CARDIAC IMPLANTED ELECTRONIC DEVICES

PURPOSE

- To ensure patients with cardiac implanted electronic devices (CIEDs) are appropriately evaluated to safely undergo MR imaging.
- To decrease the incidence of patients being inappropriately denied MR imaging due to the presence of CIEDs.

GENERAL COMMENTS

- Permanent pacemakers (PPMs) and implantable cardioverter defibrillators (ICDs) are collectively known as cardiac implanted electronic devices (CIEDs).
- Issues related to MR imaging of CIEDs include device movement, excess heating, electric current induction, electromagnetic interference, abnormal reed switch behavior, power-on reset activity and battery depletion.
- Any CIED from before 2011 or any CIED that is not labeled MR conditional is MR nonconditional by default. The first MR conditional CIED was approved by the FDA in 2011.
- If either the generator or any lead is nonconditional, the entire system is nonconditional.
- If the generator and any lead are from different manufacturers, the entire system is nonconditional.
- If any lead is broken, abandoned or permanent, the entire system is nonconditional.

DEFINITIONS

- MR conditional implants are those that have been demonstrated to pose no known hazards when imaged under specified conditions including static magnetic field strength, spatial gradient, time rate of change of the magnetic field, RF fields and specific absorption rate (SAR).
- MR unsafe implants are those that are known to pose hazards in all MR environments.
- MR nonconditional implants are those that have not received a designation of MR safe, MR conditional or MR unsafe or those implants in which any component is nonconditional.
- Active implants are those that have electronic components (pacemakers, defibrillators, cardiac event recorders, deep brain / spinal / peripheral nerve stimulators, cochlear implants, etc).
- Asynchronous pacing is a pacing mode where the device delivers stimuli at preset intervals independent of intrinsic cardiac signals.
- Inhibition pacing is a pacing mode where the device only delivers stimuli when no intrinsic cardiac signals are sensed.

- Antitachyarrhythmia therapies include therapies delivered by a device that can terminate arrhythmias. Types of therapy include antitachycardia pacing and defibrillation.
- Pacing capture threshold is the minimum electrical stimulus needed to consistently depolarize or "capture" the myocardium.
- Lead impedance is a measure of the opposition to current flow through the device's leads. Decreased lead impedance increases the drain on the battery.
- Sensing amplitude is a measure of a device's ability to detect cardiac signals.

GENERAL GUIDELINES FOR ALL CIEDS

- Completion and/or re-verification of a patient's MR safety sheet (MI-0614A) or EMR safety form must be performed by the MR technologist prior to the patient entering zones 3 or 4 of the MR environment.
- The MR technologist must research the CIED and complete the Cardiac Implanted Electronic Device form (MI-0664). The supervising radiologist will then review the form and supporting documentation and determine whether to proceed with the MR exam.
- The MR technologist will arrange for the appropriate personnel (ACLS certified nurse, device vendor) to be present for imaging (as applicable).
- All CIED patients are required to have chest radiography performed within 90 days prior to the MR exam date to determine whether there are any broken or abandoned leads or any permanent epicardial leads present. The radiograph is generally performed on the same day as the MR examination. The report must specifically mention the presence/absence of any broken, abandoned or permanent epicardial leads. Have the reading radiologist addend the report if this verbiage is not in the original report. Outside radiograph(s) within 90 days are acceptable for review if images are available in PACS (i.e. outside reports without accompanying images are not acceptable).
- If a cardiology approval form with settings specific to a certain CIED is required, the approval form is to be completed by a cardiologist prior to the MR exam being scheduled. Inpatients may have the treating cardiologist complete the form. Please use the vendor specific signature form if available. This form is to be scanned into PACS.
- Informed consent is not required for CIED patients undergoing MR imaging.
- Chest, cardiac and thoracic spine MR exams are allowed. Repeat / follow-up MR exams are allowed.
- Imaging of a CIED patient is allowed earlier than 6 weeks post implantation of the CIED if the exam is truly indicated and no other imaging modality will adequately answer the clinical indication.

GUIDELINES SPECIFIC TO MR CONDITIONAL CIEDS

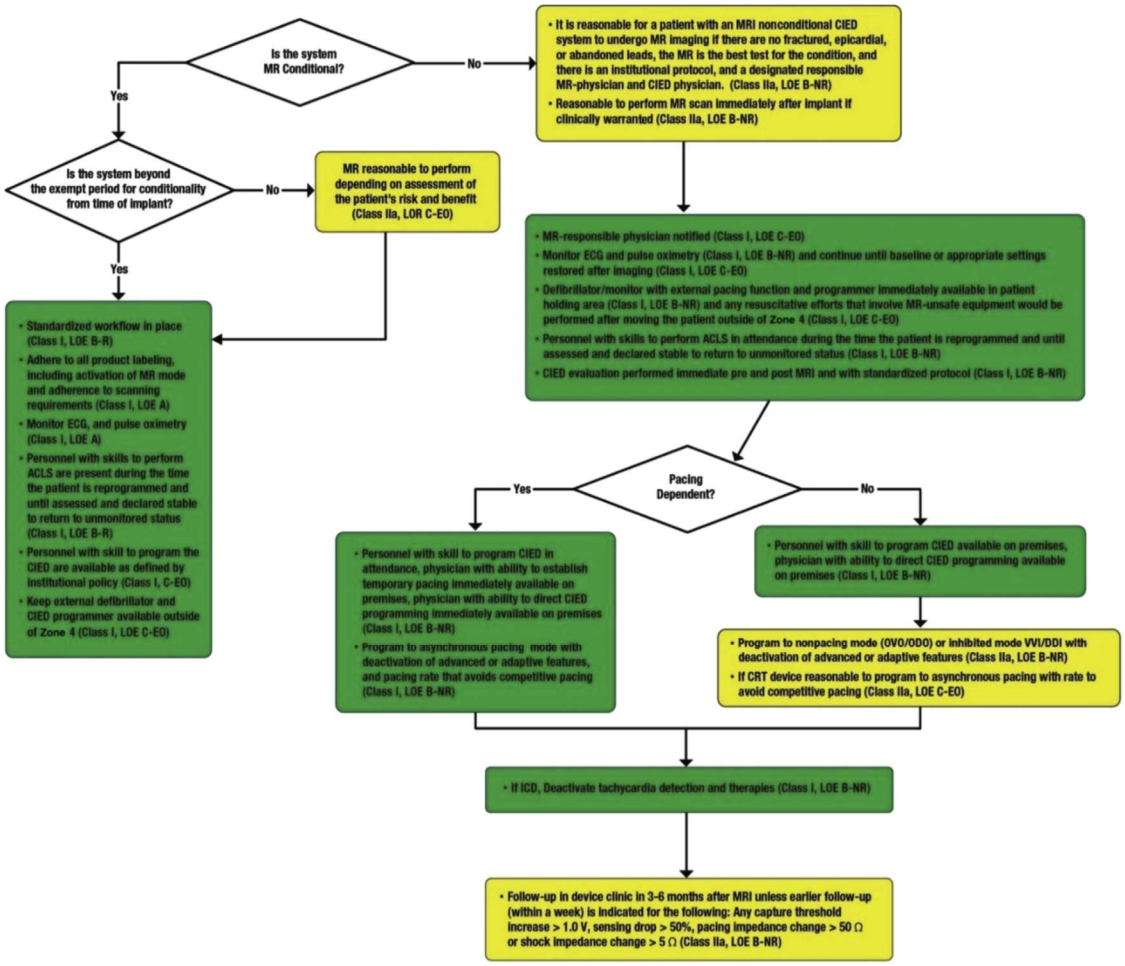
- Imaging patients with conditional CIEDs can only occur on the hospital scanners. These MR exams are not to be performed on the scanners at the Optimal Imaging centers or at the St Vincents Urgent Care centers.
- Imaging patients with conditional CIEDs can occur during normal hours, after hours, on-call hours, weekends and/or holidays as long as qualified personnel (device vendor, EP doctor or MRI technologist) are available to perform the device programming before and after the MRI examination.
- An IV line is not required for conditional CIED patients who are undergoing examinations without IV contrast.
- All manufacturer conditions regarding scan parameters must be adhered to.
- Pre and Post Scan Evaluation of the CIED
  1) Must be performed by qualified personnel.
  2) Prior to entering Zone 4, the CIED will be placed into the appropriate mode for MR imaging according to the manufacturer guidelines.
  3) Following the MR exam, the CIED will be placed back into normal operating mode.
- Monitoring of Vital Signs & EKG
  1) Continuous pulse oximetry and heart rate must be monitored by an ACLS trained nurse or other trained personnel.
  2) Vitals signs must be documented in the EMR before the CIED is placed into MR imaging mode, every 15 mins during the MR examination and following reprogramming of the CIED back into normal operating mode.
- A crash cart, external defibrillator and the CIED programmer must be readily available during the exam but kept outside of Zone 4.

GUIDELINES SPECIFIC TO MR NONCONDITIONAL CIEDS

- Imaging patients with nonconditional CIEDs is only performed on the hospital scanners during hours when an electrophysiologist or Dr. Dibu are onsite. These hours of availability are set by the Electrophysiology department and are subject to change.
- A radiologist must review the indication for the MR examination and prior imaging to assess whether the MR is the best imaging exam or if another imaging modality will adequately answer the clinical questions.
- The MR technologist will notify a radiologist at the hospital prior to and following the MR exam.
- The device vendor will notify the clinic electrophysiologist prior to and following the MR exam.
- Pre and Post Scan Evaluation of the CIED
  1) Must be performed by a qualified device vendor or an electrophysiologist.

2) Prior to entering Zone 4, the CIED will be placed into the appropriate mode for MR imaging (see below section on non-pacing-dependent versus pacing-dependent patients).
3) Following the MR exam, the CIED will be placed back into normal operating mode.
4) The CIED will be interrogated before and after the MR examination.

- For non-pacing-dependent patients:
  1) Personnel with the ability to reprogram the CIED must be present in the MR control room throughout the exam.
  1) The CIED must be programmed to nonpacing mode (OVO/ODO) or inhibited mode (VVI/DDI) and advanced/adaptive features must be deactivated.
  2) If CRT device, it is reasonable to program to asynchronous pacing with a rate that avoids competitive pacing.
  3) Tachyarrhythmia detections should be disabled in ICD patients.
- For pacing-dependent patients:
  1) Personnel with the ability to reprogram the CIED must be present in the MR control room throughout the exam.
  2) The CIED must be programmed to asynchronous pacing mode (VOO/DOO/AOO), advanced/adaptive features must be deactivated, and a pacing rate set that is faster than underlying rate to avoid competitive pacing.
  3) Tachyarrhythmia detections should be disabled in ICD patients.
- Monitoring of Vital Signs & EKG
  1) Continuous pulse oximetry and heart rate must be monitored by an ACLS trained nurse.
  2) Vitals signs must be documented in the EMR before the CIED is placed into imaging mode, every 5 mins during the MR exam and following reprogramming of the CIED back into normal operating mode.
- A crash cart, external defibrillator (with external pacing function) and the CIED programmer must be readily available but kept outside of Zone 4.
- Advise the patient to follow-up with his/her cardiologist in 3-6 months post MR imaging for device check unless earlier follow-up within 1-week post MR imaging is indicated due to any of the following:
  1) Any capture threshold increase of ≥ 1.0 Volts.
  2) P-wave or R-wave amplitude decreases ≥ 50%.
  3) Pacing lead impedance increase/decrease ≥ 50 Ohms.
  4) High-voltage (shock) lead impedance increase/decrease ≥ 5 Ohms.



Flowchart for Patients with Pacemakers and Defibrillators

GUIDELINES FOR BROKEN, ABANDONED OR PERMANENT EPICARDIAL LEADS

- Patients with broken or abandoned leads or permanent epicardial leads can under MR imaging using the nonconditional protocol.
- Patients with these leads will be scanned using the lowest SAR possible and using a local transmit/receive coil (when available).

CARDIOLOGY APPROVAL FOR INPATIENTS & ER PATIENTS WITH CIEDS

- For stat and routine MR examinations during normal hours, the MR technologist will call the pacemaker nurse at 388-1820 and inform him/her that a patient needs cardiology clearance.

IMPLANTABLE CARDIAC EVENT (LOOP) RECORDERS

- Most available implantable loop recorders (ILRs) are conditional at 1.5 Tesla and 3.0 Tesla, however the MR technologist must verify the model of loop recorder the patient has.
- MR scanning of ILRs should be performed under the conditions specified by the device's manufacturer.
- There is little risk of movement or heating of an ILD during MR imaging.
- The primary concern is that the current induced in the ILR by the MRI scanner will be recorded as artifactual noise which will fill the device's memory (overwriting data).
- The MR technologist will make a reasonable attempt to have a device representative download the data from ILR if the MR examination is performed during normal hours and if the patient has used the patient-triggered event button since he/she last had the device interrogated.
- If the MR examination is performed after hours, on weekends or on holidays, proceed with the MR exam without concern for having the device interrogated.
- Do not delay an emergent exam while waiting to interrogate the ILR.
- Patients with a St Jude Medical Confirm Rx DM3500 loop recorder must have a chest radiograph performed prior to the first MR exam to ensure that the device is between the right parasternal line and left midclavicular line and between the anterior 1st and 6th ribs. A Foreign Body / Implant / Device form (MI-0651) must be completed only prior to the first MR exam following device placement.

CARDIAC DEVICE CONTACT INFORMATION

- Electrophysiology office during normal hours – 308-1820
- Electrophysiology after hours – call operator and ask for the EP doctor on call
- Electrophysiology Lab – 308-3630
- Pacemaker Nurse – 308-1820
- Medtronic Rep – 1-800-MEDTRONIC (633876642)
- Boston Scientific Rep – 1-800-CARDIAC (2273488)
- Abbot / St Jude – 1-800-PACE ICD (7223423)
- Biotronik – 1-800-547-0394