

Position Statement

Canadian Heart Rhythm Society and Canadian Association of Radiologists Consensus Statement on Magnetic Resonance Imaging With Cardiac Implantable Electronic Devices

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ABSTRACT

Magnetic resonance imaging (MRI) has historically been considered contraindicated for individuals with cardiac implantable electronic devices (CIEDs) such as pacemakers and implantable defibrillators. Magnetic resonance scanners produce magnetic fields that can interact negatively with the metallic components of CIEDs. However, as CIED technology has advanced, newer MRI conditional devices have

RÉSUMÉ

L'imagerie par résonance magnétique (IRM) a traditionnellement été contre-indiquée chez les individus porteurs d'un dispositif cardiaque électronique implantable (DCEI) comme les stimulateurs cardiaques et les défibrillateurs implantables. Les appareils d'imagerie par résonance magnétique produisent des champs magnétiques pouvant interagir de façon négative avec les composants métalliques des DCEI. Cependant, à

Traditionally, it has been considered a contraindication to image patients who have cardiac implantable electronic devices (CIEDs) such as pacemakers and implantable

defibrillators with magnetic resonance (MR) imaging. MR scanners produce magnetic fields that can interact negatively with the metallic components of CIEDs. Risks can include migration and dislodgement of device components; generation of energy currents that might damage the device and the myocardium; oversensing or undersensing caused by magnetic artifact leading to device malfunction; and rarely, generation of life-threatening arrhythmias.¹ Even though MR scanning of these patients is associated with a low risk of life-threatening adverse events, the possibility of serious sequelae has meant that most CIED patients are denied MR examination.

It is estimated that a patient has a 50%-75% probability of requiring an MR examination over his or her lifetime after CIED implantation.² Although alternative imaging modalities

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See page 1140 for disclosure information.

been developed that are now in clinical use and these systems have had demonstrated safety in the MRI environment. Despite the supportive data of such CIED systems, physicians remain reluctant to perform MRI scanning of conditional devices. This joint statement by the Canadian Heart Rhythm Society and the Canadian Association of Radiologists describes a collaborative process by which CIED specialists and clinics can work with radiology departments and specialists to safely perform MRI in patients with MRI conditional CIED systems. The steps required for patient and scanning preparation and the roles and responsibilities of the CIED and radiology departments are outlined. We also briefly outline the risks and a process by which patients with nonconditional CIEDs might also receive MRI in highly specialized centres. This document supports MRI in patients with MRI conditional CIEDs and offers recommendations on how this can be implemented safely and effectively.

such as computed tomography (CT) are available, they might not provide imaging detail or diagnostic yield equivalent to MR imaging in selected cases. To date, MR scanning has been safely performed in selected CIED patients at specialized centres with high imaging expertise, but this practice has not been widespread. To overcome this limitation, manufacturers have modified the design and programming of CIEDs to minimize the potential risks associated with MR scanning. As a result, MR-compatible CIED systems (currently labelled as “MR-conditional”) are now available for clinical use, with more of such emerging technologies being introduced in the future (Table 1).

Despite the availability of these newer, MR-conditional CIED systems, physicians remain reluctant to perform

mesure que la technologie des DCEI avançait, de plus récents dispositifs magnétocompatibles ont été conçus et sont maintenant utilisés en clinique. De plus, ces systèmes se sont avérés sécuritaires dans un environnement d'IRM. En dépit des données qui appuient ces systèmes de DCEI, les médecins se montrent réticents à réaliser l'examen d'IRM chez les porteurs de dispositifs magnétocompatibles. Cet énoncé de position commune de la Société canadienne de rythmologie et de l'Association canadienne des radiologistes décrit un processus de collaboration qui permet aux spécialistes et aux cliniques de DCEI de travailler avec les départements et les spécialistes en radiologie pour réaliser l'IRM en toute sécurité chez les patients porteurs de DCEI magnétocompatibles. Nous exposons les grandes lignes des étapes nécessaires à la préparation du patient et de l'examen, ainsi que les rôles et les responsabilités des départements de DCEI et de radiologie. Aussi, nous soulignons brièvement les risques et un processus qui permettrait aux patients porteurs de DCEI non magnétocompatibles de subir l'IRM dans des centres hautement spécialisés. Ce document appuie l'IRM chez les patients porteurs de DCEI magnétocompatibles et présente des recommandations pour une mise en place sécuritaire et efficace.

scanning of MR-conditional systems because of lingering concerns of risk. Furthermore, accurate identification of patients with MR-conditional systems can be challenging. Accordingly, the purpose of this consensus statement document is to outline a process by which cardiac device and imaging specialists can work collaboratively to facilitate MR scanning for patients with MR-conditional CIED systems. The risks, limitations, and details of the technology are summarized. Finally, this document addresses the issue of MR scanning of non-MR-conditional CIED systems—a practice that is currently reserved for highly selected patients in centres with extensive MR imaging expertise. Ongoing studies are being conducted to assess the safety of MR scanning for existing CIED products that were originally designed without intent for exposure in the MR environment. These products are referred to as “legacy” products and will be referred to as such in this document.

Table 1. Definitions of MR-conditional devices

Terminology	Definition
MR-safe	An item that poses no known hazards in all MR environments
MR-conditional	An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. The field conditions that define the specified MR environment include parameters such as: (1) field strength; (2) spatial gradient; and (3) time rate of change of the magnetic field, radiofrequency fields, and specific absorption rate. Additional conditions, such as specific configurations of the item, might be required
MR-unsafe	An item that is known to pose hazards in all MR environments

In 1997, the United States Food and Drug Administration Center for Devices and Radiological Health requested the American Society for Testing and Materials (currently known as ASTM International) to establish a set of standardized definitions to address the safety of medical devices in an MR environment. These definitions are intended for the purpose of labelling claims for medical devices in MR environments. The most recent iteration was proposed in August 2005 (ASTM F2503-05).³ These definitions are used in this consensus document.^{3,4}

MR, magnetic resonance.

Data from Woods et al.⁴

Potential Risks of MR Imaging in Patients With CIEDs

The presence of a CIED system has traditionally been considered a contraindication to performing an MR examination. MR scanners generate a powerful static magnetic field combined with a switching gradient magnetic field and pulsed radiofrequency fields to generate images. Risks associated with MR scanning in patients with CIEDs generally arise from 3 sources: the static magnetic field, gradient magnetic fields, and radiofrequency fields.^{5,6} These sources can induce several responses in the CIED including mechanical pull, heating, torque, vibration, and electrical stimulation (Table 2). The static magnetic field can interact with ferromagnetic components on CIEDs to generate unexpected forces that can move and potentially dislodge leads. It can also unpredictably trigger the magnetic sensor in CIEDs that could trigger inappropriate magnet mode pacing in pacemakers or inhibit device therapy for implantable defibrillators. The static field can also cause reed switch closure in some devices (which would also inhibit therapy) or cause distortion in the CIED electrocardiograms

Table 2. Potential risks for low-voltage and high-voltage cardiac implantable electronic devices

Static magnetic field
<ul style="list-style-type: none">• Mechanical forces of ferromagnetic components (eg, pacemaker displacement)• Unpredictable magnetic sensor activation• Reed-switch closure and sudden loss of pacemaker function• Changes in electrocardiograms
Gradient magnetic field
<ul style="list-style-type: none">• Possible induction of serious arrhythmias (rare)• Induced voltages on leads causing over- and/or undersensing
Modulated radiofrequency field
<ul style="list-style-type: none">• Heating of cardiac tissue adjacent to lead electrodes• Possible induction of serious arrhythmias (rare)• Pacemaker reprogramming or power-on-reset• RF interactions with the device (over- and undersensing)
Combined field effects
<ul style="list-style-type: none">• Sudden and unexpected loss of device function• Alteration of device function because of EMI• Mechanical forces (vibration)• Power-on-reset of the pacemaker or ICD pulse generator• Damage to pacemaker or ICD pulse generator• Damage to pacemaker or ICD lead(s)
Imaging-related
<ul style="list-style-type: none">• Artifacts that prevent adequate image visualization

EMI, electromagnetic interference; ICD, implantable cardioverter defibrillator; RF, radiofrequency.

Data from Loewy et al.¹ and Beinart and Nazarian.⁶

resulting in undersensing or oversensing. Gradient magnetic fields are continuously changing magnetic fields with the potential to induce electrical currents. The accumulation of induced current voltage on pacing lead tips can result in either over- or undersensing of underlying myocardial potentials. Induced currents due to the radio-frequency field could result in oversensing, which could result in inappropriate suppression of pacing or false detection of ventricular arrhythmias, causing inappropriate therapy or shocks. Undersensing could result in excessive pacing or failure to detect arrhythmic events. Induced currents can also lead to heating of tissue adjacent to the device battery or pulse generator (“can”) and also at the lead tip, causing tissue injury. This could alter pacing and sensing thresholds. Abandoned leads that are not connected to pulse generators might be at particularly high risk of lead tip heating, resulting in myocardial injury. Currents conducted through unipolar pacing leads could potentially induce life-threatening arrhythmias. Finally, these interactions could also result in resetting or reprogramming of the device, resulting in loss of pacing, which can lead to asystole.

In addition, CIEDs might degrade MR image quality through the creation of imaging artifacts from ferromagnetic components. Image artifacts are dependent on the factors such as the size of the device (larger devices are associated with more artifact), position of the device, the imaging plane used, and the scanning protocol. For example, artifacts are often more pronounced in the ventricular short axis plane compared with long axis planes. Delayed gadolinium contrast acquisitions more commonly generate artifacts than other imaging sequences.

Based on our current knowledge from published reports, the incidence of life-threatening or serious adverse events from MR scanning of non-MR-conditional systems is low, at < 1% (Supplemental Tables S1 and S2).⁷ For this reason, some centres perform MR scanning for patients with such devices provided that strict, well-defined imaging and monitoring protocols are in place.

MR-Conditional CIED Technology

The first MR-conditional pacemaker system was introduced in Europe by Biotronik in 2010 (Berlin, Germany), closely followed by Health Canada and then with US Food and Drug Administration approval in January 2011 for Medtronic’s MR-conditional pacemaker (Minneapolis, MN). At the moment, selected pacemakers and implantable loop recorders (ILRs) have received MR-conditional labelling in North America. Currently, no implantable cardioverter defibrillator (ICD) system is approved as MR-conditional in North America, although one such system is available for clinical use in Europe.

The development of MR-conditional pacing leads dates back to the 1990s. The challenge in the development of device leads includes the elimination of their movement, heating, and current induction. Movement is unlikely in leads that have been in place for more than several weeks to months. Early studies suggested that modification of the materials within the leads could reduce the risk of heating and current induction. These modifications include replacement of stainless steel components with copper or nickel alloys in the inner coil or lead shaft and use of platinum/iridium electrodes at the lead tip. These early studies demonstrated the safety and feasibility of designing an MR-conditional lead.^{2,5,8} More recent MR-conditional leads have also modified the geometry of the inner coil to reduce the transfer of energy which in turn, reduces lead tip heating. Challenges have resulted with the new design including altered lead handling during implantation because of an increase in lead diameter, friction, and stiffness. Also, lead performance over the longer term is not yet known. Certain “legacy” leads containing some of these modifications and which have been on the market for many years, are also being systematically studied to see if they can be labelled MR-conditional. To date, several pacing lead models have received the MR-conditional labelling claim in Canada.

Pacemaker pulse generators manufactured in the past 15 years are smaller with less ferromagnetic material and improved protection against electromagnetic interference than their predecessors. These changes improved their resilience to artifact and heating induced by MR scanning. Roguin et al. studied the effect of MR scanning on standard, modern CIEDs in an animal model.⁹ By adhering to a specific safety protocol, the authors concluded that certain CIED systems could undergo MR scanning at 1.5 Tesla (T) without additional risk. More recently, CIED components have been redesigned to minimize the energy induced and discharged. Some of these changes include reduction of the ferromagnetic content of the pulse generator and enhanced protection of the circuitry and internal power supply. The use of a Hall effect sensor in lieu of a reed switch also reduces the risk of the device reverting to a “magnet mode” when exposed in an MR imager, which sometimes can lead to asynchronous pacing in pacemakers. The Hall effect sensor’s predictable behaviour is not influenced by the static magnetic field of the MR environment.^{10,11}

In addition to alterations in structural design, software changes have been developed for MR-conditional devices. Most devices use a special MR programming mode in which the CIED will revert to an asynchronous pacing mode at higher pacing outputs to avoid suppression of pacing during MR scanning. For MR-conditional ICDs, therapy for ventricular tachyarrhythmias will be temporarily disabled during MR

scanning. This means that patients will not be protected by their ICDs if they experience ventricular arrhythmias during MR scanning. As such, emergency external defibrillators should be readily available for resuscitative purposes.

No CIED system is “MR-safe,” but selected CIED systems are “MR-conditional,” meaning that patients may undergo MR scanning without additional known risks as long as manufacturer-specified scanning parameters are followed. It is important to note that the recommended scanning parameters vary among CIED manufacturers. This means that the MR scanning protocol will vary in accordance with the patient’s CIED system. As such, clear communication between the CIED cardiologist and the MR imaging specialist must be established to ensure that these standards are conformed to. For example, some CIED systems permit full body scanning and others specify an exclusion zone, which prohibits imaging in the thoracic region. In general, all CIED manufacturers recommend maximization of the distance between the CIED and scanner, if possible. Most manufacturers also recommend a maximum static magnetic field strength of 1.5 T, with a maximum specific absorption rate (SAR) value of 2 W/kg for each sequence, and a maximum gradient slew rate of 200 T/m/s.

Based on published reports, MR scanning of patients with MR-conditional devices is safe. Thus far, no significant or life-threatening adverse events have occurred as a direct result of MR scanning.¹²⁻¹⁴ In a randomized study by Wilkoff et al., 464 patients with MR-conditional pacemakers were randomized to MR scanning of the head and lumbar spine between 9 and 12 weeks after implant vs no MR imaging. In the MR imaging group, no serious imaging-related complications occurred during or after MR scanning. Changes in pacing capture threshold and sensed amplitude were minimal and were similar between the 2 groups.¹²

Most studies that evaluated the safety of MR scanning in patients with MR-conditional CIED systems are conducted with 1.5-T scanners. There are few data on the safety of MR scanning for MR-conditional CIEDs at 3.0 T. In addition, the long-term (eg, > 5 years) product performance of MR-conditional leads and pulse generators are unknown.

Some manufacturers have used radiopaque markers on pulse generators (“can”) and leads to try to identify them as “MR-conditional” components on chest radiography. However, the use of such markers is manufacturer-specific and is not universally applied. Furthermore, “legacy” leads that have obtained MR-conditional labelling will not have such markers. More importantly, the presence of an imaging marker does not imply that the device can undergo MR scanning without additional risks. To assess this, the patient must be assessed in the CIED clinic before MR scanning to confirm device identity, device integrity, and to activate the appropriate MR programming mode.

Special Considerations for MR Scanning of Patients With MR-Conditional CIEDs

Patient selection: Who might be eligible for an MR-conditional CIED?

When selecting potential recipients of MR-conditional CIED systems, the risk-benefit ratio of implanting an MR-conditional CIED must be considered. The following issues

should be addressed. First, the long-term reliability and performance of MR-conditional devices are unknown. Second, some MR-conditional leads are stiffer and larger than standard leads. In some reports, their use was associated with higher rates of dislodgment, repeated surgery, and perforation, although this was not consistently demonstrated.¹⁵⁻¹⁷ Finally, MR-conditional CIEDs and leads are generally more expensive than traditional ones at the current moment.

Other factors that might influence whether an MR-conditional CIED should be implanted include the patient’s age, the presence of concomitant conditions, and the existence of known absolute contraindications to MR scanning. Younger patients are more likely to require MR imaging at some point during their lifetimes. This might lower the selection threshold for an MR-conditional CIED. If a patient has a concomitant disease (eg, malignancy) for which serial MR monitoring is required, an MR-conditional device should be strongly considered. If a patient already has an absolute contraindication to MR scanning such as abandoned leads, CIED (eg, lead) remnants, or other metallic prostheses (eg, mechanical valves, brain clips), then implantation of an MR-conditional CIED will be of little benefit.

As discussed previously, some “legacy” leads are being evaluated for MR-conditionality. Approval of these “legacy” leads for MR-conditional imaging will mitigate some of the barriers to implanting MR-conditional systems, such as concerns with long-term lead performance and cost. Also, patients with existing “legacy” leads might be eligible to receive MR-conditional pulse generators at the time of device replacement, allowing the entirety of their CIEDs to become MR-conditional.

Abandoned leads

The presence of abandoned pacing or ICD leads (capped or uncapped) or lead remnants after a partially successful device extraction are considered to be absolute contraindications for MR scanning.^{6,7} Abandoned leads are associated with an increased risk of heating and myocardial damage. Metallic remnants of leads can heat, dislodge, or embolize. In rare circumstances when MR scanning is absolutely required, extraction of abandoned leads might be considered but this can be associated with a 1%-2% chance of a life-threatening complication.¹⁸ Because of these risks, it is unusual to perform device extraction for patients with leads in situ for many years to allow them to undergo MR scanning.

Simplified CIED activators for programming on MR-conditional pacing and defibrillator modes

To date, current MR-conditional devices have required “manual” activation of the MR pacing mode by the CIED clinic with a traditional CIED programmer device. Thus, the patient must visit the CIED clinic before the MR scanning to prepare their CIED for scanning. However, it is foreseeable that newer CIEDs might have simplified devices such as special wands or “activators” that can automatically reprogram the device to the MR mode without the need for a traditional programmer. In addition, some CIEDs might eventually be able to detect the MR scanner’s magnetic field and automatically reprogram itself to an MR mode without the need for any human intervention. Although such technologies

might simplify the programming process and even allow radiology suites to program the device to MR mode, they also have the potential to bypass the standard CIED evaluation process outlined in the collaborative process of this document. This can result in oversight of important prescanning information such as device malfunction or abnormalities, or presence of abandoned leads or non-MR-conditional components that would pose serious risk if MR scanning is performed. Thus, simplified or automated activation of MR modes on CIEDs should not replace a standard prescanning evaluation in the CIED clinic.

Emergency MR

The availability of emergency MR scanning, particularly after regular hours, is subject to resource and logistic limitations. Some of these factors include: scanner unavailability, need for specialized technologists to operate the scanner, and need for radiologists to specify the protocol and interpret the MR images. More importantly, there are very few medical conditions that absolutely require an urgent MR scanning. Some indications include urgent assessment of the central nervous system (venous sinus thrombosis, encephalitis, central neural system hemorrhage, and acute cerebral ischemia), the spine (spinal cord pathology and compression, including cauda equina syndrome and epidural abscess), the musculoskeletal system (detection of radiographic occult fractures of the hip and scaphoid), and the gastrointestinal system (investigation of appendicitis in pregnant patients with inconclusive ultrasound). Many of these indications, however, can be investigated using CT, CT angiography, or CT perfusion studies with or without iodine contrast enhancement. Furthermore, some of these conditions are not true emergencies and diagnostic delays of hours or even days (although not desirable) will not necessarily affect treatment or prognosis. Thus, truly emergent MR scans are uncommonly performed in clinical practice. However, in rare emergency situations in which urgent MR scanning is required, it should only be performed after the patient's CIED is assessed by the CIED clinic on an urgent basis. If this is not possible, the MR scan should be deferred and alternative methods of emergency scanning should be chosen instead. The MR scan might then be scheduled semiurgently in the following hours or days when appropriate CIED clinic evaluation can occur.¹⁹⁻²¹

Scanning Patients With MR-Conditional CIEDs: A Collaborative Process

To properly perform MR imaging for patients with an MR-conditional device, a collaborative process must be established among the CIED clinic, cardiologists with CIED expertise, MR suite, MR radiologists, and administrators. A team of radiologists, cardiologists, MR technologists, technicians, and nurses, with defined responsibilities must be created in advance of providing this specialized imaging service. Where there is a physicist with expertise in MR, he or she should be considered a member of the team. Standard operating procedures must be established and the team members should be well acquainted with the work flow. It is also expected that the requirements of this collaboration will evolve over time as newer technology emerges and as more clinical experience is gained.

Facility requirements for performing MR imaging in patients with MR-conditional CIEDs

The imaging facility must have a protocol for MR scanning of patients with CIEDs, developed via a collaborative effort of MR and CIED specialists. Ideally, it should consist of an onsite CIED clinic to interrogate and program the CIED systems. In some cases, it might be possible for a radiology suite to establish close collaboration with an offsite CIED clinic where patients are assessed before and after MR. However, on the day of MR scan, a member of the CIED team (technician, nurse, or physician) should be readily accessible for device troubleshooting or reprogramming, if required. Yet, it might not be possible for a member from the CIED clinic to be physically present in the MR suite during the entirety of the scan because of logistic reasons. However, as MR-conditional CIED technology evolves and experience with MR scanning accrues, the need for onsite CIED support might diminish over time.

The way by which the CIED team provides onsite support for patients who undergo MR scanning should be based on a mutual, collaborative agreement between the CIED clinic and the MR radiology department. It should be tailored according to the practice standards and resources of the institution. Some might require that a CIED team member be present during the entire MR scan and others might require that the CIED team provide same-day assessment before and after MR scanning. The specific personnel requirement will be left to the discretion of the institution. Finally, a cardiologist with expertise in CIED management should be readily available for consultation before, during, and after MR scanning. This physician does not need to be physically present but should be easily accessible to provide advice, if required.

The imaging facility should develop a standardized protocol to triage CIED patients for MR scanning. This protocol will systematically:

- (1) Identify patients with CIED systems;
- (2) Alert the MR team of the presence of a CIED in a given patient;
- (3) Formalize a referral process to the CIED clinic to obtain information on the CIED and to assess its function;
- (4) Identify potential relative contraindications that might increase risk during MR scanning;
- (5) Ensure that the CIED and patient have been properly assessed in preparation for MR scanning;
- (6) Ensure that the patient's CIED is reinterrogated and reprogrammed after MR scanning; and
- (7) Alert physicians (MR radiologist and CIED cardiologist) of potential CIED malfunction before, during, and after MR scanning.

The facility should also have the capability to monitor the patient's vital status during MR scanning. All of the following modalities should be available: (1) pulse oximetry; (2) electrocardiographic (ECG) monitoring; and (3) capability for verbal communication between the MR scan operator and patient. The facility should also have emergency resuscitation equipment available including, at minimum, an external defibrillator and ready access to an onsite emergency resuscitation cart and team.

MR scanning of patients with MR-conditional CIED systems: role of radiology and the CIED clinic

A sample work flow diagram of the triage and referral process for CIED patients who undergo MR scanning is shown in [Supplemental Figure S1](#).

Role of radiology before MR

Step 1. Triage of MR requisitions: is an MRI necessary for this patient? As the first step, the requisition should clearly identify patients with CIED systems. Then, the radiologist will review the requisition to determine if MR imaging is indicated. The following questions will be considered: (1) is there an alternative imaging test that can answer the clinical question equally well? and (2) will the results of the MR scan provide a significant effect on patient treatment or prognosis?

In addition, the decision to perform MR scanning should be a collaborative, risk-benefit analysis. If the radiologist determines that MR imaging might not be required, he or she should contact the requesting physician to discuss alternative imaging modalities. If an alternative test is deemed suitable, the requesting physician should inform the patient about this change in management. If the requesting physician has questions before requesting the MR scan, he or she is encouraged to discuss the case with the MR radiologist.

The MR radiologist should triage these requests into different categories, assessing the benefit of MR scan (eg, essential, beneficial, and helpful) and also its urgency. In many cases, the MR scans can be performed electively, and hence allow sufficient time for CIED clinic assessment.

In rare emergency situations in which urgent MR scanning is required, scanning should only be performed if appropriate preimaging evaluation of the patient can be done urgently as outlined in the roles of the CIED clinic. If proper urgent patient and device assessment is not possible, the MR scan should be avoided and alternative methods of emergency scanning chosen. The MR scan might then be done semi-urgently in the following hours or days when appropriate CIED clinic evaluation can take place.

If the MR scan is deemed to be clinically indicated after consideration of the aforementioned factors, the MR suite will contact the CIED clinic to arrange for patient and CIED assessment.

Step 2. Book prescanning tests and CIED assessment.

The MR suite will contact the CIED clinic for preimaging assessment of the patient. The referral process will be initiated by the MR booking clerk or MR technologist. The MR scan will then be scheduled accordingly. Other forms of imaging such as chest or orbital radiography will be arranged by the MR radiology suite as needed. Additional details of the MR scan such as urgency will be communicated to the CIED clinic to facilitate scheduling of the clinic assessment.

Step 3. Patient consent for the MR scan. Consent forms should be set up locally with the involvement of hospital administration, radiology, and the CIED clinic. Patients or their substitute decision-makers will need to have relevant information regarding the risk and benefits of the MR study from a radiologist, cardiologist, and/or their referring

physician. If the patient is unable to consent, their substitute decision-maker will consent on their behalf as per local policy.

A 2-step consenting process might be adopted with the CIED clinic explaining the MR-compatibility of the CIED, the risks to the patient and the CIED from MR scanning, and the management of possible complications to the CIED. The radiologist should explain the need and benefit of the MR scan vs other imaging modalities.

Role of the CIED clinic before MR

Step 1. Identify the MR-conditional components. The CIED clinic must identify all components of the patient's CIED system and verify that they are all MR-conditional. Performing MR scanning in a CIED patient with non-MR-conditional component(s) is contraindicated in many institutions. However, some institutions might choose to perform MR scanning in selected patients with a non-MR-conditional CIED system in a highly supervised setting. Nonetheless, if any of the following components are present, MR scanning is absolutely contraindicated:

- Broken or fractured lead(s)—known or suspected.
- Abandoned (capped) or extraneous lead(s), lead extender(s), or lead adaptor(s).
- Remnants of a lead that persist in the patient's body (eg, pacemaker pocket, vascular space, or cardiac chamber).
- Permanent epicardial pacing or ICD lead(s): these refer to epicardial pacing and/or ICD leads implanted for the purpose of permanent pacing or ICD therapy. Note: the presence of temporary epicardial wire(s) inserted at the time of cardiac surgery is not considered to be an absolute contraindication for MR scanning.²²

If the CIED clinic has determined that the entirety of the patient's CIED system is MR-conditional, proceed to step 2.

Step 2. Interrogate the device and assess for CIED problems. The CIED clinic should interrogate the device and obtain key baseline device performance data. All of the following baseline device data should be obtained and documented:

- Specification of the CIED type (ICD, pacemaker, or ILR).
- Type and serial number of the lead(s) and pulse generator.
- Manufacturer of the lead(s) and pulse generator.
- Product advisory, if any.
- Body location of the implant site.
- Date of device implant.
- Dependency on pacing.
- Battery voltage.
- Charge time (ICD devices only).
- Sensing function of the atrial and/or ventricular leads.
- Pacing threshold of the atrial and/or ventricular leads.
- Impedance of the atrial and/or ventricular leads.
- Occurrence of any atrial and/or ventricular high rate episodes since last interrogation.

- Abnormality of device function based on previous device interrogations and/or automated device performance logs.

The following parameters are considered to be “red flags” for a CIED patient who is scheduled for MR scanning:

- Presence of device performance alerts.
- Unexplained and “significant” changes in battery voltage and/or charge time.
- Unexplained and “significant” changes in sensing, pacing thresholds, or impedance of the lead(s).
- Unexplained nonphysiologic signals detected by the CIED, either by the lead(s) or the pulse generator.
- Existence of a product advisory for any component of the CIED.
- Recent CIED implant (some CIED manufacturers recommend that a MR-conditional device be implanted > 6 weeks from time of MR imaging).

Note, there is no universal definition as to what constitutes a “significant change” in the functioning of a particular CIED feature. This is at the discretion of the cardiologist with expertise in CIED management who is responsible for the care of a given patient.

There are situations in which patients with MR-conditional implantable loop recorders will undergo MR imaging. These devices cannot pace or defibrillate the heart and therefore have no direct effect on the patient’s cardiac rhythm condition. Based on published reports, MR scanning of patients with ILRs appear to be safe and no serious adverse events have been observed.²³⁻²⁵ However, the stored episodes of the ILR might be erased when exposed in a MR environment. To avoid loss of data, we recommend that the stored episodes from the ILR be downloaded to a separate source (or printed) at the preimaging visit.

Step 3. Program the CIED to the appropriate MR scanning mode. After steps 1 and 2 have been performed, the CIED staff in conjunction with the responsible CIED cardiologist will determine the programming changes for the patient during MR. This is usually done by activating the special MR mode on the device. There are 2 programming choices: (1) MR invisible; or (2) MR invulnerable. In the MR “invisible” mode, the CIED is rendered incapable of pacing and/or defibrillating the heart. In the MR “invulnerable” mode, the CIED is programmed to pace continuously (asynchronously) at a set rate (eg, 80 beats per minute). If it is an ICD, antitachycardiac pacing and shocking therapies of the device will be disabled in this mode. The “invisible” mode is typically used for patients who are not pacemaker-dependent and the “invulnerable” mode might be required for those who are pacemaker-dependent. The choice of programming should be clearly documented.

We recommend that steps 1 and 2 be performed within 4 weeks of MR imaging. Reprogramming of the CIED (step 3) should be performed on the day of MR imaging.

The device clinic should provide written documentation to the MR suite confirming the following: that the entirety of the CIED is MR-conditional, that the CIED is functioning properly, and that the CIED is appropriately

programmed for the patient to undergo MR scanning. This can be done by a checklist attached to the final device interrogation printout.

Role of radiology during MR scanning

Monitoring and resuscitation equipment must be available in working order during patient imaging. The prescribed imaging protocols should fall within device manufacturer specifications and modified accordingly. Manufacturers should be contacted if unfamiliar with the specifications. Scanning techniques to minimize device artifact should be adopted. The images should be closely monitored by a radiologist for technical quality, artifacts, and need for extra sequences and/or gadolinium. A basic list of recommended MR scanning technical parameters that are recommended for most MR-conditional CIEDs include:

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

Role of the CIED clinic during MR scanning

During MR imaging, a member of the CIED clinic (technician, nurse, or physician) should be easily accessible to the MR imaging team for assistance with device troubleshooting and device reprogramming, if required.

Role of radiology after MR scanning

The radiology department should arrange for the patient to be evaluated in the CIED clinic or by CIED personnel before being discharged from the hospital/facility.

Role of the CIED clinic after MR scanning

After the MR scan is completed, the CIED clinic staff should reinterrogate the CIED and examine for new abnormalities that might have developed. If any new abnormality is detected, the CIED cardiologist should be notified immediately to determine if further steps are required. If no new abnormality is detected, the CIED should be reprogrammed to its original (prescan) settings. Confirmation that the CIED has been reprogrammed to its original settings (or if changes are made) should be clearly documented.

Monitoring Requirements for the CIED Patient Undergoing MR With an MR-Conditional Device

To date, there are no formalized recommendations with regard to the optimal method to monitor the vital status of CIED patients undergoing MR scanning. Currently, 3 modes of monitoring are often used: ECG monitoring, pulse oximetry, and intermittent verbal communication. The advantages and limitations of each modality are summarized in [Table 3](#).

All forms of patient monitoring should be available in the imaging facility, although it is not required that all 3 need to be used at the same time. However, either ECG monitoring

Table 3. Monitoring modalities of patients with CIEDs during MR scanning

Mode of vital status monitoring	Potential advantages	Potential limitations
ECG	This is the most direct way to assess the patient's heart rhythm status in a continuous manner	(1) The use of ECG monitoring equipment is subject to significant artifacts that might preclude accurate assessment of the patient's rhythm (2) Improper positioning of the ECG lead and electrodes might cause skin burns (eg, if the lead is inadvertently wrapped around the electrode or if the lead is in contact with skin) (3) No information of the patient's respiratory status will be provided using this mode of monitoring
Pulse oximetry	(1) Allows for continuous monitoring of the patient's pulse, which reflects cardiac output (2) Provides information on the patient's respiratory status (oxygen saturation) (3) Obviates the potential risks associated with ECG monitoring	Does not provide real-time monitoring of the patient's cardiac rhythm
Intermittent verbal communication	(1) Allows for monitoring of the patient's mental status (2) Allows for patients to communicate any potential discomfort to the MR team	Not applicable for patients who are unable to verbally communicate

CIED, cardiac implantable electronic device; ECG, electrocardiographic; MR, magnetic resonance.

or pulse oximetry monitoring should be used in conjunction with intermittent verbal communication.

Monitoring of the CIED patient during MR scanning might be performed by a number of qualified individuals including: MR technologist, MR nurse, MR radiologist, cardiologist with expertise in CIED management, or CIED clinic nurse. There are 3 important factors that determine the personnel composition required for monitoring of a given CIED patient during MR scanning: (1) the patient's medical status; (2) the functional status of the CIED; and (3) experience of the team members.

Situations in which monitoring can be performed by the default personnel (as defined by each institution)

- A patient with no ongoing arrhythmia issues who has an MR-conditional CIED that is functionally normal based on preimaging assessment by the CIED clinic.
- A pacemaker-dependent patient with an MR-conditional CIED that is functioning normally based on preimaging assessment by the CIED.

Situations in which additional monitoring personnel are recommended during MR imaging (ie, beyond the default personnel as defined by each institution)

- A patient with an active arrhythmia issue. In this situation, we recommend that MR imaging be deferred until the arrhythmia issue is stabilized.
- A patient with an MR-conditional CIED with some abnormal function, but none that are absolute contraindications for MR imaging (eg, recent, nonsignificant changes in pacing and/or sensing thresholds).
- A patient with an MR-conditional ICD that is functioning normally who has had recent therapies (pacing or shocks) for ventricular arrhythmias.
- A patient with a non-MR-conditional CIED who undergoes MR scanning.

MR Scanning of Patients With Non-MR-Conditional CIED Systems: Considerations

MR scanning of patients with non-MR-conditional CIED systems is considered "off-label" and is not endorsed by regulatory agencies (eg, Health Canada, US Food and Drug Administration), joint published guidelines from cardiovascular and radiology societies, and CIED manufacturers.^{2,26-29} As such, MR imaging of a patient with a non-MR-conditional CIED system is not routinely performed and is not considered to be standard of practice. However, the writing committee recognizes the existence of clinical scenarios in which MR scanning might provide crucial information in the management of the patient's care. If this is the case, provisions can be made to allow for such "off-label" MR scanning to be performed with the understanding that serious and potentially life-threatening risks might occur.³⁰⁻³³ As such, the writing committee specifies that a detailed and explicit risk/benefit discussion be made among the: (1) referring physician (preferably a specialist in the specific body region of interest, such as a neurologist, neurosurgeon, orthopaedic surgeon, etc); (2) cardiologist with expertise in CIED management; and (3) MR radiologist. The consensus recommendation of this group and the risks of "off-label" MR scanning must be documented and communicated to the patient or the patient's substitute decision-maker. Written informed consent for MR scanning is requisite. Specifically, the following potential risks should be discussed³:

- (1) Pacemaker or ICD dysfunction;
- (2) Pacemaker or ICD damage;
- (3) Arrhythmia; and
- (4) Death.

What are the risks?

A list of potential risks associated with MR scanning of patients with non-MR-conditional CIED systems is outlined in Table 2.¹ Published reports on MR scanning of patients with non-MR-conditional CIED systems used strict MR imaging and patient monitoring protocols. In these studies,

the following changes were noted after MR scanning: (1) alteration in lead parameters such as sensing, pacing threshold, or impedance; (2) power-on-reset of the CIED; (3) inhibition of pacemaker output resulting in transient bradycardia or asystole; (4) asynchronous pacing induced by reed switch activation; and (5) decrease (minor) in battery voltage. Notably, the reported rates of device functional changes varied markedly among published studies, from 0% to 40%.³³ However, life-threatening adverse events such as induction of ventricular arrhythmia, prolonged asystole requiring temporary pacing, or death did not occur in these studies.

Which CIED patients cannot undergo MR scanning?

Absolute contraindications for MR scanning of patients with CIED system components are listed in the *Step 2. Interrogate the Device and Assess for CIED Problems* section earlier in this document.

Are there any requirements or limitations for the MR examination?

To date, MR scanning of non-MR-conditional pacemakers and ICD systems had been performed with magnet strengths up to and including 1.5 T. There are very few published data on the safety of MR scanning at 3 T or higher and is therefore not recommended.^{7,34-36}

In general, the minimum number of sequences should be performed to obtain the necessary information. Several recent studies had shown that MR imaging can be performed in various body regions (including the thorax and heart) without increased risks to the patient or the CIED.^{1,7,33,37} Although it is generally recommended that SAR be kept below 2.0 W/kg,¹ some recent studies have brought this limitation into question.^{7,37} The use of a transmit/receive coil is preferred where possible.¹

What protocol should be followed for the imaging of non-MR-conditional pacemaker and ICD systems?

A standardized protocol for MR scanning of patients with non-MR-conditional devices should be developed for institutions that provide this imaging service. A sample protocol is provided in [Supplemental Figure S2](#). Several items merit further discussion. First, institutional approval must be obtained before performing MR for patients with non-MR-conditional CIED systems. Second, written informed consent must be obtained from the patient or the appropriate substitute decision-maker before MR scanning. The risks and benefits of MR should be clearly explained. Third, support personnel with advanced cardiac life support training are a minimum requirement. These individuals should be prepared to intervene with appropriate resuscitation equipment. Fourth, continuous monitoring of patients' vital status during MR scanning is mandatory. Patients should be evaluated before and after every pulse sequence either by an attendant in the scanner room or via the intercom system from the scanning console. Finally, the patient should be supervised until he or she is assessed in the CIED clinic.

Conclusions

Patients with MR-conditional CIED systems might undergo MR scanning with minimal risks, provided that

well-defined imaging and monitoring protocols are established. In addition, the scanning protocol should adhere to the recommended settings as specified by the CIED manufacturer. Scanning of MR-conditional CIEDs can and should be done at centres meeting the conditions outlined in this document. The fundamental basis of a successful MR scanning program for CIED patients is borne from a collaborative process between the CIED clinic and radiology department.

Recommendations: Executive Summary

Full recommendations, including "Values and Preferences," in Grading of Recommendations Assessment, Development and Evaluation (GRADE) format can be found in [Supplemental Appendix S1](#).

RECOMMENDATION

1. We recommend that MR imaging of MR-conditional CIEDs can be performed with a low risk of life-threatening complications provided that patients and their CIEDs are properly evaluated before imaging and the scanning protocol be within the specified labelling for that CIED model (Strong Recommendation, Moderate-Quality Evidence).
2. We recommend that facilities that perform MR scanning of patients with MR-conditional CIED systems should establish a formalized protocol via close collaboration between the CIED clinic and radiology department (Strong Recommendation, Low-Quality Evidence).
3. We recommend that the specific roles for the CIED clinic prior to MR scanning of a patient with an MR-conditional CIED should include:
 - i. Identification and confirmation of all elements of the CIED as MR-conditional;
 - ii. Evaluation of the CIED for potential functional abnormalities;
 - iii. Programming of the CIED to the appropriate MR imaging mode to avoid inappropriate pacing, device suppression, or inappropriate therapies (Strong Recommendation, Low-Quality Evidence).
4. We recommend that the specific roles for the Radiology Department prior to MR scanning of a patient with an MR-conditional CIED should include:
 - i. Triaging of MR requisitions to determine appropriateness of imaging;
 - ii. Initiation of pre-imaging preparation of the patient with the CIED clinic;
 - iii. Initiation of local standard operating imaging procedures to perform MR scanning in accordance to manufacturer- and radiologist-suggested parameters (Strong Recommendation, Low-Quality Evidence).
5. We recommend that during the MR scan, a member of the CIED clinic (technician, nurse, or physician) should be readily accessible (although not necessarily in person) to the MR imaging team for CIED management (Strong Recommendation, Low-Quality Evidence).

6. We recommend that during the MR scan, the radiology suite must provide proper monitoring of CIED patients to minimize the occurrence of adverse events related to MR scanning. Basic monitoring requirements include methods for 2-way communication between operator and the patient and either pulse oximetry or telemetric ECG monitoring and access to emergency resuscitation equipment (Strong Recommendation, Low-Quality Evidence).
7. We recommend that the patient be reassessed by the CIED clinic personnel to evaluate for CIED abnormalities after the MR scan and for the CIED to be reprogrammed to its original (prescan) settings (Strong Recommendation, Low-Quality Evidence).
8. We recommend that a MR scan is contraindicated if any one or more of the following conditions exist:
 - i. Suspected or known fractured pacing or ICD leads;
 - ii. Abandoned epicardial pacing or ICD lead(s) intended for permanent pacing or ICD therapy;
 - iii. Lead extenders, lead adaptors, or lead remnants that persist in the patient's body (Strong Recommendation, Low-Quality Evidence).
9. We recommend that MR imaging of a non-MR-conditional CIED should only be performed at centres with a high level of expertise in MR imaging and CIED management. These centres must have established and well-defined imaging and vital status monitoring protocols, derived from close collaboration between the CIED clinic and radiology department (Strong Recommendation, Low-Quality Evidence).

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at <http://dx.doi.org/10.1016/j.cjca.2014.07.010>.