Hôpital St-Boniface Hospital CARDIAC SCIENCES MANITOBA SCIENCES CARDIAQUES MANITOBA **CARDIAC SCIENCES MANITOBA CLINICAL PRACTICE GUIDELINE**	Magnetic Resonance Imaging (MRI) in Patients with a Cardiovascular Implantable Electronic Device	
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PURPOSE/INTENT

The purpose of this guideline is to outline the assessment, pre and post care, and monitoring requirements for adult patients with an MR-conditional cardiovascular implantable electronic device (CIED) who require magnetic resonance imaging (MRI) where alternative scanning modalities have been considered and determined to be suboptimal to MRI to answer a specific clinical question.

SCOPE

This guideline applies to adult inpatients or outpatients with an MR-conditional CIED. These devices include a permanent pacemaker (PPM), implantable cardioverter defibrillator (ICD), subcutaneous implantable cardioverter defibrillator (SICD) or cardiac resynchronization therapy (CRT) devices.

Requests for an MRI scan in patients with non-conditional devices (including legacy devices) will be assessed on a case-by-case basis as it may be reasonable to perform an MRI scan in the absence of absolute contraindications such as fractured, epicardial, or abandoned leads.

PRACTICE OUTCOME

MRI scans in patients with a CIED are conducted following standard work processes to ensure patients are properly triaged and that all conditions and requirements are followed prior to, during and following the MRI scan.

DEFINITIONS

Cardiovascular Implantable Electronic Device (CIED): This includes permanent pacemakers (PPM), implantable cardioverter defibrillator (ICD), subcutaneous implantable cardioverter defibrillator (SICD) and cardiac resynchronization therapy (CRT) devices.

Magnetic resonance imaging (MRI): Is a procedure that uses a magnetic field and radio waves to create 3-D images of organs, tissues, and the skeletal system. It is used to help evaluate and diagnose a range of health issues.

MR-Conditional/MR-Safe/MR-Unsafe: Standardized definitions exist to address the safety of medical devices in an MRI environment and include MR-Safe, MR-Conditional and MR-Unsafe

(Table 1). To be considered MR-conditional the device and leads must be manufactured from the same device company.

Table 1*
Definitions

Terminology	Definition
MR-Safe	Objects that pose no known hazards in all MRI environments
MR-Conditional	Objects that pose no hazards in a specified MRI environment with specified conditions of use. The field conditions that define the 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	Objects known to pose a risk in all MRI environments

***Verma et al. (2014). Canadian Association of Radiologists Journal, 65, 290-300**

BACKGROUND

It is estimated that 50-75% of patients with a CIED will develop an indication for an MRI procedure over their lifetime. Although risks are estimated to be less than 1%, potential risks can include device heating, movement, and malfunction. As CIED technology has advanced, newer MR-Conditional devices have been developed that are now in clinical use and these systems have demonstrated safety in the MRI environment.

GUIDELINES

- MRI scans will be performed only in appropriately selected patients with an MRI-conditional CIED, and the scan will be performed ONLY at SBH
- The MRI protocols (i.e., field strength, Gradients, SAR, etc.) must adhere to the published guidelines from the device manufacturer.
- A cardiologist (or appropriately trained delegate) with expertise in management of CIEDs must be readily available (by telephone and with the ability to be available in person if required) for consultation before, during and after MRI scanning
- Standard work processes are in place to support safe practices
- Contraindications for MRI scan include:
  - -The presence of non-conditional/unsafe device/system components
  - -MRI scans arranged within the first six weeks after implantation
  - (Unless there is a strong medical indication not to delay the study)
  - -Abandoned leads
  - -The presence of permanent or temporary epicardial leads
  - -Fractured leads
  - -Lead extenders or adapters present

- Thoracic/cardiac MRI will be assessed on a case-by-case basis as the main issue with thoracic imaging is the MRI artifact over the area of interest
    - For patients with an ICD, patients will be deemed stable if there has been no arrhythmia requiring device intervention or arrhythmia management including cardioversion, pharmacologic intervention etc. within one week of the MRI scan. Exceptions to be discussed between Referring Physician and MRI Radiologist on a case-by-case basis.

COMPONENTS

Standard work processes provide guidance on safely performing the MRI scan and include the following key areas of focus:

Pre-Procedure – Screening

- Confirmation the MRI scan is the appropriate imaging modality to answer the clinical question
- Confirmation of the MR-conditional status of the CIED
- Verification of the CIED manufacturer and the identification of MRI features
- Verification there are no CIED contraindications to an MRI scan
- Communication with the inpatient team, if applicable
- Documentation as per standard work

Pre-Procedure – Clinic visit

- CIED interrogation [Note]: the maximum time frame from device interrogation (i.e., pacing threshold and lead impedance, pacemaker dependency) to MRI is 7-10 days. If the time frame is exceeded, the device will require re-interrogation
- Testing to determine clinical response while in MR mode
- Confirmation there are no extraneous device components such as lead adaptors and extenders, or any active, abandoned, or fractured leads
- Communication of potential risks of the MRI scan related to the CIED are explained to the patient (for inpatients this will occur in the MRI Department the day of the procedure)
- Communication with inpatient team if applicable
- Documentation as per standard work

Note: Patients who require MRI scans at regular intervals do not require repeat pre-procedure clinic visits. Interrogation and programming of the ICD will occur on the day of the MRI scan.

Procedure – MRI Scan

- Appropriate personnel are present (Table 2)
- Interrogation and programming of CIED
- Ongoing assessment and monitoring of patient (Table 2)
- In the event of a medical emergency or pacemaker malfunction, the exam is stopped and staff will activate a Code Blue as per policy: V11-045 Code Blue Resuscitation in Acute Care (Adult) http://intranet.sbgh.mb.ca/ManualsAdmin/files/VII-045.pdf

Responsibilities of team members:
-The Code Blue Response Team will be responsible for the management of the patient
-The Pacemaker Team will be responsible for the management of the CIED
-The Cardiology Technologist or MRI Technologist will page 'Code 25' Pacemaker Team to MRI. In this event, the Pacemaker Team will respond to the Code 25. The Pacemaker Team will include the SBH Pacemaker/Defibrillator Clinic Nursing Coordinator/Delegate and the Arrhythmia Physician on-call/Delegate

Table 2: Required personnel and monitoring**

Situation	Personnel	Responsibilities:
Urgent unstable inpatient/outpatient Hemodynamic, respiratory, or electrical instability (Arrhythmia requiring device intervention or arrhythmia management such as cardioversion, pharmacologic intervention etc. within one week of scan)	To be present in MRI: -Critical care nurse -Pacemaker nurse -Most Responsible Physician/Resident/delegate -Other staff as required, perfusion, respiratory therapist -Arrhythmia physician / Delegate available to respond to medical emergency -MRI Technologist	<u>Critical care team:</u> -Monitor cardiac rhythm when interpretable -Assess and monitor patient response to therapies/treatments/interventions -Communicate patient concerns to MRI and Pacemaker Clinic staff <u>The MRI Technologist</u>: -Screen patient per department protocol -Follow the conditions specified by the device manufacturer -Monitor pulse oximetry -Maintain visual and voice communication with the patient <u>The MRI Nurse</u>: -Follow MRI standard operating procedures for CIED patient scan preparation, assessment, and documentation <u>Pacemaker Staff:</u> -Follow standard work for scanning patients with MRI-conditional CIEDs
Stable inpatient or outpatients	To be present in MRI: -Pacemaker/Defibrillator Clinic Nurse (before and after the scan for programming) -Arrhythmia physician / Delegate available to respond to medical emergency -MRI Technologist -Cardiology Technologist upon request	<u>Pacemaker Nurse:</u> -Program CIED pre and post scan -Follow standard work for scanning patients with MRI-conditional CIEDs <u>The MRI Technologist</u>: -Screen the patient per department protocol -Follow the conditions specified by the device manufacturer -Monitor cardiac rhythm when interpretable -Monitor pulse oximetry -Maintain visual and voice communication with the patient -Follow the standard of work for scanning

		patients with MRI-conditional CIEDs The MRI Nurse: -Follow MRI standard operating procedures for CIED patient scan preparation, assessment, and documentation Cardiology Technologist -Available on request -Monitor cardiac rhythm when interpretable -Monitor pulse oximetry -Communicate patient concerns to MRI staff -Follow standard work processes

**Personnel and monitoring are dependent on the patient's clinical condition and risk for adverse events.

Post Procedure

- Reprogramming of the CIED
- Verification of proper function of the CIED (pre-MRI programmed parameters have been restored)
- Documentation completed as per standard work processes

REFERENCES

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Appendix

Adult Individuals with a CIED who Require an MRI Scan: Informed Consent Parameters

Preamble:

The decision to proceed with a MRI scan in those adult individuals with a MRI conditional CIED requires collaboration between the Department of Radiology, SBH and Cardiac Sciences. Al stakeholders bring specific expertise and knowledge to the informed consent process.

The specific information provided to the individual requiring an MRI scan should include the information that a reasonable individual would want to know to decide about the proposed course of action, or information that, if omitted, may result in a different decision. For further information the reader should refer to WRHA policy 110.000.005 'Informed Consent (for Procedures, Treatments and Investigations).

The following provides a framework of the information to be reviewed with the individual when obtaining consent for an MRI scan.

Cardiac Sciences Program Arrhythmia Physician or Designate:

a) Acknowledge that MRI scan has been deemed by Department of Radiology to be the most appropriate diagnostic test for the patient

b) Potential risks of MRI (as it relates to the CIED) may include:
- Movement of CIED components
- Temporary increase or decrease in pacing
- Resetting of pacemaker requiring reprogramming
- Irreversible damage of pacemaker requiring replacement of the device
- Arrhythmias

All these potential effects are reduced with MRI conditional devices that have been implanted for greater than six (6) weeks

c) Answers to any questions

Documentation

The Arrhythmia Physician / Delegate and Radiologist will separately document their own part of the consent discussion in the patient chart (electronic or paper). This documentation does not need to include a description of all elements mentioned above, only that the discussion took place.