UAB MEDICINE *Radiology Policy*

Title:	*MRI: Cardiac Implantable Electronic Device*				
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PURPOSE: To establish guidelines for the Department of Radiology of the UAB medical system in regards to processing requests for MRI examinations of patients with Cardiac Implantable Electronic Devices (CIEDs), such as pacemakers, defibrillators or active epicardial pacemaker wires.

SCOPE: This standard applies to all departments of Radiology within the UAB University Medical System.

POLICY STATEMENT: It is our belief that due to potential risks to the patient safety and high variability of factors impacting this risk, a detailed evaluation of each request for such examination should be performed according to procedures specified in this policy. Upon completion of the evaluation, a benefit/risk to the patient analysis will be completed. The radiologist will customize the MR scanning protocol to best accommodate the clinical goals for the examination, while limiting the patient's exposure to the risks associated with it. The benefits of the examination and risks associated with it will be explained to the patient; the patient should consent to the examination in writing before the examination could proceed.

ASSOCIATED INFORMATION:

A. **Background Information:** In the United States the management of the risks associated with MRI examinations follows the guidelines issued by the Food and Drug Administration (FDA). To date, FDA has not issued specific guidelines regarding labeling of **Active Implanted Medical Devices** (*AIMD*s), including CIEDs. However, they recently issued a Guidance for safety and compatibility of passive implants in the MRI environment [FDA 2014], where they identified four terms to identify the safety of items in MR environment: *MR Safe*, *MR Conditional*, *MR Unsafe*, and, optionally, "*Safety in MRI not Evaluated*".

B. In the past few years, all major CIED manufactures (*Biotronik, Boston Scientific, Medtronic, and St. Jude Medical*) introduced new CIED models that were approved by the FDA for labeling as *MR Conditional*. All manufactures provide detailed instructions for specific conditions and procedures to be followed while performing MR examinations of patients with those CIEDs. For the purpose of this policy, such devices shall be called **Conditional CIED**s. There is a large number of CIEDs present in the US population that do not carry the *Conditional CIED* labeling. For some of them, it is possible to track the labeling information. It typically is contained either in an "umbrella" statement, covering all CIEDs from a given manufacturer that are not labeled as *Conditional CIED*, or in documents belonging to the category *Instructions for Use* (IFU) or *Directions for Use* (DFU) for a specific device.

C. For the purpose of this policy, all CIEDs found not explicitly labeled as *MR Safe or MR Conditional CIED*s will be considered labeled as *Non-Conditional CIEDs*.

EXCLUSION CRITERIA:

Conditional devices:

A. Outside of manufacturer guidelines for lead placement or cardiothoracic surgery timeline
B. Non-conditional components (broken/abandoned lead remnants, lead extenders or adaptors). *These patients will need to be reviewed for scanning under the Non-conditional device policy.*
C. Interrogation values outside of manufacturer guidelines
D. Permanent epicardial pacing or ICD leads
E. Pacemaker manufactured before 1996 or ICD manufactured before 2000

Non-conditional devices;

A. Outside of manufacturer guidelines for lead placement or cardiothoracic surgery timeline
B. Interrogation values outside of manufacturer guidelines
C. Permanent epicardial pacing or ICD leads
D. Pacemaker manufactured before 1996 or ICD manufactured before 2000
E. Non-conditional components not associated with device (broken/abandoned lead remnants, lead extenders or adaptors) may undergo MRI on a case by case basis
F. Inability to communicate symptoms
G. Unstable angina
H. Pacemaker dependent patients (These patients might be candidates for MR imaging under extreme circumstances – Contact Radiology Vice-Chair for patient Safety and/or Chief of Electrophysiology/Cardiology)

POLICY:

A. All CIEDs found not explicitly labeled as MR Safe/MR Conditional CIEDs will be considered labeled as Non-Conditional CIEDs.
   1. Due to potential risk to the patient, associated with such an examination, a detailed benefit/risk analysis must be performed by the team of professionals, as described by this policy.
   2. The patient should give written consent to the examination.

B. Required Personnel
   1. MR Technologist
   2. ACLS prepared Registered Nurse
   3. Electrophysiology Physician or Representative

PROCEDURE:

A. The referring physician has determined that a patient needs an MRI, places the MRI order into IMPACT and indicates the patient has a CIED. Alternatively, the presence of a CIED will be discovered during routine screening.

B. The MR tech will then discuss the case with the appropriate radiologist.
   1. If the radiologist determines the MRI should NOT be performed for reasons other than the CIED or that another test would be more appropriate he/she will discuss with the referring service to cancel the MRI.
   2. If the radiologist determines the MRI should be performed, the MR tech will notify the EP Consult Attending/Dr. McElderry through UAB Paging, stating an MR has been requested and a message has been sent through IMPACT. The IMPACT message will contain the patient ID, the device, the exam requested and the urgency of the request.
   3. The EP Consult Attending will schedule the patient for an EP consultation.
      a. Once the EP Attending has determined the patient is safe to have the MR exam, the EP clinic will message “imaging guided procedure” pool in IMPACT, noting the patient can be scheduled for the requested MR exam as a “Conditional” or “Non-Conditional” exam.
   4. The imaging scheduler will then schedule the exam (2 weeks’ notice), contact the patient regarding time of scan and where to go and notify the EP group for “Non-conditional” systems.
      a. For Conditional exams, the MR staff will arrange for the appropriate device representative to be present for the MR exam.
      b. MRI scans will be scheduled Monday-Friday from 11:00am – 1:00 pm.

c. For “emergent” MR exams of patients with CIEDs, these will be handled on a case-by-case basis. MR staff should page in the following order: Radiology VC of Patient Safety (Matt Larrison, MD), Chief of MRI (Kristin Porter, MD), Appropriate section chief, Wlad Sobol, PhD.

EP CONSULATION: The EP Consultation will include, but not be limited to the following:

A. A history and physical examination.
B. Documentation of device components and history.
C. Determining whether the device has been interrogated 6 months prior to consult.
   1. If the device has been interrogated 6 months prior to the consult, then the device interrogation does not need to be repeated if all necessary information can be obtained from this interrogation.
   2. If the device has not been interrogated within this time period, the EP physician or representative will interrogate the device which includes documenting the device manufacturer, its underlying rhythm, lead impedances, and capture thresholds, arrhythmia history and battery voltage/longevity.
D. The EP physician will determine if based on the risk/benefit from a device standpoint it is reasonable for the patient to undergo the MRI.
E. If the EP physician determines there is a contraindication to MRI, he/she will inform the patient and notify MRI to cancel the MRI examination

F. The EP physician with document in their note if the CIED system is “MR Safe MR Conditional or MR Non-conditional”.

Day of Appointment:

A. ***MR Technologist will perform the following:***
   1. Outpatients arrive and check in at the Diagnostic Imaging front desk, NP 6th floor.
   2. The nursing staff with prep the patient and start an IV. They are accompanied to the MRI suite by the MR Technologists or designee.
   3. *Stable Inpatients* are brought directly to the MRI. Intensive Care Unit patients are accompanied by a Registered Nurse.
   4. Once the patient arrives to the MRI suite, the MR technologists or designee verifies the patient’s name, date of birth and MRN.
   5. Will notify the Pacemaker Nurse or NP of the patient’s arrival
      a. Any problems should be reported to the EP NP manager
   6. Performs routine screening to ensure the patient does not have any incompatible implants or devices and reviews the EP consult to determine the patient has indeed been evaluated per this protocol for the MRI.
   7. Confirms proper consent forms have been signed.
   8. Consents the patient for intravenous contrast material if required for the MRI examination
   9. Confirms presence of a functional IV and has revised MR imaging protocol
   10. Ensures the patient is scanned on the 1.5T magnet, with a SAR 2W/kg or less, limited maximum gradient slew rate of 200T/m/s, minimize the number and length of sequences as directed by radiologist.
   11. If MR Conditional device, the imaging protocol should be tailored in accordance to the scanning specifications of the manufacturer.
   12. Instructs the patient on how to use the call button

Registered Nurse will perform the following:

1. continuous vital sign monitoring throughout the MR examination

A. ***Electrophysiology Physician will perform the following:***

1. For *Conditional and Safe CIEDs*, an EP physician or representative must be available for immediate notification or consult with the team performing the MRI examination; for *all other CIEDs* an EP physician or representative must be present at the beginning of the MRI examination and direct the process of evaluation and monitoring the patient device and rhythm status during the entire MRI examination.

2. For Non-Conditional CIEDs, the EP physician will obtain written consent immediately prior to the MR exam.

3. Consent will not be required for Conditional CIEDs scanned in accordance with manufacturer's scanning specifications.

B. ***CIED Manufacturer's qualified technician (MQT) or Pacemaker Clinic Nurse will perform the following***:

1. Once the patient is in the MRI scanner suite and connected to the MRI-conditional cardiac monitor, the *MQT* or *pacemaker nurse* will:
   a. Interrogate the CIEDs and performs the following:
      1. Establishes baseline values for battery voltage/longevity, capture thresholds, intrinsic amplitude (sensing) for all leads, measured lead impedance for all leads
      2. Determine Underlying rhythm
      3. Confirm the patient is not pacemaker dependent
      4. Review Episode log to see if the patient has had multiple ventricular arrhythmias recently
2. The collected results are recorded for comparison with post-examination re-interrogation. The EP physician (if present) will review the results and clear the patient for CIED reprogramming; if the EP physician is not present then the MQT or Pacemaker Nurse will clear the patient.
3. Reprogram the CIED for MRI examination:
   a. Set the CIED in the appropriate mode as instructed in the EP consult
   b. Turn off tachycardia detection if ICD/defibrillator

C. **MR Physicist**

1. For *Conditional CIEDs*, an MR physicist may be available consult with the team performing the MRI examination.
2. For *all other CIEDs,* an MR physicist may be present during MRI examination and assist the MRI Technologist in implementation of all restrictions and special scanning instructions

MRI Examination

A. After the above steps are complete, the patient is placed on the MRI scanner

B. The patient will be monitored continuously during the MRI study by an ACLS trained Registered Nurse.

1. Monitoring should include continuous ECG, blood pressure, pulse rate, and oxygen saturation with documentation every 15 minutes.
2. The patient should be on a continuous pulse oximetry to evaluate perfused beats by evaluating oximetry waveform. The possibility of asystole masked by electromagnetic interference on the cardiac monitor is minimized by using the pulse ox waveform

C. The patient will be instructed to alert the MR Technologist and RN of any unusual sensations, feelings of near syncope or chest discomfort. In the rare event of a patient complaining of these symptoms the patient will be evaluated by the team to determine if the scan should be stopped.

D. The MRI technologist and RN will maintain visual and voice contact throughout the procedure with the patient.

E. MR scanning technical parameter recommendations The patient will be monitored continuously during the MRI study by an ACLS trained Registered Nurse.

1. Limit the field strength to 1.5 T
2. Limit maximum gradient slew rate to 200T/m/s
3. Limit the SAR to less than 2W/kg of body weight
4. Minimize the number and length of sequences
5. If possible, a transmit/receive coil is preferred for head and extremity scans

ADVERSE EVENTS:

A. The study will be terminated if the patient complains of unusual sensation, movement, or chest discomfort. If this occurs, the following physicians are notified immediately:

1. The EP Consult Attending will be paged via the paging operator

B. If an adverse event occurs, the patient is immediately removed from the table and taken out of the MR room

C. Patients will be treated commentate with the severity of their illness which may include ACLS resuscitation and summoning appropriate resources to include calling a Code Blue.

Post MRI Examination

A. All patients will have a device re-interrogation before they leave the MRI area, and they **must** remain monitored until this is complete.

B. The post interrogation includes the following:

1. Recheck all lead impedances
2. Recheck all lead capture thresholds
3. Recheck sensing
4. Recheck battery voltage and/or projected longevity
5. Reprogram to pre-procedure settings or settings determined appropriate by the EP team to include turning tachycardia detection therapy back on for ICD patients when appropriate

D. The Pacemaker RN or Designee will notify the EP Physician if any of the changes occur below

1. Increase in pacing threshold of more than 0.5Volt at 0.4ms
2. Change in sensing of more than 2 mV in the ventricular lead or 0.5mV in the atrial lead
3. A change in lead impedance of more than 10% of pre-scan value
4. Substantial change in estimated battery longevity or voltage
5. Any alert screens activated by device hardware other than magnet detection

E. A post scan interrogation note should be placed in Power Notes at the conclusion of the interrogation which documents

1. Pre-Scan – sensing, impedance, thresholds, and battery voltage
2. Post-Scan - sensing, impedance, thresholds, and battery voltage
3. Any programming changes

PATIENT DISCHARGE:

A. After the post interrogation is completed, the patient is discharged from the MRI Suite.

B. The status of the patient upon discharge from the MRI Suite will be documented by the RN

C. The patient is instructed to call their physician or 911 with any unusual chest discomfort

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CMS:	**None**	**TJCH:**	
Cross-References (CR):			

ATTACHMENTS: None

INTERDISCIPLINARY COLLABORATION

None	
Physician / Medical Committees	Endorsement Date
None	
Committee(s)/Council(s)	Endorsement Date
None	
Hospital Department(s)	Endorsement Date

Tracking Record

Action				Reasons for Development/Change of Standard							Change in Practice		
Devel-oped	Refor-matted	Re-viewed	Revised	Re-quired Review	Rele-vance	Ethics	Legal	New Knowl-edge	QA/I	Risk	No	Yes	Comment/ Explanation of Impact
	X	X	X	X	X						X		
Supersedes:	MRI Cardiac Implantable Electronic Devices 02/02/17,3/22/17, 10/13/17, 2/15/18, 2/19/19												
File Name:	MRI: Cardiac Implantable Electronic Device R#51r5												
REVISIONS: Consistent with Joint Commission Standards, this standard is to be reviewed at least every 3 years as practice change													