**Purpose:** To provide guidelines for the proper identification, assessment and monitoring of patients with cardiac implantable electronic devices (CIEDs) and/or abandoned permanent pacemaker wires that require magnetic resonance imaging (MRI) as part of the patient’s diagnostic evaluation.

**Background:** There has been historical reluctance to conduct MRI in patients with cardiac implantable electronic devices. This has been related to early 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 the considerable 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. For example, Martin et al ([1](#_ENREF_1)) presented data regarding 62 MRIs performed in 54 patients with CIEDs and no reported adverse events; Sommer et al ([2](#_ENREF_2)) presented data regarding 115 MRI studies in 82 patients with CIEDs and no adverse events; Nazarian et al ([3](#_ENREF_3)) presented data for 68 MRI studies in 55 patients with a mixture of CIEDs, including a subset with defibrillators, with no adverse events; Halshtok et al ([4](#_ENREF_4)) examined 34 MRI studies in 18 patients, also with a mixture of pacemakers and defibrillators, with no adverse events reported. A seminal study was presented by Nazarian et al in 2011 in the *Annals of Internal Medicine*, presenting a series of 555 MRI in 438 patients; while small changes in device programming were found in 0.7% of patients; no clinical adverse events were reported ([5](#_ENREF_5)). The MagnaSafe registry ([6](#_ENREF_6)) is the largest study of MRI performed in CIED patients (1500 patients, 1000 with pacers and 500 with ICDs) that also showed no significant adverse effects; specifically, no patients experience a ventricular arrhythmia, loss of capture during the MRI exam, lead/generator failure or death. Additional, more minor changes in device parameters that were observed (such as lead impedance, battery voltage and pacing thresholds) were typically not clinically significant. Given this body of evidence, we feel 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. A Heart Rhythm Society Expert Consensus Statement (2017), outlines specific recommendations for this process ([7](#_ENREF_7)).

MRI holds unique benefits in diagnostic imaging regarding diagnostic sensitivity and specificity (related to excellent soft tissue contrast) and patient safety (related to the lack of ionizing radiation). A patient with a CIED is estimated to have a 50%-75% lifetime possibility of requiring an MRI study. It has been estimated that during one year in the United States alone, 200,000 people with cardiac devices were denied an MRI scan (2004 data) ([8](#_ENREF_8), [9](#_ENREF_9)). The demonstrated low risk of MRI in patients with CIEDs must also be weighed against the risks of not performing an optimally selected diagnostic MRI ([10](#_ENREF_10)). These risks include performing an alternative test that may introduce the risks of missing an important diagnosis or introducing potential harm (such as that of iodinated contrast in patients who are allergic to these agents) or who may have impaired renal function and are at risk of contrast agent induced renal failure. MRI may also be favored in patients requiring repeated scanning in which case cumulative ionizing radiation dose may play a factor in selecting MRI as an optimal diagnostic technique.

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 and thus follow the protocol below for MR non-conditional scans. Most CIEDs in use today are not MR conditional.

The Department of Medical Imaging and Division of Cardiology at the Banner University Medical Group (Tucson Campus) has developed a policy for performing MRI in patients with CIEDs. This policy is based on recommendations approved by the BUMG-T Quality and Safety Committee, after consultation with members of the MRI Safety Committee and in conjunction with the Electrophysiology service in the Division of Cardiology, and is founded upon the extensive body of peer-reviewed data.

**PROTOCOL**

When a patient with a CIED requires an MRI (***regardless of conditionality status***) the following protocol should be followed:

1. **Scheduling/Pre-MRI protocols:** Radiology scheduling will contact the pacer clinic with patient information/request for assessment. The CIED status will be evaluated by the pacemaker clinic and CIED physician to determine if the patient requires further in-clinic screening in a separate visit.
	1. Patients that do not require a separate pre-MRI screening will be those who have had a complete CIED evaluation with normal findings within the past 6 months, and who are not pacing dependent; these patients can be directly scheduled for their MR scan. However, the pacer clinic will write a note that the patient has been cleared for MRI, in order to communicate this assessment with Medical Imaging.
	2. Patients that do require a separate pre-MRI screening visit will be scheduled for an appointment:
		1. **Outpatients that require a screening in-clinic visit**: Radiology schedulers will facilitate scheduling the patient for the pacer clinic appointment prior to the MRI appointment, if deemed to be needed by the pacemaker clinic. Based upon the findings in the screening clinic visit, the patient can be scheduled for the MR scan if deemed to be suitable.
		2. **Inpatients**: Order for inpatient consultation should be placed with the pacer service by the ordering physician.
			1. Contact information: 694-7223, pager 7223
		3. A written assessment of the recommendations from the EP service should be accessible for medical imaging staff to review prior to MRI.
2. **Exam-Day Protocols/Monitoring (conditional AND non-conditional systems):**
	1. These patients will only be scheduled in the hospital setting. Patients with non-conditional CIED systems will only be scheduled on a 1.5 Tesla MRI system. Scheduling should aim to be prior to 3pm to assure the pacemaker clinic staff is available for post exam device interrogation.
		1. For patients with a MRI non-conditional CIED, and ***who is pacing dependent***, a physician with the skill to establish temporary transvenous pacing and a physician with the skill to direct CIED programming must be immediately available on the premises (in hospital, not in a procedure), and personnel with the skill to program the CIED (pacer technologist) must be in attendance in the MR control area.
		2. For patients with a MRI non-conditional CIED ***who is not pacing dependent***, a physician with the ability to direct CIED programming must be immediately available on the premises.
		3. Outpatients: The MRI staff will notify the pacemaker clinic the day before the MRI appointment and again when the patient arrives at the MRI department.
		4. Inpatients: The MRI staff will notify the pacemaker clinic that day before the MRI appointment and again when the patient’s floor is called to send the patient to the MRI department
		5. **Conditional CIEDs:**
			1. May be performed off hours
			2. May be performed at South Campus or University Campus
			3. CIED personnel (typically a device representative) must be available for the scan, but does NOT have to be in immediate physical attendance at the scanner.
			4. Must be monitored in the same fashion as patients with non-conditional CIEDs.
	2. When the patient arrives in the MRI department, the patient will be placed in one of the holding bays and will be placed on ECG monitoring and pulse oximetry. At this time, the radiologist on service will obtain and document informed consent from the patient. The consent must include a full explanation of the risks and benefits of the MRI.
	3. Before entering the MR exam room, the pacemaker staff will perform a pre-exam device evaluation with re-programming appropriate for the MRI scan in the holding area.
	4. The patient must be monitored continuously before and during the MRI by an ACLS certified Registered Nurse. The monitoring will include ECG, blood pressure, pulse rate and oxygen saturation. The ECG monitoring will continue after the completion of the MRI until the pacemaker staff member has completed the post procedure evaluation and re-programming of the CIED in the MR holding area.
	5. The MRI code cart and defibrillator will be immediately available throughout the procedure to address an adverse event.
	6. The MR Technologist and RN must maintain visual and voice contact with the patient throughout the procedure.
	7. The patient will be instructed on how to communicate with the MR Technologist and RN of any unusual sensations or chest pain. The MRI study will be **terminated immediately if the patient complains of any unusual sensation or chest pain.**
3. **Special Circumstances:**
	1. Scanning immediately after device placement: MR scanning is permitted immediately after implantation of a lead or generator and will then follow the non-conditional protocol (regardless of FDA conditional labelling).
	2. Abandoned Leads, Fractured Leads and Epicardial Leads: There may be special circumstances where it may be of great benefit to the patient to undergo an MRI who has abandoned leads, fractured leads or epicardial leads. These cases must be evaluated individually by consultation between the CIED physician, the ordering physician and MR physician, and these studies will be approved by both the electrophysiology physician and the Director of MRI (or designee). All workflow protocols will proceed as outlined above if the patient is approved for scanning, including all monitoring protocols.
	3. CIED battery at end of life:These will be evaluated on a case by case basis to determine if they must first undergo generator change.

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