

**UNIVERSITY HOSPITAL OF BROOKLYN/SUNY DOWNSTATE HEALTH SCIENCES
UNIVERSITY
POLICY AND PROCEDURE**

Subject: Magnetic Resonance Imaging for Patients with Cardiac Implantable Electronic Devices (CIED)

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No: MRI-17

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Original Issue Date: April 21, 2021

Supersedes: New

Effective Date: April 21, 2021

Related Policies:

The JC Standards: EC.02.01.01
The hospital manages safety and security risks.

Issued by: Regulatory Affairs

I. PURPOSE

To provide guidelines to ensure patient and staff safety when performing Magnetic Resonance Imaging (MRI) on patients with Cardiovascular Implantable Electronic Devices (CIED's).

II. DEFINITIONS

The following devices are classified as CIED's: implantable cardiac pacemakers, cardioverter defibrillators, cardiac resynchronization therapy pacemakers, and cardiac resynchronization therapy defibrillators.

Terminology used to describe MRI compatibility:

MR safe: Any object, device, implant, or equipment that poses no known hazards in the MRI environment because they have no magnetic pull and are therefore safe to enter the MRI scan room.

MR-conditional: Are devices that pose no known hazards in a specific MRI environment, under specific device and MRI scanner conditions.

MR-nonconditional devices: Objects not deemed MR-conditional or MR-safe.

MR unsafe: Objects that are known to pose a risk in all MRI environments.

Note: ALL CIED's are classified as either MR-conditional or MR-nonconditional devices, they are NOT classified as MR-safe by the FDA.

III.

RESPONSIBILITIES

- MRI Technologists
- Radiology Attending Physicians
- Radiology Residents
- Cardiologist Electrophysiologist (EP)
- RN, Nurse Practitioner
- Physician Assistant

IV. POLICY

All patients with CIEDs require completion (in Healthbridge) of the "CIED Safety Assessment and Recommendation for MRI Report" form (see Appendix A) by the EP physician prior to MRI. The form includes but is not limited to:

- Documentation of the type of implanted device generator, lead(s)
- Presence of abandoned or fractured lead(s)
- Classification of whether the device is MR-conditional or MR-nonconditional
- Recommendations regarding pre-, peri- and post-scan requirements
- Documentation of any contraindication/s for the procedure

V. PERSONNEL REQUIREMENTS

1. An ACLS-certified physician, physician assistant, RN or NP must be in attendance for the duration of the scan for continuous patient monitoring
2. An electrophysiology (EP) fellow or attending physician with CIED management expertise must be immediately available while the scan is in process.

VI. PROCEDURES

A. Pre-MRI Procedures: Prior to scheduling the patient, the following procedures must be completed.

1. Patient selection:

Despite the relative safety when MR is performed according to prescribed safety measures, serious adverse events have been reported (and likely underreported). Therefore, patients with CIEDs should only undergo MRI when there is a strong indication for the study and the potential benefit outweighs the potential risk.

2. Review of ordered imaging study:

Every MRI order (except for emergent studies) is reviewed by a radiology resident or radiology attending physician for appropriateness of study selection.

The reviewing radiologist (attending or resident) should complete a consultation form (see Appendix B) on all patients with CIED's before scheduling an MR. The workflow is detailed as follows:

- a. Contact the EP to discuss the risks and benefits of the procedure. This discussion should include whether the examination results will directly impact patient care/goals of care, etc.
- b. If the discussion reveals that the risk to the patient is not worth the benefit, the radiology (resident or attending physician) should contact the provider who ordered the MRI and suggest alternate studies.
- c. Scan the completed consultation form into the electronic medical record in RIS.

3. Absolute Contraindications:

The following are absolute contraindications for MR:

- ICDs implanted before the year 2000 or pacemakers implanted before 1998
- Patients who are dependent on an ICD (not a pacemaker) for pacing (i.e., have no intrinsic escape or an escape that is too slow to be acceptable for pacing to be turned off during the scan)
- Temporary pacemakers (e.g., transvenous temporary wires)
- Leads that have no fixation (e.g., free-floating SVC coil)
- Abandoned leads (capped or retained leads and not attached to a device)

4. Relative Contraindications:

The following are relative contraindications that may pose an increased risk. MRI may still be deemed necessary after careful consideration of risks/benefits as determined by the EP attending physician, referring physician, and/or Radiologist:

- Pacemakers or ICD's implanted < 6 weeks prior to proposed MRI
- Non-transvenous leads (e.g., epicardial leads)
- Lead/s that is/are known or suspected to be fractured
- Subcutaneous leads
- Dislodged right atrial leads (in the internal jugular, etc.)
- Permanently implanted devices temporarily externalized and adhered to the skin
- If MRI is requested in an unresponsive patient, the attendings physicians must agree with the indication for the exam and documentation of the absence of any acceptable alternative imaging modalities

5. Scheduling:

a. Inpatients:

- The referring physician/service must obtain an Electrophysiology consult.
- A current chest X-ray (CXR) is required for the EP physician to complete the required pre-MR assessment.
The referring physician/service must ensure that a CXR was obtained during the current admission prior to consulting EP.
- Once approved by EP, the ordering physician shall place an MR order.
- Radiology will then schedule the imaging exam and:
 - ✓ coordinate/arrange for staff (resident, RN, NP or PA) to monitor the patient during the scan
 - ✓ coordinate/arrange for an EP fellow or attending physician to place the device in “MRI mode” prior to beginning the scan

b. Outpatients:

- Radiology scheduling staff shall contact the radiology resident/attending radiologist to confirm that the case has been reviewed and is indicated
- Radiology scheduling staff shall verify the reviewing radiologist (attending or resident) completed consultation form in RIS before scheduling MR
- Radiology scheduling staff will contact the patient to obtain a copy of the device implant card which contains the manufacturer’s information and forward it via email to the EP physician providing device clearance/MRI device compatibility.
- A recent CXR report is required to complete the EP pre-MR assessment.
The CXR report will be obtained by Radiology scheduling staff and forward it to the EP. If the patient does not have a recent CXR report available, the Radiology scheduling staff will schedule the patient for a CXR prior to contacting the EP physician.
- Radiology will schedule the MRI exam and:
 - ✓ coordinate/arrange for staff (resident, RN, NP, or PA) to monitor the patient during the scan
 - ✓ coordinate/arrange for an EP fellow or attending physician to place the device in “MRI mode” prior to beginning the scan

- **Peri-MRI Procedures:** On the day of the MRI, the following procedures must be completed before imaging begins.

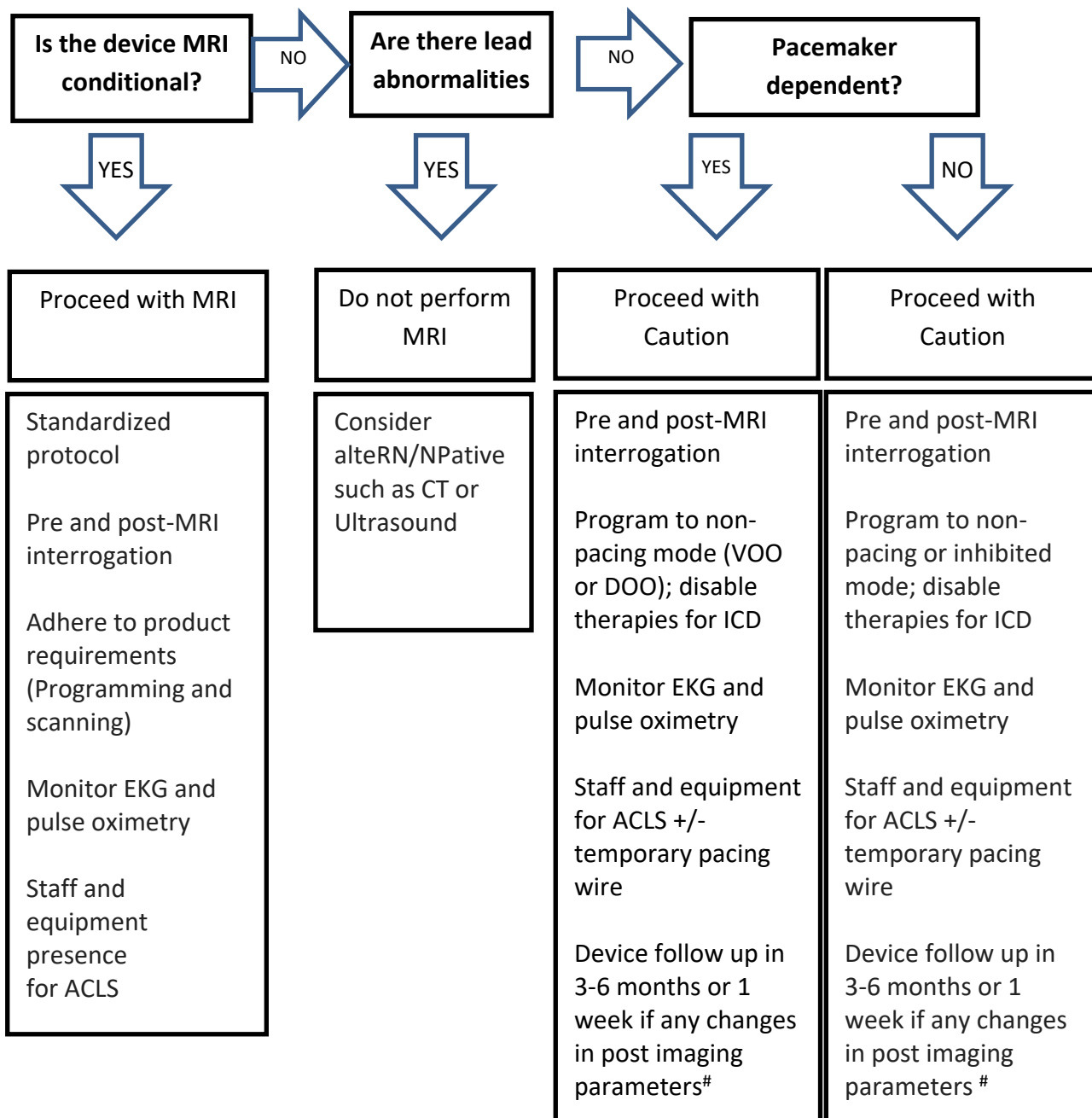
The following must be completed on the day of scanning:

1. The MR technologist will review the "MRI Safety Form" with the patient to screen for any other objects/implants and obtain the patient's signature.
2. The technologist must sign, date, and time the "MRI Safety Form".
3. The MR Technologist must confirm there is a signed "General Consent" form on record before proceeding.
4. MRI Technologist will complete "Radiology Timeout Checklist for Critically Ill Patients for Imaging," and scan completed form into the patient records in RIS
5. The MR Technologist contacts the RN, NP, MD, or PA who is scheduled to perform the monitoring, and informs them of the patient's arrival. **Subsequent steps may not proceed until the assigned RN, NP, MD, or PA arrives in the MR suite to monitor the patient.**
6. When the RN, NP, MD, or PA arrives in the MRI suite, the radiology nurse technician shall apply the continuous monitoring equipment and obtain a baseline ECG.
7. The assigned RN, NP, MD or PA will perform continuous cardiac monitoring for the duration of the scan.
8. After the baseline ECG is obtained, the MR Technologist shall notify the EP fellow or attending physician, who will perform the following in the MR suite:
 - a. Conduct a pre-scan interrogation of the device.
 - b. Perform the required device programming changes, as specified in the MRI Safety Assessment that is documented in Healthbridge (Appendix A).
 - c. Place the CIED in "MR mode".
9. The MRI technologist will review the EP assessment and ensure that the MR protocol follows all recommendations, including Specific Absorption Rate (SAR) and total scan time duration recommendations.
10. MRI exams for patients with CIEDs should not exceed 30 minutes.

11. The radiology registrar/radiology technologist shall page the EP fellow or attending physician approximately mid-way through the exam, to notify them to return to the MR suite because study completion is imminent.
12. The MR staff shall maintain visual and voice communication with the patient from the control room, throughout the procedure.
13. The scan shall be aborted immediately in the event of an untoward event or hemodynamic instability.

Post- MRI Scan Assessment: On the day of the MRI, the following procedures must be completed after imaging is completed:

1. Directly after scanning, while the patient is still in the MRI suite, the EP fellow or attending physician will perform the post-scan interrogation of the device and complete the programming as indicated in their initial MRI Safety Assessment in Healthbridge.
2. All printed reports generated from the pacemaker programming device used by EP, become part of the patient's medical record.
3. If any exceptions to the MR Imaging protocol were required, they will be documented in the Radiology Information System (RIS) by the MR Technologist.
4. The MR/Radiology registrar will contact the patient's primary care physician to:
 - a. confirm that the MRI was completed
 - b. reiterate to the PCP that the patient requires a follow up visit with the EP physician within three months.
*The patient's PCP is responsible for scheduling the post-imaging follow-up appointment with the EP physician within three months, unless otherwise specified.
5. For patients with MR-nonconditional devices, the MD, RN, NP, or PA who monitors the patient during the study, will write a progress note attesting to their presence during the scan (Appendix C), including documentation of any adverse or untoward events and appropriate recommendations. A physician must sign the discharge note for outpatients.



Checklist for treatment of patients referred for MRI with implantable electrical device.
Adapted from the Heart Rhythm Society 2017

*Fractured, abandoned, or epicardial leads

VII. ATTACHMENTS

- Appendix A: CIED Safety Assessment and Recommendations for MRI Report
- Appendix B Radiology Consult form for Patients with CIED
- Appendix C: MRI Supervision of Patients with CIED
- Appendix D: Radiology Timeout Checklist for Imaging Critically Ill Patients

VIII. REFERENCES

1. MRI in Patients with Cardiac Implantable Electronic Devices. Muthalaly RG, Nerlekar N, Ge Y, et.al. Radiology 2018; 289:281-292. <https://doi.org/10.1148/radiol.2018180285>
2. Making MRI available for patients with cardiac implantable electronic devices: growing need and barriers to change. Bhuvana AN, Moralee R, Moon JC, Manisty CH. EUR Radiol. 2020; 30(3):1378-1384. <https://doi.org/10.1007/s00330-019-06449-5>.
3. ACR Manual on MR Safety version 1.0, 2020

Date Reviewed	Revision Required (Check One)		Responsible Staff Names and Title
	Yes	No	
	Yes	No	Donna McKenzie EMBA, RT
	Yes	No	

APPENDIX A:

CIED Safety Assessment and Recommendations for MRI Report

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 the 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

[] 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 from the time the patient's device is reprogrammed and until assessed and declared stable to return to unmonitored status.
- Keep an 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 pacemaker evaluation.
- Schedule follow-up in Cardiology Clinic in 3 months after MRI unless earlier follow-up (within 1 week) is indicated for the following
 - o Any capture threshold increase > 1.0 V
 - o Any sensing drop > 50%
 - o Any pacing impedance change > 50 Ohms
 - o Any shock impedance change > 5 Ohms

SECTION 4 – APPROVALS / DENIALS

The attending Cardiologist of record must sign this form 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 the institutional MRI Protocol."
- "CONTRAINDICATED: May NOT Proceed with MRI."

Following the completion of this form and its review by Radiology, it 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."

MR scans are scheduled when both Cardiology and Radiology have unanimously approved recommendations within this report. Specific contraindications or reasons for rejection are to be documented as an addendum to this report.

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

APPENDIX B:

Department of Radiology

Consult for Patients with CIED's

If an MRI scan is the only test that can provide a medical diagnosis or information for treatment planning, a series of steps must be followed to ensure patient safety during the examination. A comprehensive review of the patient's clinical history must occur to rule out alternative imaging options. Before scheduling the patient, all parties involved (radiology, referring physician, and cardiology) must agree that the benefits outweigh the risk of the procedure.

Please complete this form as part of the patient evaluation process:

Patient History: _____

How will the information obtained from this examination aid in diagnosis and/or treatment:

Risks: _____

Benefits: _____

Alternate Imaging:

Signature

Date

Signature

Date

Radiology Attending/ Resident Signature

Electrophysiology (EP) Services

APPENDIX C:

MRI Supervision of Patient with CIED

The following template is an example for the physician or PA, RN, NP 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

Signature

Time

Date

APPENDIX D:

DEPARTMENT OF RADIOLOGY			
Radiology Timeout Checklist for Imaging Critically Ill Patients			
(To be conducted by Radiologic Technologist)			
Patient Name:		MR#:	
Date & Time:		Imaging Modality:	
Technologist conducting Timeout:			
I: On arrival in the Imaging suite, the following must be confirmed:			
Equipment checked prior to use	Responsible Department	Zone	Check completed Yes/No/NA
MRI Ventilator/Compatibility/Pre-Use Check	Respiratory	3	
MRI compatible O ₂ tank	Respiratory	3	
MRI compatible infusion pump	Anesthesia/Nursing	3	
II: While transferring patient to Imaging stretcher/table, the following must be confirmed:			
Procedure	Responsible Department	Zone	Check completed Yes/No/NA
Ensure IV lines are intact	Nursing	2	
Patient transferred from transport ventilator; Patient checked for adequate chest rise" & "no alarms present"	Respiratory	2	
III: During Imaging, the following must be observed and confirmed:			
Procedure	Responsible Department	Zone	Yes/No/NA
Monitor IV pump to address any alerts	Nursing	4	
Ventilator monitor for alarm conditions	Respiratory	4	
Monitor MR patient (EKG, Pulse Ox, Blood Pressure)	Physician/Clinician/ Nursing	4	
Scan patient and maintain verbal communication and observation	Radiology	4	
IV Line monitoring during contrast injection	Radiology	4	
IV: While transferring patient back to transport stretcher, the following must be confirmed:			
Procedure	Responsible Department	Zone	Check completed Yes/No/NA

Ensure IV lines are intact	Nursing	2	
Patient returned to transport ventilator; Patient checked for adequate chest rise” & “no alarms present”	Respiratory	2	
MRI patients with pacemakers:			
I: To be conducted before and during study for all INPATIENTS:			
Procedure	Responsible Department	Zone	Check completed Yes/No/NA
RN, NP or Resident to monitor patient	Physician/Clinician/ Nursing	2	
EP to place device into MRI safe mode	EP	2	
II: To be conducted before and during study for all OUTPATIENTS:			
Procedure	Responsible Department	Zone	Check completed Yes/No/NA
Nurse Tech to place patient on monitor and perform baseline EKG	Radiology	2	
RN, NP or Resident to monitor patient	Physician/Clinician/ Nursing	2	
EP to place device into MRI safe mode	EP	2	
III: To be conducted after completion of study for ALL patients:			
Procedure	Responsible Department	Zone	Check completed Yes/No/NA
EP to place device back to regular mode	EP	2	
Timeout checklist reviewed and completed by:	Date & Time		
Radiologic Technologist			Revised (4/7/2021)

THIS DOCUMENT MUST BE SCANNED INTO THE PATIENT’S MEDICAL RECORD IN RIS