Diagnostic Services – Department of Radiology – Diagnostic Division

SUBJECT/TITLE: **MR Imaging of Adult Patients with FDA-Approved Cardiac Implantable Electronic Devices (CIED)**

PURPOSE: To provide guidelines for the proper identification, assessment and monitoring of adult patients with cardiac implantable electronic devices (CIEDs) who require magnetic resonance imaging (MRI) as part of the patient's diagnostic evaluation. This policy specifically refers to implantable devices that are considered *MRI Conditional*.

BACKGROUND: There has been historical reluctance to conduct MRI in patients with cardiac implantable electronic devices. This has been related to reports about the potential hazardous effects of MRI related to changes of pacing thresholds, inappropriate activation or inhibition of tachyarrhythmia therapies and thermal injury. However, these concerns are not well-supported in a sizeable body of peer-reviewed literature that collectively shows that MRI may be safely performed in patients with CIEDs, when proper assessment and monitoring protocols are in place. The evidence supports that MRI may be safely performed in patients with CIEDs, when patients are properly selected, screened and monitored as there are important considerations and requirements for a CIED patient to undergo MRI.

MRI holds unique benefits in diagnostic imaging regarding diagnostic sensitivity and specificity. A patient with a CIED is estimated to have a 50%-75% lifetime possibility of requiring an MRI study. The validated low risk of MRI in patients with CIEDs must also be weighed against the benefits of performing an optimally selected diagnostic MRI.

DEFINITIONS: The FDA has designated certain CIED systems to be *MRI conditional*. This means that when specific conditions of use are met, an MRI can be performed safely in a patient with such a system. Conditions of use include both the type of CIED hardware present (generator and leads), the type of MRI scan and scanning parameters, and a minimal time from implant to MR scan (usually 6 weeks). Any CIED that does not meet all of the conditions of use will then be regarded as an *MR non-conditional* system for that MR scan. Many CIEDs still in use today are *not* MR conditional.

POLICY: The Department of Radiology and the Electrophysiology (EP) service in the Division of Cardiovascular Medicine at the University of Iowa Hospitals and Clinics have developed the following procedure for performing MRI in adult patients with *MR Conditional* CIEDs.

PROCEDURE:

The following steps must be completed before performing an exam on an adult patient with an MR conditional CIED. Table 1 specifies who performs the various functions.

1. **Determine if CIED is MR conditional:** If a request for MRI is received during normal business hours (0700 to 1600, Monday – Friday), the MR staff will make an initial determination as to whether the CIED is MR conditional. If the request is received outside of these hours, the EP attending physician will make this determination.

2. **Absolute contraindications:** Patients with abandoned, broken or epicardial leads cannot undergo MRI.

3. **Exam appropriateness:** The responsible attending radiologist or fellow will review the MRI request to determine if a suitable alternative imaging modality can be performed based on the clinical indication for the exam. If an alternative test is recommended, the radiologist will contact the ordering provider to discuss.

4. **Scheduling:** If the request is approved, MR staff will schedule the MRI exam in coordination with the availability of the appropriate device representative.

5. **Order for management of device during procedure:** After being notified that a procedure is scheduled, the EP attending physician will create a cardiology device order. This order will be used by the device representative to manage the CIED during the MR procedure. If the patient is new to the EP service, the patient will need a recent chest x-ray and recent device interrogation. These can be performed at UIHC or, when available, forwarded from an outside facility.

6. **Consent:** On the day of the exam, a radiologist will obtain written informed consent from the patient to do the MRI.

7. **Interrogation (Pre/post):** A device representative must be present before and after the MRI and perform the following functions if not interrogated by a EP LIP:
    - Review the order provided by the EP LIP
    - Complete the interrogation of device pre-MRI
    - Place device in the correct setting for MRI per EP staff physician order
    - Complete post-MRI interrogation and reset device to previous settings
    - Print interrogation form and give to MR reception desk.

8. **Monitoring:** An ACLS certified nurse will monitor the patient from the time the CIED programming is altered for MRI until it is restored to its normal settings. Monitoring includes a baseline set of vital signs (HR, 02 saturation, BP, pain, initial ECG waveform) before the device is reprogramed. Document oxygen saturation, BP, and heart rate every 5 minutes for the duration of the scan with continuous visual monitoring of ECG until the device is returned to normal programming and the patient is deemed stable. Once the device is reprogrammed back into normal mode, a complete post set of vitals must be documented.

For scheduled outpatients, a radiology nurse will monitor the patient. If the request is for an inpatient/ER or for after hours, a unit/ER nurse should accompany and monitor the patient. If the patient develops complications during the procedure, call a rapid response or code blue, as appropriate.

9. **Epic documentation:** An EP staff physician will create a procedure note to document the CIED interrogation and programming/restoration after receiving notification from the MR staff that the interrogation form from the device representative has been scanned into the medical record.

10. **After hours requests:** If notified of a request to perform a study after hours, the responsible attending radiologist or fellow on call for that division will review the request and determine (a) if the clinical question could be answered with another imaging modality, and (b) if the study can be postponed until normal business hours. After hours, there is limited availability of personnel to support requests for MRI in CIED patients. Consequently, MRI scans should only be performed after hours if there is a critical need for the diagnostic information and no other imaging modality will suffice.

    If an after-hours MRI study is approved by the radiologist, the physician requesting the MRI must contact the EP staff physician on call, who will determine if the device is MR conditional and, if so, coordinate appropriate programming of the device. Once this step is completed, the MR staff will schedule the procedure.

Table 1: Assignment of Responsibilities for MR Imaging w/ CIED.

	Is CIED MR Conditional?	Approval Procedure	Schedule	Device Order	Consent	Interrogation and programming	Monitor	Post Interrogation and programming	Documentation in EMR
Outpatient	MR staff	Staff Radiologist Fellow	MR Staff & Device Rep	EP LIP	Radiologist	Device Rep	Radiology RN	Device Rep	EP LIP
Inpatient & Emergency during the day	MR staff	Staff Radiologist Fellow	MR Staff & Device Rep	EP LIP	Radiologist	Device Rep	Floor RN	Device Rep	EP LIP

	Approval Procedure	Is CIED MR Conditional?	Schedule	Device Order	Consent	Interrogation and programming	Monitor	Post Interrogation and programming	Documentation in EMR
Emergency after hours	Staff Radiologist Fellow	Ordering MD consults with EP physician	MR Staff	EP LIP	Radiologist	Device Rep or EP physician	Floor RN	Device Rep or EP physician	EP LIP

Vendor Phone #'s:

Boston Scientific	1-800-227-3422 (will need patient name and DOB)
Biotronik	1-800-633-8766, #3, #1
St. Jude	1-800-722-3774, #5
Medtronic	1-800-633-8766, #3, #1

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