Canadian Heart Rhythm Society (CHRS) and Canadian Association of Radiologists (CAR)
Joint Consensus Statement on Magnetic Resonance Imaging with Cardiac Implantable
Electronic Devices

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INTRODUCTION

Traditionally, it has been considered a contraindication to image cardiac implantable electronic devices (CIEDs) such as pacemakers and implantable defibrillators with magnetic resonance imaging (MR). MR scanners produce a magnetic field which can interact negatively with the metallic components of CIEDs. Risks can include migration and dislodgement of device components; generation of energy currents which may damage both the device and myocardium; oversensing or undersensing caused by magnetic artifact leading to device malfunction; and rarely generation of life threatening arrhythmias. [Lowey] Even though magnetic resonance (MR) scanning of these patients is associated with a low risk of life-threatening adverse event, the possibility of serious sequelae has meant that most CIED patients are denied MR examination.

However, given the advanced age of most patients receiving CIEDs, it is estimated that a patient has a 50-75% probability [Kalin PACE] of requiring an MR examination over his or her lifetime after CIED implantation. Although alternative imaging modalities such as computed tomography are available, they may not provide equivalent imaging detail or diagnostic yield as an MR in selected cases. To date, MR scanning has been safely performed in selected CIED patients at specialized centers with high imaging expertise, but this practice has not been widespread. To overcome this limitation, manufacturers have modified the design and programming of CIED’s 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 upcoming future.

Definitions of MR-conditional devices:

In 1997, the United States Food and Drugs Administration (FDA) Center for Devices and Radiological Health (CDRH) 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). [Levine] These definitions will be used by this consensus document.

<table>
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<th>Terminology</th>
<th>Definition</th>
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<td>MR safe</td>
<td>An item that poses no known hazards in all MR environments.</td>
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<tr>
<td>MR conditional</td>
<td>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: i) field strength, ii) spatial gradient, iii) time rate of change of the magnetic field (dB/dT), radiofrequency fields, and specific absorption rate (SAR). Additional conditions, such as specific configurations of the item, may be required.</td>
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MR unsafe

| MR unsafe | An item that is known to pose hazards in all MR environments |

MR = magnetic resonance.


**“Legacy” CIED products**

Ongoing studies are being conducted to assess the safety of MR scanning for existing CIED products which 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.

Despite the availability of these newer, MR-conditional CIED systems, physicians remain reluctant to perform scanning of MR-conditional systems due to 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 will work collaboratively to facilitate MR scanning for patients with MR-conditional CIED systems. The risks, limitations, and details of the technology will be summarized. Finally, this document will address the issue of MR scanning of non-MR-conditional CIED systems - a practice that is currently reserved for highly selected patients in centers with extensive MR imaging expertise.

**POTENTIAL RISKS OF MR IMAGING IN PATIENTS WITH CIEDs**

The presence of CIED’s has traditionally been considered a contraindication to performing MR examination. MR scanners generate a powerful static magnetic field combined with a switching gradient magnetic field and pulsed radiofrequency energy to generate images. Risks associated with MR in patients with CIEDs generally arise from three sources: the static magnetic field, gradient magnetic fields, and radiofrequency energy. [Nyenhuis, Beinart] These sources can induce several responses in the CIED including mechanical pull, heating, torque, vibration, and electrical stimulation (Table 1).

The static magnetic field can interact with ferromagnetic components on CIEDs to generate unexpected forces which can move and potentially dislodge leads. It can also unpredictably trigger the magnetic sensor in CIEDs which 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 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. Oversensing 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 which are not connected to pulse
generators may 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 may degrade MR image quality through the creation of imaging artifacts from ferromagnetic components. Image distortion is 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 employed, and the scanning protocol. For example, artifacts are often more pronounced in the ventricular short axis plane when compared to long axis planes. Late gadolinium contrast acquisitions are more susceptible to generate artifacts than other imaging sequences due to longer acquisition times.

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% (Tables 2 and 3). [NAZARIAN CIRCEP] For this reason, some centers perform MR 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 US FDA approval for Medtronic’s MR-conditional pacemaker (Minneapolis, MN, USA) in 2011. At the current moment, selected pacemakers and implantable loop recorders (ILR) have received MR-conditional labelling in North America. Currently, no 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 1990’s. The challenge in the development of device leads includes the elimination of movement, heating and current induction. Movement is unlikely in leads which 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. [Nyenhuis, Kalin, Sutton] 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 due to 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 the above-mentioned 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 magnetic material and improved protection against electromagnetic interference than their
In addition to alterations in structural design, software changes have been developed for MR-conditional devices. Most devices utilize 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 tachy-arrrhythmias will be temporarily disabled during MR scanning. This means that patients will not be protected by their ICD’s 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’s 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 amongst CIED manufacturers. This means that the MR scanning protocol will vary in accordance to 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 while 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 Tesla, 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. [Wilkoff, Gimbel, Wollmann CG] 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 post-implant versus no MR. In the MR group, no serious imaging-related complications occurred during or after MR. Changes in pacing capture threshold and sensed amplitude were minimal and were similar between the 2 study groups. [Wilkoff]

The majority of studies which evaluated the safety of MR scanning in patients with MR-conditional CIED’s are conducted with 1.5 Tesla scanners. There is little data on the safety of MR scanning at 3.0 Tesla. [Gimbel 2008+2009, Naehle] In addition, the long-term (e.g. >5 years) product performance trajectories of MR-conditional leads and pulse generators are unknown.
Some manufacturers have employed 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 which 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 prior to MR 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 may be eligible for a MR-conditional CIED?

When selecting potential recipients of MR-conditional CIED’s, 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 dislodgments, reoperations, and perforation, although this was not consistently demonstrated. [Rickard, Forleo, Elmouchi] Finally, MR-conditional CIEDs and leads are generally more expensive than traditional ones at the current moment.

Other factors which may influence whether an MR-conditional CIED should be implanted include the patient’s age, the presence of concomitant conditions, and the presence of known absolute contraindications to MR. Younger patient are more likely to require MR at some point during his or her lifetime. This may lower the selection threshold for an MR-conditional CIED. If a patient has a concomitant disease (e.g. 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 such as abandoned leads, CIED (e.g. lead) remnants, or other metallic prostheses (mechanical valves, brain clips, etc), then implant 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 may 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. (Beinart, Narazian) Abandoned leads are associated with an increased risk of heating and myocardial damage. Metallic remnants of leads can heat, dislodge, or embolize.
rare circumstances where MR scanning is absolutely required, extraction of abandoned leads may be considered but this can be associated with a 1-2% chance of a life-threatening complication. [Rickard 2011] Given these risks, it is unusual to offer device extraction to patients in order for 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 to prepare their CIED for scanning. However, it is foreseeable that newer CIEDs may have simplified devices such as special wands or “activators” that can automatically re-program the device to the MR mode without the need for a traditional programmer. In addition, some CIEDs may eventually be able to detect the MR field and automatically reprogram itself to an MR mode without the need for any human intervention. While such technologies may 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 (see below). This can result in oversight of important pre-scanning information such as device malfunction or abnormalities, or presence of abandoned leads or non-MR-conditional components which will pose serious risk if MR scanning is performed. Thus, simplified or automated activation of MR modes on CIEDs should not replace a standard pre-scanning 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. More importantly, there are very few medical conditions that absolutely require an urgent MR. 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 equine 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 by computed tomography (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 (though not desirable) will not necessarily impact treatment or prognosis. Thus, truly emergent MRs are uncommonly performed in current clinical practice. However, in rare emergency situations where 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 should be deferred and alternative methods of emergency scanning should be chosen instead. The MR can then be scheduled semi-urgently in the following hours or days when appropriate CIED clinic evaluation can occur. [Pedrosa, Quint, Korley]
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 amongst the CIED clinic, Cardiologists with CIED expertise, MR suite, and MR Radiologists. A team of radiologists, cardiologists, MR technologists, technicians, and nurses, with defined responsibilities must be created in advance of providing this specialized imaging service. Standard operating procedures must be established and the team members should be well-acquainted with the workflow. 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 setup for MR scanning of patients with CIED’s, 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’s. In some cases, it may be possible for a radiology suite to establish close collaboration with an offsite CIED where patients are assessed before and after MR. However, on the day of MR, a member of the CIED team (technician, nurse, or physician) should be readily accessible for device troubleshooting or reprogramming, if required. Yet, it may not be possible for a member from the CIED clinic to be physically present in the MR suite during the entirety of the scan due to logistic reasons. However, as MR-conditional CIED technology evolves and experience with MR scanning accrues, the need for onsite CIED support may diminish over time.

The way by which the CIED team provides on-site support for patients undergoing MR 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 may require that a CIED team member be present during the entire MR scan while others may require that the CIED team provide same-day assessment before and after MR. 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:

(i) Identify patients with CIED’s.
(ii) Alert the MR team of the presence of a CIED in a given patient.
(iii) Formalize a referral process to the CIED clinic to obtain information of the CIED and to assess its function.
(iv) Identify potential relative contraindications which may increase risk during MR.
(v) Ensure that the CIED and patient have been properly assessed in preparation for MR.

(vi) Ensure that the patient’s CIED is re-interrogated and reprogramed after MR.

(vii) Alert physicians (MR radiologist and CIED cardiologist) of potential CIED malfunction before, during, and after MR.

The facility should also have the capability to monitor the patient’s vital status during MR. All of the following modalities should be available: (i) pulse oximetry; (ii) electrocardiographic (ECG) monitoring; and (iii) capability for verbal communication between the MR 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’s: Role of Radiology and the CIED clinic

A sample workflow diagram of the triage and referral process for CIED patients who undergo MR is shown in Figure 1.

Role of Radiology before MR

STEP 1: Triaging of MR requisitions: Is an MRI necessary for this patient? As the first step, the requisition should clearly identify patients with CIED’s. Then, the radiologist will review the requisition to determine if MR imaging is indicated. The following questions will be considered: i) is there an alternative imaging test which can answer the clinical question equally well? and ii) will the results of the MR provide significant impact upon 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 may 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 prior to making the request for MR, 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 (e.g. essential, beneficial and helpful) and also its urgency. In many cases, the MR scans can be performed electively, hence allowing sufficient time for CIED clinic assessment.

In rare emergency situations where urgent MR scanning is required, scanning should only be performed if appropriate pre-imaging 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 may then be done semi-urgently in the following hours or days when appropriate CIED clinic evaluation can take place.
If the MR 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 pre-scanning tests and CIED assessment. The MR suite will contact the CIED clinic for pre-imaging assessment of the patient. The referral process will be initiated by the MR booking clerk or MR technologist. The MR 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 may be adopted with the CIED clinic explaining the MR compatibility of the CIED, the risks to both the patient and CIED from MR, and the management of possible complications to the CIED. The radiologist, on the other hand, should explain the need and benefit of the MR scan vs other imaging modalities. The following categories of potential risks should be discussed with patients and documented: i) Pacemaker or ICD dysfunction; ii) Pacemaker or ICD damage; iii) Arrhythmia; iv) Death.

**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 in a CIED patient with non-MR-conditional component(s) is contraindicated in many institutions. However, some institutions may choose to perform MR in selected patients with non-MR-conditional CIED’s in a highly supervised setting (see later). Nonetheless, if any of the following components is 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 which persist in the patient’s body (e.g. 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 contra-indication for MR scanning. (Hartnell)

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 (implantable cardioverter defibrillator (ICD), pacemaker, or implantable loop recorder (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:

• 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 non-physiologic signals detected by 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).

*There is no universal definition 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 for 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 impact on the patient’s cardiac rhythm condition. Based on published reports, MR scanning of patients with ILR’s appeared to be safe and no serious adverse events had been observed. [Gimbel 2005, Wong, Shellcock] However, the stored episodes of the ILR may be erased when exposed in an 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 pre-imaging visit.

**STEP 3: Program the CIED to the appropriate MR mode.** After steps 1 and 2 have been reviewed, 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: (i) MR Invisible or (ii) 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 (e.g. 80 beats per minute). If it is an ICD, anti-tachycardic 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 while the “invulnerable” mode may 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. This can be done by a checklist attached to the final device interrogation printout.

**Role of Radiology during MR**

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. Scanning techniques to minimize device artifact should be adopted. The images should be closely monitored by radiologist for technical quality, artifacts and need for extra sequences and/or gadolinium. A basic list of recommended MR 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.

**Role of the CIED clinic during MR**

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**

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

**Role of the CIED clinic after MR**

After the MR is completed, the CIED clinic staff should re-interrogate the CIED and examine for new abnormalities that may 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 (pre-scan)
settings. Confirmation that the CIED has been re-programmed 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 regards to the optimal method to monitor the vital status of CIED patients undergoing MR. Currently, 3 modes of monitoring are often used: electrocardiographic monitoring, pulse oximetry, and intermittent verbal communication. The advantages and limitations of each modality are summarized in Table 4.

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

Monitoring of the CIED patient during MR may 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 2 important factors which determine the personnel composition required for monitoring of a given CIED patient during MR scanning: i) the patient’s medical status and ii) the functional status of the CIED.

**Situations where 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 pre-imaging assessment by the CIED clinic.
- A pacemaker-dependent patient with an MR-conditional CIED that is functioning normally based on pre-imaging assessment by the CIED.

**Situations where additional monitoring personnel are recommended during MR imaging (i.e.: 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 (e.g. recent, non-significant 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 (see later).

**MAGNETIC RESONANCE SCANNING OF PATIENTS NON-MR-CONDITIONAL CIED’s: CONSIDERATIONS.**

Magnetic resonance scanning of patients with non-MR-conditional CIED’s is considered “off-label” and is not endorsed by Regulatory agencies (e.g. FDA), joint published guidelines from Cardiovascular and Radiology societies, and CIED manufacturers. (Faris, Levine GN, Smith, Stanton, Levine PA) As such, MR imaging of patients with non-MR-conditional CIED’s
is not routinely performed and is not considered to be standard of practice. However, the writing committee recognizes the existence of clinical scenarios where MR scanning may 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 may occur. (Hayes JACC 1987, Martin ET JACC, Gimbel 2001, Avery JK) As such, the writing committee specifies that a detailed and explicit risk/benefit discussion be made amongst the: i) referring physician (preferably a specialist in the specific body region of interest, such as a neurologist, neurosurgeon, orthopedic surgeon, etc.), ii) cardiologist with expertise in CIED management, and iii) 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 discussed: (Levine CIRC 2007)

1) Pacemaker or ICD dysfunction.
2) Pacemaker or ICD damage.
3) Arrhythmia.
4) Death.

What are the risks?
A list of potential risks associated with MR scanning of patients with non-MR-conditional CIED’s are outlined in Table 1. [Loewy] Published reports on MR scanning of patients with non-MR-conditional CIED’s employed strict MR imaging and patient monitoring protocols. In these studies, the following changes were noted after MR scanning: i) alteration in lead parameters such as sensing, pacing threshold, or impedance; ii) power-on-reset of the CIED; iii) inhibition of pacemaker output resulting in transient bradycardia or asystole; iv) asynchronous pacing induced by reed switch activation; v) decrease (minor) in battery voltage. Notably, the reported rates of device functional changes varied markedly amongst published studies, from 0% to 40%. [MARTIN ET JACC] 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’s:

- 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 which persist in the patient’s body (e.g. 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. (Hartnell)

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 Tesla. There is very little published
data on the safety of MR scanning at 3 Tesla or higher and is therefore not recommended at the current moment. [Nazarian]

In general, the minimum number of sequences (and therefore the shortest scan time) should be performed in order to obtain the necessary information. Several recent studies had shown that MR can be performed in various body regions (including the thorax and heart) without increased risks to the patient or the CIED. [Lowey, Martin ET, Nazarian, Cohen] While it is generally recommended that specific absorption rate (SAR) be kept below 2.0 W/kg [Lowey], some recent studies have questioned this limitation. [Nazarian, Cohen]. The use of a transmit/receive coil should be considered where possible [Lowey].

What protocol should be followed for the imaging of non-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 Figure 2. Several items merit further discussion. First, institutional approval should be obtained prior to performing MR for patients with non-MR-conditional CIED’s. Second, written informed consent must be obtained from the patient or the appropriate substitute decision maker prior to MR scanning. The risks and benefits of MR should be clearly explained. Third, support personnel with ACLS 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 by the CIED clinic.

CONCLUSIONS

Patients with MR-conditional CIED’s may undergo MR without additional 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 centers 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.
RECOMMENDATIONS

1. We recommend that magnetic resonance imaging (MR) of MR-conditional cardiac implantable electronic devices (CIEDs) can be performed with a low risk of life-threatening complications provided that patients and their CIEDs are properly evaluated prior to imaging and the scanning protocol be within the specified labelling for that CIED model. (Strong recommendation, moderate quality evidence). VALUES AND PREFERENCES: This recommendation places high value on the accumulated research of MR scanning of MR-conditional CIEDs, performed prior to and after their approval by medical device regulatory agencies.

2. We recommend that facilities which perform MR scanning of patients with MR-conditional CIEDs should establish a formalized protocol via close collaboration between the CIED clinic and Radiology (Strong recommendation, low quality evidence). VALUES AND PREFERENCES: This recommendation places high value on collaboration between the CIED clinic and Radiology. Each discipline provides complementary expertise to ensure successful and safe MR scanning of patients with MR-conditional CIED’s. This is based on the unanimous consensus opinion of the writing group.

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) evaluating 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). VALUES AND PREFERENCES: This recommendation places high value on the proper preparation of the patients by the CIED clinic prior to MR so as to minimize potential risks related to MR scanning.

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) initiate pre-imaging preparation of the patient with the CIED clinic; (iii) initiate local standard operating imaging procedures to perform MR scanning in accordance to manufacturer- and radiologist-suggested parameters (strong recommendation, low quality evidence). VALUES AND PREFERENCES: This recommendation places high value on the proper selection of patients for MR and to create appropriate imaging protocols which adhere to recommended imaging specifications.

5. We recommend that during the MR, a member of the CIED clinic (technician, nurse, or physician) should be readily accessible to the MR imaging team for CIED management (Strong recommendation, low quality evidence). VALUES AND PREFERENCES: This recommendation places high value on having ready access to staff with CIED training when a CIED complication occurs during MR scanning.

6. We recommend that during MR, 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). VALUES AND PREFERENCES: This recommendation places high value on assuring patient safety during MR scanning by having the ability to readily detect for potential CIED-related problems and to urgently intervene if a life-threatening event occurs during imaging.

7. We recommend that the patient be reassessed by the CIED clinic to evaluate for CIED abnormalities after the MR and for the CIED to be reprogrammed to its original (pre-scan) settings (Strong recommendation, low quality evidence). VALUES AND PREFERENCES: This recommendation places high value on assuring patient safety by ensuring that the patient’s CIED is functioning and programmed appropriately before, during, and after MR scanning.

8. We recommend that an MR be contraindicated if any one or more of the following conditions exist: (a) suspected or known fractured pacing or ICD leads; (b) abandoned epicardial pacing or ICD lead(s) intended for permanent pacing or ICD therapy; (c) lead extenders, lead adaptors, or lead remnants which persist in the patient’s body. (Strong recommendation, low quality evidence). VALUES AND PREFERENCES: This recommendation places high value on assuring patient safety since there are reports of serious and potentially life-threatening adverse events occurring in patients with fractured, abandoned, or remnant leads during MR scanning.

9. We recommend that MR imaging of a non-MR-conditional CIED should only be performed at centers with high MR and CIED expertise. These centers must have established and well-defined imaging and vital status monitoring protocols, derived from close collaboration between the CIED clinic and radiology (Strong recommendation, low quality evidence). VALUES AND PREFERENCES: This recommendation places value on studies which demonstrated that MR may be safely performed in selected patients with non-MR-conditional CIED’s. The writing committee discourages MR scanning of patients with non-MR-conditional CIED’s in centers without established, well-defined imaging and monitoring protocols.
TABLE 1: Potential Risks for Low Voltage and High Voltage Cardiac Implantable Electronic Devices [Beinart and Lowey]

<table>
<thead>
<tr>
<th>Static magnetic field</th>
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<tbody>
<tr>
<td>• Mechanical forces of ferromagnetic components (e.g. pacemaker displacement).</td>
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<tr>
<td>• Unpredictable magnetic sensor activation.</td>
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<tr>
<td>• Reed-switch closure and sudden loss of pacemaker function.</td>
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<tr>
<td>• Changes in electrocardiograms.</td>
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<table>
<thead>
<tr>
<th>Gradient magnetic field</th>
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<tbody>
<tr>
<td>• Possible induction of serious arrhythmias (rare).</td>
</tr>
<tr>
<td>• Induced voltages on leads causing over- and/or under-sensing.</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Modulated radiofrequency field</th>
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<tbody>
<tr>
<td>• Heating of cardiac tissue adjacent to lead electrodes.</td>
</tr>
<tr>
<td>• Possible induction of serious arrhythmias (rare).</td>
</tr>
<tr>
<td>• Pacemaker reprogramming or power-on-reset.</td>
</tr>
<tr>
<td>• RF interactions with the device (over- and under-sensing).</td>
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</table>

<table>
<thead>
<tr>
<th>Combined field effects</th>
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<tbody>
<tr>
<td>• Sudden and unexpected loss of device function.</td>
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<tr>
<td>• Alteration of device function because of EMI.</td>
</tr>
<tr>
<td>• Mechanical forces (vibration).</td>
</tr>
<tr>
<td>• Power-on-reset of the pacemaker or ICD pulse generator.</td>
</tr>
<tr>
<td>• Damage to pacemaker or ICD pulse generator.</td>
</tr>
<tr>
<td>• Damage to pacemaker or ICD lead(s).</td>
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<tr>
<th>Imaging related</th>
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<tr>
<td>• Artifacts preventing adequate image visualization.</td>
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<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Patients</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gimbel et al†</td>
<td>5</td>
<td>No device abnormalities were noted after MRI (0.5 Tesla). A 2-a pause was noted on pulse oximetry in the pacemaker-dependent patient whose device (with unipolar leads) was programmed to dual-chamber asynchronous pacing. Patients did not report generator movement or warmth.</td>
</tr>
<tr>
<td>Sommer et al‡</td>
<td>18</td>
<td>Reed switch activation and continuous pacing at a fixed rate noted in the static field. Programming changes, dislocation of components, dislodging of thegenerator, and rapid pacing were not observed. Atrial and ventricular stimulation thresholds remained unchanged.</td>
</tr>
<tr>
<td>Veithaus et al§</td>
<td>32</td>
<td>MRI at 0.5 Tesla did not inhibit pacing output or cause pacemaker malfunction.</td>
</tr>
<tr>
<td>Martin et al†</td>
<td>54</td>
<td>Lead impedance and sensing and stimulation thresholds did not change immediately or 3 mo after MRI at 0.5 Tesla. However, diminished battery voltage was noted immediately after MRI with recovery 3 mo later. Reed switch temporary defibrillation was seen in 12 of 32 patients when positioned in the center of the bore.</td>
</tr>
<tr>
<td>Del Osp et al‡</td>
<td>13</td>
<td>MRI of 2.0 Tesla was unassociated with pacemaker inhibition, inappropriate rapid pacing, or significant changes in device parameters.</td>
</tr>
<tr>
<td>Gimbel et al†</td>
<td>10</td>
<td>Seven patients showed a rise or fall of 0.5 V in pacing threshold values between baseline and 3-month follow-up. More patients had a decrease than a rise in pacing capture threshold.</td>
</tr>
<tr>
<td>Sommer et al†</td>
<td>82</td>
<td>MRI of 1.5 Tesla was unassociated with inhibition of pacemaker output or induction of arrhythmias. However, increased capture threshold was noted post-MRI in 4 of 114 examinations. Troponin increased from a normal baseline value to above normal after MRI (one was associated with a significant increase in capture threshold.</td>
</tr>
<tr>
<td>Nazarian et al‡</td>
<td>31 (with pacemakers, of 55 total patients)</td>
<td>MRI at 1.5 Tesla was not associated with any inappropriate inhibition or activation of pacing. There were no significant differences between baseline and immediate or long-term median 9 days after MRI sensing amplitudes, lead impedances, or pacing thresholds.</td>
</tr>
<tr>
<td>Nashie et al‡</td>
<td>44</td>
<td>MRI at 1.5 Tesla was unassociated with changes in lead impedance, pacing capture threshold, or serum troponin-I.</td>
</tr>
<tr>
<td>Muller et al‡</td>
<td>32 (with pacemakers, of 37 total patients)</td>
<td>MRI of 1.5 Tesla was unassociated with changes in troponin-I levels or pacing capture thresholds.</td>
</tr>
<tr>
<td>Nashie et al‡</td>
<td>47</td>
<td>Repetitive MRI at 1.5 Tesla (71 examinations on 47 patients) was associated with decreased pacing capture threshold and battery voltage.</td>
</tr>
<tr>
<td>Muller et al‡</td>
<td>46 (with pacemakers, of 52 total)</td>
<td>Ectopy was observed but was unrelated to peak SAI, scan time duration, or landmark. Significant changes in pacing thresholds were not observed.</td>
</tr>
<tr>
<td>Muller et al‡</td>
<td>105 (with pacemakers, of 127 total)</td>
<td>MRI of 1.5 Tesla was associated with decreased sensing amplitudes and pacing impedances. Other parameters were unchanged.</td>
</tr>
<tr>
<td>Halidek et al‡</td>
<td>9 (with pacemakers, of 18 total)</td>
<td>MRI of 1.5 Tesla was associated with 5 power-on-reset events in 2 patients. No other effects were reported and device replacement was unnecessary.</td>
</tr>
<tr>
<td>Strach et al‡</td>
<td>114</td>
<td>MRI at 0.2 Tesla was unassociated with changes in lead impedance, capture threshold, or battery voltage.</td>
</tr>
<tr>
<td>Burke et al‡</td>
<td>24 (with pacemakers, of 36 total)</td>
<td>MRI of 1.5 Tesla was unassociated with device circuit damage, programming abnormalities, inappropriate shocks, failure to pace, or changes in sensing, pacing, or demand threshold.</td>
</tr>
<tr>
<td>Besada et al‡</td>
<td>28 (with pacemakers of 33 total patients)</td>
<td>Temporary communication failure in 2 cases, sensing errors during imaging in 1 case, and a unsafe signal in 1 pacemaker were noted.</td>
</tr>
<tr>
<td>Nazarian et al‡</td>
<td>237 (with pacemakers, of 438 total patients)</td>
<td>MRI at 1.5 Tesla was associated with 2 power-on-reset events. Statistically significant but clinically small cost not requiring device revision or reprogramming changes in lead parameters were observed.</td>
</tr>
<tr>
<td>Cohen et al‡</td>
<td>69 (with pacemakers, of 1109 total patients)</td>
<td>Decreases in battery voltage of ≥0.04 V in 4%. pacing threshold increases of ≥0.5 V in 3%, and pacing lead impedance changes of ≥20% in 6% were observed. Clinically important differences were not observed between the MRI group and a historic control group.</td>
</tr>
<tr>
<td>Belton et al‡</td>
<td>32</td>
<td>Power-on-reset was noted in 6 patients. Magnet-mode asynchronous pacing was seen in 3 patients. Significant changes were not observed in battery voltage, P/R wave amplitudes, pacing thresholds, lead impedances, or cardiac enzymes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Patients</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coman et al 19</td>
<td>11</td>
<td>One patient felt mild heating near the generator during spin echo sequences. One patient had a brief, but asymptomatic, pause in pacing during scanning. One patient with a device past the effective replacement interval had power-on-reset, and the device could not be interrogated after the scan. Normal device function and circuit integrity were noted at destructive testing.</td>
</tr>
<tr>
<td>Gimbel et al 20</td>
<td>7</td>
<td>No changes in pacing, sensing, impedances, change times, or battery status were observed with MRI at 1.5 Tesla. However, 1 implantable cardioverter defibrillator (Medtronic 7227C, lumbar spine MRI) experienced a power-on-reset.</td>
</tr>
<tr>
<td>Nazarian et al 21</td>
<td>24 (with ICDS, of 55 total patients)</td>
<td>MRI at 1.5 Tesla was not associated with any inappropriate inhibition or activation of pacing. There were no significant differences between baseline and immediate or long-term (median 95 days after MRI) sensing amplitudes, lead impedances, or pacing thresholds.</td>
</tr>
<tr>
<td>Mollerus et al 22</td>
<td>5 (with ICDS, of 37 total patients)</td>
<td>MRI at 1.5 Tesla was unassociated with changes in troponin-I levels or pacing capture thresholds.</td>
</tr>
<tr>
<td>Naehle et al 23</td>
<td>18</td>
<td>MRI at 1.5 Tesla was unassociated with device circuitry damage, changes in lead parameters, or troponin-I levels. However, battery voltage decreased post MRI, and oversensing of EMI as ventricular fibrillation occurred in 2 devices, but therapies were not delivered.</td>
</tr>
<tr>
<td>Mollerus 24</td>
<td>9 (with ICDS, of 52 total)</td>
<td>Ectopy was observed but was unrelated to peak SAR, scan time duration, or landmark. Significant changes in pacing thresholds were not observed.</td>
</tr>
<tr>
<td>Pfeifer 25</td>
<td>8</td>
<td>Inappropriate pacing or significant changes in generator or lead parameter were not observed.</td>
</tr>
<tr>
<td>Mollerus et al 26</td>
<td>22 (with ICDS, of 127 total patients)</td>
<td>MRI at 1.5 Tesla was associated with decreased sensing amplitudes and pace impedances. Other parameters were unchanged.</td>
</tr>
<tr>
<td>Halikost 27</td>
<td>9 (with ICDS, of 18 total patients)</td>
<td>MRI at 1.5 Tesla was unassociated with any unintended effects, and device replacement was unnecessary.</td>
</tr>
<tr>
<td>Burke et al 28</td>
<td>14 (with ICDS, of 38 total patients)</td>
<td>MRI at 1.5 Tesla was unassociated with device circuitry damage, programming alternations, inappropriate shocks, failure to pace, or changes in sensing, pacing, or defibrillator thresholds.</td>
</tr>
<tr>
<td>Buehler et al 29</td>
<td>5 (with ICDS of 33 total patients)</td>
<td>Sensing errors during imaging in 1 case was noted.</td>
</tr>
<tr>
<td>Nazarian et al 30</td>
<td>201 (with ICDS, of 438 total patients)</td>
<td>MRI at 1.5 Tesla was associated with 1 power-on-reset event. Statistically significant but clinically small (not requiring device revision or reprogramming) changes in lead parameters were observed.</td>
</tr>
<tr>
<td>Cahay et al 31</td>
<td>40 (with ICDS, of 109 total patients)</td>
<td>Decreases in battery voltage of ≥0.04 V in 4%, pacing threshold increases of ≥0.5 V in 3%, and pacing lead impedance changes of ≥50 Ω in 6% were observed. Clinically important differences were not observed between the MRI group and a historic control group.</td>
</tr>
</tbody>
</table>

EMI indicates electromagnetic interference; ICD, implantable cardioverter defibrillator; and SAR, specific absorption rate.
### TABLE 4. Monitoring modalities of CIED patients during MR scanning.

<table>
<thead>
<tr>
<th>Mode of vital status monitoring</th>
<th>Potential advantages</th>
<th>Potential limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrocardiographic (ECG) monitoring</td>
<td>This is the most direct way to assess the patient’s heart rhythm status in a continuous manner.</td>
<td>1) The use of ECG monitoring equipment is subject to significant artifact which may preclude accurate assessment of the patient’s rhythm. 2) Improper positioning of the ECG lead and electrodes may cause skin burns. (e.g. 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 by this mode of monitoring.</td>
</tr>
<tr>
<td>Pulse oximetry</td>
<td>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.</td>
<td>Does not provide real-time monitoring of the patient’s cardiac rhythm.</td>
</tr>
<tr>
<td>Intermittent verbal communication</td>
<td>1) Allows for monitoring of the patient’s mental status. 2) Allows for patients to communicate any potential discomfort to the MR team.</td>
<td>Not applicable for patients who are unable to verbally communicate.</td>
</tr>
</tbody>
</table>
Figure 1: Sample workflow diagram of the triage and referral process for MR scanning of patients with CIED’s

Request for MR scanning for a patient with CIED received by Radiology

The MRI request is felt to be clinically indicated after review by the responsible Radiologist (done in conjunction with the referring physician)

Absence of routine MRI contra-indications, as determined by Radiology (additional imaging such as Chest X-ray and Eye X-ray may be required)

The MRI unit contacts the CIED clinic for a pre-imaging CIED assessment

Patient assessment in the CIED (preferably done within 4 weeks of MR scanning in elective cases)

CIED clinic: Identification of MR-conditional CIED components

Are there absolute contra-indications for MR scanning?

Yes

MR imaging is not performed

No

Presence of non-MR-conditional CIED components?

Yes

“Off-label” MR scanning on non-MR-conditional CIEDs. (The clinical indication and safety of MR scanning needs to be individualized)

No

“MR-conditional” CIED system

Assessment of CIED function

“Abnormal” CIED function, as determined by the responsible Cardiologist

Individualized decision to proceed with MR imaging must be made amongst Radiology, CIED team, and Referring physician.

Proceed to MR imaging as per the imaging and monitoring protocol of the facility

“Normal” CIED function, as determined by the responsible Cardiologist

MR imaging is performed with additional monitoring precautions

MR imaging is not performed
Figure 2: Sample workflow diagram of MR scanning of patients with CIEDs

MR scanning can be performed with an acceptable benefit/risk ratio, as determined by Radiology, CIED Cardiologist, and Referring physician

**Checklist of required tasks prior to MR scanning:**

1) Are there any absolute contraindications to MR scanning?
2) Has the radiologist obtained informed consent?*
3) Has the patient been assessed by the CIED clinic in a pre-imaging visit?
   - Was the CIED interrogated and were these results documented? Is there any discussion of device function abnormality which may necessitate review by the CIED clinic before proceeding with MR scanning?
4) Are the CIED settings appropriately programmed for MR scanning? (documentation required)
5) Is there a cardiac arrest cart with an external defibrillator readily available?
6) Is the patient’s vital status being monitored?
   - At least one of: ECG or pulse oximetry
7) Is the MR imaging protocol appropriate for this patient?
   - Recommended general points: 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.
   - If the patient has a MR-conditional CIED, is the imaging protocol tailored in accordance to the scanning specifications of the CIED manufacturer?

*The need for informed consent may not be universally required for all CIED patients undergoing MR scanning. However, documented informed consent is recommended for CIED patient who undergo “off-label” MR scanning.

**Checklist of required tasks after MR scanning:**

1) Is the CIED re-interrogated by the CIED clinic? (documentation required)
2) Are the CIED settings re-programmed to the original ones? (documentation required)
3) If changes in CIED function are noted post-MRI, are they communicated to the responsible CIED Cardiologist? (documentation required)
4) Is a CIED follow-up plan (if necessary) discussed with the patient? (documentation required)
References


Gimbel JR. Unexpected asystole during 3T magnetic resonance imaging of a pacemaker-dependent patient with a 'modern' pacemaker. Europace. 2009 Sep;11(9):1241-2.


