

Policy: MRI Policy for Patients with Cardiac Implanted Electronic Device (CIED) Devices

ORGANIZATIONAL: Affects two or more departments.							
Folder	Organizational Choices: Clinical			Sub-Folder (If Applicable)	Cardiac Patient Care		
Original Effective Date	5/1/2018	Scope	What departments does this policy apply to? State "All" as is may apply to the entire organization. Radiology/MRI, Cardiology				
Approved (Approver/Date)	Dr. Soto 3/19/18; Dr. Murdock 3/19/18; MDRC:4/19/18; MEC: 4/24/18						
Last Reviewed/ Revised Date	4/24/2018	OSHA Category (If Applicable)	Not Applicable	Standard (If Applicable)	n/a	Number of pages	10

PURPOSE: *Why does this policy exist?*

To define conditions that will allow patients with a Cardiac Implanted Electronic Device (CIED) to undergo elective Magnetic Resonance (MR) imaging.

SKILL LEVEL: *Who is qualified to perform this procedure or affected?*

Providers-Cardiologist, Radiologists, MRI Tech, Nursing

GUIDELINES: *What are some general statements regarding the use of the policy?*

Although the presence of a CIED has historically been a contraindication for the performance of MR imaging, sufficient evidence has accumulated in recent years to conclude that MR imaging of patients with a CIED is reasonable when necessary for the diagnosis or treatment of illness or injury. This document outlines an institutional policy of the performance of MR imaging in patients having either an MR-Conditional or MR-Nonconditional CIED in accordance with the *2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices*.

PROCEDURE: *Include: Definitions, Equipment, Process, and Documentation*

Definitions:

MR-Conditional

Any device for which a specified MRI environment with specified conditions of use does not pose a known hazard. Field conditions that define the MRI environment can include the region of imaging, static magnetic field strength, spatial gradient, time-varying magnetic field (dB/dt), radiofrequency (RF) fields, and specific absorption rate (SAR).

Additional conditions might be required, including the use of specific leads and generator combinations, as well as MRI mode programming of the CIED system.

MR-Nonconditional

All devices other than those that meet MR-conditional labeling. This includes MR conditional components that have been combined with those that are nonconditional or MR conditional systems implanted in patients that do not meet all specified conditions of use.

Procedure Scheduling:

- The Department of Radiology will designate one or more physicians as the **CIED Radiology Physician(s)** for the purposes of reviewing all requests for the performance of *elective* MR imaging in patients with CIEDs.
- The presence of a CIED is to be documented on all MRI requests.
- If a CIED is present, then the diagnostic need for the *elective* MRI and alternatives will be reviewed by the **CIED Radiology Physician(s)**; if the need for an MRI is confirmed, then the request will be forwarded to the CRM Device Clinic Manager at Cardiovascular Consultants (CVC). All requests forwarded to CVC must include the following elements:
 - Type of MRI scan and indication(s)
 - Name of provider who ordered the MRI
 - Name of the **CIED Radiology Physician** who reviewed the request for the MRI
- All patients with a CIED who are not already established with a CVC physician will need to be seen by a CVC Cardiologist with CIED privileges in consultation at the request of the physician ordering the MRI. In circumstances where Electrophysiology consultation is required, such a request may be made by the physician ordering the MRI or by the patient's primary CVC Cardiologist.
- A **CIED Safety Assessment and Recommendations for MRI Report (CSR)** is to be generated for all patients with a CIED for whom an *elective* MRI is requested (see Appendix A). The **CSR** will be generated by the CRM Device Clinic Manager, and will contain the following elements:
 - Patient identification
 - Identification of currently implanted lead(s) and device
 - Presence of abandoned and fractured lead(s)
 - Full evaluation of the device and lead(s)
 - Manufactures' recommendation for MR conditionality (*for MR-conditional devices only*)

- The CSR will either specify recommendations addressing pre-, peri- and post-scan requirements and follow-up or will document contraindications for proceeding with a scan.
- The **CSR** will be reviewed by the patient’s Cardiologist of record, who will append the CSR with one of the two following recommendations and sign the **CSR** electronically:
 - “APPROVED BY CARDIOLOGY: May proceed with MRI pending adherence to recommendations contained within this report and in accordance with institutional MRI Policies.”
 - “CONTRAINDICATED: May NOT Proceed with MRI.”
- The signed **CSR** will be forwarded to the Radiology Department upon completion. For MRIs determined to be “CONTRAINDICATED” by Cardiology, the request for the scan will be cancelled. The ordering provider will be notified by the Radiology Department as to Cardiology’s objections to the scan. For MRIs “APPROVED” by Cardiology, the CSR will be forwarded to the **CIED Radiology Physician(s)** for review to make sure that all requisite conditions and recommendations can be met for the safe performance of the scan. The **CIED Radiology Physician(s)** will append the CSR with one of the two following recommendations and sign the **CSR** electronically:
 - “APPROVED BY RADIOLOGY: Plan for adherence to all recommendations contained within this report.”
 - “REJECTED: Unable to provide adherence to all recommendations.”
- Upon documentation of approval by both Cardiology and Radiology, the *elective* MRI scan will be scheduled by the Department of Radiology in coordination with CVC to ensure that a qualified cardiologist, nurse practitioner or physician assistant and CIED Technician will be on the main hospital campus at the time that the MRI is performed (and in attendance, if required).
- In the event Radiology feels that the recommendations contained within the **CSR** cannot be followed, the **CIED Radiology Physician(s)** will contact Cardiology to discuss the reasons why those recommendations cannot be followed and to see if alternate recommendations can be made that—if followed—would allow for the safe performance of the exam. If such changes can be made, then they are to be documented (either as a new **CSR** submission or as an addendum to the original **CSR**), with such documentation electronically signed by both Cardiology and Radiology.
- This policy specifically excludes all urgent and emergent MR imaging of patients with a CIED (*e.g.*, a patient with an acute spinal cord compression syndrome or spinal cord abscess in whom a delay in timely diagnostic testing may lead to permanent loss of

function or death). In these cases, Cardiology Consultation will be obtained for specific guidance and recommendations.

Pre-Scan (Day of MRI):

- Patient will undergo any pre-scan interrogations or device programming changes as outlined in the CSR.
- The MR Technologist will review the CSR and ensure that the planned scan protocol includes adherence to all recommendations outlined in the CSR.
- The MR Technologist will confirm documentation of consent, which is to specifically address: “**Consent to MRI Examination with Implanted Cardiac Device**”.
- In the MRI prep-area, the MR-compatible oximetry or ECG will be attached to the patient and activated.
- The MR Technologist will confirm that all pertinent staff have been notified and are in position as outlined below prior to the patient leaving the prep-area.

MR Scan:

- Personnel Requirements:
 - Patients with an **MR-Conditional** CIED Undergoing MRI:
 - MR Technologist must in in attendance for the scan duration.
 - ACLS-trained nurse must be in attendance for the scan duration.
 - CIED Representative must be at the main hospital campus for the scan duration.
 - A qualified cardiologist, nurse practitioner or physician assistant with expertise in CIED management must be at the main hospital campus for the scan duration.
 - Patients with an **MR-Nonconditional** CIED Undergoing MRI:
 - MR Technologist must in in attendance for the scan duration.
 - ACLS-trained nurse must be in attendance for the scan duration.
 - CIED Representative must be in attendance for the scan duration.
 - A qualified cardiologist, nurse practitioner or physician assistant with expertise in CIED management must directly supervise the scan as defined in 42 CFR §410.28 and § 410.32.¹

¹ For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65, “direct supervision” means that the provider must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the provider must be present in the room where the procedure is performed.

- Perform scan subject to SAR and duration recommendations as outlined in the CSR.
- Continuous monitoring of oximetry and ECG is to be performed by a nurse or physician.
- Visual and voice communication will be maintained with the patient.
- Abort scan immediately in the event of any observed inhibition of pacing in a pacemaker-dependent patient, ventricular tachyarrhythmia in any patient, or any unexpected hemodynamic instability.

Post-Scan (Day of MRI):

- Return patient to the prep area.
- Patient will undergo any post-scan interrogations or device programming changes as outlined in the **CSR**.
- Printed reports from the CIED programmer are to become part of the patient’s medical record.
- Any exceptions to the performance of the planned MR protocol will be documented by the MR Technologist and added to the patient’s Medical Record.
- Follow-up in the CRM Device Clinic is to be scheduled as recommended in the **CSR**.
- For patients with MR-nonconditional devices, the cardiologist, nurse practitioner or physician assistant supervising the study will leave a progress note attesting to their presence during the scan—noting any adverse events—and will make any appropriate recommendations not contained within the CSR (if indicated).

EDUCATION AND TRAINING

- All staff will be trained according the MRI staff safety policy.
- Appropriate nursing staff will receive an in-service delivered by the Electrophysiology Department regarding the performance of MR imaging in patients with CIEDs.

REFERENCES: *What resources are used to support the policy and procedure?*

2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices. © 2017 Published by Elsevier Inc. on behalf of Heart Rhythm Society.

CMS Memo

CMS Decision Memo for Magnetic Resonance Imagery (MRI) (April 10, 2018) Retrieved from

<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=289> on

April 16, 2018

Attachments: (Label as Appendix A, B, C, etc.)

Appendix A: CIED Safety Assessment and Recommendations for MRI Report (CSR)

Appendix B: MRI Supervision of Patient with CIED

Appendix A

The following template is meant to serve as a guide for the general contents that are to be included in the CSR. The actual format and/or contents may change subject to future updates to professional practice guidelines, changes in CIED manufacturer's recommendations, of the needs of the Cardiology and Radiology Departments for the safe performance of the MRI studies.

CIED Safety Assessment and Recommendations for MRI Report (CSR)

SECTION 1 – CIED SYSTEM INFORMATION:

General:

Date of Interrogation: [mm/dd/yyyy]

Pacing Dependent: [Yes | No]

Presence of any fractured, abandoned or epicardial leads: [Yes | No]

Device implantation or any lead revision or surgical modification within last 6 weeks: [Yes | No]

Generator:

Type: [ILR | PPM | CRT-P | ICD | CRT-D]

Manufacturer: [Abbott | Medtronic | Boston Scientific | Biotronik]

Model#: []

Battery Voltage: [] V

Leads:

RA:

Manufacturer: [Abbott | Medtronic | Boston Scientific | Biotronik]

Model#: []

Sensing (mV): []

Capture Threshold (V): []

Impedance (Ohms): []

RV:

Manufacturer: [Abbott | Medtronic | Boston Scientific | Biotronik]

Model#: []

Sensing (mV): []

Capture Threshold (V): []

Impedance (Ohms): []

Shock Coils (if applicable):

RV Impedance (Ohms): []

SVC Impedance (Ohms): []

LV:

Manufacturer: [Abbott | Medtronic | Boston Scientific | Biotronik]

Model#: []

Sensing (mV): []

Capture Threshold (V): []

Impedance (Ohms): []

SECTION 2 – MR CONDITIONAL STATUS

Is the system classified as MR-Conditional: [Yes | No]

Scan Requirements for MRI Conditionality:

- Static magnetic field of 1.5 T
- Cylindrical bore
- Maximum SAR of 2 W/kg
- Maximum head SAR of 3.2 W/kg
- Maximum gradient slew rate of 200 T/m per second

Other Scan Requirements for MRI Conditionality: [None | Specify]

Patient Requirements for MRI Conditionality:

- Absence of any fractured, abandoned or epicardial leads
- Implant date for most recent lead \geq 6 weeks

SECTION 3 – RECOMMENDATIONS

General:

- MRI May be scheduled subject to adherence to the specific recommendations below and verification of the following:

MR-Conditional Devices:

- All scan and patient requirements for MRI Conditionality are met.

MR-Nonconditional Devices:

- There are no fractured, abandoned or epicardial leads

Pre-Scan:

MR-Conditional Devices:

[] Activate pre-MR imaging pacing mode

MR-Nonconditional Devices:

[] Program pacing to OVO/ODO

or

[] Program pacing to VOO/DOO

- If programming to VOO/DOO and there is an underlying rhythm, program the pacing rate faster than the underlying rate to avoid competitive pacing.
- Deactivate magnet, rate, and noise response and all advanced features.
- Deactivate tachycardia detection and therapies.
- Monitor the ECG and pulse oximetry by ACLS-trained personnel during the time the patient's device is reprogrammed and until assessed and declared stable to return to unmonitored status.
- Keep external defibrillator and CIED programmer available.

Scan:

- Monitor the ECG and pulse oximetry by ACLS-trained personnel throughout the scan and maintain voice contact with the patient.

Post-Scan:

- Restore all original programming unless pacing output or sensing needs to be adjusted based on post-MRI CIED evaluation.
- Schedule follow-up in CRM Device Clinic in 3 months after MRI unless earlier follow-up (within 1 week) is indicated for the following:
 - Any capture threshold increase > 1.0 V
 - Any sensing drop > 50%
 - Any pacing impedance change > 50 Ohms
 - Any shock impedance change > 5 Ohms

SECTION 4 – APPROVALS / DENIALS

After completion of this report and its review by Cardiology, this form must be signed by the attending Cardiologist of record with an addendum containing one of the following two statements:

- “APPROVED BY CARDIOLOGY: May proceed with MRI pending adherence to recommendations contained within this report and in accordance with institutional MRI Protocol.”
- “CONTRAINDICATED: May NOT Proceed with MRI.”

Following the return of this form to and its review by Radiology, this form must be signed by the attending Radiologist of record with an addendum containing one of the following two statements:

- “APPROVED BY RADIOLOGY: Plan for adherence to all recommendations contained within this report.”
- “REJECTED: Unable to provide adherence to all recommendations.”

MRI scans are only to be scheduled when recommendations within this report have been unambiguously approved by both Cardiology and Radiology. Specific contraindications or reasons for rejection are to be documented as an addendum to this report.

This report and its recommendations are valid for a period of 30 days from its initial generation.

Appendix B

The following template is meant to serve as an example for the physician or APRN documentation that is to be left in the medical record following the conclusion of all MRI scans on patients with MR-nonconditional devices.

MRI Supervision of Patient with CIED

I directly supervised the MRI scan in a standby service capacity for any potential CIED-related complications associated with the scan, as well as any pre- and post-scan CIED programming changes.

Complications: None Other:

Time spent participating in the care of this patient: min