageReady Pacing System patient who needs an MRI scan is described below.

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. Electrophysiology/cardiology HCP determines patient eligibility for scan per the information in this Technical Guide[1], and ensures communication of patient eligibility to HCPs involved in performing the MRI scan.
4. The model number of each lead implanted in the patient is identified, and this information is communicated to the HCPs involved in performing the MRI scan to determine the radiology conditions of use.
5. If the patient is eligible, the Programmer is used to put the pulse generator in MRI Protection Mode as close in time to the scan as reasonable. 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.

   For a more detailed description of the programming and scanning procedure, see "Programming the Pulse Generator for a Scan" on page 2-3.
6. The radiologist checks the patient file and/or printed report. If the Time-out feature is used, the radiologist verifies that adequate time remains to complete the scan.
7. Patient undergoes scan according to the conditions of use described in this Technical Guide.
8. The pulse generator is returned to pre-MRI operation, either automatically if the Time-out parameter was set, or manually using the Programmer. Follow-up testing of the pacing system may be performed.

MRI PROTECTION MODE GENERAL INFORMATION

MRI Protection Mode pacing options include asynchronous pacing (DOO, AOO, VOO) or no pacing (Off). 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. 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

1. It is important to confirm pulse generator-lead system integrity before performing an MRI scan. Consider checking for evidence of a fractured lead or compromised pulse generator-lead system integrity by reviewing patient records for the most recent lead impedance values and for a history of noise on EGMs. Review the Daily Measurements on the Leads Status Summary Screen to verify stability over time of pace impedance, pace threshold, and intrinsic amplitude values.

judged to be clinically capable of receiving no pacing during the time the pulse generator is in MRI Protection Mode, including during the scan.

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

- PaceSafe
- 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

NOTE: *Twenty-four hours in MRI Protection Mode (with pacing on) reduces pulse generator longevity by approximately 5 days (pacemaker) or 7 days (CRT-P).*

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.

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 2-3)
2. Confirm the MRI scanner settings and configurations ("Confirming MRI Scanner Settings and Configuration" on page 2-9)
3. Prepare the patient for the scan ("Preparing the Patient for the Scan" on page 2-9)

Programming the Pulse Generator for a Scan

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

NOTE: *See "MR Conditional Pacing System Warnings and Precautions" on page 1-6 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 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).

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 Device Mode button to enable MRI Protection Mode. The Change Device Mode dialog is displayed (Figure 2–1 Change Device Mode dialog on page 2-4).

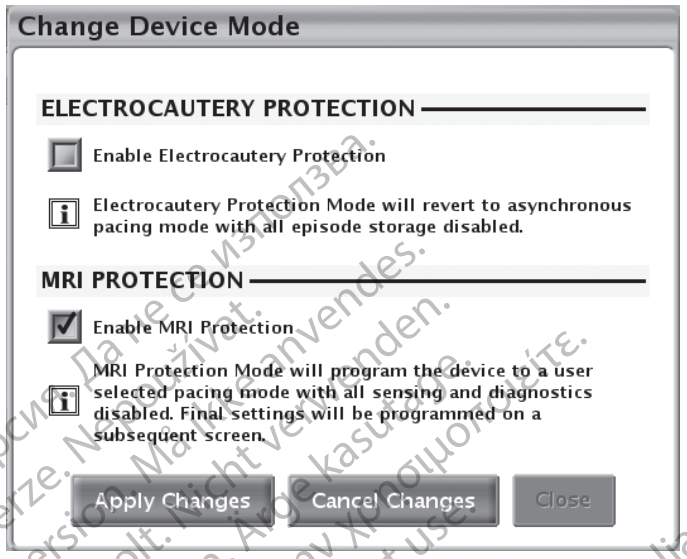


Figure 2–1. Change Device Mode dialog

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

The MRI Protection Checklist screen is displayed (Figure 2–2 MRI Protection Checklist on page 2-4). 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 or previous MRI scan.

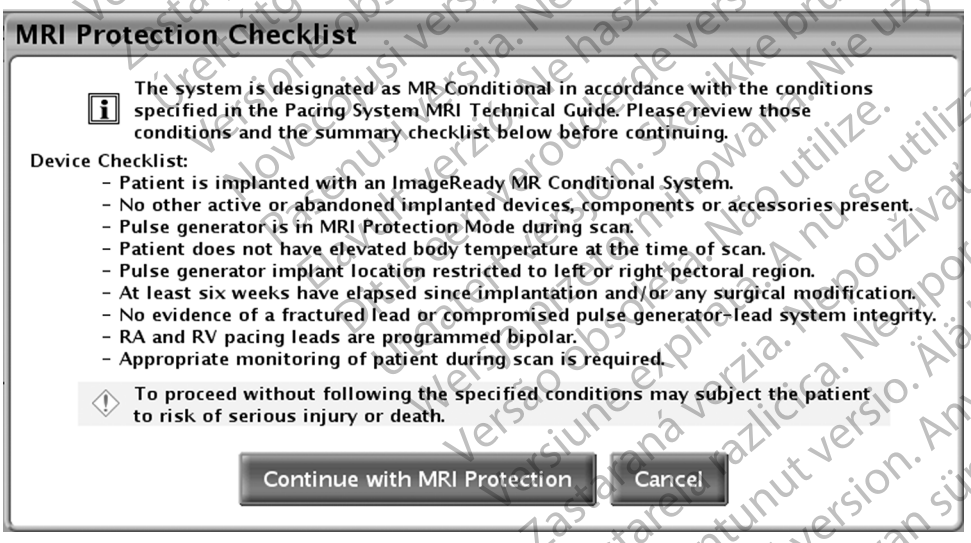


Figure 2–2. MRI Protection Checklist

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 2-5).

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).

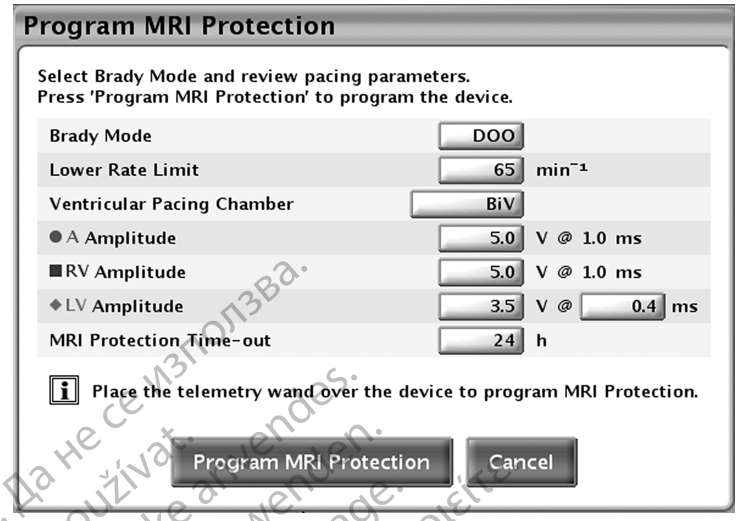


Figure 2-3. Program MRI Protection dialog

The programmed pacing mode prior to entry into MRI Protection Mode determines the default MRI Protection pacing mode. Pacing mode may be set to asynchronous pacing (DOO, AOO, VOO) or no pacing (Off).

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 if the patient is judged to be clinically capable of tolerating no Bradycardia therapy and/or no CRT for the entire duration in which the pulse generator is in MRI Protection Mode. It is recommended to have the Programmer powered On near the MRI room in case the patient develops the urgent need for pacing. Certain conditions, including but not limited to the following, may indicate increased risk of developing transient pacing-dependence:

- Intermittent AV block
- Progressive AV block
- Trifascicular block (alternating bundle branch block or PR interval > 200 ms with left bundle branch block [LBBB] or other bifascicular block)

If an asynchronous pacing mode is selected, program the following parameters.

- 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 an appropriate pacing amplitude safety margin may result in loss of capture.

NOTE: *In CRT-P devices, the RA pace pulse may decay more rapidly in MRI Protection Mode than in normal mode if all 3 chambers (RA, RV, and LV) are simultaneously paced. Pacing amplitude of 5.0 V is recommended to ensure RA 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.*

Set MRI Protection Time-out (nominally set to 24 hours, programmable values of Off, 3, 6, 9, 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 session started with wanded telemetry while the device is still in MRI Protection Mode will reset the Time-out feature to the start of the initially selected time period.*

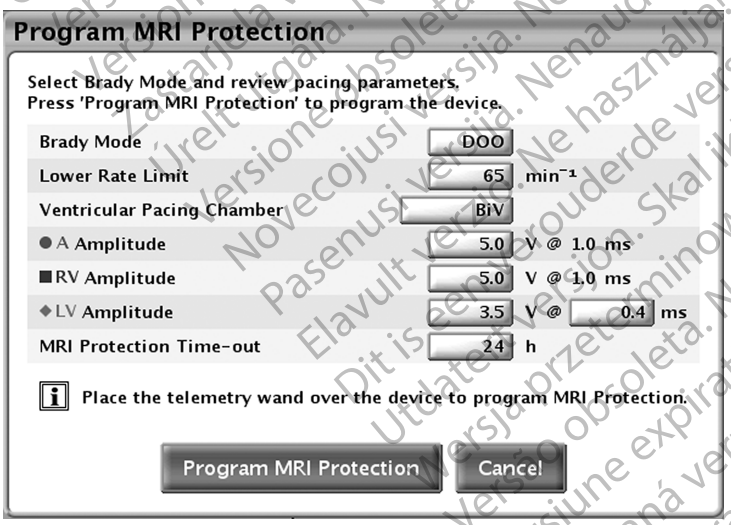


Figure 2–4. Program MRI Protection dialog

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 Mode Programmed dialog on page 2-7). 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.*

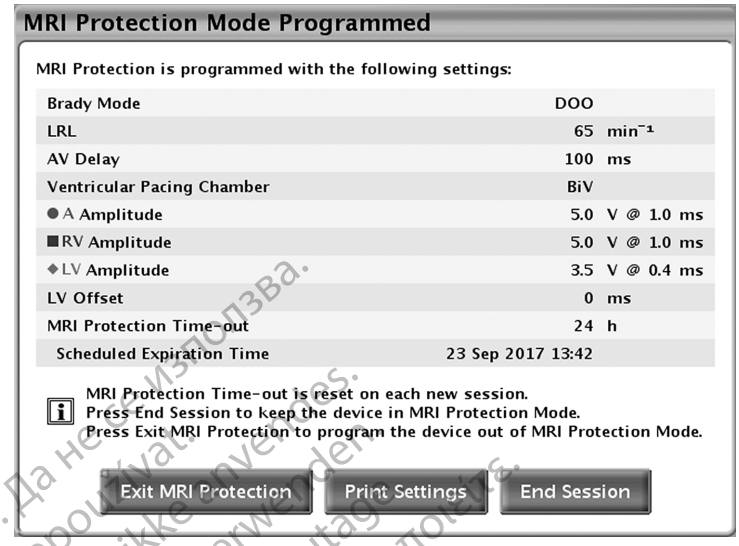


Figure 2–5. MRI Protection Mode Programmed dialog

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

The printed report can be placed in the patient's file and used by radiology personnel, for example, to confirm that sufficient time remains to complete the MRI scan. A sample Settings Report and checklist printout is shown in Figure D–1 Sample MRI Protection Settings Report printout with Time-out set to 24 hours (Pages 1–2) on page D-1 and Figure D–2 Sample MRI Protection Settings Report printout with MRI Protection Checklist (Pages 3–4) (Cont.) on page D-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 2-7).

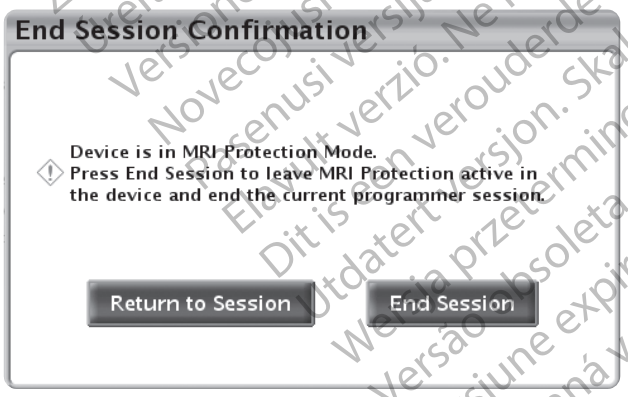


Figure 2–6. End Session Confirmation dialog

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 mode
- Unipolar pacing configuration in the RA or RV 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 2–7 Episode in progress attention message on page 2-8.

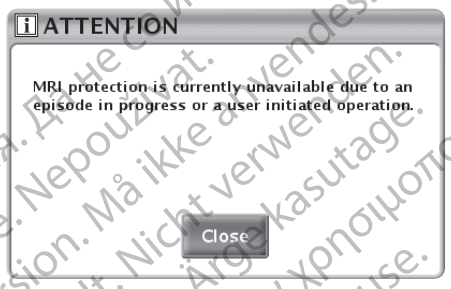


Figure 2–7. Episode in progress attention message

In addition to the above-listed conditions that prevent entry into MRI Protection Mode, the Programmer will assess the following prior to entering MRI Protection Mode.

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

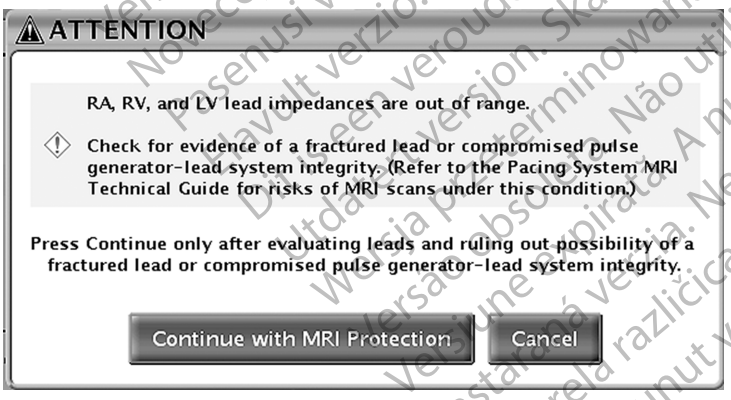


Figure 2–8. Lead impedance out of range attention message

2. **Time Since Implant**

   The Programmer also determines the time since implant, based on the date 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.

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 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 an appropriate pacing amplitude safety margin may result in loss of capture.

Confirming MRI Scanner Settings and Configuration

Ensure that the MRI scanner equipment meets the "MRI Conditions of Use" on page 1-4. See Table 1–3 System Configuration for 1.5 T on page 1-3 and Table 1–4 System Configuration for 3 T on page 1-3 for a complete list of the model numbers of MR Conditional Pacing System components.

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 D–1 Sample MRI Protection Settings Report printout with Time-out set to 24 hours (Pages 1–2) on page D-1.

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).

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). See "MRI Conditions of Use" on page 1-4.

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 Pacing System pulse generator extended approximately 7.9 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 Pacing System lead extended 0.9 cm when testing with gradient-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. Exit can always be performed manually using the Programmer (see Manual Exit from MRI Protection Mode).

For ADVANTIO MRI, INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI, and ACCOLADE MRI 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 D–3 Sample stored event detail printout on page D-3. 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.

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 2–9 MRI Protection Mode Programmed dialog on page 2-10).

NOTE: *If necessary, STAT PACE 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).*

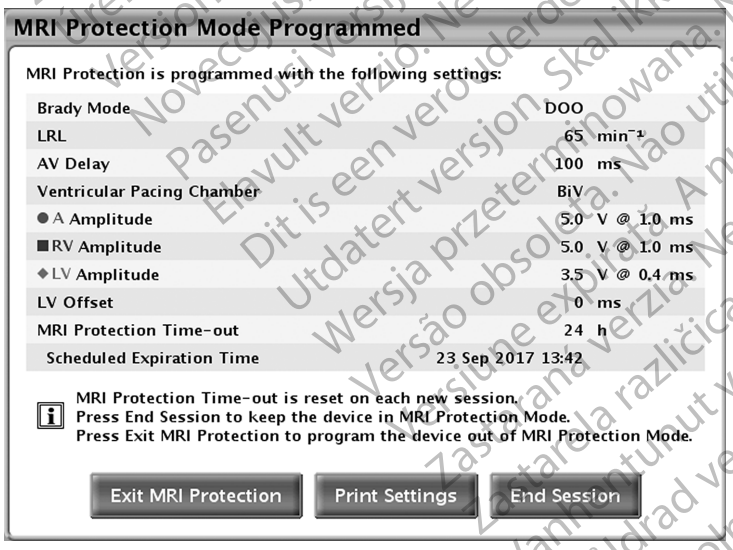


Figure 2–9. MRI Protection Mode Programmed dialog

2. Evaluate Device

After exit from MRI Protection Mode, electrophysiology/cardiology HCP may choose to check system integrity by running lead impedance, pacing threshold, and intrinsic amplitude tests. 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 2–10 MRI Protection Exited dialog on page 2-11).

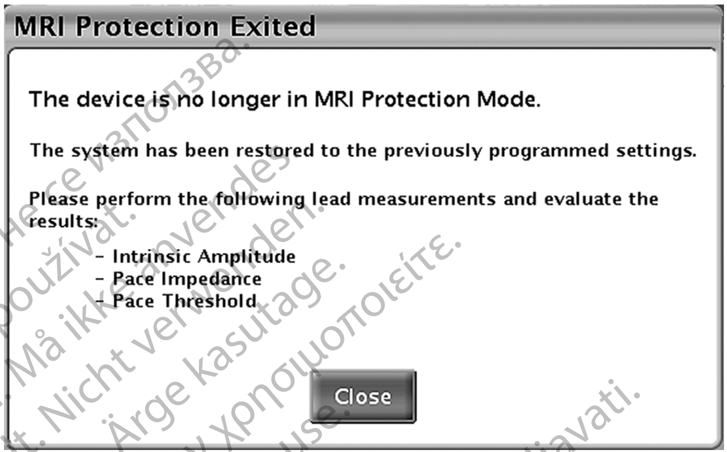


Figure 2–10. MRI Protection Exited dialog

When testing is complete, it is recommended that the Programmer be used to save all patient data.

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

- PaceSafe Automatic Capture (RVAC)
- Minute Ventilation (MV)

If PaceSafe Automatic Capture (RVAC) was programmed on, this feature enters suspension upon entry of the device into MRI Protection 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 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.

CARDIOLOGY CHECKLIST FOR THE IMAGEREADY PACING 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 Pacing System.

Conditions of Use – Cardiology

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

☐ Patient is implanted with an ImageReady MR Conditional Pacing System (see "ImageReady Pacing System Components for 1.5 T and 3 T" on page C-1)

☐ Pulse generator in MRI Protection Mode during scan

☐ RA and RV leads programmed to bipolar pacing operation or pacing off

☐ 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 Pacing System

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

☐ RA and RV pacing threshold ≤ 2.0 V in paced leads for pacing-dependent patients

☐ 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. 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.

3. As close to the start of the scan as possible, program the pulse generator into MRI Protection Mode.

4. Print the MRI Protection Settings Report, place it in the patient's file, and provide to radiology personnel.

- The report documents MRI Protection Mode settings and details. If the Time-out feature is used, the report includes the exact time and date when MRI Protection Mode will expire

During Scan

5. Ensure the patient is monitored by pulse oximetry and/or electrocardiography (ECG), with backup therapy available.

After Scan

6. Ensure the pulse generator is returned to pre-MRI operation, either automatically if the Time-out parameter was set, or manually using the Programmer. Cardiology HCP may choose to perform follow-up testing of the pacing system 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.

RADIOLOGY CHECKLIST FOR THE IMAGEREADY PACING 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 Pacing System.

Conditions of Use – Radiology

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

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

☐ MRI magnet strength of 1.5 T (64 MHz) or 3 T (128 MHz)

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

☐ Specific Absorption Rate (SAR) limits:

- For all ImageReady Pacing Systems, SAR limits for Normal Operating Mode[a] 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
- For ImageReady Pacing Systems utilizing only INGEVITY MRI and/or INGEVITY+ leads (see "Valid Combinations of Pulse Generators and Leads to Use in 1.5 Tesla and 3 Tesla Environments" on page 1-2), SAR limits up to First Level Controlled Operating Mode[b] may be applied for the entire active scan session as follows:
  - Whole body averaged, ≤ 4.0 W/kg
  - Head, ≤ 3.2 W/kg

☐ Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis

☐ There are no restrictions for positioning the pacing 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 pacing system

☐ Patient in supine or prone position only

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

a. As defined in IEC 60601-2-33, 201.3.224, 3rd Edition.
b. As defined in IEC 60601-2-33, 201.3.208, 3rd Edition.

Scanning Procedure

Pre-scan

1. Ensure Cardiology has cleared the patient for scanning eligibility based on the Cardiology MRI Conditions of Use (see "Cardiology Checklist for the ImageReady Pacing System" on page A-1) and has provided the model numbers of the pulse generator and lead (s) implanted in the patient.

2. Ensure patient meets all Radiology Conditions of Use for MRI scanning (see left column).

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 monitored by pulse oximetry and/or electrocardiography (ECG), with backup therapy available.

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. Cardiology HCP may choose to perform follow-up testing of the pacing system 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: 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).

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.

CAUTION: The presence of the implanted Pacing System may cause MRI image artifacts.

IMAGEREADY PACING SYSTEM COMPONENTS FOR 1.5 T AND 3 T

APPENDIX C

Only specific combinations of pulse generators and leads constitute an ImageReady Pacing System. Consult the following tables to determine which combinations are valid for use with **1.5 T** or **3 T scanners**.

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

	INGEVITY MRI / INGEVITY+ Leads only	FINELINE II Leads only	Combination of one INGEVITY MRI / INGEVITY+ Lead and one FINELINE II Lead
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. *Normal Operating Mode or First Level Controlled Operating Mode.*	1.5 T scanner only. 3 T scanner not allowed. *Normal Operating Mode only.*	1.5 T scanner only. 3 T scanner not allowed. *Normal Operating Mode only.*
ESSENTIO MRI Pulse Generator **PROPONENT MRI Pulse Generator** **ACCOLADE MRI Pulse Generator**	1.5 T or 3 T scanner allowed. *Normal Operating Mode or First Level Controlled Operating Mode.*	1.5 T or 3 T scanner allowed. *Normal Operating Mode only.*	1.5 T or 3 T scanner allowed. *Normal Operating Mode only.*

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

	Combination of an ACUITY X4 Lead with INGEVITY MRI / INGEVITY+ Lead(s)	Combination of an ACUITY X4 Lead with FINELINE II Lead(s)	Combination of an ACUITY X4 Lead with one INGEVITY MRI / INGEVITY+ Lead and one FINELINE II Lead
VALITUDE X4 Pulse Generator **VISIONIST X4 Pulse Generator**	1.5 T or 3 T scanner allowed. *Normal Operating Mode only.*		

Table C–3. ImageReady MR Conditional Pacing System Components for 1.5 T and 3 T

Component	Model Number(s)	MR Status	Valid Combinations
Pacemaker Pulse Generators			For valid combinations for 1.5 T and 3 T, see the tables above.
ADVANTIO MRI	J065, J066, J067	MR Conditional	
INGENIO MRI	J175, J176, J177	MR Conditional	
VITALIO MRI	J275, J276, J277	MR Conditional	
FORMIO MRI	J279	MR Conditional	
ESSENTIO MRI	L110, L111, L131	MR Conditional	
PROPONENT MRI	L210, L211, L231	MR Conditional	
ACCOLADE MRI	L310, L311, L331	MR Conditional	
CRT-P Pulse Generators			
VALITUDE X4	U128	MR Conditional	
VISIONIST X4	U228	MR Conditional	
Leads and Accessories			
Right Atrial and Right Ventricular Leads and Accessories			
FINELINE II Sterox Pacing Leads	4456, 4457, 4458, 4459, 4479, 4480	MR Conditional	
FINELINE II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional	
Suture Sleeve for FINELINE II leads	6220, 6221	MR Conditional	

Table C–3. ImageReady MR Conditional Pacing System Components for 1.5 T and 3 T (continued)

Component	Model Number(s)	MR Status	Valid Combinations
INGEVITY MRI Pacing Leads (Tined Fixation)	7731, 7732, 7735, 7736	MR Conditional	
INGEVITY MRI Pacing Leads (Extendable/Retractable Fixation)	7740, 7741, 7742	MR Conditional	
INGEVITY+ Pacing Leads (Extendable/Retractable Fixation)	7840, 7841, 7842	MR Conditional	
Suture Sleeve for INGEVITY MRI / INGEVITY+ leads	6402	MR Conditional	
IS-1 Lead Port Plug	7145	MR Conditional	
Left Ventricular Leads and Accessories			
ACUITY X4 (IS4) Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	
Suture Sleeve for ACUITY X4 leads	4603	MR Conditional	
IS4 Lead Port Plug	7148	MR Conditional	

MR CONDITIONAL PACING PROGRAMMER REPORTS

APPENDIX D

MRI Protection is Programmed

MRI Protection Entry Time 11 Jan 2018 13:59

MRI Protection Time-out **24 h** ①

Scheduled Expiration Time 12 Jan 2018 13:59 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	45 min^{-1}	65 min^{-1}
AV Delay	180 - 180 ms	100 ms

Page 1 of 4

Settings During MRI Protection (Continued)

Parameter	Previous Value	MRI Protection Value
Ventricular Pacing Chamber	BiV	BiV
Pacing Output		
Atrial	Trend 3.5 V @ 0.4 ms	5.0 V @ 1.0 ms
Right Ventricular	Trend 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
LV Offset	0 ms	0 ms

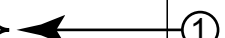
The following features are disabled during MRI Protection:
- Ventricular Tachy EGM Storage
- RA Automatic Threshold
- RV Automatic Threshold
- Daily diagnostics
- Magnet detection
- RF Telemetry

Page 2 of 4

[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.

Figure D–1. Sample MRI Protection Settings Report printout with Time-out set to 24 hours (Pages 1–2)

Leads Data	Pre-MRI Scan Measurement	Measurement Date
Atrial		
Intrinsic Amplitude	3.0 mV	10 Jan 2018 10:10
Pace Impedance	1000 Ω	11 Jan 2018 13:59
Pace Threshold	1.5 V @ 0.5 ms	10 Jan 2018 10:10
Right Ventricular		
Intrinsic Amplitude	3.1 mV	10 Jan 2018 10:10
Pace Impedance	1100 Ω	11 Jan 2018 13:59
Pace Threshold	1.6 V @ 0.6 ms	10 Jan 2018 10:10
Left Ventricular		
Intrinsic Amplitude	3.2 mV	10 Jan 2018 10:10
Pace Impedance	1200 Ω	11 Jan 2018 13:59
Pace Threshold	1.7 V @ 0.7 ms	10 Jan 2018 10:10



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.

Page 3 of 4

MRI Protection Checklist (Continued)

Cardiology Checklist:
- Patient is implanted with an ImageReady MR Conditional System.
- No other active or abandoned implanted devices, components or accessories present.
- Pulse generator is in MRI Protection Mode during scan.
- Patient does not have elevated body temperature at the time of scan.
- Pulse generator implant location restricted to left or right pectoral region.
- At least six weeks have elapsed since implantation and/or any surgical modification.
- No evidence of a fractured lead or compromised pulse generator-lead system integrity.
- RA and RV pacing leads are programmed bipolar.

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.

Page 4 of 4

[1] 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 D–2. Sample MRI Protection Settings Report printout with MRI Protection Checklist (Pages 3–4) (Cont.)

Event MRI-1: 11 Jan 2018 07:49

Settings During MRI Protection		
Brady Mode	DOO	
Lower Rate Limit	65 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	3.0 mV	10 Jan 2018 10:10
Pace Impedance	1000 Ω	11 Jan 2018 07:49
Pace Threshold	1.5 V @ 0.5 ms	10 Jan 2018 10:10
Ventricular		
Intrinsic Amplitude	3.1 mV	10 Jan 2018 10:10
Pace Impedance	1100 Ω	11 Jan 2018 07:49
Pace Threshold	1.6 V @ 0.6 ms	10 Jan 2018 10:10
MRI Protection Exit Status	User Terminated	
MRI Protection Exit Time	11 Jan 2018 07:56	

Event Ended 00:06:40

For ADVANTIO MRI, INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI, and ACCOLADE MRI devices

Figure D–3. Sample stored event detail printout

SYMBOLS ON PACKAGING

APPENDIX E

The following symbols may be used on packaging and labeling.

Table E–1. Symbols on Packaging

Symbol	Description
CE 2797	CE mark of conformity with the identification of the notified body authorizing use of the mark
EC REP	Authorized Representative in the European Community
	Manufacturer
	MR Conditional
REF	Reference Number

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Q

R

S

T

U

V

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

EC REP

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CE 2797

The following devices are no longer placed on the EU market, and no longer carry an active CE Mark: FORMIO MRI, VITALIO MRI, INGENIO MRI, and ADVANTIO MRI.