
Diagnostic Services – Department of Radiology – Diagnostic Division

SUBJECT/TITLE: **Magnetic Resonance Imaging of Pediatric and Adult Congenital Heart Disease (ACHD) Patients with FDA-Approved Cardiac Implantable Electronic Devices (CIED)**

PURPOSE: To provide guidelines for the proper identification, assessment and monitoring of pediatric and adult congenital heart disease (ACHD) patients with cardiac implantable electronic devices (CIEDs) who require magnetic resonance imaging (MRI) as part of their diagnostic evaluation. This policy specifically refers to CIEDs that the FDA considers *MRI Conditional*.

BACKGROUND: The historical reluctance to conduct MRI in patients with CIEDs derives from reports about the potential hazardous effects of MRI, including changes of pacing thresholds, inappropriate activation or inhibition of tachyarrhythmia therapies and thermal injury. However, these concerns are not well-supported by a sizeable body of peer-reviewed literature that collectively shows MRI may be safely performed in patients with CIEDs, when proper assessment and monitoring protocols are in place. Furthermore, the evidence indicates that patients with CIEDs must be properly selected, screened and monitored prior to undergoing MRI as there are important safety considerations and requirements.

Among the diagnostic imaging modalities, MRI holds unique benefits with regard to diagnostic sensitivity and specificity. A patient with a CIED is estimated to have a 50%-75% lifetime possibility of requiring an MRI study. Safety concerns in this population should not reflexively preclude the use of the MRI. The perceived risk of MRI must be weighed against the documented low risk in patients with CIEDs as well as the diagnostic benefits of performing an optimally selected MRI.

The Centers for Medicare and Medicaid Services (CMS) declared the need for MRI in patients with CIEDs as both “reasonable and necessary for the diagnosis or treatment of illness or injury” with some conditions.¹ The American College of Cardiology (ACC), American College of Radiology (ACR), American Heart Association (AHA), American Society for Radiology Oncology (ASTRO), and Heart Rhythm Society (HRS) released a joint consensus statement providing guidance for MRI performed on patients with CIED systems.²

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 device implant to MR scan. Any CIED not meeting all of the conditions of use will be regarded as an *MR non-conditional* system for that MR scan. Some legacy CIEDs in use today are *not* currently considered MR conditional.

POLICY: The Department of Radiology and the Pediatric Electrophysiology (EP) service in the Division of Pediatric Cardiology, Stead Family Children's Hospital, at the University of Iowa Hospitals and Clinics have developed the following procedure for performing MRI in pediatric and ACHD patients with *MR Conditional* CIEDs.

PROCEDURE:

The following steps must be completed before performing an exam on a pediatric or ACHD 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 after-hours, the Pediatric EP attending physician will make this determination.
2. **Absolute contraindications:** Patients with abandoned, broken or epicardial leads cannot undergo MRI under this protocol.
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 additional information is required to determine the appropriateness or necessity of MRI, the responsible radiologist may contact the ordering provider for clarification. If an alternative imaging modality is recommended, the radiologist will contact the ordering provider to discuss.
4. **Scheduling:** If the request is approved, MR staff will coordinate scheduling of the MRI with the availability of the appropriate device representative or Pediatric EP LIP (Physician, Physician Assistant, or Nurse Practitioner).
5. **Order for management of device during procedure:** After being notified that a procedure is scheduled, the Pediatric EP LIP will sign a cardiology device order. This order will be used by the device representative or Pediatric EP LIP to manage the CIED during the MR procedure. If the patient is new to the Pediatric EP service, the patient will need to have a recent chest x-ray and a recent device interrogation prior to undergoing MRI. These can be performed at UIHC, or, when available, forwarded from an outside facility.
6. **Consent:** On the day of the exam, a radiologist in the relevant division will obtain written informed consent from the patient or parent/guardian, as appropriate, to perform the MRI.
7. **Interrogation (Pre/post):** A device representative or pediatric EP LIP must be present before and after the MRI and perform the following functions:

- Review the order provided by the Pediatric EP LIP
 - Complete the interrogation of device pre-MRI
 - Place device in the correct setting for MRI per Pediatric EP LIP order
 - Complete post-MRI interrogation and reset device to previous settings
 - Print interrogation form and give to MR reception desk
8. **Monitoring:** A PALS-certified nurse for pediatric patients or an ACLS-certified nurse for ACHD patients 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, O₂ saturation, BP, pain, initial ECG waveform) before the device is reprogrammed. 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. Alternatively, a PALS and ACLS-certified Pediatric EP LIP may perform monitoring in lieu of a nurse, but the monitoring needs to be documented in a peri-procedure CIED programming note. Properly certified anesthesia personnel may also provide the monitoring for sedated or anesthetized patients. Once the device is reprogrammed back into normal mode, a complete post set of vitals must be documented. For scheduled ACHD outpatients with an MR scheduled in the main hospital, a radiology nurse will monitor the patient under the adult protocol for MR conditional CIEDs. For ACHD outpatients with an MRI scheduled in the Stead Family Children's Hospital (SFCH), an ACLS-certified pediatric cardiology nurse or an ACLS-certified Pediatric EP LIP may perform the monitoring. If the MRI request is for an inpatient/ED for after hours, a unit/ED nurse with the appropriate ACLS or PALS certification 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:** A Pediatric EP LIP 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. For procedures during which the Pediatric EP LIP is present, they will manage the form and complete EPIC documentation.
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, the availability of hospital personnel to support requests for MRI in CIED patients is limited. Consequently, MRI scans should only be performed after hours if the diagnostic information is needed urgently and no other imaging modality will suffice. If additional information is needed, the responsible radiologist or radiology fellow may contact the ordering provider.

If an after-hours MRI study is approved by the radiologist, the physician requesting the MRI must contact the Pediatric EP attending 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 Pediatric & ACHD MR Imaging w/ MR Conditional CIED

	Determine if CIED is MR Conditional	Approval Procedure	Schedule	Device Order	Consent	Interrogation and programming	Monitor*	Post Interrogation and programming	Document in EMR
Adult CHD Outpatient in SFCH MR	MR staff	Staff Radiologist Fellow	MR Staff & Device Rep or Ped EP LIP	Ped EP LIP	Radiologist	Device Rep or Ped EP LIP	ACLS RN or Ped EP LIP	Device Rep or Ped EP LIP	Ped EP LIP
Adult CHD Outpatient in UIHC MR	MR staff	Staff Radiologist Fellow	MR Staff & Device Rep or Ped EP LIP	Ped EP LIP	Radiologist	Device Rep or Ped EP LIP	ACLS Radiology RN or Ped EP LIP	Device Rep or Ped EP LIP	Ped EP LIP
Pediatric Outpatient in SFCH MR	MR staff	Staff Radiologist Fellow	MR Staff & Device Rep or Ped EP LIP	Ped EP LIP	Radiologist	Device Rep or Ped EP LIP	PALS Ped Card RN or Ped EP LIP	Device Rep or Ped EP LIP	Ped EP LIP
Adult CHD Inpatient & ED daytime in UIHC MR	MR staff	Staff Radiologist Fellow	MR Staff & Device Rep or Ped EP LIP	Ped EP LIP	Radiologist	Device Rep or Ped EP LIP	ACLS Floor/ED RN or Ped EP LIP	Device Rep or Ped EP LIP	Ped EP LIP
Pediatric Inpatient & ED daytime in SFCH MR	MR staff	Staff Radiologist Fellow	MR Staff & Device Rep or Ped EP LIP	Ped EP LIP	Radiologist	Device Rep or Ped EP LIP	PALS Floor/ED RN or Ped EP LIP	Device Rep or Ped EP LIP	Ped EP LIP

*Anesthesia staff can monitor for sedated or anesthetized patients instead of an RN or LIP

	Determine if CIED MR Conditional	Approval Procedure	Schedule	Device Order	Consent	Interrogation and programming	Monitor	Post Interrogation and programming	Documentation in EMR
Adult CHD Inpatient & ED after hours in UIHC MR	Ordering MD consults with Ped EP LIP	Staff Radiologist Fellow	MR Staff	Ped EP LIP	Radiologist	Device Rep or Ped EP LIP	ACLS floor or ED RN	Device Rep or Ped EP LIP	Ped EP LIP
Pediatric Inpatient & ED after hours in UIHC MR	Ordering MD consults with Ped EP LIP	Staff Radiologist Fellow	MR Staff	Ped EP LIP	Radiologist	Device Rep or Ped EP LIP	PALS floor or ED RN	Device Rep or Ped EP LIP	Ped 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

REFERENCES:

- 1) Indik JH, Gimbel JR, Abe H, et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. Heart Rhythm. 2017;14:e97–e153.
- 2) April 2018 Medicare MRI for patients with CIEDs Update. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=177>. Effective Date 4/10/2018. Implementation Date 12/10/2018.

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