

 Winnipeg Regional Health Authority Office régional de la santé de Winnipeg Caring for Health À l'écoute de notre santé  Hôpital St-Boniface Hospital WRHA CARDIAC SCIENCES PROGRAM CLINICAL PRACTICE GUIDELINE	Magnetic Resonance Imaging (MRI) in Patients With Permanent Pacemakers at St. Boniface Hospital	
	Approved By: Professional Advisory Committee Standards Committee	Effective Date: September 27, 2019
	Originated from: <input type="checkbox"/> CI <input type="checkbox"/> LEAN <input type="checkbox"/> QI <input checked="" type="checkbox"/> Other	Page: 1 of 9
	Leads: Dr. C. Khoo, Dr. L. Avery, E. Hyde, M. Lukianchuk, C. Kuttig, Dr. M. Essig, Dr. B. Memauri, E. Ebru, S. Harlos, J. Grift, K. Lewington, L. McLean, N. Pawlyshyn, T. Santos	Number: New

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PURPOSE/SCOPE

The purpose of this guideline is to outline the assessment, pre and post care and monitoring requirements for adult individuals with a permanent pacemaker who require a magnetic resonance imaging (MRI) scan.

This guideline applies to the care of appropriate adult individuals with an MRI-Conditional permanent pacemaker who require a non-urgent MRI scan at St. Boniface Hospital (SBH) on an outpatient basis.

- Requests for MRI in patients with other types of cardiovascular implantable electronic devices (CIEDs), example implantable cardioverter defibrillator, will be assessed on a case-by-case basis
- Requests for a MRI for inpatients will be assessed on a case-by-case basis

GUIDELINE ASSUMPTIONS

- Alternative scanning modalities have been assessed and determined to be suboptimal to MRI to answer the specific clinical question.

DEFINITIONS

Permanent Pacemaker: Is a type of a cardiovascular implantable electronic device (CIED) that is implanted in patients who have significant bradyarrhythmias. The device will ensure that the heart rate does not drop below a pre-specified rate.

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.

MRI-Conditional/MR-Conditional: Standardized definitions exist to address the safety of medical devices in a MRI environment and include MR-Safe, MR-Conditional and MR-Unsafe (Table 1). MR compatible CIEDs are currently labelled as ‘MR-Conditional’.

Table 1*
Definitions

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 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

*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.

PROTOCOL

Pre MRI

1. Due to the requirement for well defined, strict imaging and monitoring protocols, all MRI procedures in those individuals with an identified MRI-Conditional permanent pacemaker will be performed **ONLY** at SBH.
 - 1.1 Contraindications include:
 - The presence of MRI unsafe device system components
 - 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
 - Broken leads
 - Lead extenders or adapters present
 - 1.2 Thoracic/cardiac MRI will be assessed on a case by case basis
 - 1.3 A copy of the device interrogation summary will be provided to the MRI Department in advance of the scan

Note: To be considered MRI-Conditional/MR-Conditional the device and leads must be manufactured from the same device company. On a case by case base, and if the MRI is

essential, it may be appropriate to consider replacing the device to ensure the device and the leads are from the same manufacturer

2. The referring physician will complete the request for consultation diagnostic imaging requisition (Item #1221)
 - 2.1 The MRI Department will fax to the referring physician a copy of the:
 - MRI pre-screening checklist
 - Patient MRI Safety Checklist
3. The radiologist will review the MRI request and sign part A on the magnetic resonance imaging (MRI) – permanent pacemakers: pre procedure checklist. The radiologist’s signature indicates that an MRI is clinically required or preferred over other diagnostic modalities.
 - 3.1 An MRI should be performed only if absolutely necessary and if no other options are able to answer the clinical question
 - 3.2 If an MRI scan is indicated, the MRI Department will fax a copy of the magnetic resonance imaging (MRI) – permanent pacemakers: pre procedure checklist to the Pacemaker and Defibrillator Clinic, SBH
4. The Pacemaker and Defibrillator Clinic Nursing staff will:
 - 4.1 Document on part B on the magnetic resonance imaging (MRI) – permanent pacemakers: pre procedure checklist the:
 - Manufacturer and model of the MRI-Conditional/MR-Conditional device and leads
 - Manufacturer’s conditions and restrictions regarding MRI scanning
 - Pacing threshold and lead impedance
 - Any contraindications to pacing
 - Pacemaker dependency
 - 4.2 Provide the patient with a copy of the Pacemakers and MRI Patient Information Sheet

Note: the maximum time frame from device interrogation (i.e. pacing threshold and lead impedance, pacemaker dependency) to MRI is 7-14 days. If this time frame is exceeded, the device will require re-interrogation
5. The Cardiologist/Electrophysiologist will:
 - 5.1 Order and review a PA/Lateral Chest X-ray to rule out abandoned or broken leads when:
 - There is uncertainty of the implant history (example: no X-ray films or chest computed tomography results available locally)
 - A Chest X-ray has not been obtained between last device procedure and time of clinic appointment pre MRI
 - Deemed appropriate/discretion of the Cardiologist/
Electrophysiologist
 - Review the information on Parts A & B on the magnetic resonance imaging (MRI) – permanent pacemakers: pre procedure checklist. The

Cardiologist/Electrophysiologist's signature indicates agreement to proceed to booking the MRI scan

-The form is faxed to MRI central booking

6. Booking
 - 6.1 Standard booking dates/times are established in order for the Pacemaker/Defibrillator clinic visits and the MRI scan to occur on the same day
 - 6.2 Upon receipt of the magnetic resonance imaging (MRI) – permanent pacemakers: pre procedure checklist from the Pacemaker/Defibrillator Clinic an appointment is booked in the next available standard booking date/time
 - 6.3 The MRI Department will send an appointment letter to the patient and fax a copy of the appointment to the Pacemaker/Defibrillator Clinic
 - 6.4 The Pacemaker/Defibrillator Clinic will fax a copy of the booking confirmation to Holter Lab Reception
 - 6.5 Holter Lab Reception will book the Cardiology Technologist
 - 6.6 The Pacemaker/Defibrillator Clinic and the Holter Lab Reception will telephone MRI booking to confirm availability of appointment times and/or staff availability for the date of the MRI scan

Day of MRI

Pacemaker/Defibrillator Clinic Visit

7. During the Pacemaker and Defibrillator Clinic visit, the Pacemaker/Defibrillator Clinic Nursing staff will:
 - 7.1 Program the permanent pacemaker to the appropriate MRI mode
 - 7.2 Document on the magnetic resonance imaging (MRI) - permanent pacemakers: Day of procedure checklist:
 - The patient's underlying rhythm
 - Baseline vital signs
 - 7.3 Give the patient/escort the magnetic resonance imaging (MRI) - permanent pacemakers: Day of procedure checklist and a copy of the device summary report to take to MRI
8. Following the Pacemaker and Defibrillator Clinic visit, the Electrophysiologist/Cardiologist will:
 - 8.1 Verify that all conditions for safe scanning of the permanent pacemaker have been met
 - 8.2 Review Chest X-ray (if required)
 - 8.3 Obtain informed consent as outlined in Appendix A
 - 8.4 Document that this discussion occurred in Paceart Optima
9. Transport
 - 9.1 For safety reasons, the individual will be transported by wheelchair/Staxichair to MRI. The Pacemaker/Defibrillator Clinic and the MRI Department will collaborate to determine the availability of human resources to assist with transport

MRI Department

10. Prior to the MRI scan the Radiologist will:
 - 10.1 Be available to answer any questions from the Pacemaker/Defibrillator Staff or patient

11. The MRI scan will be conducted using the following guidelines:
 - 11.1 Static Magnetic field of 1.5 T
 - 11.2 Maximum spatial gradient of $\leq 20\text{T/M}$
 - 11.3 Gradient systems with maximum slew rate performance per axis of $\leq 200\text{ T/M/S}$
 - 11.4 Whole body averaged specific absorption rate (SAR) must be $\leq 2\text{ W/Kg}$ (normal operating mode only)
 - 11.5 Any additional restrictions or conditions as specified by device manufacturers
Note: A cardiologist 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

12. Continuous patient monitoring is required during the procedure
 - 12.1 The Cardiology Technologist will report directly to the MRI Department and is responsible for:
 - Monitoring the cardiac rhythm when interpretable
 - Communicating any patient concerns to MRI staff
 - 12.2 The MRI Technologist is responsible for
 - Screening the patient per department protocol
 - Following the conditions specified by the device manufacturer
 - Monitoring the pulse oximetry
 - Maintaining visual and voice communication with the patient
 - Following the standard of work for scanning patients with permanent MRI-Conditional/MR-Conditional permanent pacemakers

13. In the event of a medical emergency or pacemaker malfunction, the exam will be stopped and staff will activate a Code Blue as per policy: V11-045 Code Blue Resuscitation in Acute Care (Adult)
<http://intranet.sbggh.mb.ca/ManualsAdmin/files/VII-045.pdf>
 - 13.1 -The Code Blue Response Team will be responsible for the management of the patient and ACLS protocols
 - The Pacemaker Team will be responsible for the management of the permanent pacemaker
 - 13.2 The Cardiologist 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

14. Following the MRI scan
 - 15.1 MRI staff will obtain vital signs and document on the MRI Documentation for IV Sedation flow sheet

- 15.2 Transport/arrange for transport the patient back to the Pacemaker/
Defibrillator Clinic

Pacemaker/Defibrillator Clinic Visit

16. The Pacemaker/Defibrillator Clinic nurse will verify continued proper operation of the permanent pacemaker, reprogram to the appropriate mode and fulfill any other requirements as indicated by the device manufacturer

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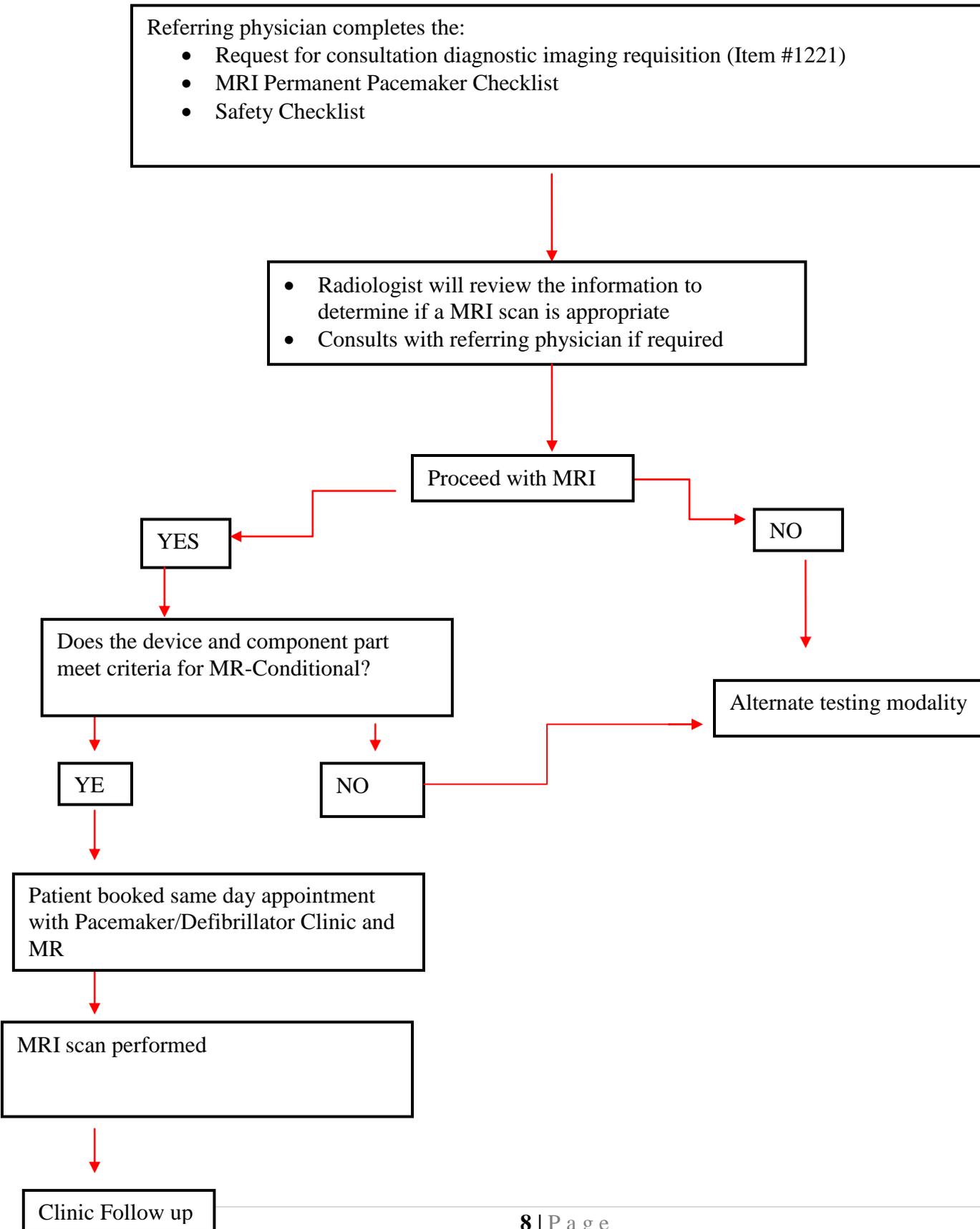
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Figure 1: Protocol for MR-Conditional Permanent Pacemakers



Appendix A:

Adult Individuals with a Permanent Pacemaker who Require a MRI Scan: Informed Consent

Preamble:

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

The specific information provided to the individual requiring a MRI scan should include the information that a reasonable individual would want to know in order to make a decision 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 a MRI scan.

WRHA Cardiac Sciences Program Electrophysiologist or Designate:

- a) Acknowledge that MRI scan has been deemed by Department of Radiology to be most appropriate diagnostic test for the patient
- b) Potential risks of MRI (as it relates to the permanent pacemaker) may include:
 - Movement of pacemaker components
 - Temporary increase or decrease in pacing
 - Resetting of pacemaker requiring reprogramming
 - Irreversible damage of pacemaker requiring replacement of the device
 - Arrhythmias

All of 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 Electrophysiologist 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.