Boston Scientific

MRI TECHNICAL GUIDE

⚠ IMAGEREADY™ MR Conditional S-ICD System

REF A209 and A219 pulse generators and 3010, 3401, and 3501 subcutaneous electrodes

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 S-ICD 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 S-ICD System.

This manual contains:

- Information about the ImageReady MR Conditional S-ICD System (Boston Scientific S-ICD and Boston Scientific/Cameron Health Electrodes)
- Information about ImageReady MR Conditional S-ICD System patients who can and cannot undergo an MRI scan and the Conditions of Use that must be met in order for an MRI scan to be performed
- Instructions for carrying out an MRI scan on ImageReady MR Conditional S-ICD 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 Table 1–1 ImageReady MR Conditional S-ICD System Components on page 1-2 to determine if *all* components of the patient's implanted system are found within the table. If any of the components cannot be found within the table, the system is not an ImageReady MR Conditional S-ICD 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 Pulse Generator User's Manual, Electrode User's Manuals, LATITUDE Clinician Manual, or Programmer User's Manual for detailed information about non-MRI aspects of implantation, features, programming, and use of the components of the ImageReady MR Conditional S-ICD System.

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INTRODUCTION TO THE IMAGEREADY MR CONDITIONAL S-ICD SYSTEM

CHAPTER 1

This chapter contains the following topics:

SYSTEM DESCRIPTION

An ImageReady MR Conditional S-ICD System consists of specific Boston Scientific and Cameron Health model components including pulse generators, electrodes, accessories, and the programmer. For the model numbers of MR Conditional S-ICD System components, see Table 1–1 ImageReady MR Conditional S-ICD System Components on page 1-2.

The ImageReady S-ICD System was evaluated as a system for use with MRI scans performed under the Conditions of Use described in this Technical Guide. The pulse generator uses minimal ferromagnetic materials, which can interact with the fields generated during a typical MRI scan. The pulse generator's circuits can tolerate voltages that may be induced during scans. Any part of the body may be imaged. Boston Scientific MR Conditional pulse generators and Boston Scientific/Cameron Health electrodes, when used together, have mitigated risks associated with MRI scans as compared to non-MRI pulse generators. 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. The ImageReady S-ICD System was designed for ease of use, and MRI Protection Mode is accessible via a single button on the main menu, isolated from all other programmable features (see "Main Menu" on page 2-4). MRI Protection Mode modifies the behavior of the pulse generator to accommodate the MRI scanner electromagnetic environment (see "MRI Protection Mode General Information" on page 2-2). A Time-out feature is programmed to allow automatic exit from MRI Protection Mode after a set number of hours chosen by the user. These features have been evaluated to verify their effectiveness. Other MRI-related risks are further reduced by adherence to the conditions for scanning specified in this Technical Guide.

Only specific combinations of pulse generators and electrodes constitute an ImageReady S-ICD System that is valid for use with **1.5 T scanners** (see Table 1–1 ImageReady MR Conditional S-ICD System Components on page 1-2).

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

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

System Configuration for 1.5 T

Table 1–1. ImageReady MR Conditional S-ICD System Components

Component		Model Numbers	MR Status
Pulse Generators	EMBLEM S-ICD, EMBLEM MRI S-ICD	A209[a] , A219	MR Conditional
Electrodes and Accessories	Boston Scientific EMBLEM S-ICD Electrode	3401[b] , 3501	MR Conditional
	Cameron Health Q-TRAK S-ICD Electrode	3010[b]	MR Conditional
	Boston Scientific and Cameron Health S-ICD Electrode Suture Sleeves	4760 and those packaged with MR Conditional electrodes	MR Conditional

a. Only A209 models that have been upgraded (firmware version 3.1.529 or later upgrade to add MRI protections mode) are MRI compatible.
b. These models are no longer placed on the EU market, and no longer carry an active CE Mark. These devices and the MR Conditional system they are a part of continue to be supported by Boston Scientific.

MRI CONDITIONS OF USE

While any part of the body may be imaged, the following Conditions of Use must be met in order for a patient with an ImageReady S-ICD 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 S-ICD System (Table 1–1 ImageReady MR Conditional S-ICD System Components on page 1-2).

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

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

4. As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and electrocardiography (ECG). Ensure backup therapy is available (external rescue).

5. Patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

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

7. At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady S-ICD System.

8. No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.

Radiology

1. MRI magnet strength RF field Maximum spatial gradient MRI equipment specification	1.5 T only Approximately 64 MHz 30 T/m (3,000 G/cm) Horizontal, ^{1}H proton, closed bore scanners only
2. Specific Absorption Rate (SAR) limits for the entire active scan	Normal Operating Mode[a] : • Whole body averaged, ≤ 2.0 watts/kilogram (W/kg) • Head, ≤ 3.2 W/kg
3. Maximum specified gradient slew rate	≤ 200 T/m/s per axis
4. The use of local 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 ImageReady S-ICD System.	
5. Patient in supine or prone position only	
6. Patient must be continuously monitored by pulse oximetry and electrocardiography (ECG) for the entire duration in which the pulse generator is in MRI Protection Mode. Ensure backup therapy is available (external rescue).	

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

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.

MRI BASIC CONCEPTS

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

- A static magnetic field generated by a superconducting electromagnet coil, 1.5 T in strength.

- Gradient magnetic fields of much lower intensity, but with high rates of change over time. Three sets of gradient coils are used to create the gradient fields.

- A pulsed radio frequency (RF) field produced by transmission RF coils (approximately 64 MHz for 1.5 T).

These fields may create physical forces or electrical currents that can affect the functioning of active implantable medical devices (AIMDs) such as pulse generators and electrodes. Therefore, only patients implanted with an ImageReady MR Conditional System optimized and evaluated for the ability to function correctly under specified conditions during an MRI scan are eligible to be scanned. Furthermore, by complying with the MRI Conditions of Use, outlined in this Technical Guide ("MRI Conditions of Use" on page 1-2), ImageReady MR Conditional System patients can undergo MRI scans with risks mitigated to the best current standard of care.

MR CONDITIONAL S-ICD SYSTEM WARNINGS AND PRECAUTIONS

General

WARNING: Ensure the device is in MRI Protection Mode before entering the scanner and that the patient is out of the scanner before the programmed Time-out period elapses. This will ensure that inappropriate therapy and potential unintended arrhythmia induction do not occur while undergoing an MRI scan.

WARNING: Unless all of the MRI Conditions of Use ("MRI Conditions of Use" on page 1-2) 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 1-5.

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

WARNING: The patient must be out of the scanner before the programmed Time-out period elapses. Otherwise, the patient will no longer meet Conditions of Use (see "MRI Conditions of Use" on page 1-2).

WARNING: The Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

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

Programming Considerations

WARNING: If Tachycardia therapy is 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.

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 for Safe MR 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, et al., American Journal of Roentgenology 188:1447-74, 2007.

WARNING: Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[2]. Some of the accessories used with pulse generators and electrodes, including the torque wrench and electrode implant tools, 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: MR scanning when other active implants such as lead adaptors, extenders, leads or pulse generators are present may increase MRI-related risks. If MR scanning is required, refer to product labeling to ensure that the MR conditions of use are met for all implanted products.

CAUTION: Following any sensing parameter adjustment or any modification of the subcutaneous electrode, always verify appropriate sensing.

CAUTION: The presence of the implanted ImageReady S-ICD System may cause MRI image artifacts (see "3. Preparing the Patient for the Scan" on page 2-9).

NOTE: *All normal risks associated with an MRI procedure apply to MRI scans with the ImageReady S-ICD 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 S-ICD System.*

POTENTIAL ADVERSE EVENTS

Potential adverse events differ depending on whether the MRI Conditions of Use (see "MRI Conditions of Use" on page 1-2) are met. For a complete list of potential adverse events, refer to the pulse generator User's Manual.

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

- Damage to the pulse generator and/or electrode
- Muscle stimulation
- Patient death
- Patient discomfort or heating of the device and/or electrode

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

- Arrhythmia induction
- Damage to the pulse generator and/or electrode
- Erratic pulse generator behavior
- Defibrillation therapy not available
- Inappropriate shock
- Muscle stimulation
- Patient death

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

- Patient discomfort due to slight movement or heating of the device and/or electrode

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 1-2). 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 1-2) 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 1-5.

PATIENT FLOW

A sample patient flow sequence for an ImageReady S-ICD 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 ImageReady S-ICD System.

3. Electrophysiologist/cardiologist determines patient eligibility for scan per the information in this Technical Guide, and ensures communication of patient eligibility to HCPs involved in performing the MRI scan. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper ("Beeper volume after MRI" on page 2-3).

4. If the patient is eligible, a trained HCP or Boston Scientific representative, acting under the direction of a electrophysiologist/cardiologist, programs the pulse generator into MRI Protection Mode as close in time to the scan as reasonable. Ensure continuous monitoring of the patient in MRI Protection Mode. The MRI Protection Mode Settings Report is printed, placed in the patient's file, and provided to radiology personnel. The report documents MRI Protection Mode settings and details. The report includes the exact time and date when MRI Protection Mode will expire via the Time-out feature.

5. The radiologist checks the patient file and any communication from the electrophysiologist/cardiologist. The radiologist verifies that adequate time remains to complete the scan based on the programmed Time-out value. Ensure continuous monitoring of the patient before, during, and after the MRI scan.

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

6. Patient undergoes scan according to the conditions of use described in this Technical Guide.

7. The pulse generator is returned to pre-MRI operation, either automatically via the Time-out feature, or manually using the Programmer. If desired, system integrity may be checked by evaluating the Beeper and/or real-time S-ECGs. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

MRI PROTECTION MODE GENERAL INFORMATION

Prior to the patient undergoing an MRI scan, an ImageReady S-ICD System must be programmed to the MRI Protection Mode using the programmer. In MRI Protection Mode:

- Tachycardia therapy is suspended

- A Time-out feature is nominally set to 6 hours, with programmable values of 6, 9, 12, and 24 hours
- Beeper is disabled (turned off)

NOTE: *Six hours in MRI Protection Mode reduces pulse generator longevity by approximately 2 days.*

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 for Safe MR 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.

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

- Tachycardia Detection and Therapy
- System diagnostics (electrode impedance, battery performance monitoring, AF Monitor)
- Magnet detection

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

- Magnet presence is detected by magnet sensor
- Tachy Episode is in progress
- Setup process was not completed
- Battery capacity status is End of Life (EOL)

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

Beeper

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

The Beeper will emit tones due to a device reset even after the device is programmed into MRI Protection Mode. Although the Beeper may still be audible following an MRI scan, the Beeper volume will be decreased.

NOTE: *In situations where the MRI scan did not occur, the Beeper can be re-enabled after exiting MRI Protection Mode (see "After the Scan" on page 2-10).*

Upon subsequent interrogations, a notification that the Beeper is disabled will be provided on the Device Status Since Last Follow-up screen (see "Beeper Disabled dialog" on page 2-11). If the Beeper is re-enabled, the Beeper status will no longer be provided on the Device Status Since Last Follow-up screen.

WARNING: The Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the

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

risk of losing the Beeper. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

Situations that will no longer trigger the Beeper to emit audible tones following exit from MRI Protection Mode (if the Beeper is not re-enabled) include:

- Elective Replacement (ERI) and End of Life (EOL) indicators
- Electrode impedance out of range
- Prolonged charge times
- Irregular battery depletion

PRE-SCAN ACTIVITIES

Three activities are required before the MRI scan takes place:

1. Prepare the pulse generator for the scan by programming into MRI Protection Mode ("1. Programming the Pulse Generator for a Scan" on page 2-4)
2. Confirm the MRI scanner settings and configurations ("2. Confirming MRI Scanner Settings and Configuration" on page 2-9)
3. Prepare the patient for the scan ("3. Preparing the Patient for the Scan" on page 2-9)

1. Programming the Pulse Generator for a Scan

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

NOTE: *Print or save (via End Session) any desired data from the current session prior to programming the device into MRI Protection Mode.*

From the Main Menu screen, select the MRI Protection Mode button (see "Main Menu" on page 2-4).

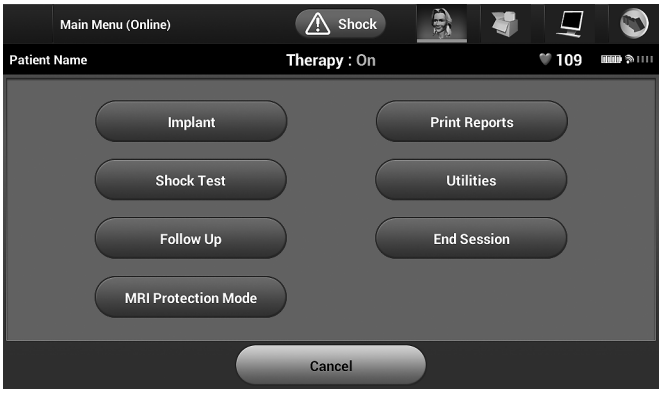


Figure 2–1. Main Menu

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

If one or more of these conditions are present, a dialog box will appear describing the condition, and MRI Protection Mode cannot be entered.

Upon selecting the MRI Protection Mode button, the MRI Protection Checklist screen is displayed (see "MRI Protection Checklist" on page 2-5). The Checklist summarizes the conditions that must be met at the time of scanning in order for a patient to be eligible for an MR Conditional scan. Re-verification is required before every scan to guard against the possibility that changes in the system or patient occurred subsequent to the original pulse generator/system implant. These conditions are described in greater detail in "MRI Conditions of Use" on page 1-2.

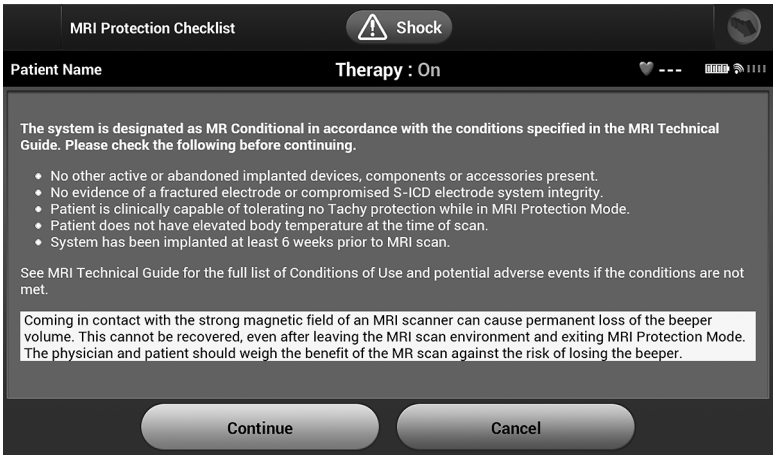


Figure 2–2. MRI Protection Checklist

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

If the Conditions of Use are met, or if the Conditions of Use are not met but the user elects to continue with MRI Protection Mode after reviewing the risks of proceeding, the Continue button is selected.

In addition to the above-listed conditions that prevent entry into MRI Protection Mode, another condition, electrode impedance, is assessed by the programmer upon a request to enter MRI Protection Mode. If the impedance value is within normal range, a screen will automatically appear where the user programs the current date/time and Time-out value (see "Program Date/Time and MRI Protection Time-out dialog" on page 2-6).

Enter the current date and time to ensure the MRI Protection Settings Report accurately reflects the time of MRI Protection Mode expiration.
Use the slider to set the MRI Protection Time-out (nominally set to 6 hours; programmable values of 6, 9, 12, and 24 hours) (see "Program Date/Time and MRI Protection Time-out dialog" on page 2-6).

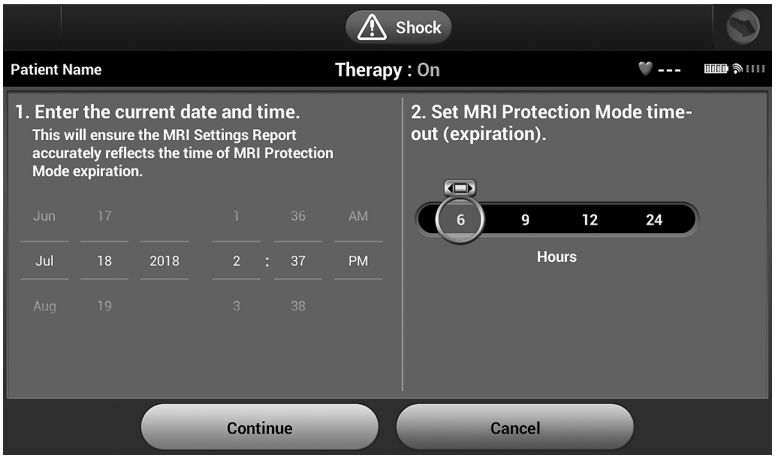


Figure 2–3. Program Date/Time and MRI Protection Time-out dialog

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 current date and time are set correctly to ensure the accuracy of the projected expiration time (displayed on the screen and on the printed MRI Protection Settings Report). When the programmed time has elapsed, the pulse generator automatically exits MRI Protection Mode and all parameters (except for the Beeper) return to the previously programmed settings.

WARNING: The patient must be out of the scanner before the programmed Time-out period elapses. Otherwise, the patient will no longer meet Conditions of Use (see "MRI Conditions of Use" on page 1-2).

If the impedance value obtained from this test is outside the normal range, the programmer provides a screen 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 (see "Impedance Out of Range" on page 2-6). After selecting the Continue button, a screen will appear which allows the user to program the current date/time and Time-out value as described above (see "Program Date/Time and MRI Protection Time-out dialog" on page 2-6).

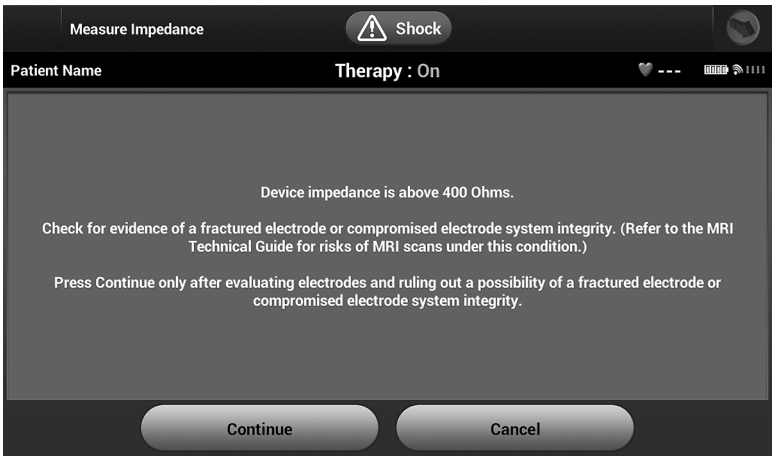


Figure 2–4. Impedance Out of Range

After the current date and time and Time-out values are chosen, select the Continue button. On the subsequent MRI Protection Mode programming screen, select the Program MRI Protection button to program the device into MRI Protection Mode (see "Program MRI Protection dialog" on page 2-7). The MRI Protection Mode programmed screen appears indicating that the device has successfully been programmed into MRI Protection Mode (see "MRI Protection Mode programmed dialog with Exit MRI Protection button" on page 2-7).

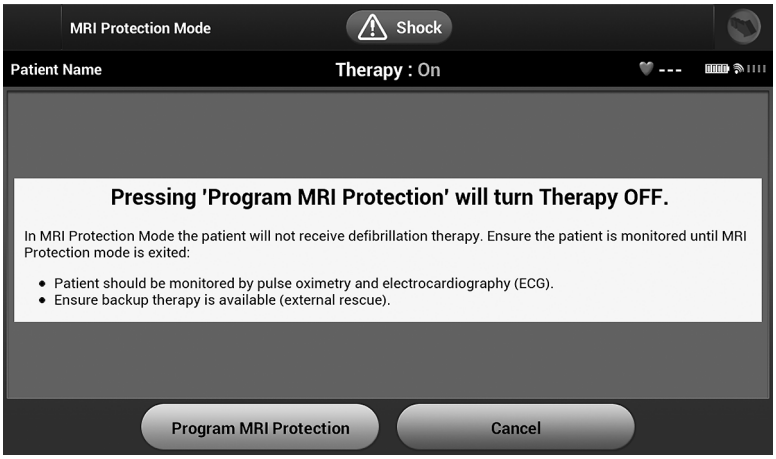


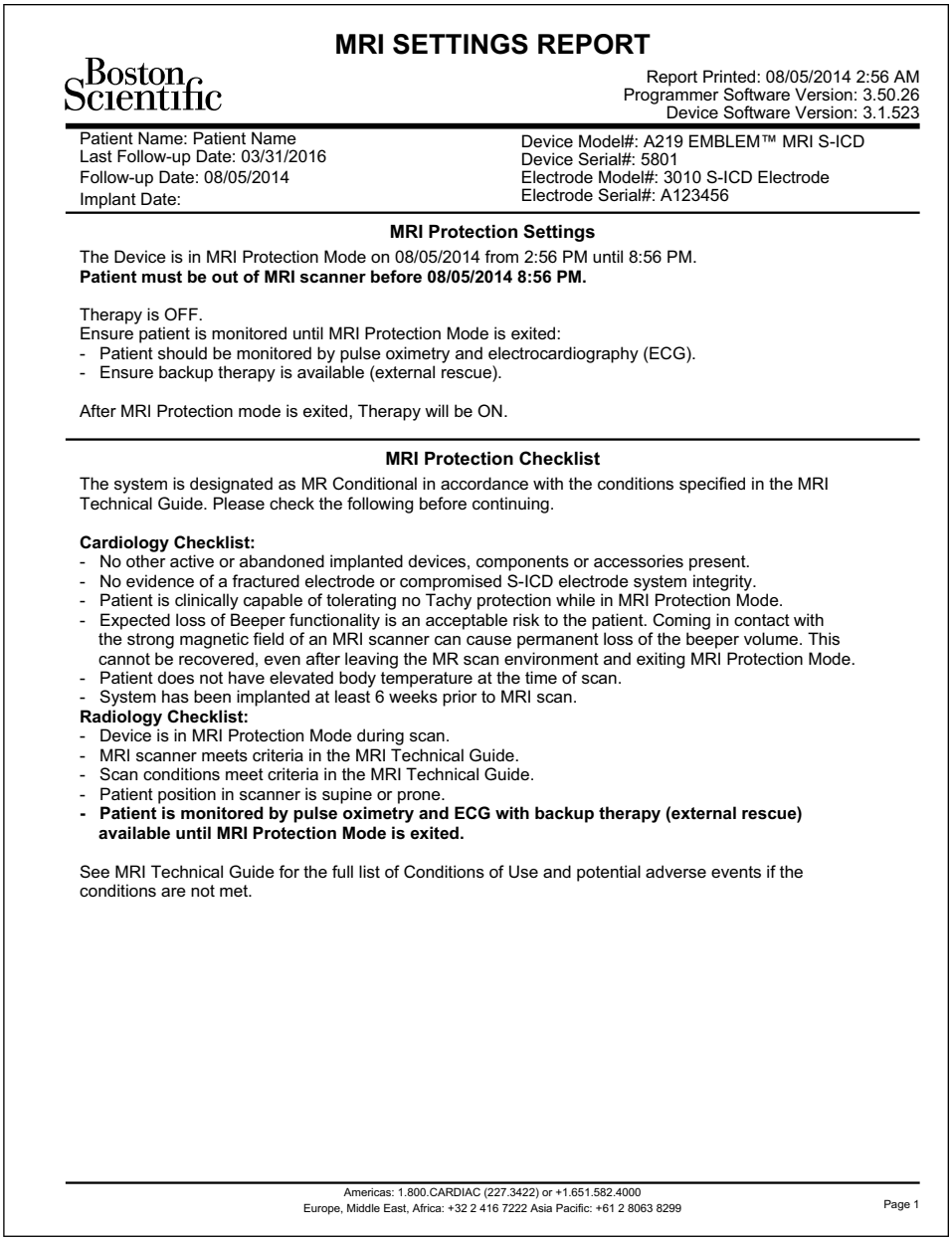
Figure 2–5. Program MRI Protection dialog

Figure 2–6. MRI Protection Mode programmed dialog with Exit MRI Protection button

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

Once MRI Protection Mode has successfully been programmed, print a copy of the MRI Protection Settings Report by selecting the Print MRI Settings button on the MRI Protection Mode programmed screen. The report lists the settings in operation during MRI Protection Mode. The report includes the time and date when MRI Protection Mode will expire, returning the pulse generator to the pre-MRI Protection Mode settings (except for the Beeper).

The printed report can be placed in the patient's file and used by radiology personnel, for example to confirm that sufficient time remains to complete the MRI scan. A sample Settings Report and Checklist printout is shown with the Time-out set to 6 hours (see "Sample Settings report and Checklist printout (Time-out 6 hours)" on page 2-8).



MRI SETTINGS REPORT

Boston Scientific

Report Printed: 08/05/2014 2:56 AM
Programmer Software Version: 3.50.26
Device Software Version: 3.1.523

Patient Name: Patient Name
Last Follow-up Date: 03/31/2016
Follow-up Date: 08/05/2014
Implant Date:

Device Model#: A219 EMBLEM™ MRI S-ICD
Device Serial#: 5801
Electrode Model#: 3010 S-ICD Electrode
Electrode Serial#: A123456

MRI Protection Settings

The Device is in MRI Protection Mode on 08/05/2014 from 2:56 PM until 8:56 PM.
Patient must be out of MRI scanner before 08/05/2014 8:56 PM.

Therapy is OFF.
Ensure patient is monitored until MRI Protection Mode is exited:
- Patient should be monitored by pulse oximetry and electrocardiography (ECG).
- Ensure backup therapy is available (external rescue).

After MRI Protection mode is exited, Therapy will be ON.

MRI Protection Checklist

The system is designated as MR Conditional in accordance with the conditions specified in the MRI Technical Guide. Please check the following before continuing.

Cardiology Checklist:
- No other active or abandoned implanted devices, components or accessories present.
- No evidence of a fractured electrode or compromised S-ICD electrode system integrity.
- Patient is clinically capable of tolerating no Tachy protection while in MRI Protection Mode.
- Expected loss of Beeper functionality is an acceptable risk to the patient. Coming in contact with the strong magnetic field of an MRI scanner can cause permanent loss of the beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode.
- Patient does not have elevated body temperature at the time of scan.
- System has been implanted at least 6 weeks prior to MRI scan.

Radiology Checklist:
- Device is in MRI Protection Mode during scan.
- MRI scanner meets criteria in the MRI Technical Guide.
- Scan conditions meet criteria in the MRI Technical Guide.
- Patient position in scanner is supine or prone.
- **Patient is monitored by pulse oximetry and ECG with backup therapy (external rescue) available until MRI Protection Mode is exited.**

See MRI Technical Guide for the full list of Conditions of Use and potential adverse events if the conditions are not met.

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Europe, Middle East, Africa: +32 2 416 7222 Asia Pacific: +61 2 8063 8299

Page 1

Figure 2–7. Sample Settings report and Checklist printout (Time-out 6 hours)

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

WARNING: The patient must be out of the scanner before the programmed Time-out period elapses. Otherwise, the patient will no longer meet Conditions of Use (see "MRI Conditions of Use" on page 1-2).

Once a copy of the MRI Protection Settings Report has been printed, select the End Session button on the MRI Protection Mode programmed screen (see "MRI Protection Mode programmed dialog with Exit MRI Protection button" on page 2-7).

To end the programmer session with the pulse generator remaining in MRI Protection Mode, select Continue on the End Session confirmation screen (see "End Session Confirmation dialog" on page 2-9).

Figure 2–8. 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 1-2.

3. Preparing the Patient for the Scan

Be sure to note the time at which the pulse generator is scheduled to exit MRI Protection Mode via the Time-out feature. Refer to "MRI Protection Mode programmed dialog with Exit MRI Protection button" on page 2-7.

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

WARNING: The patient must be out of the scanner before the programmed Time-out period elapses. Otherwise, the patient will no longer meet Conditions of Use (see "MRI Conditions of Use" on page 1-2).

The patient must not have an elevated temperature or compromised thermoregulation. Patient position within the bore must be prone or supine, and the appropriate monitoring system must be put in place (pulse oximetry and ECG). See "MRI Conditions of Use" on page 1-2.

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

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

DURING THE SCAN

Patient Monitoring

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

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

AFTER THE SCAN

1. Exit MRI Protection Mode

   MRI Protection Mode can be exited either automatically via the Time-out feature or manually (see details below). After exit from MRI Protection Mode, system integrity may be checked by evaluating the Beeper and/or real-time S-ECGs.

   Time-out (automatic) Exit from MRI Protection Mode

   The pulse generator will automatically exit MRI Protection Mode via the Time-out feature once the selected number of hours has elapsed. The patient must be continuously monitored for the entire duration in which the system is in MRI Protection Mode. Once the Time-out period has elapsed, the system will return to previously programmed settings (except for the Beeper as described below).

   Manual Exit from MRI Protection Mode

   Alternatively, 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

   b. Select the Exit MRI Protection button from the MRI Protection Mode programmed screen (see "MRI Protection Mode programmed dialog with Exit MRI Protection button" on page 2-7)

   Following exit from MRI Protection Mode, an MRI Protection Exited confirmation screen will appear (see "MRI Protection Exited dialog" on page 2-10).

   NOTE: *If necessary, Rescue Shock can also be used to exit MRI Protection Mode.*

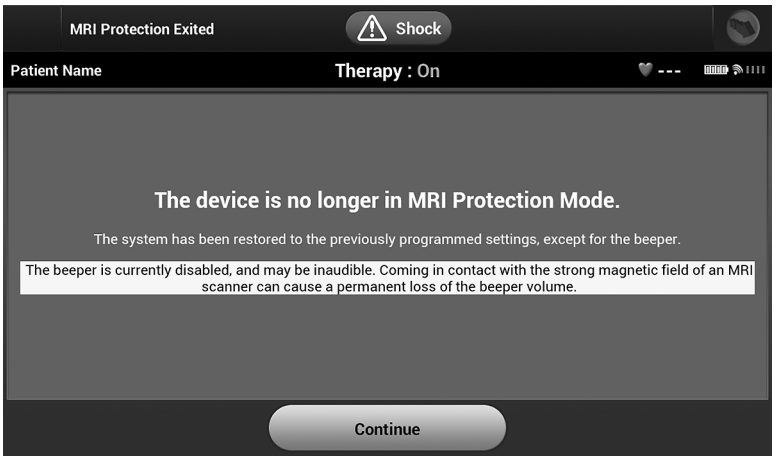

Figure 2–9. MRI Protection Exited dialog

2. Evaluate Device

   If desired, interrogate the device and evaluate sensing by capturing real-time S-ECGs via the Capture All Sense Vectors button on the Utilities screen.

   NOTE: *If Manual Setup was previously used to override a sensing configuration, careful consideration should be taken when selecting Automatic Setup.*

   Upon exit from MRI Protection Mode, all parameters are immediately restored to pre-MRI Protection Mode values with the following exception:

   a. The Beeper will remain disabled upon exiting MRI Protection Mode (see "Beeper Disabled dialog" on page 2-11). Coming into contact with the strong magnetic field of an MRI scanner can cause a permanent loss of the Beeper volume.

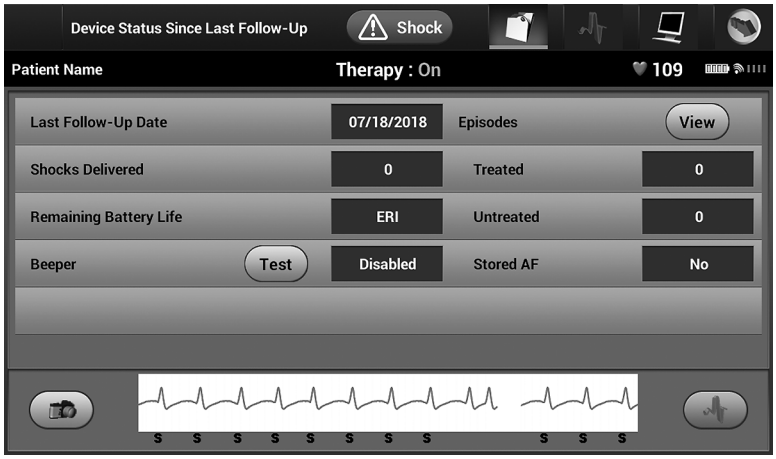

Figure 2–10. Beeper Disabled dialog

   If desired, the user can manually attempt to re-enable the Beeper (see "Set Beeper Function screen" on page 2-12).

   Perform the following steps to program the Beeper:

   i. Select the Continue button from the MRI Protection Exited screen (see "MRI Protection Exited dialog" on page 2-10)

   ii. Select the Test Beeper button from the Set Beeper Function (see "Set Beeper Function screen" on page 2-12)

   iii. Evaluate if the Beeper is audible (use a stethoscope if necessary)

   iv. If the Beeper is audible, select the Yes, Enable Beeper button. If the Beeper is not audible, select the No, Disable Beeper button (see "Beeper Audible screen" on page 2-12)

   If the Beeper is not audible to the patient, it is strongly recommended that the patient has a follow-up schedule of every three months, either on LATITUDE NXT or in-clinic to monitor device performance.

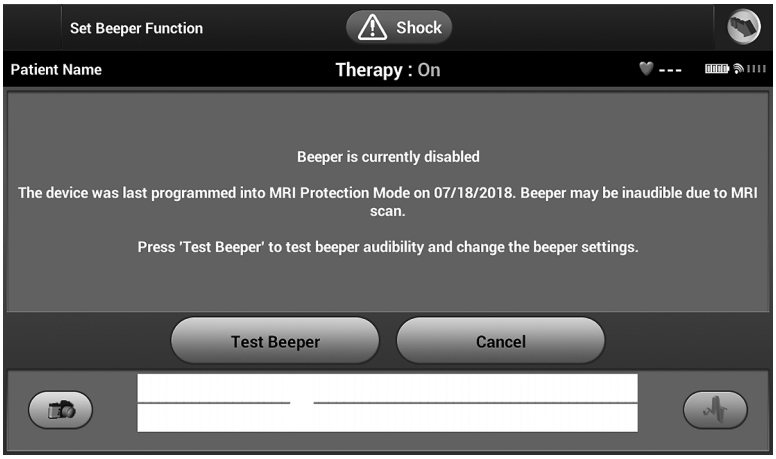

Figure 2–11. Set Beeper Function screen

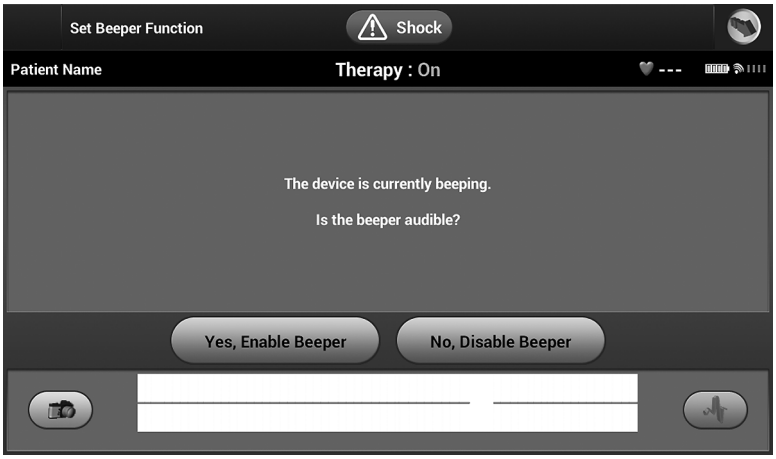

Figure 2–12. Beeper Audible screen

Consider performing these device evaluations subsequent to automatic (Time-out) exit from MRI Protection Mode as well.

CARDIOLOGY CHECKLIST FOR THE IMAGEREADY MR CONDITIONAL S-ICD 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 S-ICD System.

Conditions of Use - Cardiology

The following Conditions of Use must be met in order for a patient with an ImageReady S-ICD System to undergo an MRI Scan.

☐ Patient is implanted with an ImageReady S-ICD System (see "ImageReady MR Conditional S-ICD System Components for 1.5 T" on page C-1).

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

☐ Pulse generator in MRI Protection Mode during scan.

☐ As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and electrocardiography (ECG). Ensure backup therapy is available (external rescue).

☐ Patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

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

☐ At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady S-ICD System.

☐ No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.

Scanning Procedure

Pre-scan

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

2. Exposure to MRI scanning can cause a permanent loss of the Beeper volume. The physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper.

3. As close to the start of the scan as possible, program the pulse generator into MRI Protection Mode and begin continuous monitoring of the patient.

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

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

During scan

5. Ensure the patient is continuously monitored by pulse oximetry and electrocardiography (ECG), with backup therapy available (external rescue), while the device is in MRI Protection Mode.

After scan

6. Ensure the pulse generator is returned to pre-MRI operation, either automatically via the Time-out feature, or manually using the programmer. Continue patient monitoring until the pulse generator is returned to pre-MRI operation. Follow-up testing of the S-ICD system may be performed after exiting MRI Protection Mode.

7. The Beeper will remain disabled upon exiting MRI Protection Mode.

WARNING: Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.

WARNING: The 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 for Safe MR 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, et al., American Journal of Roentgenology 188:1447-74, 2007.

RADIOLOGY CHECKLIST FOR THE IMAGEREADY MR CONDITIONAL S-ICD 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 S-ICD System.

Conditions of Use - Radiology

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

☐ MRI magnet strength = 1.5 T only

☐ RF field = Approximately 64 MHz

☐ Maximum spatial gradient = 30 T/m (3,000 G/cm)

☐ MRI equipment specification = Horizontal, ^{1}H proton, closed bore scanners only

☐ Specific Absorption Rate (SAR) limits for the entire active scan (Normal Operating Mode[a]):

- Whole body averaged, ≤ 2.0 watts/kilogram (W/kg)
- Head, ≤ 3.2 W/kg

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

☐ The use of receive-only coils is not restricted. Local transmit-only coils or local transmit/receive coils may be used, but should not be placed directly over the ImageReady S-ICD System.

☐ Patient in supine or prone position only.

☐ Patient must be continuously monitored by pulse oximetry and electrocardiography (ECG) for the entire duration in which the pulse generator is in MRI Protection Mode. Ensure backup therapy is available (external rescue).

Scanning Procedure

Pre-scan

1. Ensure Cardiology has cleared the patient for scanning eligibility based on the Cardiology MRI Conditions of Use ("Cardiology Checklist for the ImageReady MR Conditional S-ICD System" on page A-1).

2. As close to the start of the scan as possible, the patient's pulse generator is programmed into MRI Protection Mode and continuous monitoring of the patient begins.

3. Refer to the MRI Protection Settings Report to confirm that the patient's device is in MRI Protection Mode. The report includes the exact time and date when MRI Protection Mode will expire via the Time-out feature. ***Verify that adequate time remains to complete the scan.***

During scan

4. Ensure the patient is continuously monitored by pulse oximetry and electrocardiography (ECG), with backup therapy available (external rescue), while the device is in MRI Protection Mode.

After scan

5. Ensure the pulse generator is returned to pre-MRI operation, either automatically via the Time-out feature, or manually using the programmer. Continue patient monitoring until the pulse generator is returned to pre-MRI operation. Follow-up testing of the S-ICD system may be performed after exiting MRI Protection Mode.

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

WARNING: Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.

WARNING: The Programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR 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, et al., American Journal of Roentgenology 188:1447-74, 2007.

IMAGEREADY MR CONDITIONAL S-ICD SYSTEM COMPONENTS FOR 1.5 T

APPENDIX C

Only specific combinations of pulse generators and electrodes constitute an ImageReady S-ICD System that is valid for use with **1.5 T scanners**.

ImageReady MR Conditional S-ICD System Components for 1.5 T

Component		Model Number(s)	MR Status	1.5 T
Pulse Generators	EMBLEM S-ICD, EMBLEM MRI S-ICD	A209[a] , A219	MR Conditional	X
Electrodes and Accessories	Boston Scientific EMBLEM S-ICD Electrode	3401[b] , 3501	MR Conditional	X
	Cameron Health Q-TRAK S-ICD Electrode	3010[b]	MR Conditional	X
	Boston Scientific and Cameron Health S-ICD Electrode Suture Sleeves	4760 and those packaged with MR Conditional electrodes	MR Conditional	X

a. Only A209 models that have been upgraded (firmware version 3.1.529 or later upgrade to add MRI protections mode) are MRI compatible.

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

SYMBOLS ON PACKAGING

APPENDIX D

The following symbols may be used on packaging and labeling.

Table D–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
AUS	Australian Sponsor Address
	MR Conditional
REF	Reference Number

INDEX

V

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

EC REP

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

AUS

Boston Scientific (Australia) Pty Ltd
PO Box 332
Botany NSW 1455 Australia
Free Phone 1 800 676 133
Free Fax 1 800 836 666

www.bostonscientific.com

1.800.CARDIAC (227.3422)

+1.651.582.4000

92346927-001 EN Europe 2020-09

CE 2797

The following devices are no longer placed on the EU market, and no longer carry an active CE Mark: 3010 and 3401 subcutaneous electrodes.