

**Recommendations for Imaging Patients with Cardiac Implantable Electronic Devices  
(CIEDs)**

Karl K. Vigen, PhD<sup>1</sup>, Scott B. Reeder, MD, PhD<sup>2</sup>, Maureen N. Hood, PhD, RN<sup>3</sup>, Michael Steckner, PhD, MBA<sup>4</sup>, Tim Leiner, MD, PhD<sup>5</sup>, David A. Dombroski, MD<sup>6</sup>, Vikas Gulani, MD, PhD<sup>7</sup> on behalf of the ISMRM Safety Committee

<sup>1</sup>Department of Radiology, University of Wisconsin-Madison, Madison, Wisconsin, USA

<sup>2</sup>Departments of Radiology, Medical Physics, Biomedical Engineering, Medicine, and Emergency Medicine, University of Wisconsin-Madison, Madison, Wisconsin, USA

<sup>3</sup>Department of Radiology, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA

<sup>4</sup>Canon Medical Research USA, Mayfield Village, Ohio, USA

<sup>5</sup>Department of Radiology, Utrecht University Medical Center, Utrecht, The Netherlands

<sup>6</sup>Department of Radiology, University of Rochester Medical Center, Rochester, NY, USA

<sup>7</sup>Department of Radiology, University of Michigan, Ann Arbor, Michigan, USA

**Corresponding Author:** Karl K. Vigen, Department of Radiology, University of Wisconsin-Madison, 1111 Highland Avenue, Madison, WI, 53705. Email: [kkvigen@wisc.edu](mailto:kkvigen@wisc.edu)

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1002/jmri.27320](https://doi.org/10.1002/jmri.27320)

**Running Title:** Recommendations for MRI with CIEDs

Author Manuscript

## **Recommendations for Imaging Patients with Cardiac Implantable Electronic Devices (CIEDs)**

### **Abstract**

Historically, the presence of cardiac implantable electronic devices (CIEDs), including pacemakers and implantable cardioverter defibrillators (ICDs), was widely considered an absolute contraindication to magnetic resonance imaging (MRI). The recent development of CIEDs with MR Conditional labeling, as well as encouraging results from retrospective studies and a prospective trial on the safety of MRI performed in patients with CIEDs without MR Conditional labeling, have led to a re-evaluation of this practice. The purpose of this report is to provide a concise summary of recent developments, including practical guidelines that an institution could adopt for radiologists who choose to image patients with CIEDs that do not have MR Conditional labeling. This report has been written on behalf of and approved by the International Society for Magnetic Resonance in Medicine (ISMRM) Safety Committee.

**Keywords:** magnetic resonance imaging safety, cardiac implantable electronic device, pacemakers, implantable cardioverter defibrillators.

## Introduction

Historically, the presence of cardiac implantable electronic devices (CIEDs), including pacemakers and implantable cardioverter defibrillators (ICDs), was an absolute contraindication for magnetic resonance imaging (MRI). Several incidents including deaths and other serious outcomes in patients with such devices undergoing MR imaging exams have been reported, primarily before the year 2000 (see, for example, US FDA MDR Records M351516-1989 and M175218-1992(1,2)), as well as descriptions of irregular CIED function in the MRI environment.(3) Many of these incidents were poorly documented and the nature of the exact interactions between the devices and MRI were often not reliably determined.(4) Recent developments in CIED engineering have led to devices which do not appear to cause significant clinical harm to patients undergoing MRI, and whose operation appears to be largely resilient to the electromagnetic interference (EMI) present in the MRI environment, particularly at 1.5T.(5)

Further, a recent prospective trial and a number of retrospective studies (in patients with CIEDs that do not have MR conditional labeling) have supported these observations, and formed the basis of a comprehensive consensus report from the Heart Rhythm Society in 2017 detailing recommendations for MRI, CT, and radiation therapy, in patients with CIEDs.(6) Notably, the HRS statement provided a Class I recommendation for MRI in patients with MR Conditional CIEDs, and a Class IIa recommendation for MRI in patients with non-MR-conditional CIEDs. (The American College of Cardiology and American Heart association define several classes of recommendations for magnitude of benefit over risk; Class I is the strongest, with the highest

benefit vs. risk; Class IIa is not as strong, but still applies to situations where benefit is much greater than risk.(7)) That consensus statement was endorsed by several societies, including the American College of Radiology (ACR).

While MRI in patients with devices that are not MR Safe or MR Conditional is generally to be avoided, there are situations in which a radiologist might need to make a decision regarding the relative risk/benefit of performing an MRI exam, and the benefits of obtaining an MRI scan far outweigh the risk, particularly when an alternative imaging method is not appropriate. The primary purpose of this report is to provide a concise summary of recent developments in MR imaging of patients with CIEDs and to provide practical guidelines that summarize best practices for MRI practitioners seeking to perform MRI of patients with CIEDs that do not have MR Conditional labeling. This report has been written on behalf of and approved by the International Society for Magnetic Resonance in Medicine (ISMRM) Safety Committee, and also approved by the ISMRM Board of Trustees.

### **Classification of Devices**

For the purpose of this report, only cardiac implantable electronic devices (CIEDs) that can actively pace the heart are considered. These include cardiac pacemakers, implantable cardioverter defibrillators (ICD), subcutaneous ICDs (S-ICD), and cardiac resynchronization therapy pacemakers and defibrillators (CRT-P/CRT-D). Other devices, including implantable

cardiac rhythm monitors (“loop recorders”), and active devices for other locations in the body, such as neuro-stimulators, are not included.

MR Conditional labeling refers to an object or device which has been demonstrated to pose no known hazards within specified conditions of use.(6,8) Such labeling generally includes requirements for static field strength, maximum spatial field gradient, maximum gradient switching (dB/dt), maximum specific absorption rate (SAR) (or an alternative radiofrequency (RF) exposure parameter such as  $B_{1+rms}$ ), and limitations such as allowed RF coils. For devices such as CIEDs, the conditions also specify the configuration of the device (e.g. combination of generator and leads and allowed implant locations), specific device programming requirements during the MRI exam, and required staff for device programming and patient monitoring.

Beginning in 2011, cardiac device manufacturers began offering CIEDs with MR Conditional labeling. For the purposes of this report, a device will be considered “MR Conditional” if this status is included as part of a device’s official labeling in the regulatory approval of an institution’s locale, for example through the Food and Drug Administration (FDA) in the United States, or via the European CE marking.

**When MR imaging is performed in patients with implanted devices with MR Conditional labeling, the exam should be strictly performed as labeled by the device manufacturer. Institutions are advised to develop a standard operating procedure for imaging patients with MR Conditional devices, which includes conformance with the labeled MR conditions.(6)**

CIED systems that have not met regulatory criteria for MR Conditional labeling are usually labeled by the device manufacturer and/or MRI system manufacturer as contraindicated for MRI; and in practice, they have often been considered MR Unsafe. These CIEDs have often been referred to as “non-MR-conditional” (or “MR non-conditional”, “conventional”, or “legacy”) devices. Many institutions now use the term “legacy” to differentiate these devices from MR Conditional CIEDs. As mentioned above, the presence of such CIEDs was traditionally considered an absolute contraindication to MRI. However, as discussed below, there is considerable evidence that MRI can be performed without serious negative clinical consequences in nearly all patients with legacy CIEDs, provided certain guidelines are followed, and these legacy or “non-MR-conditional” devices are now considered by many as a relative contraindication to MR imaging. This provides a challenge with respect to the current standard device labels (MR Safe, MR Conditional and MR Unsafe, the latter which labels “an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment”).(8) The clinical risks for scanning a particular patient with an implanted device not labeled as MR Conditional might be considered acceptable for a physician in a risk/benefit decision process, given the large number of patients with these devices for whom an MRI exam may provide clinically important information and the developing evidence for low risk in scanning some of these patients with appropriate precautions.

This classification includes device systems in a non-conforming configuration or with some components which do not have MR Conditional labeling. For example, an implanted system

could have pacing leads that are not MR-conditional, but the generator has MR Conditional labeling. In such a case, the system is not MR Conditional.(6) In addition, MR imaging in a patient with a CIED system that does not strictly follow the labeled MR conditions (such as patient position, implant location, RF coil restrictions, or a higher or lower field strength) would also render the system not MR Conditional. Also, CIEDs that have obtained MR Conditional labeling with geographic authority outside an institution's location (such as a CE Marking, but the patient is undergoing MRI in a US-based institution) should be treated as not MR Conditional.

The historical contraindication of the presence of a CIED in patients undergoing MRI is based on a number of potential interactions between the MRI system and the CIED. These interactions have been reviewed in detail elsewhere (see for example, Shinbane *et al.*(9)). They include translation or torque on device components due to the B<sub>0</sub> field; induced currents in the leads, possibly resulting in over sensing, inadvertent myocardial stimulation, or heating at the lead tips; inhibition of pacing output; partial- or full-device resets (including power-on resets); activation of the reed switch (which can revert the device into "magnet mode"); loss of the device's programmed data; premature battery depletion; and severe image artifacts which can affect image interpretation. However, continued advances in CIED technology over the past several decades have led to likely improvement in risk for even non-MR-conditional CIEDs. These advances include reduction of the amount of ferromagnetic material for measurably



reduced force and torque in the magnetic field, and improvements in circuitry, sensing/detection algorithms, and general robustness to EMI.(5,10)

### **Recent Developments**

Numerous recent studies have reported the institutional experience of MR imaging in patients with non-MR-Conditional CIEDs. We note that the majority of these studies are small scale studies from a single institution. A comprehensive review of these is beyond the scope of this report, and many are summarized in the HRS consensus statement.(6) Several notable and recently published studies are worth noting, including studies with patients with non-MR-conditional devices. Nazarian and colleagues have published extensively on a broader experience; an early report in 2011 covered 438 patients with 555 MRI studies(11) (with a more recent update totaling 1509 patients with 2103 MRI examinations.(12)) Further, a large, multi-center registry study (the Magnasafe study) enrolled 1500 patients with non-MR-conditional pacemakers (1000 patients) and ICDs (500 patients) across 23 sites.(13) A recent meta-analysis by Shah *et al.*(14) analyzed these and many other published reports from January 1990 through October 2017, covering 5099 patients who received 5908 MRI exams. In all studies, the rate of complications was extremely low: One report of an inadvertent shock from an ICD occurred when the device was programmed incorrectly during an MRI exam.(14) Of 94 reports of full- or partial-device reset, all occurred in CIEDs manufactured prior to 2007.(14) This date is noteworthy because the typical CIED lifespan is 10 years or less before replacement is required.

In these studies, the device parameters most frequently changed following MRI (measured before and after the exam) included small changes in lead sensing voltage, lead impedance, and battery voltage; the magnitudes of which were typically considered to be clinically insignificant.(12-14) Clinically significant changes in pacing capture threshold of >1V were reported in 0.55% of patients in the meta-analysis by Shah et al.(14)

Guidelines for MR imaging in patients with non-MR-conditional CIEDs have been published, most notably by the American Heart Association in 2007(15), Nazarian and colleagues(11), the Magnasafe study(13), and the Heart Rhythm society (in collaboration with 11 other societies including the ACR).(6) Additional resources include guidelines from the Canadian Heart Rhythm Society and Canadian Association of Radiologists(16), a consensus statement of the German Cardiac Society and German Roentgen Society(17), and a letter of support from the British Cardiovascular Society and Royal College of Radiologists.(18)

The Centers for Medicare and Medicaid Services (CMS), which administers the Medicare and Medicaid programs in the United States, had until recently provided coverage only for MR exams in patients with MR Conditional devices, excluding non-MR-conditional devices. In response to the increasing evidence supporting MRI even in patients with non-MR-conditional CIEDs, CMS in 2018 adopted a revised decision memo, with coverage for MR imaging in patients with non-MR-conditional CIEDs, provided specific guidelines are met.(19)

### **Recommended Guidelines for Non-MR-conditional Systems**

For physicians, primarily radiologists in coordination with cardiologists who specialize in electrophysiology, including the care of patients with CIEDs (cardiac electrophysiologists), recommendations are provided below for MRI in patients with non-MR-conditional CIEDs. These guidelines are intended to provide a concise yet practical strategy to implement a program for safely imaging such patients, while recognizing that individual institutions might need to customize according to their own needs. The guidelines include elements from widely used protocols in prior studies(11,13), including the HRS statement.(6) For institutions operating in the United States, they are designed to be compliant with the checklist in the recent CMS Decision Memo allowing MRI in patients with non-MR-conditional CIEDs(19). An institution-specific procedural checklist is likely needed (see, for example, sample checklists in the online Supporting Information, or Figure 3 in the HRS consensus statement(6)). The CMS Decision Memo requires a checklist which includes certain elements(19), all of which are included in these guidelines.

It is essential that the institution involve both Radiology and Cardiac Electrophysiology (EP) in developing an institution-specific protocol, including guidelines for how cardiac electrophysiologists will assist the referring clinician and radiologist in determining whether a particular patient is a good candidate for an MRI examination, to confirm appropriate device programming settings for the study, and to define specific personnel required for each step of the process.

1. The implanted device must first be identified as MR Conditional or non-MR-conditional. The CIED device manufacturer should be consulted, if necessary, to determine the MR Conditional status.(6,16-19)
  - a. If the device is MR Conditional, the exam should instead proceed following the device manufacturer's labeled MR conditions for the device, as discussed above.
  - b. Eligible non-MR-conditional devices under these guidelines include cardiac pacemakers, ICDs, CRT-Ds, CRT-Ps, and S-ICDs without any fractured or epicardial leads. Further, the patient should not have any abandoned leads (but see Note (A) below).
2. Both pacing-dependent and non-pacing dependent patients may undergo MRI. The institution may designate certain groups of patients, such as those that are pacing dependent, as higher-risk, requiring additional scrutiny during the risk/benefit determination, including patient monitoring during the MRI exam by additional personnel such as a cardiac electrophysiologist.(6,19)
3. In consultation with the referring physician, the radiologist (or other physician responsible for the MRI study) should determine whether an alternative imaging modality is available, or whether MRI is the only diagnostic method that will adequately address the clinical question. Physicians should keep in mind when making the risk/benefit

determination that, while the risk of MRI in patients with non-MR-conditional CIEDs appears to be low at the present time, it is not inconsequential.(6,11,15-17)

4. The cardiac electrophysiologist should help determine whether the patient is an appropriate candidate for MRI, for example based on the patient's condition and possible device programming during the exam.(6,13,15)
5. The MRI exam should be performed during hours when the entire CIED/MRI team is available, as determined by the institution (see Note (B) below).
6. (Optional) The pacemaker system (generator plus leads) must be implanted at least 6 weeks prior to the MRI exam (see Note (C) below). While there are no data that demonstrate the need for a 6-week waiting period, the majority of studies have including either no patients or not significant numbers of patients with shorter waiting times.(11,13)  
At a minimum, we recommend that the first post-implantation device check per institutional norms be performed to ensure the device is functioning properly, prior to MRI.
7. Prior to entering MRI Zone III or IV (as defined by the ACR(20)), the potential risks and benefits of MRI in comparison with alternative imaging modalities must be communicated with the patient, the patient provides their consent, and these are documented in the patient's medical record (see Note (F) below).(6,11,13,15-17)
8. MRI is limited to 1.5T (based on current available data(11,13,16,17,19)), using Normal Operating Mode for both SAR and dB/dt. The RF body coil is permitted for RF

transmission. Local transmit/receive (T/R) coils (such as a T/R head coil, or a T/R knee or extremity coil) may be used only if not positioned directly over the CIED.

9. Prior to the patient entering MRI Zone III or IV, the CIED should be interrogated and programmed to a mode appropriate for the MRI scan, as determined by the cardiac electrophysiology (EP) service (a qualified physician, nurse practitioner, or physician assistant).(6,11,13,15-17,19) This includes turning off therapy for ICD, CRT-D, and S-ICD devices, and disabling the “magnet mode” of the device (see Notes (D) & (E) below).
10. In addition to the MRI scanner operator, a separate individual (registered nurse, nurse practitioner, or cardiac electrophysiology physician) with Advanced Cardiac Life Support (ACLS) training should be present in the MRI suite throughout the entire MRI exam to monitor the patient’s vital signs and cardiac rhythm via ECG and pulse oximetry; voice and visual contact must also be maintained.(6,11,13,15-17,19) This individual must also have MRI safety training in the event the patient needs to be removed urgently from the MRI scanner; and the ability to monitor the patient for cardiovascular issues stemming from MR imaging with the CIED. An individual with expertise in programming the device, as well as the responsible cardiac electrophysiologist, must be present in the physical facility and immediately reachable and able to appear at the MRI imaging suite during the MRI study (see Note (D) below).

11. An external defibrillator and CIED programmer should be located just outside Zone III.(6,11,15-17) The institution must have a written plan for managing the patient, including immediate evacuation to this location outside Zones IV and Zone III, in the event of a cardiac emergency.
12. Immediately following the MRI study, and after the patient has been moved from MRI Zone IV and Zone III, the patient should be evaluated.(6,11,13,15-17,19) The CIED should be interrogated (including lead impedance, pacing thresholds, and P- and R-wave amplitudes(6)) to detect any abnormalities that might have resulted from the MRI study. The device should be reprogrammed by EP personnel to a setting appropriate for that patient. All changes in device parameters and any adverse events, if observed, should be documented in the patient's medical record (see Note (F) below).

#### Implementation Notes:

- (A) Abandoned Leads: These guidelines do not address imaging in patients with abandoned leads or retained lead fragments, as minimal data are available. Phantom studies have shown significant higher heating in abandoned leads compared with leads terminated at the pulse generator(21), and interactions between abandoned leads and nearby operational CIED systems.(22) However, a small number of cases have been reported for patients with abandoned leads (for example, see Padmanabhan et al.(23)). Published

guidelines do not provide specific recommendations for abandoned leads, although the HRS statement does not exclude imaging these patients when the clinical need exists.(6) For US institutions, it should be noted that the CMS Decision Memo specifically excludes reimbursement for patients with abandoned leads.(19) If an institution decides to include patients with abandoned leads, these patients should likely be placed in the higher-risk category.

- (B) Hours of Availability: It is highly advised that the institution determine clear and specific hours of availability and hospital or clinic locations where the service will be offered; and to set specific conditions regarding exceptions to this availability. With the need for Radiology and EP staff for device programming and patient monitoring during the MRI exam, availability will likely be restricted to limited day-time hours, which could be more limited than normal MRI operating hours. For example, a tertiary care center which normally offers 24/7 MRI coverage for inpatient and/or emergency care may need to restrict hours in which CIED patients can be imaged with MRI due to EP staff availability. If desired, a process for well-defined exceptions can be developed (e.g. through a call schedule, or utilizing on-site personnel trained in the procedures).
- (C) Time since Implantation: These guidelines include a waiting period of 6-weeks following CIED implantation, before the MRI study can be performed. Many initial studies used this waiting period to avoid possible uncertainty as to whether changes in device parameters are due to the effects of MRI, or possible lead dislodgement from non-



MRI related causes that can occur soon after implantation. However, MRI has been performed successfully in a limited number of studies without a waiting period (see, for example, Friedman *et al.*(24)), and the HRS consensus statement advises that this waiting period is not necessary if the exam is clinically indicated.(6) The CMS Decision Memo ultimately did not include a mandatory waiting period, in response to public comments expressing opposition.(19)

(D) Personnel Requirements: These guidelines also do not address site-specific workflow issues, including the exact composition of the entire “team”; i.e. the exact mix of EP and Radiology personnel evaluating the patient prior to the study, interrogating the CIED before and after the scan, and providing patient monitoring during the scan. The institution’s guidelines should clearly specify the personnel required for the exam and these guidelines should be available to the teams ordering and performing the scan. For example, at minimum, a nurse or other provider with ACLS training (either Cardiology or Radiology) should be present to monitor the patient during the MRI study. An institution may require a higher level of monitoring. For example, institutions may require that a cardiac electrophysiologist be present for “higher risk” patients with more advanced device parameters (such as pacing dependent patients, or for patients who do not strictly follow the criteria listed above, such as patients with abandoned leads, if the institution chooses to offer MRI exams in such patients). The CMS Decision Memo requires qualified staff to provide “Direct Supervision”; i.e. a physician, nurse

practitioner, or physician assistant with expertise in CIEDs must be in the facility (but not necessarily present) for device programming and during the MRI exam.(19)

- (E) Patient Monitoring Hardware: For monitoring patient vital signs, ECG and quantitative pulse oximetry is required. It should be noted that the ECG and peripheral gating waveforms displayed on the MRI console are generally not sufficient for robust physiologic monitoring. A dedicated MR Conditional patient monitoring system is likely required. Even with such a system, the ECG waveform might be interrupted while the MRI sequence is active, at which time the pulse oximetry waveform can be used.(6)
- (F) Device Programming: The cardiac EP service will need to determine the required pacing mode for the patient for the duration of the MRI exam. For patients that are not pacing dependent, this is often either a non-pacing mode (ODO/OVO/OAO), or an inhibited mode (DDI/VVI/AAI), but may also be an asynchronous mode in some cases.(6) For pacing dependent patients, programming will likely be an asynchronous pacing mode (DOO/VOO/AOO) that does not compete with any intrinsic rate.(6) For patients with an ICD, CRT-D, or S-ICD, therapies should be turned off. As part of device reprogramming, the “magnet mode” of the CIED should also be disabled; this mode generally sets the device to one device-specific pacing mode which is likely not the most appropriate mode for the patient during the MRI exam.
- (G) Documentation: Appropriate documentation should be made in the patient’s medical record in accordance with local institutional and clinical standards governing the

procedure. Since documentation standards and requirements vary by institution, it is beyond the scope of this manuscript to provide detailed requirements. In setting documentation standards, the institution could include considerations such as the clinical need (especially in patients with legacy CIEDs), physician-patient discussions/documentation regarding the risks and benefits, and relevant clinical details about the procedure, including complications (if any).

### **Additional Considerations**

It should be noted, at the time of CIED implantation, when all factors are equal, an MR Conditional device ideally should be selected to provide the greatest future MRI access for the patient. However, there are many possible reasons, beyond the scope of this article (including, but not limited to, cost and reimbursement issues; age of device; market availability; and re-use of existing non-MR-conditional leads) where a non-MR-conditional CIED is present in a patient for whom an MRI exam is desired; exact device selection is ultimately the responsibility of the implanting cardiac electrophysiologist.

Subcutaneous ICDs (S-ICD) are a class of ICD in which the device is typically implanted in the side of the patient's torso, and a single, shorter lead is used which does not directly contact the heart. Currently available S-ICDs are MR Conditional. A single study of 22 patients with an older non-MR-conditional model showed no serious safety concerns(25); however, the low

likelihood of encountering a non-MR-conditional S-ICD, combined with the paucity of data, preclude a full recommendation at this time.

The recommendations for non-MR-conditional devices made in this document rely on published data that include certain categories of patients or devices. Several studies, including the Magnasafe trial(13), specifically excluded pacing dependent patients with ICDs. Based on the HRS consensus statement(6), however, no such limitations are included here. Very few studies have been performed at 3T or field strengths other than 1.5T. For this reason, at this time, these guidelines allow *only 1.5T to be used with non-MR-conditional devices*.

The base version (1-12 above) of these guidelines might be considered restrictive by some practitioners, considering that some institutions now perform MRI in patients that would be excluded by these guidelines. For example, patients with epicardial or abandoned leads are excluded here; and patient monitoring is required throughout the MRI exam, even though the rates of complications are reported to be low. The primary reasons for the above recommendations are (a) to conform to the 2018 CMS Decision Memo(19), and (b) minimal data currently exist that demonstrate it is safe to go beyond these guidelines. However, as new data become available, it may be prudent to revise these restrictions or alter other parts of the guidelines.

Reimbursement for MRI in patients with CIEDs is an important factor that may limit widespread adoption in some regions. In the United States, the recent decision by CMS to

provide reimbursement, provided certain guidelines are met, will likely encourage other payers to follow suit.

Importantly, MRI exams that evaluate anatomy in close vicinity to the CIED, such as thoracic, cardiac and shoulder MRI, are often impacted by artifact from the device components, particularly strong  $B_0$  variations surrounding the CIED generator. For cardiac and thoracic MRI alternative imaging protocols may be needed. For example, it may be helpful to replace balanced steady-state free precession (bSSFP) with spoiled gradient echo sequences(26), and to use wide-bandwidth inversion pulse for late-gadolinium enhanced (LGE) acquisitions(27) to reduce  $B_0$  related artifacts. A thorough discussion of artifact mitigation strategies is beyond the scope of this report.

This report is primarily designed for MR imaging in adult populations. Little data exist regarding MRI with CIEDs in the pediatric population, and there are no published guidelines on the use of MRI in children with CIEDs. Many pediatric patients with CIEDs are imaged for congenital heart conditions, and have epicardial leads implanted for temporary pacing. We note that the HRS consensus statement concludes that children with MR Conditional CIEDs that meet all criteria for MRI in the presence of CIEDs should be eligible for clinically appropriate MRI exams.(6) One should keep in mind that many MR Conditional CIEDs list left or right pectoral implantation of the generator as a condition; implantation in another location such as the abdomen (not uncommon in pediatric patients), would render the system non-MR-conditional.

**Summary**

Magnetic resonance imaging of patients with CIEDs (including pacemakers and ICDs) can be performed safely in patients with MR Conditional devices. MRI in these patients should be performed following the MR Conditional labeling supplied by the device manufacturer. Further, there is a growing body of evidence demonstrating MRI can be performed nearly always without serious clinical consequences in patients with CIEDs that do not have MR Conditional labeling, provided certain guidelines are followed. Based on a large and growing body of evidence, we have provided practical guidelines, limited to 1.5T, to assist physicians and institutions develop protocols for imaging patients with non-MR-conditional devices.

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**Recommendations for Imaging Patients with Cardiac Implantable Electronic Devices  
(CIEDs)**

Karl K. Vigen, PhD<sup>1</sup>, Scott B. Reeder, MD, PhD<sup>2</sup>, Maureen N. Hood, PhD, RN<sup>3</sup>, Michael Steckner, PhD, MBA<sup>4</sup>, Tim Leiner, MD, PhD<sup>5</sup>, David A. Dombroski, MD<sup>6</sup>, Vikas Gulani, MD, PhD<sup>7</sup> on behalf of the ISMRM Safety Committee

<sup>1</sup>Department of Radiology, University of Wisconsin-Madison, Madison, Wisconsin, USA

<sup>2</sup>Departments of Radiology, Medical Physics, Biomedical Engineering, Medicine, and Emergency Medicine, University of Wisconsin-Madison, Madison, Wisconsin, USA

<sup>3</sup>Department of Radiology, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA

<sup>4</sup>Canon Medical Research USA, Mayfield Village, Ohio, USA

<sup>5</sup>Department of Radiology, Utrecht University Medical Center, Utrecht, The Netherlands

<sup>6</sup>Department of Radiology, University of Rochester Medical Center, Rochester, NY, USA

<sup>7</sup>Department of Radiology, University of Michigan, Ann Arbor, Michigan, USA

**Corresponding Author:** Karl K. Vigen, Department of Radiology, University of Wisconsin-Madison, 1111 Highland Avenue, Madison, WI, 53705. Email: [kkvigen@wisc.edu](mailto:kkvigen@wisc.edu)

**Running Title:** Recommendations for MRI with CIEDs