States of Jersey

The States of Jersey Department for
Health & Social Services

MRI Conditional Devices

March 2017

DOCUMENT PROFILE

Document Registration	HSSD-GD-CG-0440-02
Document Purpose	Procedure / Guideline
Short Title	MRI Safe Scanning for Implantable Cardiac Devices
Author	Angela Hall (Moss)
Publication Date	June 2017
Target Audience	Patients requiring MRI scans with MRI safe cardiac devices
Circulation List	Radiology, Clinical Investigations, Cardiology, MyStates HSS Intranet
Description	MRI Scanning of Safe Implantable Devices
Linked Policies	
Approval Route	Local governance committee, Cardiology and Radiology
Review Date	3 years
Contact Details	an.hall@health.gov.je

CONTENTS LIST:

Amendments made for March 2017 review are highlighted in yellow.

Additional **checklists** for radiology and cardiology are provided in the appendix section which were previously unavailable. These can be referred to directly at the relevant website links listed on **page 6** for additional copies / hard copy.

1. INTRODUCTION

1.1 Rationale and Scope

MRI is one of the fastest growing areas in diagnostic imaging and is considered the standard of care for soft tissue imaging (1). The number of patients benefiting from implantable cardiac devices is escalating (1).

50-75% of patients with an implantable cardiac device will need an MRI scan over the lifetime of their device (1). After the age of 65 years a persons chance of needing an MRI doubles (2), the same demographic group that is most likely to need a pacemaker.

There are now more MRI compatible devices that can be implanted and hence the update of this policy. Device specifics are detailed further. Please also refer to the Cardiac Devices Guidelines, available on hssnet.

2. GUIDELINE PURPOSE

The purpose of this document is to provide guidance on the safe management of patients and their implantable cardiac device when an MRI safe device has been implanted and they require an MRI scan. Checklists are included in the appendices for the Cardiac Physiologists and Radiologists to use prior to scanning. These highlight device specifics with safety checks.

3. PROCEDURE

The procedure pre and post scan is highlighted in the checklists. A form should be used per patient with their identification details attached.

The typical patient flow is summarised in Appendix 3.

Once an MRI scan has been requested, the Cardiac Physiologist (via the Clinical Investigation Department) should be informed with patient details and the proposed MRI date. The Clinical Physiologist or Cardiologist will confirm pre-scan conditions. The Clinical Physiologist will then make the arrangements to attend and carry out the specifics prior to the scan. A ‘Cardiac Device Pre-MRI Scan Checklist’ (see appendices) will be completed.

The ‘Radiologist Checklist for MRI Safe Cardiac Device’ will be competed in the MRI department at the time of scanning (see appendices) and scan the patient in accordance with systems labelling.

Following the MRI scan, the Cardiac Physiologist will re-programme the MRI safe device prior to the patient leaving the department. Any relevant checks will be made at this time.

The following links are recommended for further information.

www.medtronic.com/surescan/designedforsafety.html
Link to how Medtronic SureScan works

www.medtronic.com/surescan/resources.html
Link to resources and technical manuals

https://www.sjm.com
St Jude website, links to products and specifics

https://www.bostonscientific.com/en-US/products.html
Boston Scientific website and relevant product links

The SureScan Pacing Systems Overview Brochure is available through the relevant company website.

4. DEVELOPMENT AND CONSULTATION PROCESS

4.1 Consultation Schedule

Name and Title of Individual	Date Consulted
Andrew Norman, Rachel Plange, Jo Tulett	4.12.13 meeting held
Dr Andrew Mitchell	15.1.14
Paul Roche, Andrew Norman	16.1.14
Rachel Plange, Jo Tulett	16.1.14

Policy review, March 2017

Name and Title of Individual	Date Consulted
Andrew Norman, Paul Roche, Kari Pitcher	12.1.17, feedback 17.5.17
Re-sent to above with amendments	17.5.17
Dr Andrew Mitchell	16.1.17, 17.5.17
Rachel Plange	17.5.17
Chris Hare	17.5.17

5. REFERENCE DOCUMENTS

1. Kalin, R. & Stanton, M. (2005). Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE. April, 28 (4), 326 – 328.

2. Medtronic data on file www.medtronic.com/surescan. Accessed 14th January 2014.

Additional sources of information:

St. Jude Medical available at www.sjm.com.

Boston Scientific available at www.BostonScientific.com

6. IMPLEMENTATION PLAN

A summary of how the policy will be implemented.

Action	Timeframe
Guideline circulated to Clinical Investigation Department	16.1.14
Guideline sent to Dr Andrew Mitchell	16.1.14, 6.6.14
Guideline sent to Rachel Plange and Jo Tulett, Radiology	16.1.14, 6.6.14
Guideline sent to Chris Hare	4.7.14
Feedback from Clinical Investigation Department	6.6.14
Completed guideline sent to Ann Kelly for checking	complete
Ratified in local governance meetings then forwarded with sign off sheet to Ann Kelly for formatting and entering onto hss net	complete

Policy review, March 2017

Action	Timeframe
Reviewed and circulated to Paul Roche, Kari Pitcher and Andrew Norman	End Jan 2017
Sent to Andrew Mitchell	End Jan 2017
Sent to Rachel Plange	End Jan 2017
Sent to Chris Hare	End Jan 2017

Feedback received from Kari Pitcher, Clinical Investigations, discussed and amendments made. Sent back for final review	May 2017
Re-sent to Rachel Plange, Andrew Norman, Paul Roche, Andrew Mitchell and Chris Hare. For presentation at next Cardiology Governance meeting	End May 2017

Final amendments made, ratification signed, sent to hssnet / governance	14th June 2017

7. APPENDICES

Appendix 1 Patient checklist (prior to scan). All devices

Appendix 2 Cardiac Device MRI Scan Checklists
MEDTRONIC ICD / PACING

Radiology information link:
http://www.medtronic.com/content/dam/medtronic-com/mri-surescan/documents/04jan2017/patient-scanning-process.pdf

Cardiology information link:
http://www.medtronic.com/us-en/healthcare-professionals/mri-surescan/implantable-cardiac-devices/patient-care-pathway.html#1

Appendix 2a MEDTRONIC INSERTABLE CARDIAC MONITOR
Reveal LINQ device

http://www.medtronic.com/us-en/healthcare-professionals/mri-surescan/implantable-cardiac-devices/mr-conditional-icms.html

Appendix 3 Cardiac Device MRI Scan Checklists
BOSTON SCIENTIFIC ICD

Radiology defibrillator information link:
https://www.bostonscientific.com/content/dam/ImageReady/English/Documents/FV_BG35714_MRI_Cardiology_Checklist_Update_Languages_EA_72dpi.pdf

Cardiology defibrillator link:
https://www.bostonscientific.com/content/dam/bostonscientific/Rhythm%20Management/portfolio-group/ImageReady/ImageReady_Checklist_flow_chart.pdf

Appendix 3a BOSTON SCIENTIFIC PACING

Radiology pacing information link:
http://www.bostonscientific.com/content/dam/ImageReady/English/Documents/FV_BG26514_MRI_Radiology_Checklist_72dpi.pdf

Cardiology pacing information link:
http://www.bostonscientific.com/content/dam/ImageReady/English/Documents/MRI_Cardiologist_Checklist.pdf

Technical Guide:

https://www.bostonscientific.com/content/dam/ImageReady/English/Documents/CRM-334807-AAImagReadyMR_ProgramManualVERT.pdf

Appendix 4 Cardiac Device MRI Scan Checklists
ST JUDE ICD

Radiology and Cardiology information link:
file:///C:/Users/angel/Downloads/11125_SJM-CRM-0715-0043%20_FORM_r4_FNL_RGB.pdf

Plus pre-scan checklist:
file:///C:/Users/angel/Downloads/11249_SJM-ELP-0815-0016%20_POSTER_r4_FNL_RGB.pdf

Appendix 4a ST JUDE PACING

Radiology and Cardiology information link:
file:///C:/Users/angel/Downloads/Brady_MRI_Clinician_Checklist_Final_ID_2000265AEN.pdf

Appendix 5 MRI safe implantable cardiac device patient flow

Appendix 1

Cardiac Device Pre-MRI Scan Checklist

Patient label **MRI appointment _____**

Device (note make, type of device, can and leads)

The information below is correct (tick alongside to confirm):

1. The implant has been in situ for more than 6 weeks	
2. It is a pectoral implant	
3. The pacing threshold is less than 2.0V @ 0.4MS	
4. The lead impedence(s) is 200-1500 ohms	
5. There are NO other devices, leads (including abandoned), adaptors or extenders	
6. Chest x-ray viewed	

Program MRI SureScan ON before the scan
(OFF after the scan)

After consideration of the above information I confirm that the above patient is now safe to proceed for an MRI scan.

Signed: Clinical Physiologist Date:

Signed: Clinical Physiologist / Cardiologist Date:

Radiologist Checklist for MRI safe Cardiac Device

Patient label **MRI appointment**_____

Left blank as device specifics incorporate MRI scanning requirements

The use of local transmit-only coils or local transmit-receive coils placed directly over the pacing system is contraindicated.

Perform the indicated scan

Cardiac Physiologist to program the MRI SureScan Mode OFF

Appendix 2

MEDTRONIC Pacing / ICD / CRT

1.5 AND 3T MRI Checklist

CARDIOLOGIST CHECKLIST

☐ Full Medtronic MRI SureScan System implanted

☐ SureScan Systems Verification
Consult patient records to verify only Medtronic MR-Conditional Systems constructed from the following components are implanted:

Medtronic SureScan MRI pacemakers

Advisa MRI™ A3DR01 and A3SR01, Ensura MRI™ EN1DR01 and EN1SR01, *EnRhythm MRI™ EMDR01
*EnRhythm MRI is not labelled for 3T, 1.5T conditions apply!

Medtronic SureScan MRI ICDs

Evera MRI™ DDMB2D4, DDMC3D4, DVMB2D4, DVMC3D4 Visia AF MRI™ DVFB2D4, DVFC3D4

Medronic SureScan MRI CRT-Ds

Claria MRI™ DTMA2D4, Claria MRI Quad DTMA2QQ Amplia MRI™ DTMB2D4, Amplia MRI QuadDTMB2QQ Compia MRI™ DTMC2D4, Compia MRI Quad DTMC2QQ
Note: For Medtronic SureScan MRI CRT-Ds without an atrial lead, a model 6725 pin plug can be used to plug the right atrial port.

Medtronic SureScan MRI leads

Medtronic Sprint Quattro Secure MRI™ leads (Models: 6947M-55, 6947M-62, 6935M-55, 6935M-62) Medtronic CapSure Sense MRI™ leads (Models: 4574-45, 4574-53, 4074-52, 4074-58) Medtronic CapSureFix™ 5086MRI leads (Models: 5086MRI-45, 5086MRI-52, 5086MRI-58) Medtronic CapSureFix Novus MRI™ leads (Models: 5076-35, 5076-45, 5076-52, 5076-58, 5076-65, 5076-85) Attain Ability™ MRI SureScan leads (Models: 4196-78, 4196-88, 4296-78, 4296-88, 4396-78, 4396-88) Attain™ Performa™ MRI SureScan leads (Models: 4298-78, 4298-88, 4398-78, 4398-88, 4598-78, 4598-88) Attain Stability™ MRI SureScan leads (Models: 20066-88)

Cardiology Requirements for Medtronic SureScan MRI pacemakers	Cardiology Requirements for Medtronic SureScan MRI defibrillators (ICDs) and Medtronic SureScan MRI Cardiac Resynchronization defibrillators (CRT-Ds)
Post-lead maturation period (approximately 6 weeks) * EnRhythm MRI > 6 weeks	
RV Pacing Threshold ≤ 2.0 V at 0.4 ms for pacemaker dependent patients * EnRhythm MRI Pacing Threshold ≤ 2.0 V at 0.4 ms	
The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.	The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance

(Pacing lead impedance 200 ≥ 1,500 Ω)	history. (Pacing lead impedance 200 -3,000 Ω, Defibrillation lead impedance 20-200 Ω)

The patient has no implanted lead-extenders, lead adaptors or abandoned leads.

Multiple MR-Conditional devices acceptable if MR labeling conditions for all implants can be satisfied.

1. EnRhythm MRI patients with previously implanted (active or abandoned) medical devices, leads, lead extenders or lead adaptors are contraindicated for an MRI scan.

The SureScan system is implanted in the left or right pectoral region and operating within the projected service life.

Do not scan patients who exhibit diaphragmatic stimulation when the device is pacing asynchronously during the MRI SureScan mode. It may be difficult for the patient to remain still in order to obtain a quality MRI scan.

☐ Program MRI SureScan Mode ON before the scan (OFF after the scan)

☐ Patient Monitoring

Proper patient monitoring must be provided during the MRI scan and includes both of the following actions: ■ maintaining continuous visual and verbal contact with the patient ■ continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography	Proper patient monitoring is required during the entire time when the MRI SureScan mode is programmed to On and includes both of the following actions: ■ maintaining continuous visual and verbal contact with the patient ■ continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography

Preparation for patient rescue: In the event that patient rescue is required, an external defibrillator must be immediately available.

☐ Patient ready to get an MRI Scan

For a complete set of operating and programming guidelines and restrictions, refer to the respective MRI Technical Manual for any SureScan device.

Medtronic

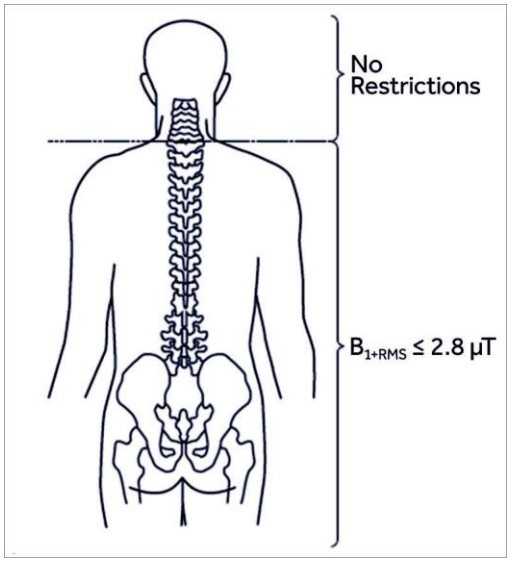
RADIOLOGIST CHECKLIST

OFF

☐ A Full Medtronic MR-Conditional System Confirmed by Cardiologist or Patient Records

Scanner type	Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
Scanner characteristics	▪ Static magnetic field of one of the following strengths: – 1.5T (EnRhythm MRI is 1.5T only) – 3T ▪ Maximum spatial gradient of ≤ 20 T/m (2,000 gauss/cm) ▪ Gradient systems with maximum gradient slew rate performance per axis of ≤ 200T/m/s

3T scan location requirements →



☐ MRI Scanner Operation

1.5T—MRI radiofrequency (RF) power—Normal Operating Mode
- The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg
- Head SAR must be ≤ 3.2 W/kg

3T—MRI radiofrequency (RF) power
- No restrictions for specific absorption rate (SAR)
- Scans can be performed without restriction when the isocenter (center of the MRI bore) is at or superior to the C7 vertebra (see Figure above)
- B_{1+RMS} must be ≤ 2.8 µT when the isocenter is inferior to the C7 vertebra

For Pacemaker Patients:	**For Defibrillator and CRT-D (Cardiac Resynchronisation Defibrillator) Patients:**
▪ Continuous patient monitoring is required during the MRI scan ▪ In the event that patient rescue is required, an external defibrillator must be immediately available ▪EnRhythm MRI patient may not be positioned on his or her side within the MRI bore (lateral decubitus position). The use of local transmit-only coils or local transmit-receive coils placed directly over the pacing system is contraindicated.	▪ Continuous patient monitoring is required while the MRI SureScan mode is programmed to On ▪ In the event that patient rescue is required, an external defibrillator must be immediately available

☐ Perform the Indicated Scan

☐ Cardiology to Program the MRI SureScan Mode

- devices have not been tested by Medtronic.

Check that the data in the Reveal XT/DX ICM has been saved. Before the MRI procedure is started,

- it is recommended that the data stored in the Reveal XT/DX ICM be read out and saved to a diskette using the programmer as the MRI procedure could corrupt the recorded data in the device

- The Patient Assistant (handheld activator) should be left outside the MRI-controlled room (magnetic room).

Appendix 2a

MEDTRONIC LINQ insertable cardiac monitor

Step 1: Screen Patient

Verify that the patient has a Reveal XT/DX Insertable Cardiac Monitor (ICM)

There are two ways to verify that a patient has a Reveal XT/DX ICM:

- There is a radiopaque symbol on all implanted Reveal XT/DX ICM devices. An X-ray of the implanted system can verify whether the device is a Reveal XT/DX ICM. The radiopaque symbol (RAB) is located in the header of the device 

- The patient's medical records or device identification cards, if applicable, must be complete and accurate if they are to be used to verify that the patient has a Reveal XT/DX ICM or that the patient has no additional implanted devices.

Step 2: Preparing a Reveal XT/DX ICM for an MRI Procedure

The following tasks must be completed before performing an MRI procedure on a patient with a Reveal XT/DX ICM:

Check that the system has been implanted for more than six weeks. The six-week post-implant waiting period allows sufficient time for implant pocket and wound healing and minimizes the effects of "tugging" on the device caused by the magnetic fields.

Check that additional implantable devices are not present. Interactions with all other implanted

Step 3: During the MRI Operation

The Reveal XT can be safely scanned in patients under the following conditions:

- Closed bore, cylindrical magnet with static magnetic field must be 1.5 T or 3.0 T.

- Whole body gradient systems with gradient slew rate specification must be ≤200/T/m/s per axis.

- Whole body Specific Absorption Rate (SAR) as reported by the MRI equipment must be ≤2.0 W/kg; head SAR as reported by the MRI equipment must be ≤3.2 W/kg.

- The uninterrupted duration of active scanning (when radio frequency (RF) and gradients are on) over the chest during MRI must not exceed 30 min. If additional chest scans beyond 30 min. are necessary, a waiting period between scans of at least 10 min. is required.

Radiology considerations during the MRI scan: image artifact and distortion

- Reveal XT/DX ICM may cause image distortion in areas that surround the implanted device; this must be considered when selecting the field of view and imaging parameters, as well as during the image interpretation.

Step 4: Post-MRI Operation

After the MRI procedure is complete, it is helpful to check the device to review and erase any episodes that may have been

stored during the MRI procedure due to interference from the magnetic field.

monitors, etc., may adversely affect the performance of this device.

Brief Statement

Indications

9529 Reveal® XT and 9528 Reveal® DX Insertable Cardiac Monitors

The Reveal XT and Reveal DX Insertable Cardiac Monitors are implantable patient-activated and automatically-activated monitoring systems that record subcutaneous ECG and are indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia.

9539 Reveal® XT and 9538 Reveal® Patient Assistants

The Reveal XT and Reveal Patient Assistants are intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event. (Model 9539 only)
- To initiate recording of cardiac event data in the implanted device memory.

Contraindications

There are no known contraindications for the implant of the Reveal XT or Reveal DX Insertable Cardiac Monitors. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings/Precautions

9529 Reveal XT and 9528 Reveal DX Insertable Cardiac Monitors

Patients with the Reveal XT or Reveal DX Insertable Cardiac Monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing. MRI scans should be performed only in a specified MR environment under specified conditions as described in the device manual.

9539 Reveal XT and 9538 Reveal Patient Assistants

Operation of the Model 9539 or 9538 Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer

Potential Complications

Potential complications include, but are not limited to, device rejection phenomena

(including local tissue reaction), device migration, infection, and erosion through the skin.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

Medtronic CareLink Monitor/Medtronic CareLink Network

Intended Use

The Medtronic CareLink Monitor and the Medtronic CareLink Network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician.

Contraindications

There are no contraindications for the Medtronic CareLink Monitor.

Warnings and Precautions

The Medtronic CareLink Monitor must only be used for interrogating compatible Medtronic implantable devices. The Medtronic CareLink Monitor is intended for use within the prescribing country.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physic

REVEAL LINQ LNQ11. Insertable cardiac monitor.

MRI procedural information

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1 Introduction

The Medtronic Reveal LINQ Model LNQ11 Insertable Cardiac Monitor (ICM) is an MR Conditional device and, as such, is designed to allow patients to be safely scanned by a magnetic resonance imaging (MRI) machine. Preclinical testing has demonstrated that the Reveal LINQ device is safe for use in the MRI environment when used according to the MRI conditions for use. Before performing an MRI scan on a patient that has an implanted Reveal LINQ device, the radiology and cardiology staff involved in the procedure should understand the requirements and instructions in this manual. For non-MRI related instructions for use for a Reveal LINQ device, such as the implant procedure and programming instructions, cardiologists should refer to the Reveal LINQ ICM Clinician Manual.

2 MRI conditions for use

The Reveal LINQ device is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to specified MRI conditions for use. The MR Conditional symbol shown below is used to indicate the conditional safety of devices and components in the MR environment.

MR Conditional symbol.

A patient with a Reveal LINQ device can be safely scanned in an MR system that meets the following conditions. Failure to follow these conditions for use may result in a hazard to the patient during an MRI scan:

4. Horizontal cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) or 3.0 T must be used.
5. Hydrogen proton MRI equipment must be used.
6. Maximum spatial gradient of the static magnetic field specification must be ≤25 T/m (2500 gauss/cm).
7. Whole body gradient systems with gradient slew rate specification must be ≤200 T/m/s per axis.
8. The Whole Body Specific Absorption Rate (WB-SAR) as reported by the MRI equipment must be ≤4.0 W/kg; the head SAR as reported by the MRI equipment must be ≤3.2 W/kg.
9. Do not use local transmit coils on the chest, trunk, or shoulder region.
10. There are no restrictions on the placement of receive-only coils, and there are no restrictions on the use of local transmit or receive coils for imaging of the head or extremities.

3 Potential adverse events

There are no known potential adverse events for MRI scans performed on Reveal LINQ patients when the conditions in Chapter 2 are followed.

4 Cardiology responsibilities before and after the MRI scan

Before a radiologist performs an MRI scan on a Reveal LINQ device patient, the cardiology staff should ensure the patient record is up to date with all pertinent information about the implanted Reveal LINQ device, such as model name, model number, and serial number. The patient records must be complete and accurate because the radiology staff uses the records to verify that the patient has a Reveal LINQ device and that the patient has

no other devices, leads, or implanted items that are known to pose a hazard in an MR environment.

After a radiologist performs the MRI scan, Medtronic recommends that a clinician review the patient's data for inappropriately collected episodes that may have occurred during the MRI scan. The data can be collected at the clinician's convenience through a programmer interrogation or by the patient through manual interrogation with the patient's home monitor (for example, the MyCareLink patient monitor).

5 Radiology requirements

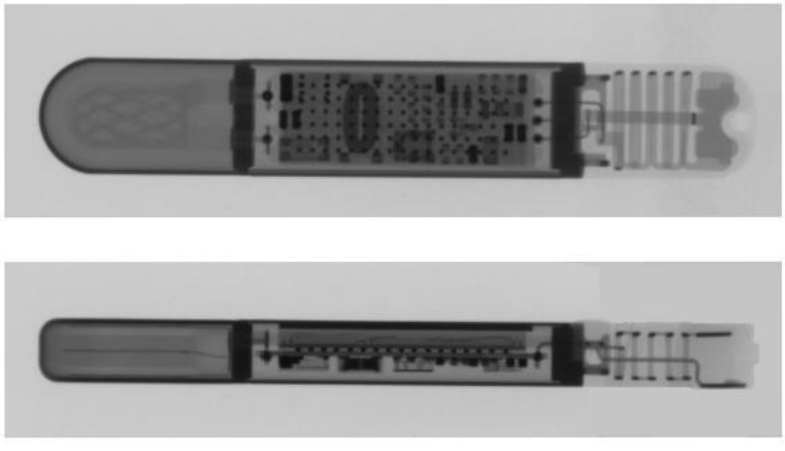
Before the patient receives an MRI scan, the radiology staff should confirm that the following requirements are met:

- The MRI equipment meets all requirements specified in Chapter 2, "MRI conditions for use", page 4.
- The pre-scan cardiology responsibilities have been performed (for more information, see Chapter 4, "Cardiology responsibilities before and after the MRI scan", page 4).

If the radiology staff has questions about whether the patient should receive an MRI scan, the staff should contact the patient's cardiologist. The cardiologist may need to contact Medtronic for guidance.

An X-ray image of the Reveal LINQ device, such as shown in Figure 1, can be used to identify that a patient has a Reveal LINQ device (typically implanted in the left chest area).

Figure 1. Front and side view X-ray images of an implanted Reveal LINQ device



6 Potential effects during an MRI scan

The Reveal LINQ device design and the MRI conditions for use (described in Chapter 2) limit potential effects during an MRI scan to the following. Such effects will not harm the patient or damage the device.

MRI interactions – Due to the static magnetic field and gradient magnetic fields produced by MRI equipment, the magnetic material of an implanted device may exert force, vibration, and torque effects that the patient may or may not feel. The MRI scan may induce currents and voltages in the device, which could lead to tissue heating, nerve stimulation, and electrical stress on device components.

Image artifact and distortion – Image artifact and distortion can result from the presence of the Reveal LINQ device within the field of view. Image artifact and distortion resulting from the presence of the device within the

field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

False Detection and Data Corruption – The MRI scan may impact the sensing circuitry of the Reveal LINQ device which may corrupt the recorded data in the device or could cause false event detection and recording of inappropriate data.

7 Following the MRI scan

The radiology and cardiology staff should ensure that the post-scan cardiology responsibilities described previously in this manual are performed.

Appendix 3

BOSTON SCIENTIFIC Pacing Systems Checklist

ImageReady™ Checklist for Cardiology Department

Refer to the Boston Scientific ImageReady™ MR Conditional Pacing System MRI Technical Guide or link: www.bostonscientific-international.com/MRI

Patient Name: _____

Pacemaker Model: _____ Lead Model(s): _____

Patient Flow

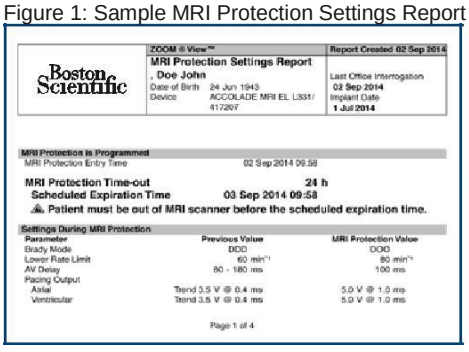
- ☐ Ensure patient eligibility for MRI scan (refer to MRI Conditions of Use, see the right column).
- ☐ As close to start of the scan as possible, program the pulse generator in MRI Protection Mode.
  11. The MRI Protection Settings Report is printed, placed in the patient's file, and provided to radiology personnel.
  12. The report documents MRI Mode settings and details. If the Time-out feature is used, the report includes the exact time and date when MRI Protection Mode will expire. (Figure 1).
  13. Each lead implanted in the patient is identified, and this information is communicated to the health care professionals involved in performing the MRI scan.
- ☐ 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.
- ☐ Patient undergoes scan according to the MRI scan procedure protocol outlined in Technical Guide.
- ☐ The pulse generator is returned to pre-MRI operation, either using the programmer, or automatically if the Time-out parameter was set. Follow-up testing of the pacing system may be performed.

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.

- ☐ Patient is implanted with an ImageReady™ MR Conditional Pacing System (see reverse.)
- ☐ Pulse generator in MRI Protection Mode during scan.
- ☐ 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 cardiac-related implanted devices, components, or accessories present other than an ImageReady™ MR Conditional Pacing System.
- ☐ Pacing threshold ≤ 2.0 V in pace-dependent patients.
- ☐ No abandoned leads or pulse generators.
- ☐ No evidence of a fractured lead or compromised pulse generator-lead system integrity.

Figure 1: Sample MRI Protection Settings Report


Boston Scientific

ZOOM ® View™ — Report Created 02 Sep 2014

MRI Protection Settings Report

, Doe John — Date of Birth 24 Jun 1943 — Device ACCOLADE MRI EL L331/ 417207

Last Office Interrogation 02 Sep 2014 — Implant Date 1 Jul 2014

MRI Protection is Programmed

MRI Protection Entry Time 02 Sep 2014 09:58

MRI Protection Time-out 24 h

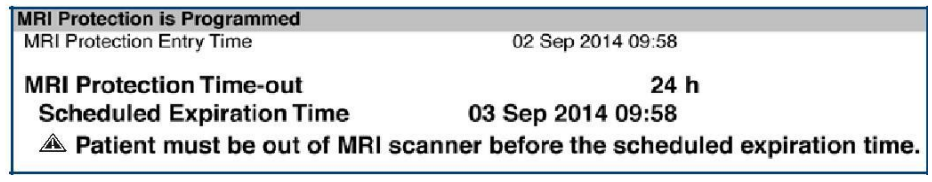
Scheduled Expiration Time 03 Sep 2014 09:58

⚠ Patient must be out of MRI scanner before the scheduled expiration time.

Settings During MRI Protection

Parameter	Previous Value	MRI Protection Value
Brady Mode	DDD	DOO
Lower Rate Limit	60 min⁻¹	80 min⁻¹
AV Delay	80 - 180 ms	100 ms
Pacing Output		
Atrial	Trend 3.5 V @ 0.4 ms	5.0 V @ 1.0 ms
Ventricular	Trend 3.5 V @ 0.4 ms	5.0 V @ 1.0 ms

Page 1 of 4


MRI Protection is Programmed

MRI Protection Entry Time 02 Sep 2014 09:58

MRI Protection Time-out 24 h

Scheduled Expiration Time 03 Sep 2014 09:58

⚠ Patient must be out of MRI scanner before the scheduled expiration time.

Name and signature: _____ Date: _____

ImageReady™ MR Conditional Pacing System Quick Reference 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 only 1.5 T scanners and combinations that are valid for use with both 1.5 T and 3 T scanners.

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

Component	INGEVITY™ MRI Leads	FINELINE™ II Leads
ACCOLADE™ PROPONENT™ ESSENTIO™	3T or 1.5T	1.5T
VITALIO™ MRI FORMIO™ MRI ADVANTIO™ MRI INGENIO™ MRI	1.5T	1.5T
MRI Scanner Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode	Normal Operating Mode

Warnings:

- The combined use of a FINELINE™ II lead and an INGEVITY™ MRI lead with a Boston Scientific MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady™ MR Conditional Pacing System.
- Only the combination of INGEVITY™ MRI lead(s) with an ESSENTIO™ MRI, PROPONENT™ MRI, or ACCOLADE™ MRI pulse generator is valid to use with either 1.5 T or 3T scanners. All other allowable combinations of Boston Scientific MR Conditional system components must use only 1.5 T scanners.

ImageReady™ MR Conditional Pacing System Components for 1.5T and 3T

Component	Model Number(s)	MR Status	3T	1.5T
Pulse Generators				
ESSENTIO™ MRI	L110, L111, L131	MR Conditional	✔	✔
PROPONENT™ MRI	L210, L211, L231	MR Conditional	✔	✔
ACCOLADE™ MRI	L310, L311, L331	MR Conditional	✔	✔
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		✔
Leads and Accessories				
INGEVITY™ MRI Leads				
INGEVITY™ MRI Pacing Lead	7731, 7732, 7735, 7736, 7740, 7741, 7742	MR Conditional	✔	✔
Suture Sleeve for INGEVITY™ MRI Pacing Leads	6402	MR Conditional	✔	✔
IS-1 Lead-Port Plug	7145	MR Conditional	✔	✔
FINELINE™ II Sterox / Sterox EZ Leads				
FINELINE™ II Sterox Pacing Lead	4456, 4457, 4458, 4459, 4479, 4480	MR Conditional		✔
FINELINE™ II Sterox EZ Pacing Lead	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional		✔
Suture Sleeve for FINELINE™ II Pacing Leads	6220, 6221	MR Conditional		✔
IS-1 Lead-Port Plug	7145	MR Conditional		✔
ZOOM™ LATITUDE™ Programmer/Recorder/Monitor (PRM) and PRM Software Application				
ZOOM™ LATITUDE™ PRM	3120	MR Unsafe**		
ZOOM™ LATITUDE™ PRM Software App.	2869	Not Applicable		

Radiology Checklist for the ImageReady™ Defibrillation System

Refer to the Boston Scientific ImageReady™ MR Conditional Defibrillation System MRI Technical Guide[1] or link: www.bostonscientific.com/imageready

Patient Name: _____

Defibrillator Model: _____ Lead Models: _____

Conditions of Use – Radiology

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

- ☐ MRI magnet strength = 1.5 T only.
- ☐ RF field = Approximately 64 MHz
- ☐ Maximum spatial gradient = 50 T/m (5,000 G/cm)
- ☐ MRI equipment specification = Horizontal, 1 H proton, closed bore scanners only
- ☐ Specific Absorption Rate (SAR) limits for the entire active scan (Normal Operating Mode[a]):
  14. Whole body averaged, ≤ 2.0 watts/kilogram (W/Kg)
  15. Head, ≤ 3.2 W/Kg
- ☐ Maximum specified gradient slew rate ≤ 200 T/m/s per axis
- ☐ The use of receive-only coils is not restricted. Local transmit-only coils or local transmit/receive coils may be used, but should not be placed directly over the defibrillation system.
- ☐ Patient in supine or prone position only.
- ☐ Patient must be continuously monitored by pulse oximetry and electrocardiography (ECG) for the entire duration in which the pulse generator is in MRI Protection Mode. Ensure backup therapy is available (external rescue).

[a]As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.

Scanning Procedure

Pre-Scan

- Ensure Cardiology has cleared the patient for scanning eligibility based on the Cardiology MRI Conditions of Use (“Cardiology Checklist for the ImageReady Defibrillation System”).
- 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.
- 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

n 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

n Ensure the pulse generator is returned to pre-MRI operation, either automatically if the Time-out parameter was set, or manually using the PRM. Perform follow-up testing of the defibrillation system after exiting MRI Protection Mode, and continue patient monitoring until the pulse generator is returned to pre-MRI operation.

Warnings:

- nUnless 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.
- nThe Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

ImageReady™ Defibrillation System Components for 1.5 T

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

ImageReady™ MR Conditional Defibrillation System Components for 1.5 T

Component	Model Number(s)	MR Status	1.5 T
Pulse Generators			
AUTOGEN™ ICD	D044, D046, D174, D176	MR Conditional	✔
AUTOGEN™ X4 CRT-D	G179	MR Conditional	✔
Dynagen™ ICD	D020, D022, D150, D152	MR Conditional	✔
Dynagen™ X4 CRT-D	G158	MR Conditional	✔
INOGEN™ ICD	D010, D012, D140, D142	MR Conditional	✔
INOGEN™ X4 CRT-D	G148	MR Conditional	✔
ORIGEN™ ICD	D000, D002	MR Conditional	✔
Leads and Accessories			
FINELINE™ II Sterox Pacing Leads	4479, 4480	MR Conditional	✔
FINELINE™ II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional	✔
Suture Sleeve for FINELINE™ II leads	6220, 6221	MR Conditional	✔
INGEVITY™ MRI Pacing Leads	7735, 7736, 7740, 7741, 7742	MR Conditional	✔
Suture Sleeve for INGEVITY™ MRI leads	6402	MR Conditional	✔
IS--1 Lead Port Plug	7145	MR Conditional	✔
ENDOTAK RELIANCE® (DF4) Defibrillation leads	0265, 0266, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional	✔
RELIANCE 4-Front™ Defibrillation leads	0636, 0654, 0655, 0657, 0658, 0665, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional	✔
Suture Sleeve for RELIANCE 4-Front™ leads	6403	MR Conditional	✔
Acuity™ X4 Pacing leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	✔
Suture Sleeve for Acuity™ X4 leads	4603	MR Conditional	✔
ZOOM™ LATITUDE™ Programmer/Recorder/Monitor (PRM) and PRM Software Application			
ZOOM™ LATITUDE™ PRM	3120	MR Unsafe*	
ZOOM™ LATITUDE™ PRM Software App.	2869	Not Applicable	

***Warning:**

- The Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

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Appendix 3a

BOSTON SCIENTIFIC Defibrillation Systems Checklist

Cardiology Checklist for the ImageReady™

Refer to the Boston Scientific ImageReady™ MR Conditional Defibrillation System MRI Technical Guide or link: www.bostonscientific.com/imageready

Patient Name: _____

Defibrillator Model: _____ Lead Models: _____

Conditions of Use - Cardiology

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

- ☐ Patient is implanted with an ImageReady MR Conditional Defibrillation System (see reverse).
- ☐ No other active or abandoned implanted devices, components or accessories present such as lead adaptors, extenders, leads or pulse generators.
- ☐ Pulse generator in MRI Protection Mode during scan.
- ☐ As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and electrocardiography (ECG). Ensure backup therapy is available (external rescue).
- ☐ Patient is judged to be clinically capable of tolerating no Tachycardia protection and no Bradycardia support (including CRT) for the entire duration in which the pulse generator is in MRI Protection Mode.
- ☐ Patient does not have elevated body temperature or compromised thermoregulation at time of scan.
- ☐ Pulse generator implant location restricted to left or right pectoral region.
- ☐ At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR Conditional Defibrillation System.
- ☐ No evidence of a fractured lead or compromised pulse generator--lead system integrity.

Scanning Procedure

Pre-Scan

16. Ensure patient meets all Cardiology Conditions of Use for MRI scanning (see left column).
17. Exposure to MRI scanning causes a permanent loss of the Beeper volume. The physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper.
18. 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.
19. Print the MRI Protection Settings Report, place it in the patient's file, and provide to radiology personnel.
    - The report documents MRI Protection Mode settings and details. If the Time--out feature is used, the report includes the exact time and date when MRI Protection Mode will expire.

During Scan

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

After Scan

6. Ensure the pulse generator is returned to pre--MRI operation, either automatically if the Time--out parameter was set, or manually using the PRM. Perform follow--up testing of the defibrillation system after exiting MRI Protection Mode, and continue patient monitoring until the pulse generator is returned to pre--MRI operation.
7. The Beeper will remain OFF upon exiting MRI Protection Mode.

Warnings:

- 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.
- The Beeper will no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner causes a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is

performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper. It is recommended that patients are followed on LATITUDE™ NXT after an MRI scan if they are not already, or that the frequency of in-clinic follow-ups is increased.

- If the MRI Protection Time-out value is programmed to Off, the patient will not receive Bradycardia pacing, Cardiac Resynchronization Therapy, or Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.
- The Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

ImageReady™ Defibrillation System Components for 1.5 T

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

ImageReady™ MR Conditional Defibrillation System Components for 1.5 T

Component	Model Number(s)	MR Status	1.5 T
Pulse Generators			
AUTOGEN™ ICD	D044, D046, D174, D176	MR Conditional	✔
AUTOGEN™ X4 CRT-D	G179	MR Conditional	✔
Dynagen™ ICD	D020, D022, D150, D152	MR Conditional	✔
Dynagen™ X4 CRT-D	G158	MR Conditional	✔
INOGEN™ ICD	D010, D012, D140, D142	MR Conditional	✔
INOGEN™ X4 CRT-D	G148	MR Conditional	✔
ORIGEN™ ICD	D000, D002	MR Conditional	✔
Leads and Accessories			
FINELINE™ II Sterox Pacing Leads	4479, 4480	MR Conditional	✔
FINELINE™ II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional	✔
Suture Sleeve for FINELINE™ II leads	6220, 6221	MR Conditional	✔
INGEVITY™ MRI Pacing Leads	7735, 7736, 7740, 7741, 7742	MR Conditional	✔
Suture Sleeve for INGEVITY™ MRI leads	6402	MR Conditional	✔
IS--1 Lead Port Plug	7145	MR Conditional	✔
ENDOTAK RELIANCE® (DF4) Defibrillation leads	0265, 0266, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	MR Conditional	✔
RELIANCE 4-Front™ Defibrillation leads	0636, 0654, 0655, 0657, 0658, 0665, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	MR Conditional	✔
Suture Sleeve for RELIANCE 4-Front™ leads	6403	MR Conditional	✔
Acuity™ X4 Pacing leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	✔
Suture Sleeve for Acuity™ X4 leads	4603	MR Conditional	✔
ZOOM™ LATITUDE™ Programmer/Recorder/Monitor (PRM) and PRM Software Application			
ZOOM™ LATITUDE™ PRM	3120	MR Unsafe*	
ZOOM™ LATITUDE™ PRM Software App.	2869	Not Applicable	

***Warning:**

- The Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

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Appendix 4

ST JUDE Defibrillator Systems Checklist

ICD Systems

Ellipse™ VR ICD
Ellipse™ DR ICD
Fortify Assura™ VR ICD
Fortify Assura™ DR ICD

Patient: _____

Device model: _____ Lead model(s): _____

Steps for an MRI Scan[1] for the Cardiology Department

ICD System Identification	
Implanted ICD and leads are labeled as St. Jude Medical MRI Conditional	☐
Confirmed that other previously implanted (active or abandoned) cardiac hardware that may include medical devices, leads, lead extenders, lead adaptor or port plugs are not present	☐
St. Jude Medical MRI Ready system is implanted in the left or right pectoral region	☐
St. Jude Medical MRI Ready defibrillation lead type identified as either Durata™ lead or Optisure™ lead Note: Please see the St. Jude Medical MRI Procedure Information document for appropriate lead lengths	
St. Jude Medical MRI Ready defibrillation lead identifies as either 58 cm or 65 cm	☐

Preparing Patient for MRI	
MRI settings have been selected and saved	☐
Review the checklist on the Merlin™ programmer and perform required tests[2]	
St. Jude Medical Merlin programmer is used to enable MRI settings	☐
After patient receives MRI scan, disable MRI settings	

Name: _____

Signature: _____ Date: _____

Steps for an MRI Scan[1] for the Radiology Department

MRI Scan Conditions	
Static magnetic field strength of 1.5 Tesla (T) only	☐
Maximum gradient slew rate of 200 T/m/s per axis	
Body coil built into MRI machine used as RF transmitter (Use of local transmit-only or local transmit/receive coils has not been studied. Receive-only coils can be safely used)	☐
Patient properly positioned (not on his or her side within the MRI bore)	
Full St. Jude Medical MRI Ready system pre-approved by Cardiology Department	☐
Continuous monitoring of the patient's hemodynamic function using at least one of the following systems: electrocardiography, pulse oximetry, noninvasive blood pressure measurements	
External defibrillator available during the MRI scan	☐
Different scan zone, whole body SAR levels, and scan time restrictions may apply – St. Jude Medical MRI Procedure Information document consulted to identify the appropriate scan exclusion zone and SAR limit depending on the lead that is used	☐

Name: _____

Signature: _____ Date: _____

Assurity MRI™ Pacemaker Tendril MRI™ Pacing Leads
Endurity MRI™ Pacemaker Tendril™ STS Pacing Leads
Accent MRI™ Pacemaker IsoFlex™ Optim™ Pacing Leads
Endurity™ Pacemaker

Patient: _____

Address: _____

Pacemaker model: _____ Lead model: _____

Steps for an MRI Scan[1] for the Cardiology Department

PACEMAKER SYSTEM IDENTIFICATION	
Implanted pulse generator and leads are labeled as St. Jude Medical MRI Conditional	☐
Confirmed that other previously implanted (active or abandoned) cardiac hardware that may include medical devices, leads, lead extenders, lead adaptor or port plugs are not present	☐
St. Jude Medical MRI Ready pacing system is implanted in the left or right pectoral region	☐
St. Jude Medical MRI Ready lead type identified as either Tendril MRI™ lead, Tendril™ STS lead or IsoFlex™ Optim™ lead Note: Please see the St. Jude Medical MRI Procedure Information document for appropriate lead lengths	☐

PREPARING PATIENT FOR MRI SCAN	
MRI settings have been selected and saved	☐
Review the checklist on the Merlin™ programmer and perform required tests	☐
If the SJM MRI Activator™ device is used[2] (optional): SJM MRI Activator hand-held device has been enabled for use	☐
If St. Jude Medical Merlin programmer[2] is used: Enable MRI settings	☐
After patient receives MRI scan, disable MRI settings	☐

Name: _____

Signature: _____ Date: _____

Steps for an MRI Scan[1] for the Radiology Department

MRI SCAN CONDITIONS	
Static magnetic field strength of 1.5 Tesla (T) only	
Maximum gradient slew rate of 200 T/m/s per axis	
Body coil built into MRI machine used as RF transmitter (Use of local transmit-only or local transmit/receive coils has not been studied. Receive-only coils can be safely used)	
Patient properly positioned (not on his or her side within the MRI bore)	
Full St. Jude Medical MRI-Ready system pre-approved by Cardiology Department	
Continuous monitoring of the patient's hemodynamic function using at least one of the following systems: electrocardiography, pulse oximetry, noninvasive blood pressure measurements	
External defibrillator available during the MRI scan	
Scan zone and scan time restrictions may apply - St. Jude Medical MRI Procedure Information document, or the symbology table, consulted to identify the appropriate scan exclusion zone and SAR limit depending on the lead that is used	

IF SJM MRI ACTIVATOR™ DEVICE IS USED[2] (optional)	
Verify with cardiologist that SJM MRI Activator device has been enabled through the Merlin™ Patient Care System (PCS)	
Check MRI settings status using the SJM MRI Activator hand-held device	
Enable MRI settings before the MRI scan using the SJM MRI Activator hand-held device	
After patient receives MRI scan, disable MRI settings right after the scan using the SJM MRI Activator hand-held device	

20. For the complete set of instructions, refer to the St. Jude Medical MRI Procedure information document, the Accent MRI pacemaker, IsoFlex Optim, Tendril STS, and Tendril MRI lead manuals and the SJM MRI Activator device manual.
Do not take the Merlin Programming system or SJM MRI Activator device into the MRI room (Zone IV) or past the 5 Gauss line.

Name: _____

Signature: _____ Date: _____

Appendix 4a

ST JUDE Pacing Systems Checklist

Assurity MRI™ Pacemaker Tendril MRI™ Pacing Leads
Endurity MRI™ Pacemaker Tendril™ STS Pacing Leads
Accent MRI™ Pacemaker IsoFlex™ Optim™ Pacing Leads
Endurity™ Pacemaker

Patient: _____

Address: _____

Pacemaker model: _____ Lead model: _____

Steps for an MRI Scan[1] for the Cardiology Department

PACEMAKER SYSTEM IDENTIFICATION	
Implanted pulse generator and leads are labeled as St. Jude Medical MRI Conditional	☐
Confirmed that other previously implanted (active or abandoned) cardiac hardware that may include medical devices, leads, lead extenders, lead adaptor or port plugs are not present	☐
St. Jude Medical MRI Ready pacing system is implanted in the left or right pectoral region	☐
St. Jude Medical MRI Ready lead type identified as either Tendril MRI™ lead, Tendril™ STS lead or IsoFlex™ Optim™ lead Note: Please see the St. Jude Medical MRI Procedure Information document for appropriate lead lengths	☐

PREPARING PATIENT FOR MRI SCAN	
MRI settings have been selected and saved	☐
Review the checklist on the Merlin™ programmer and perform required tests	☐
If the SJM MRI Activator™ device is used[2] (optional): SJM MRI Activator hand-held device has been enabled for use	☐
If St. Jude Medical Merlin programmer[2] is used: Enable MRI settings	☐
After patient receives MRI scan, disable MRI settings	☐

Name: _____

Signature: _____ Date: _____

ST. JUDE MEDICAL

Steps for an MRI Scan[1] for the Radiology Department

23.

MRI SCAN CONDITIONS	
Static magnetic field strength of 1.5 Tesla (T) only	☐
Maximum gradient slew rate of 200 T/m/s per axis	☐
Body coil built into MRI machine used as RF transmitter (Use of local transmit-only or local transmit/receive coils has not been studied. Receive-only coils can be safely used)	☐
Patient properly positioned (not on his or her side within the MRI bore)	☐
Full St. Jude Medical MRI-Ready system pre-approved by Cardiology Department	☐
Continuous monitoring of the patient's hemodynamic function using at least one of the following systems: electrocardiography, pulse oximetry, noninvasive blood pressure measurements	☐
External defibrillator available during the MRI scan	☐
Scan zone and scan time restrictions may apply - St. Jude Medical MRI Procedure Information document, or the symbology table, consulted to identify the appropriate scan exclusion zone and SAR limit depending on the lead that is used	☐

IF SJM MRI ACTIVATOR™ DEVICE IS USED[2] (optional)	
Verify with cardiologist that SJM MRI Activator device has been enabled through the Merlin™ Patient Care System (PCS)	☐
Check MRI settings status using the SJM MRI Activator hand-held device	☐
Enable MRI settings before the MRI scan using the SJM MRI Activator hand-held device	☐
After patient receives MRI scan, disable MRI settings right after the scan using the SJM MRI Activator hand-held device	

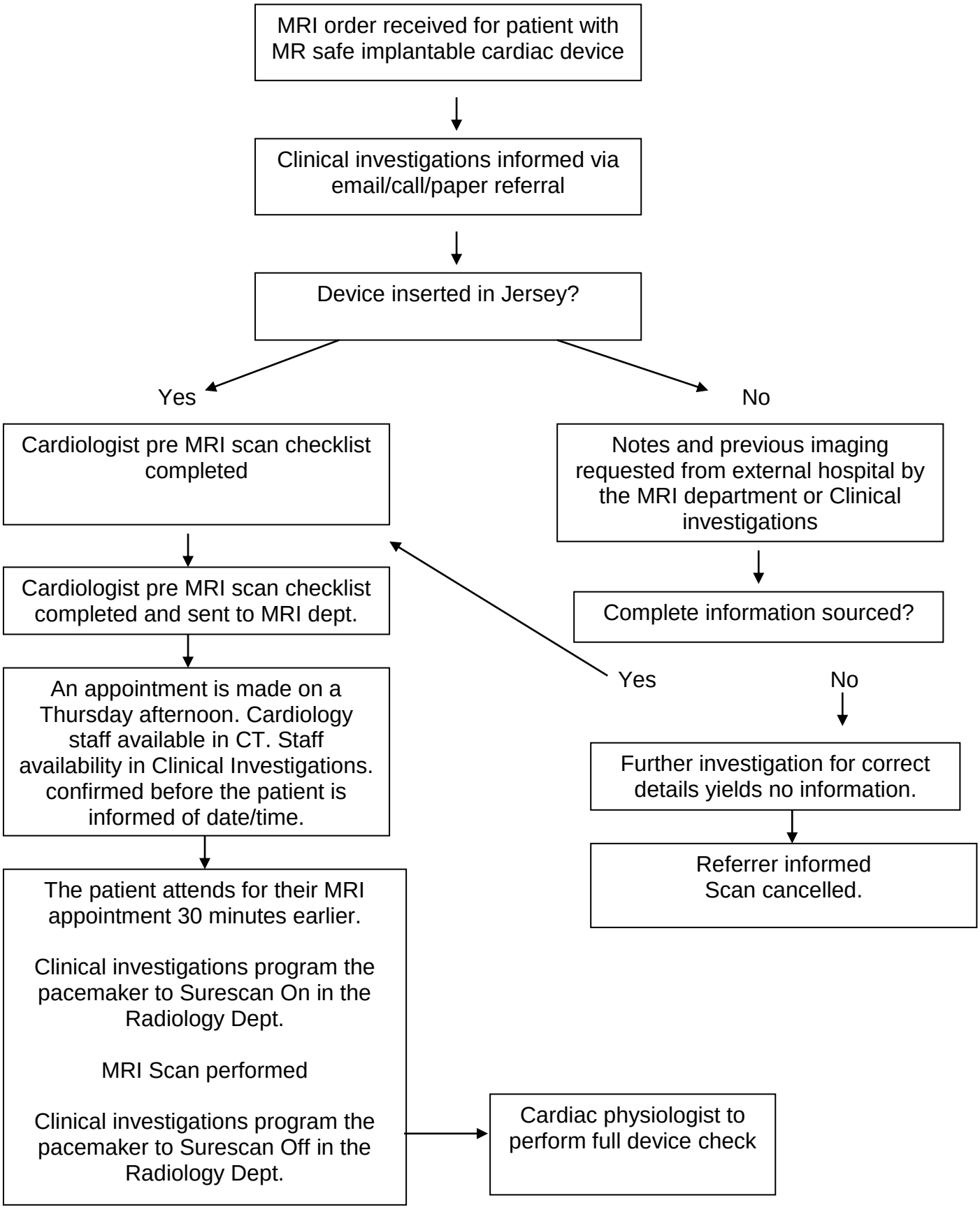
21. For the complete set of instructions, refer to the St. Jude Medical MRI Procedure information document, the Accent MRI pacemaker, IsoFlex Optim, Tendril STS, and Tendril MRI lead manuals and the SJM MRI Activator device manual.
22. Do not take the Merlin Programming system or SJM MRI Activator device into the MRI room (Zone IV) or past the 5 Gauss line.

Name: _____

Signature: _____ Date: _____

Appendix 5

MRI patient pathway for MR compatible cardiac devices



Appendix 6

Pacemaker Pathway

Refer also to Policy for MRI Scanning of Implantable Cardiac Devices