MRI Safety Policies
YNHH Fitkin MRI  
789 Howard Ave, New Haven CT 06510  
203 688 5656

Smilow MRI  
20 York Street, New Haven CT 06510  
203 200 5146

Smilow MR Breast Center  
20 York Street, New Haven CT 06510  
203 200 5253

Smilow MR OR  
20 York Street, New Haven CT 06510  
203 200 6655

YNHH Pediatric MRI  
20 York Street, New Haven CT 06510  
203 200 2646

Shoreline MRI  
111 Goose Lane, Guilford CT 06437  
203 453 7181

Temple St MRI  
60 Temple Street, New Haven CT 06510  
203 688 2391

ST Raphael Campus MRI  
1450 Chapel Street, New Haven CT 06511  
203 789 4120

North Haven MRI  
6 Devine Street North Haven, CT 06473  
203 287 6969
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## Acronyms

- **0.5 mT**: 5 Gauss Line
- **ACR**: American College of Radiology
- **AED**: Automated Emergency Defibrillator
- **ASTM**: American Society for Testing and Materials
- **ARRT**: American Registry of Radiologic Technologists
- **CPR**: Cardiopulmonary Resuscitation
- **DB**: Decibel
- **FDA**: Food and Drug Administration
- **GBCA**: Gadolinium based contrast agent
- **MR**: Magnetic Resonance
- **MRI**: Magnetic Resonance Imaging
- **RF**: Radio Frequency
- **RMS**: Root Mean Square
- **SAR**: Specific Absorption Rate
- **SMS**: staples/superficial metallic sutures
- **SOP**: Standard Operating Procedure
- **TVMF**: Time Varying Magnetic Fields
- **T**: Tesla
- **W/kg**: Watt/kilogram

Magnetic Resonance Imaging is an ever changing, evolving technology. There are potential risks in the MR environment, not only for the patient but also for the accompanying family members, attending health care professionals and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security, housekeeping personnel, firefighters, police, etc. This manual has been developed to help guide the MR staff regarding these issues.

It is the intent of the Yale New Haven Hospital safety manual to:

- Protect and educate all patients, direct and ancillary personal about the possible risks, associated with the MR Suite including but not limited to static, time-varying magnetic fields and RF pulses.
- To be in compliance with the most up to date MR safety information provided by the Joint Commission and the ACR
- Prove helpful as the field of MRI continues to evolve and mature, providing MR services that are among the most powerful, yet safest, of all diagnostic procedures to be developed in the history of modern medicine.
1. All clinical and research MR sites, irrespective of magnet format or field strength, including installations for diagnostic, research, interventional, and/or surgical applications, should maintain MR safety policies.

2. These policies and procedures will be regularly reviewed by the MR Safety Officer and the Medical Director to account for the significant changes in the MR center environment. This will take into account ACR, Joint Commission and international standards.

3. The responsibility for implementation and maintenance of these policies and procedures belong to the Medical Director of the YNHH MRI Centers.

4. Annually, all MR personnel will review safety within the MR environment.

5. Provide all non-MR staff, patients and their families with appropriate materials (e.g., guidelines, brochure, and poster) that explain the potential for accidents and adverse events in the MRI environment.

6. Provide Access to all updates safety policies to all MR staff online and/or an updated hard copy in every MR area.

7. MR safety incidents or "near incidents" that occur in the MRI center are to be reported to the Manager of the center, the MR safety officer, and the Medical Director in a timely manner, an Event Report (RL solutions) should be documented by the
technologist via the intranet and to the FDA Maude website if any equipment was involved www.fda.gov/medwatch.

The MR task group of the American Society for Testing and Materials (ASTM) International has developed a set of MR safety terms. This terminology is NOT being applied retrospectively to implants and devices that previously received FDA approved labeling using the terms "MR safe" or "MR compatible". This applies to those objects tested prior to December 2005.

Particularly with regard to nonclinical and incidental equipment, current products marketed with ill-defined terminology such as “nonmagnetic”, or the outdated classifications described above (“MR compatible”), should NOT be presumed to conform to a particular current ASTM classification.

To go along with the new terminology, the ASTM introduced corresponding icons consistent with international standards for colors and shapes of safety signs. They are intended for use on items that may be brought into or near the MRI environment as well as in product labeling.
• **MR SAFE** - is an item that poses no known hazards in all MRI environments. Using the new terminology, "MR Safe" items include non-conducting, non-metallic, non-magnetic items such as a plastic Petri dish. The "MR Safe" icon consists of the of the letters "MR" in green in a white square with a green border - or - the letters "MR" in white in a green square.

• **MR CONDITIONAL** - is an item that has been demonstrated to pose no known hazards in a specified MR environment as long as specified conditions of use are met. The "MR Conditional" icon consists of the letter "MR" in black inside a yellow triangle with a black border. The item labeling must include the results of testing and the specific conditions of use sufficient to characterize the behavior of the item in the MRI environment.

• **MR UNSAFE** - is an item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors. The "MR Unsafe" icon consists of the letters "MR" in black in a white field inside a red circle with a diagonal red band.

• **Safety in MRI Not Evaluated** - For devices that have historically not provided any information about MRI safety
NEW ASTM Approved Labeling, No other Labeling is acceptable

Image 1
The ACR established the 4 zone concept as defined in the ACR Guidance Document for Safe MR Practices: 2007. The four zone concept provides for progressive restrictions in access to the MRI scanner. All MRI Suites are marked with Zone signs

- **Zone I**: General public freely accessible to the public. This area is typically outside the MR environment.

- **Zone II**: Limited Access: This is the Zone located between the public uncontrolled Zone 1 and the strictly controlled Zone 3. This area has limited access - available to patients, family members and hospital personnel who have been safety trained or safety screened by Level 2 MR personnel. It is in Zone II that the answers to MR screening questions, patient histories, medical insurance questions, etc. are typically obtained.
• **Zone III:** The MR scanner (Zone 4) itself is located adjacent to this space. Zone III can be defined as regions from which potentially hazardous energies (related to the MR imaging process) may be accessed. Zone III regions should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method. Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III. Patients, family members, or hospital staff that has undergone safety screening or safety training will be allowed access to this area only when accompanied by appropriate MR personnel.

• **Zone IV:** Is the room housing the MR scanner itself. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. Zone IV, by definition, will always be located within Zone III as it is the MR magnet and its associated magnetic field which generates the existence of Zone III. Only patients and family members, or hospital staff accompanied by Level 2 MR personnel who have undergone safety screening or safety training will be admitted to this Zone.
Non-MR Personnel should be accompanied by, or under the immediate supervision of and visual contact with, one specifically identified MR person for the entirety of their duration within Zone III and a level 2 MR person in Zone IV restricted regions.

**SITE ACCESS RESTRICTIONS:**

**MRI Center, Fitkin Basement**

The MRI outpatient center is located at 789 Howard Avenue. Stretcher/wheelchair bound patients will be transferred to MR safe equipment in the prep hold area located adjacent to MR 5 and MR 1. The amount of additional hospital staff for any procedural MRI's will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents.
Smilow (Level 2), MRI Suite

The Smilow MRI Suite is located at 20 Park Street, second floor of the Smilow Cancer Hospital. Stretcher and wheelchair bound patients will be transferred to MR safe equipment in the prep hold area. The amount of additional hospital staff for any procedural MRI’s will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents in the suite.

Smilow (Level 1) Breast Center MRI Suite

The Breast Center MRI Suite is located at 20 Park Street; first floor of the Smilow Cancer Hospital is divided into four zones. All stretcher bound patients will attempt to be scheduled on the second floor MRI suite. Wheelchair bound patients will be transferred to MR safe equipment in the changing area.

North Haven, MRI Suite

The North Haven MRI suite located at 6 Devine Street in North Haven is divided into four zones. Stretcher and wheelchair bound patients will be transferred to MR safe equipment in the transfer area.

Pediatric Suite West Pavilion:

The Pediatric MRI Suite is located on the second floor of the YNHH Children’s Hospital. Due to limited space in the suite, stretcher bound patients will be transferred to MR safe stretchers in the MRI intake room. The amount of additional hospital staff for procedural
MRI will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents. For the safety of patients, families and staff, the detachable table at this location must be used.

**Temple Street, MRI Suite**

The YNHH Temple Street MRI is located in New Haven CT. The address is 60 Temple Street New Haven. The detachable table will be used to transfer wheelchair or stretcher patients from MR safe area to MR scan room.

**Shoreline Medical Center Guildford, CT MRI Suite**

The YNHH Temple Street MRI suite located at 111 Goose Lane Guilford CT. The amount of additional hospital staff for procedural MRI will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents. The detachable table will be used to transfer wheelchair or stretcher patients from MR safe area to MR scan room.

**St Raphael, MRI Center**

The St Raphael's Campus MRI center located 1450 Chapel Street New Haven CT. Due to limited space in the suite, stretcher bound and wheelchair patients will be transferred to MR safe equipment in the nursing area. The amount of additional hospital staff for procedural MRI will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents.
MRI Functional Diagram

Outpatient Entrance → Patient Waiting → Toilet → Patient Screening → Ferromagnetic Detection

Patient Waiting → Patient interview → Changing/Gowning → Ferrous Quarantine

Patient Waiting → Toilet → Safe Storage → Patient Screening

Patient Waiting → Patient interview → Patient Transfer → Inpatient Entrance

Post-Screened Patient Holding → Toilet → Induction Recovery

Post-Screened Patient Holding → Curtained Preparation/Bed Holding → Vestibule

Post-Screened Patient Holding → Control Room

Post-Screened Patient Holding → MRI Scanner Room

Image 4 STANDARD ACR ZONE
The time varying magnetic fields in MRI produce auditory, induced voltage and thermal issues that we should be aware of.

**Auditory Considerations:**
Patients **ALWAYS** need to have ear plugs as well as their family members who accompany them into the scan room. Hearing loss can occur in those that don’t wear the earplugs during the scan. The earplugs we supply are Latex Free and have an acceptable NNR rating. In pediatric patients, sometimes the earplugs are not a perfect fit but in addition, MRI staff will place towels by their ears and tape the earplugs in place.

SAR-Specific Absorption Rate is defined as the RF power absorbed per unit of mass of an object. It is measured in watts per kilogram (W/kg). The SAR describes the potential for heating of the patient’s tissues due to application of the RF necessary to produce the MR signal. Technologists will monitor SAR levels introduced to the patient, and will stay within appropriate levels.

**Induced Voltage Considerations:**
Implanted wires pose a possibility of creating a current along the wire inside the MRI

- Patients with implanted wires in anatomically and/or functionally sensitive area should be considered at a higher risk. The decision to perform imaging and/or
limit the rate of magnetic field change and strength of the magnetic field should be reviewed by the radiologist supervising the case.

**Thermal Considerations:**

Electric currents can be created during MR imaging which could cause burns to the patient.

- All electrical connections such as surface coil leads, monitoring devices, etc., must be physically checked by the scanning technologist before beginning the scan to ensure the integrity of the thermal and electrical insulation.

- All unnecessary or unused electrically conductive materials external to the patient should be completely removed from the MR system before scanning starts.

- For electrically conductive material, wires, leads, implants, etc., that are required to remain in the bore of the magnet with the patient during imaging, pads, etc. should be placed between the patient and the electrically conductive material during imaging to keep the electrical conductor from directly contacting the patient. Pads can also be placed between the conductive material and the wall of the magnet if the body coil is being used, no loops should be created.

- Care is needed to ensure that the patients' tissues do not directly come into contact with the inner bore if the scanner during the imaging process. Pads should be placed between the patient and the magnet walls. It is also important to ensure that the patients' own tissues do not form large conductive loops. Therefore, care should be taken to ensure that the patients' arms and legs not be positioned in such a way as to form a loop within the bore of the magnet.
• There have been rare reports of thermal injuries/ burns associated with clothing that contained electrically conductive materials, such as metallic threads and silver impregnated clothing. As such, all patients remove their own clothing and instead change into provided gowns.

• Tattoos should be discussed. In certain circumstances RF heating may cause a burn around the tattooed area. Patients will be instructed to contact the technologist during the exam if any sensations are felt. A cold compress/ice pack may be placed over the area to minimize RF heating at the patient’s request.

• All unconscious/unresponsive patients should have attached leads insulated from their skin during scanning.

• It is important to follow established product MR Conditional labeling and safety guidelines carefully and precisely, applying them to and only to the static magnetic field strengths at which they had been tested. MR scanning at either stronger and/or weaker magnetic field strengths than those tested may result in significant heating where none had been observed at the tested field strength(s).

• The patient should immediately report any burning/or discomfort to the MR technologist, the scan should be stopped and the situation accessed. A RL solution should be documented by the technologist via the Intranet and to the FDA Maude website if any equipment was involved www.fda.gov/medwatch
A.) All MR sites should arrange to prospectively educate their local fire marshals, police and security personnel about the potential hazards of responding to emergencies in the MR suite.

B.) It should be stressed that even in the presence of a fire or other emergency the magnetic field may be present and fully operational. Free access to Zone IV by firefighters and other non-MRI personnel with air tanks, axes, crowbars, guns, etc. can prove to be catastrophic or even lethal. Helium is not flammable and does not pose a fire hazard directly; however, the liquid oxygen that can result from the super cooled air might well increase the fire hazard in this area. If there are appropriately trained MRI personnel available during the emergency who are able to keep the emergency responders from the magnet room and the five gauss line, then quenching the magnet should not be a requirement. As part of the Zone III and IV restrictions, all MR sites must have clearly marked, readily accessible MR Conditional or MR Safe fire extinguishing equipment physically stored within Zone III or IV.

C.) If the fire or emergency is in the magnet room, and the emergency response personnel and their equipment must enter the room, a decision to quench the magnet should be made to protect the health and lives of the emergency responders. Should a quench be performed, appropriately designated MRI personnel still need to ensure that
all non MRI personnel continue to be restricted from the magnet room until the designated MRI personnel have verified that the static field is either no longer detectable or at least sufficiently attenuated so as to no longer present a potential hazard (see Cryogen related policy)

In the event of a fire at any YNHH MRI suites and please follow the following procedure:

R.A.C.E. RESPONSE PROTOCOL:

- **R.A.C.E.** Stands for RESCUE, ALARM, CONFINE AND EXTINGUISH.
- **RESCUE**: Injured visitors, employees or staff must rapidly be rescued from the immediate area of the fire/smoke origin.
- **ALARM**: At the sight of flames or smoke, immediately activate a Fire Alarm Pull Station.
- **CONFINE**: Fire, Smoke and Toxic combustion products must be confined to the area of fire origin as much as possible. Close the door to the room of fire origin as soon as any rescue is accomplished.
- **EXTINGUISH**: If at all possible, staff should make one attempt to extinguish the fire with a hand-held fire extinguisher. They are to be used only after Rescue, Alarm and Confine have been completed. A fire extinguisher is not a replacement for activating the fire alarm system. Any fire that a fire extinguisher has been used on is to be reported to the Governing Police Department and/or Fire Marshal.

To Use a fire Extinguisher use the PASS Protocol

P.A.S.S. FIRE EXTINGUISHER PROTOCOL:

P.A.S.S.: method is used for the proper operation of a hand held fire extinguisher.
• **P.A.S.S.:** Stands for *Pull, Aim, Squeeze, Sweep.*

- **PULL:** Pull the safety ring/pin at the top of the fire extinguisher.
- **AIM:** Aim the discharge nozzle at the base of the fire.
- **SQUEEZE:** Squeeze the handle of the fire extinguisher together to discharge the agent.
- **SWEEP:** Sweep the agent side to side at the base of the fire.

Whenever using a fire extinguisher the following is to be remembered.
- Maintain a clear exit
- Keep your back to that clear exit.
- If at anytime you feel as if you are in danger evacuate the area and close the door behind you.

**YNHH MRI CENTERS GENERAL EVACUATION PLAN**

**IN CASE FIRE OR SMOKE**

1. Stay calm.
2. Always sound the building fire alarm immediately. If the alarm fails to operate, warn other occupants by knocking on doors and shouting warnings.
3. Call your centers Emergency number. (Temple ST 911, YNHH 155, ST Raphael’s=155, Guilford 911, North Haven 911, Yale University Office of the Fire Marshal @ (203) 4329923) from a safely located telephone. Give as much information as possible to the dispatcher. Do not assume that someone else has already notified them. They will immediately notify the Fire Department and
dispatch officers to the scene. Do not hang up until told to do so by the dispatcher.

4. Before opening the door, feel it with the back of your hand. If it is not hot skip to STEP 5. If it is hot, do the following
   - Seal cracks around the door with towels, tape, bed clothing or similar items to keep out the smoke. Shout for help. Call your centers Emergency number. (Temple ST 911, YNHH 155, ST Raphael’s=155, Guilford 911, North Haven 911 Yale University Office of the Fire Marshal @ (203) 4329923) and tell them that you are unable to get out of your room. They will be in contact with officers at the fire. Remain calm until firefighters reach you from the hallway or window. Their first duty upon arriving at a fire is to search for persons trapped in the burning building.

5. If you are able to leave your room, do so immediately and:
   - Take your key with you in case you are forced to return. Close all doors behind you as you exit. This will lessen the spread of smoke and damage.
   - Go to the nearest exit or stairway. Do not use an elevator.
   - If smoke, heat or fire blocks your exit, go to an alternate exit.
   - If all exits from a floor are blocked go back to your room and follow the procedures described above in step 4

6. If smoke is present, keep low to the floor. Take short breaths to avoid inhaling any more smoke than necessary.

7. Leave the building immediately. When the Police and/or Firefighters arrive, direct them to the fire.

Non-essential staff should follow exit signs and or the directions of Police and Firefighters. Do not re-enter the building for any reason until the Fire Department has declared it safe.

**FIRE ALARM ACTIVATION PROCEDURE**

In the event of a fire alarm activation alarm or other emergency, visitors, employees and non-essential staff are to evacuate the building using the nearest
stairway or exit. Essential staff and patients undergoing procedures should be aware of their surroundings and be vigilant in checking for smoke or fire. An immediate evacuation order may be issued by Governing Fire, Security, Police Department, or a representative from the Fire Marshal’s Office. If an evacuation order is issued, it must be followed immediately.

Elevators are not to be used during a fire alarm or smoke/fire condition. During a fire alarm evacuation, non-essential staff should assist ambulatory patients in evacuating the building by following the exit signs which lead to the building exits. Once outside, everyone should move away from the exit discharge doors of the building and to avoid congregating close to the building where they may hamper emergency operations. Do not block the exits or fire department access to the building.

The onsite administrator or business manager of each department will be responsible for the management of the evacuation process. They are to have a list of all employees in their department with them and are to advise the fire department of any employee that is missing. If the onsite administrator or business manager is not available, they are to have designated someone who is to manage the evacuation process for their department or group.

Any disabled individual who cannot evacuate using the outside means of egress are to be moved to the other side of the smoke barrier doors and wait for the fire department to remove them safely from the building. The buddy system is to be used for these employees. YNHH staff is to notify the fire department when they reach the street that there may be disabled individuals still in the building and where they are located.

The fire alarm system is not to be silenced or reset without the permission of the fire department.

Occupants are not to reenter the building until the "All Clear" is given by the fire department.

**MRI EMERGENCY PROCEDURES**

- When a call has been placed for a fire or police emergency in the MRI Center, MR technologists at all scanners should immediately stop scanning and remove patients from the scanner room.
• The MR safety officer should be called and informed of the emergent situation so that they can be on site prior to the arrival of emergency personnel.
• The MR safety officer and a designated MR staff member should monitor the scanner room doors to prevent free access by emergency personnel. (NOTE: Even in the event of a fire or other emergency the magnetic fields are likely to be present and fully operational.)
• In the case of a fire that is not in the scanner room, quenching the magnet should not become necessary.
• If the fire is in a location that fire fighters and there equipment (oxygen, canisters, crowbars, axes, defibrillators, ETC.) need to enter the scanner room, a decision to quench the magnet may become necessary to protect the health and lives of the emergency personnel.
• If a quench is performed the MR safety officer and MR technologists need to ensure that all emergency personnel are restricted from the scanner room until the static magnetic field is no longer present.

FIRE PREVENTION PLAN:
Accumulations of flammable or combustible waste material are not to be left in the building. Computer rooms are not to be used for storage. All combustible waste materials are to be removed each day. Smoking is not allowed anywhere in the building. Corridors and stairs are not to be used for storage or equipment areas since they become an obstruction during an emergency. Storage and equipment can cause a fire if it is energized equipment, or contribute fuel to a fire, which will fill the corridor with smoke and toxic fumes. The building has a fire alarm system with consists of smoke detectors and pull stations and a fire sprinkler system. The building has also been provided with emergency lighting and exit signs to locate the exit stairwells. Hand held fire extinguishers have been provided throughout the building. Questions regarding Yale University building be directed to the Yale University Office of the Fire Marshal @ (203) 4329923
In the event of a system quench it is imperative that all personnel/patients be evacuated from the MR scan room as quickly and as safely feasible.

- Stop all scanning and open the scan room door immediately. If the door to the scan room is closed the pressure may build up making it impossible to open the door. In this event, it may become necessary to break the glass window to allow the gasses to escape and the pressure to lessen so that the scan room door may be opened.

- The access to the scan room should be immediately restricted to all individuals until the arrival of the MR equipment service personnel.

- Do not rely upon the oxygen sensors in the room to warn of low oxygen levels in the room. This technology is now considered by industry experts not to be sufficiently reliable to allow for continued operations during situations of power outage, etc.

- It is especially important to ensure that all police and fire response personnel are restricted from entering the MR scan room with their equipment (axes, air tanks, guns, etc.) until it can be confirmed that the magnetic field has been successfully dissipated, as there may still be considerable static magnetic field present despite a quench or partial quench of the magnet.

- MR Safety Officer and MR Medical Director need to be informed immediately
MRI Personnel Screening:
All MR personnel are to undergo an MR Screening process as part of their employment interview to ensure their own safety in the MR environment. At this time it is the employees' responsibility to fully disclose any trauma, procedure or surgery that they have experienced or undergone in which ferromagnetic objects or devices may have become introduced within them or on them. This will permit an appropriate screening to be performed upon the employee to determine the safety of introducing them to the MR environment.

Personnel Definitions:
Non-MR Personnel
Patients, visitors or facility staff who do not meet the criteria of level 1 or level 2 MR personnel will be referred to as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.
Level 1 MR Personnel

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III will be referred to as level 1 MR personnel (e.g., MRI department office staff and patient aides.) Level 1 MR personnel are not permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.

Level 2 MR Personnel

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to as level 2 MR personnel (e.g., MRI technologists, radiologists, radiology department nursing staff.)

MRI Personnel and Non MRI Personnel:

All individuals working in Zones III and/or IV of the MR environment should be documented to have completed the MR safety program consisting of at least one MR safety lecture a year approved by the medical director. These educational efforts should be documented and reviewed annually.

Personnel MR Training:

All employees must be safety training before entering the suite. Specific training will be up to the medical director and continually accessed to meet department needs. At many YNHH facilities training includes filling out an employee MRI screening
sheet, watching a designated MR safety video and speaking with a level 2 MR employee.

**Family Members and Non MR Personnel:**

All family members and companions entering Zones III and/or Zone IV will be required to complete an MRI safety form. Any positive responses and possible contraindications to these areas will be discussed with the MR technologist. If the technologist cannot resolve the issues the radiologist will be consulted.

In addition to the screening form, pregnant family members who want to go into zone IV will also be given information about pregnancy and MRI. It is their choice to stay in the room during the MRI.


All non MR Personnel and family members who are going into Zone IV - the scanner room - will remove all metal objects and personal belongings, and will be wanded by a ferrous metal detector in Zone II before given permission to enter Zone III and Zone IV.

**Device/Object Screening:**

- MRI staff members should pay particular attention to the stretchers and beds of inpatient and remove all oxygen tanks and any other potential hazards.
- All portable metallic or partially metallic devices that are on or external to the patient (e.g., oxygen cylinders) are to be positively identified in writing as non-
ferromagnetic and either MR safe or MR compatible prior to admitting them into Zone III.

- As part of the Zone III site restriction and equipment testing and clearing responsibilities, all sites should have ready access to a strong handheld magnet (1000-Gauss) and/or a handheld ferromagnetic detection device. This will enable the site to test external, and even some superficial internal devices or implants for the presence of grossly detectable ferromagnetic attractive forces.

- If external devices/objects are demonstrated to be ferromagnetic and non MR safe/conditional, they may still, under specific circumstances, be brought into Zone IV if deemed by MR personnel to be necessary and appropriate for the care of the patient (ex. arterial line, catheter bag with clip). These devices/objects must be appropriately secured at all times. The safe utilization of these devices is the responsibility of MR personnel to ensure that they do not inadvertently become introduced too close to the MRI scanner and become a hazardous projectile or no longer accurately function.

- Never assume MR safety information about any device if it s not clearly documented in writing and following ASTM testing standards. If a devices MR compatibility/safety status is unknown it should not be permitted in the magnet field.

- A prior MR examination with an implanted device at any given static magnetic field strength (stronger or weaker) is not in and of itself sufficient
evidence, and will not be relied upon to determine the MR safety/compatibility for that device

**Gun Shot Wounds**

- If the patient states they have been shot and no fragments remain, no further investigation of the area is recommended. If the patient is unsure or fragment pieces are remaining, the issue should be brought to the radiologist’s attention.
• Out patients will be checked in by the receptionist as the front desk of the MRI department. Two Patient identification markers will be used. (Example Full Name, DOB, Address). They will be given a wrist band and be handed a safety sheet to fill out. Anyone accompanying the patient will also fill out a safety sheet.

• The MR personnel (level 1 or 2) will review the safety sheet to ensure that there are no positive responses. Any positive responses will be discussed between the patient and a level 2 staff member to confirm that the patient has understood the safety form and understands any risks that are involved with the MRI procedure.

• If the patient is getting contrast two additional steps should be taken before scheduling the patient. The patients eGFR and pregnancy status (if applicable) should be known.

• The patient will be instructed to remove any metal objects and secure their belongings in the lockers. All patients will be requested to change into hospital attire.

• After the patient has changed, the patient and any accompanying companions or facility staff members will have a final check for metallic objects, pregnancy
screening and any contraindications to the MRI procedure with Level 2 MR staff and using a ferromagnetic wand.

- Having safely undergone a prior MR examination with an implanted device at any given static magnetic field strength (stronger or weaker) is not in and of itself sufficient evidence, and will not be relied upon to determine the MR safety/compatibility for that device.

Figure 5 Ferromagnetic wand

MRI Screening Process for all Inpatients

- Inpatient safety needs to be reviewed every time a patient has an MRI. They will be screened utilizing the inpatient screening form located in Epic. The form will be filled out on the floor with the patient. The patient needs to be alert and orientated x3 to be able to fill out their own screening sheet. If the patient is unable to complete the form (i.e. due to altered mental status) a nurse, physician, and/or family member may complete the form on the patient’s behalf. (Unresponsive patients with no family members please see page 36)

- If the patient is getting contrast two additional steps should be taken before scheduling the patient. The patients eGFR and pregnancy status (if applicable) should be known

- Inpatients will have their safety form reviewed for any contraindications to the MR procedure by the MR personnel before an appointment will be scheduled. Inpatients will not be scheduled without a complete and signed safety form.

- After these steps the patient will be scheduled.
The patient will be put into the transport system. The inpatient transporter will transport the patient to the designated Zone II area, where staff will inform the technologists of the patient arrival.

The patient will be changed into appropriate attire as needed, any unsafe medical equipment shall be removed. If metallic objects or personal belongings have come with the patient they will be secured in a locker..

If the patient is on oxygen they will be put on walled oxygen.

The patient will be transferred to MR conditional equipment.

Before entering Zone III the patient will be wanded with a ferromagnetic detector and have a final recheck of all safety concerns with level 2 MR staff.

During Transport to Zone IV, the patient is disconnected from the ventilator and is manually ventilated with room air into the MRI scanner room.

Any accompanying companions or facility staff members will also be wanded and safety screened by MR staff for any ferromagnetic objects or safety concerns.

Having safely undergone a prior MR examination with an implanted device at any given static magnetic field strength (stronger or weaker) is not in and of itself sufficient evidence, and will not be relied upon to determine the MR safety/compatibility for that device.


### I. Policy

Screening of patients for whom an MR examination is deemed necessary but who are unconscious, unresponsive, not AOx3 or for other reasons unable to provide their own reliable histories regarding prior surgery or exposure to metallic foreign objects, and for whom such histories cannot be reliably obtained from others:

The patient should be physically examined for evidence of possible surgery or trauma involving metal, and these areas should be subject to plain-film radiography (if recently obtained imaging of such areas is not already available).

The patient should undergo plain film radiography of the chest and skull or orbits to exclude potentially dangerous metallic foreign objects/devices.

Final determination of whether or not to scan any given patient will be made by the supervising radiologist.

### II. Procedure

If a patient is unconscious, unresponsive or for other reasons unable to provide their own reliable histories, the responsible health care professional or supervising radiologist will order plain-film radiographs of the chest and skull or orbits. A verbal order to MRI technologist is acceptable.

The ordering health care professional will examine the patient for any additional areas of scars or deformities that might be anatomically indicative of an implant, or foreign body. **This examination will be documented in Epic (progress notes) before the patient will be scheduled for their MRI exam.** If any areas of concern are found, they can be imaged with plain film radiography based on the ordering physician and/or the radiologist’s request.

A radiologist from the service (i.e. Neuro, MSK, Body, Peds) that will interpret the ordered MRI examination will determine whether there are any contraindications for the
MRI. The same service will interpret and dictate the plain-film radiographs obtained for MRI screening.

Prior to the patient being scheduled, the supervising radiologist will sign a safety sheet that approves the patient for an MRI study. The sheet will be scanned into the chart via EPIC. Alternatively, the radiologist may review the safety sheet with the MRI technologist and provide verbal approval, but such approval must be documented and scanned into the patient’s chart.

After the patient has been cleared by the radiologist, the standard inpatient process will continue.
Under no circumstances will standard ferromagnetic oxygen tanks be brought into Zones III or Zone IV.

Hospital staff transporting inpatients with standard ferrous oxygen cylinders will exchange the O2 from tank to wall O2. All ferromagnetic oxygen cylinders will be stored in a holder.

MRI compatible oxygen cylinders are silver with a light green top. These tanks will be stored in a Zone II holder.

MRI compatible oxygen cylinders are allowed in Zone III only NEVER Zone IV.

The "Oxytote" oxygen cylinders are not MRI safe. They indeed have ferromagnetic components. They are to be treated as any other ferrous oxygen cylinder and will be exchanged for our traditional aluminum cylinders as outlined above.

While the patient waits for their exam or wants to be transported back to their room the wall mounted oxygen will be used. When the patient enters Zone IV - the scan room - the patient will be hooked up to wall mounted oxygen.

MRI compatible oxygen cylinders will not be filled with the general population of the ferromagnetic cylinders in the hospital. The aluminum MR compatible cylinders will be sent out to be filled separately at the request of the MRI center.

No oxygen cylinders of any kind will be allowed in Zone IV - the scan room.
<table>
<thead>
<tr>
<th>SUBJECT: Penile Implants</th>
</tr>
</thead>
</table>

There are 2 penile Implants that are considered unsafe for MRI. They are the Omniphase by Dacomed, which was discontinued and replaced with the Duraphase by Dacomed. The Duraphase model was discontinued in 1995.

YNHH all penile implants implanted after 1997 are considered safe on our 1.5 and 3T systems.
I. Policy
“All patients who have a history of orbit trauma by a potential ferromagnetic foreign body *for which they sought medical attention* are to have their orbits cleared by either plain X-ray orbit films (2 views) or by a radiologist’s review and assessment of contiguous cut prior CT or MR images (obtained since the suspected traumatic event) if available”. -ACR white paper 2013

II. Procedure
At YNHH a patient will have orbital x-rays for foreign body if the following criteria are met:
- They have sought out medical attention in the past for a foreign body in the orbit.
- No available CT or MRI for a radiologist to verify they are cleared.

If a patient arrives for an MRI and needs orbital x-rays, it is appropriate for the technologist to take a verbal or written order from the radiology attending physician.

There is no need to obtain an order from the patient’s referring physician.

**Ordering & Scheduling Foreign Body X-ray of Orbits:**

Please use Order entry in Epic.

From Tech Worklist:

- From tech worklist Select the patient, right click and select Order Entry
- Change Order Mode to cosign required OR per protocol: no cosign required
- Under New Order select XR EYE Foreign Body as the exam
- Click the Provider Button Change the Ordering DR to Radiology Referring MED Physician
- Click Sign Order
CARDIAC VALVES
All cardiac valves are considered immediately safe on 1.5T and 3T.

CORONARY ARTERY STENTS
All coronary stents are considered immediately safe on 1.5T and 3T

CARDIAC LEADS
Abandoned Epicardial Leads are considered safe on 1.5 and 3T.

Abandoned intracardiac pacing or ICD leads should be brought to an attending radiologist's attention for further evaluation. If it is unclear if there are abandoned leads a recent chest xray should be reviewed or a new chest xray ordered if needed. Any MR scan where the intracardiac leads are in the RF field is not recommended due to potential of significant heating and conduction and should only be done after attending radiologist approval after risk/benefit discussion. Informed patient consent is required.

Scans where the retained leads are not within the RF field for the ordered MRI are at very low risk for heating. These require attending radiologist approval but do not require informed consent from the patient.

Note, abandoned/retained intracardiac leads may be present when the patient still has a working pacemaker/ICD. These abandoned leads can also effect leads of a MRI conditional pacemaker and should be handled in similar fashion.

CARDIAC PACEMAKER/ICD
Patients with cardiac pacemakers or ICDs may be able to undergo an MRI at YNHH Main Campus. Devices and models have specific processes that must be followed before a MR imaging. For specific information contact the MRI department.

IMPLANTED CARDIAC MONITORS CARDIAC LOOP RECORDERS
Please check miscellaneous implants for for information on Revel Loop recorders
There is no waiting period for coils, stents, or filters on a 1.5 or 3T device. All devices are able to be scanned on a 3T magnet with proper documentation of the implanted device. To be imaged on 3T specific information (i.e., manufacturer or model) must be known and documents. The technologist will check the manufacturer’s recommendations. Implant must be tested with ASTM standards. Some exceptions are listed below.

**EMBOLIZATION COILS**

Embolization coils implanted at YNHH Main campus are considered safe from the onset on 1.5T and are safe on a 3T.

**STENTS**

All biliary, urethral and coronary stents can be immediately scanned on a 1.5T and 3T. All other stents are immediately safe on a 1.5T and with proper documentation 3T.

**FILTERS**

All filters are immediately safe on a 1.5T and 3T.
In the event that it is unclear whether a patient does or does not have an aneurysm clip in place, plain films should be obtained.

If the patient is identified to have an aneurysm clip the type of aneurysm clip must be documented. All documentation must be in writing, phone or verbal histories are not permitted.

Having safely undergone a prior MR examination with an aneurysm clip at any given static magnetic field strength is not in and of itself sufficient evidence, and will not be relied upon to determine the MR safety/compatibility or that aneurysm clip.

All Aneurysm clips surgically placed here at YNHH Main Campus after and including 1986 are MR Conditional and can be scanned on a 3T. (Sugita aneurysm Clip, Yasargil Phynox aneurysm clip (FE), Yasargil Titanium aneurysm clip (FT))

Other aneurysm clips may acceptable on a 3T as long as guidelines are met. To image an aneurysm clip on 3T, specific information (i.e., manufacturer, type or model, and material) about the aneurysm clip must be known and documented. The technologist will check the implant against Dr Shellocks “The List” located at www.mrisafety.com for confirmation, or the company’s site if ASTM guidelines for testing have been followed.

If the type of aneurysm clip cannot be identified and documented the MRI will not be done.

If the artifact is great, moving the patient to a 1.5 might be considered if possible.
The lead of a stimulator may heat and cause injury during an MRI scans using the body coil. This may occur even when a part of the body remote from the head or neck is scanned. Magnetic and RF fields produced by MRI may change the pulse generator settings or activate the device. Always identify the device and follow its specific instructions.

**LIVA NOVA (formally CYBERONICS) VAGAL NERVE STIMULATOR**

- The vagal nerve stimulator must be turned off by qualified personnel prior to starting the exam. The patient should have it turned back on after the exam.
- MRI areas and parameters are restricted based on VNS model and implant location.
- [https://us.livanova.cyberonics.com/healthcare-professionals/mri](https://us.livanova.cyberonics.com/healthcare-professionals/mri)

**SCHEDULING LIVA NOVA (CYBERONICS) VNS**

- Before the procedure starts, identify the make/model and confirm it is eligible for the exam ordered. Contact the adult or pediatric epilepsy fellow. The Continuous Auditory and Visual EKG Department (C.A.V.E 688 3269) can provide current adult or pediatric epilepsy fellow pager numbers.
- **PLEASE CONTACT AS EARLY AS POSSIBLE TO CONFIRM AVAILABILITY**
DEEP BRAIN STIMULATORS

- Depending on the Brand some DBS systems can be imaged in a MRI
- Medtronic Deep Brain Stimulators, imaging areas and parameters are restricted based on model.


SCHEDULING MEDTRONIC DBS

- Before the procedure starts, identify the make/model and confirm it is eligible for the exam ordered and follow the appropriate guidelines
- For the head only T/R approved models, please schedule them on a 1.5 and use the transmit receive coil head only imaging. (no scan time limits) SAR as low as possible
- For the whole body DBS models, an eligibility sheet must be filled out by the DBS physician and scanned into EPIC before the procedure can start. B1 RMS under 2mT for all sequences and total scanning time >30 mins in a 90 min period.
- A qualified person should be made aware of the time and location of the scan to coordinate the turning on/off of the Medtronic DBS. DBS Rep 405 659 1643

PLEASE CONTACT AS EARLY AS POSSIBLE TO CONFIRM AVAILABILITY

NEUROPACE RNS therapy

- The RNS therapy system by Neuropace is currently contraindicated for MRI. Any imaging would be on a case by case basis, after a risk verse benefit decision by the attending radiologist the ordering physician and the patient. This should be documented in EPIC.
For some programmable shunts pressure setting may need to be known pre mri and verified and post MRI by a qualified personnel. Please verify the shunts FDA approved MRI process before calling Neuro-Surgical Resident. (Neuro-Surgical Resident on call at Main Campus 203 412 1030)

- For a programmable shunt that's settings need to be verified post MRI, if the patient is an adult, their “shunt manager” (i.e. physician, device rep or possibly neurosurgeon) can check the shunt within 24 hrs. The patient needs to have an appointment set up prior to the MR being started or if it's an inpatient, this needs to be coordinated with the floor or neurosurgery before scanning.

- IF YNHH NEURO SURGERY IS BEING USED PLEASE CONTACT EARLY AS POSSIBLE TO COORDINATE.

- There are no MR coil restrictions,

- Programmable shunts can be scanned up to and including 3T.

**Common Shunt Processes**

Pro Gav Shunts by Aesclup, settings do not need to be known pre or checked post MRI

Delta Shunts by Medtronic, settings do not need to be known pre or checked post MRI

Strata Shunts by Medtronic, settings NEED to be known pre and checked post MRI
Many implantable devices can be imaged safely under specific conditions. All devices should be researched through the manufacturer, referencing the make model and serial number of the patient’s device. The manufacturer’s current recommendations should always be followed. Medtronic Manual Resource: **1-800 505 INFO** Technical Support 8007070933

**Common Device List:**

**MEDTRONIC INTERSTIM bladder control**  
CHECK THE MODEL AND SERIAL NUMBER  
ONLY SOME 3023 ARE MR Conditional need SERIAL NUMBER The patient should have their own remote control to turn on and off the device before and after the MRI. MRI Imaging only allowed in transmit receive head coil, 1.5T Only.

MEDTRONIC    Local Bladder Stimulator    REP 617 512 1355

**8637 Medtronic Synchomed II baclofen pain pump** allowed on a 1.5T and 3T needs to be checked by a device programmer **after** the MRI (melanie.s.grippe@medtronic.com (203)-464-5887 or the patient’s device programmer.)

**8626, 8627 Medtronic Synchomed EL baclofen pain pump** allowed on a 1.5T and 3T. Pump settings need to be known **before** MRI starts and needs to be checked by a device programmer **after** the MRI (melanie.s.grippe@medtronic.com (203)-464-5887 or the patient’s device programmer.)

**MEDTRONIC Technical Support 8007070933**
Orthodontic Appliances Policy

Most dental braces/orthodontic hardware is non-ferromagnetic, but some exhibit measurable deflection in a strong magnetic field, and others include magnetic components.

Patients may experience vibrations. Loosening is possible if the dental implant is not firmly bonded or ligated.

Artifacts from metal components may interfere with assessment of certain parts of the brain or cervical spine, especially at 3T.

**MRI PROCESS**

**Prior to appointment**
During the pre-appointment call, the MRI tech aid\(^1\) will alert patients with orthodontic appliances that they may feel slight vibrations during MRI. The patient will be advised that they are not required to remove fixed appliances (including wires) prior to any spine/chest/abdominal/pelvic/extremity MRI. However any components that are easily detachable should be removed before the exam, and loose components should be tightened or secured prior to the exam.

Patients undergoing MRI of the brain should be informed that their MRI images will be monitored for significant MRI artifact, which may necessitate a repeat exam following removal of orthodontic appliance. Outpatients who require general anesthesia (intubation) to undergo MRI are required to have orthodontic appliances removed prior to exam. Patients who are intubated for other reasons (eg. from the ED) do not require hardware removal.

Patients undergoing MRI with conscious/moderate sedation do not require orthodontic hardware removal.

**Immediately prior to exam**
Confirm with patient that their orthodontic appliance is not loose, does not employ magnets, and is not otherwise MRI conditional or unsafe.
During MRI

If there is interfering artifact, the images should be reviewed by the supervising radiologist to ensure the scan is diagnostic. If necessary, sequences may be repeated after swap of phase and frequency encoding directions to move artifact away from area of interest and/or moving patient to a 1.5 Tesla scanner, if available.

If the radiologist determines that the artifact is serious enough to request removing the wires from the braces, the patient will reschedule after removal.

In truly emergent (hospitalized or ED patients) cases where the scan must be repeated for patient care, the referring service (not MRI or radiologist) should contact pediatric or adult dentistry services via page operator to assist with hardware removal prior to attempting re-scan.

1 Recommended script for tech aid for a patient that has orthodontic hardware/braces that is undergoing a brain MRI:

“Almost all dental appliances such as braces decrease the MRI scan quality, but the test is usually still diagnostic. We do not recommend that you have them removed unless you need general anesthesia to complete the MRI, but if they make it difficult for the radiologist to evaluate certain parts of the brain, we may ask that you return for a repeat MRI after having them removed. Any parts that are easily detachable should be removed before the exam, and any that are loose should be tightened or secured prior to the exam.”

Recommended script for tech aid for a patient that has orthodontic appliance that is undergoing MRI of any body part besides MRI brain:

“Your braces/dental hardware, including wires, should not affect the quality of your MRI and do not need to be removed, but you may feel some vibration or mild tugging during the test. Any parts that are easily detachable should be removed before the exam, and any that are loose should be tightened or secured prior to the exam.”
Wound Dressings and Trans-Dermal Medication Patches

There are thousands of medical dressings and trans-dermal medication patches that are available and have never been tested for MRI safety. Some wound dressings may contain silver, and some Trans dermal medication patches have a metallic backing. Even clear medication patches could contain metallic particles that are invisible to the naked eye.

Exposing these dressings or patches to excessive (RF) can increase their temperature. Increased temperature of metallic particles could cause burns to the patient. Also an increase temperature of a trans dermal patch could in theory alter the dosage given by the transdermal patch.

**Transdermal Medication Patches**

Patients at YNHH will remove all transdermal drug delivery patches that are in the radio frequency (RF) field before a MR exam. After the exam the patient will be given the original patch back and should contact their prescribing physician for a replacement if needed.

**Wound Dressings that do not contain metallic components or medication**

Wounds dressings that don’t contain silver or any medication have no MRI restrictions.

**Wounds Dressings that possibly contain metallic components or medication**

Wound dressings that contain or possibly contain silver /medication are evaluated on an individual basis before having an MRI by the MRI team and the Radiologist

Some of the questions to consider are

Is the dressing in the RF field?

Will the chemical makeup of the dressing (i.e. does it contain significant amounts of silver) degrade image quality a significant percent?

Can the dressing be removed easily before the exam?

How urgent is the MRI?

Can the exam be shortened?
MRI Information for Gyrus ACMI Otology Implant Devices

MR imaging is considered contraindicated for patients with metallic implant because of risks associated with movement or dislodgment for ferromagnetic implants and MRI-related heating for metallic implants that are a certain length or that form a closed conducting loop. With the exception of several production lots of a particular type of middle ear implant (see Table One) manufactured and distributed in late 1987 and early 1988, materials used by Gyrus ACMI in the manufacture of middle ear implant devices are generally considered acceptable for patients undergoing MRI procedures (see below).

Table One
Specific Lots of S&N, Inc. (Richards) McGee Platinum/Stainless Steel Pistons Contraindicated for MRI

This series of McGee Platinum/Stainless Steel pistons were manufactured with a ferromagnetic stainless steel in late 1987 and early 1988. The affected production lots of these pistons, given in Table 1 below, were recalled by Smith & Nephew, Inc. in 1989. Importantly, MRI is contraindicated for anyone having received a McGee Platinum/Stainless Steel piston from these lots.

<table>
<thead>
<tr>
<th>S&amp;N Catalog No.</th>
<th>Lot No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-0330</td>
<td>1W91110, 4U09690</td>
</tr>
<tr>
<td>14-0331</td>
<td>4U09700</td>
</tr>
<tr>
<td>14-0332</td>
<td>1W91110, 4U58540, 4U86300</td>
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<tr>
<td>14-0333</td>
<td>4U09710, 1W91120</td>
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<tr>
<td>14-0334</td>
<td>4U09720, 1W34390, 2WR4073</td>
</tr>
<tr>
<td>14-0335</td>
<td>1W34400, 4U09730</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>S&amp;N Catalog No.</th>
<th>Lot No.</th>
</tr>
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<tbody>
<tr>
<td>14-0336</td>
<td>3U18330, 3U50470, 4UR2889</td>
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<td>14-0337</td>
<td>3U18370, 4UR2889</td>
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<tr>
<td>14-0338</td>
<td>3U18390, 4U02900, 4UR1453</td>
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<tr>
<td>14-0339</td>
<td>3U18400, 3U50480</td>
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<tr>
<td>14-0340</td>
<td>3U18410, 3U50500</td>
</tr>
<tr>
<td>14-0341</td>
<td>3U41200, 4UR2889</td>
</tr>
</tbody>
</table>

MRI Information

All current Gyrus ACMI MR Conditional implants are packaged with an MRI Patient Card. (*Please review the explanation of the previous and current labeling terms applied to implants and devices. to follow.):

MR-Safe*

Devices that are made from non-metallic materials (i.e. implants and Ventilation Tubes made from HA, Plastipore, Silicone, Fluoroplastic) are inherently non-conducting and non-magnetic and pose no known hazards in all MR environments and therefore are considered MR Safe.

MR-Conditional*

Devices that have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system), may be required.

OLYMPUS SURGICAL TECHNOLOGIES AMERICA
Gyrus ACMI - 2925 Applinig Road - Bartlett, TN 38133 - USA
901.373.0200 • Fax 901.373.0220 • www.olympus-osta.com
The MRI Conditional Information for Gyrus ACMI implants (excluding the Lots listed in Table One above) is as follows:
Non-clinical testing of representative worst case samples has demonstrated that patients with these specific Gyrus ACMI otologic implants can undergo MRI safely, immediately after implantation under the following conditions:
- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient field of 720-Gauss/cm or less.
- MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 –W/kg for 15 minutes of scanning (i.e., per pulse sequence).

The following tables summarize the Gyrus ACMI implants, based on worst case representative sample testing (data on file), available literature reviewed as referenced below **1**, and a review of the materials used in their construction as allowed by ASTM F2503.

**Table 2: MR Safe (Materials include: Hydroxyapatite (HA), Fluoroplastic, Plass-pore, Hapex)**

<table>
<thead>
<tr>
<th>Device Family</th>
<th>Family Product Number(s)</th>
<th>Device Family</th>
<th>Family Product Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grote Canal, HA</td>
<td>1408XX, 709217XX</td>
<td>Applebeum Incus Replacement</td>
<td>1409XX</td>
</tr>
<tr>
<td>Reconstruction Blocks, Artic Defect</td>
<td>1409XX, 70143019</td>
<td>Austin Mod TORP</td>
<td>140063</td>
</tr>
<tr>
<td>Vocol</td>
<td>1402XX, 70143019</td>
<td>Black Oval</td>
<td>1408XX, 1409XX</td>
</tr>
<tr>
<td>HA Granules</td>
<td>911101</td>
<td></td>
<td></td>
</tr>
<tr>
<td>John Tube</td>
<td>1409XX</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 3: MR Conditional (Materials include: Nitinol, Stainless Steel, Titanium, Tantalum, Platinum)**

<table>
<thead>
<tr>
<th>Device Family</th>
<th>Family Product Number(s)</th>
<th>Device Family</th>
<th>Family Product Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAP / TORP / PORP</td>
<td>140063, 1408XX, 701430XX, 701458XX, 7014057, 701431XX, 701430XX, 1400XX, 140XXX, 14071XX</td>
<td>House Type</td>
<td>1401XX</td>
</tr>
<tr>
<td>Micron, Micron II</td>
<td>701430XX, 701411XX</td>
<td>Karlinsh Incus</td>
<td>1408XX, 701453XX</td>
</tr>
<tr>
<td>Smart Pistons</td>
<td>701430XX, 701431XX, 701453XX</td>
<td>Ribbon loops</td>
<td>1407XX</td>
</tr>
<tr>
<td>Pistons (various)</td>
<td>1403XX, 1400XX, 701405XX, 701431XX, 1400XX, 701457XX, 14071XX</td>
<td>Scheley-type incus</td>
<td>1404XX</td>
</tr>
<tr>
<td>Bucket Handles, Cups, Classic</td>
<td>701430XX, 1405XX, 1404XX, 1400XX, 709211XX, 701453XX</td>
<td>Wels Incus</td>
<td>701458XX, 701409XX, 140XXX</td>
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<tr>
<td>Goldenberg</td>
<td>1409XX, 701459XX</td>
<td>Wire loop</td>
<td>140721, 140722</td>
</tr>
<tr>
<td>Grate, Grote</td>
<td>1408XX, 701409XX</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(XX = 00 through 99) (XXX = 000 through 999)

2. Applebeum EL, Valtzsson GE. Effects of magnetic resonance imaging fields on stapedectomy prostheses. Archives of Otologyryology 1983; 111:820-821
6. Sherlock FG. Implants and Device: Labelling for MRI and an explanation of Terminology. MRIsafety.com
**MISCELLANEOUS IMPLANTS**

<table>
<thead>
<tr>
<th>Device</th>
<th>1.5</th>
<th>3.0</th>
<th><strong>Comments, Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bivona Trach</td>
<td>yes*</td>
<td>yes*</td>
<td>If you are imaging the Brain Cspine Tspine, or Chest area these should be replaced with a shiley due to the massive artifact they produce. Imagine in the Brain, Cspine, Tspine or chest with a Bivona trach present is typically not diagnostic.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device</th>
<th>1.5</th>
<th>3.0</th>
<th><strong>Comments, Guidelines</strong></th>
</tr>
</thead>
</table>
   All CONTOUR PROFILE® Breast Tissue Expanders /CPX™ Tissue Expanders (product codes 354-6XXX, 354-7XXX, 354-8XXX, 354-9XXX) **NO** |

<table>
<thead>
<tr>
<th>Device</th>
<th>1.5</th>
<th>3.0</th>
<th><strong>Comments Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Loop Recorder Implantable Cardiac Monitor</td>
<td>Yes</td>
<td>Yes</td>
<td>See Revel Devices or other brand names page 55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device</th>
<th>1.5</th>
<th>3.0</th>
<th><strong>Comments, Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cochlear Implants</td>
<td>Some models yes</td>
<td>Some models yes</td>
<td>Some types of cochlear implants employ an internal magnet used in conjunction with an external magnet to align and retain a radio frequency transmitter coil. Other types of cochlear implants are electronically activated. Follow manufacturers FDA approved guidelines. For these devices.</td>
</tr>
<tr>
<td>Device</td>
<td>1.5</td>
<td>3.0</td>
<td>Comments, Guidelines</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----</td>
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<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>External Ventricular Drain</td>
<td>Yes</td>
<td>Yes</td>
<td>An external ventricular drain (EVD) is a device used in neurosurgery that relieves raised intracranial pressure and monitors CSF fluid levels. Both are safe to use on either the 1.5 or 3.0T. This device does not cause artifacts.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device</th>
<th>1.5</th>
<th>3.0</th>
<th><strong>Comments Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraosseous Vas acces</td>
<td>NO</td>
<td>NO</td>
<td>Should be removed before MRI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EZ-10 is a brand paramedic but these in in the field sometimes if rapid access is necessary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device</th>
<th>1.5</th>
<th>3.0</th>
<th>Comments, Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linux Reflux</td>
<td>Some models yes</td>
<td>No</td>
<td>Patients who have the newer LINX device implanted June 2015 and later can undergo a 1.5T MRI. These patients should have a blue implant card.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device</th>
<th>1.5</th>
<th>3.0</th>
<th>Comments, Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnimplant Magnatract Sternum</td>
<td>No</td>
<td>No</td>
<td>Magnimplant” and “Magnatract”in a combined system to correct for pectus excavatum or sunken chest Deformity, in pediatric patients.</td>
</tr>
<tr>
<td>Device</td>
<td>1.5</td>
<td>3.0</td>
<td><strong>Comments Guidelines</strong></td>
</tr>
<tr>
<td>---------------------</td>
<td>-----</td>
<td>-----</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Paraguard</td>
<td>Yes</td>
<td>Yes</td>
<td>ALL copper IUD, Paraguards can be imaged on 1.5,3T</td>
</tr>
<tr>
<td>Perifix Polyamide Catheter</td>
<td>Yes</td>
<td>Yes</td>
<td>This Catheter is used in epidural procedures. It is made of polyamide nylon and tungsten powder. It has been tested for use on 1.5 and 3 Tesla magnets. All Perifix catheters, gauges and length and tip configurations are considered safe and these strengths</td>
</tr>
<tr>
<td>Reveal XT 9529 DX 9528</td>
<td>Yes</td>
<td>Yes</td>
<td>6 week waiting period, Its best practice to send the data collected on the device before the MRI. If an appointment was never set up it is not necessary to delay care. The technologist should continue with the MRI. For more information contact (800) 742-0884 ask for the representative in the area Check the most up to date Specific MRI instructions on the site below or call 800 505 INFO <a href="http://manuals.medtronic.com/manuals/main/us/en_US/home">http://manuals.medtronic.com/manuals/main/us/en_US/home</a></td>
</tr>
<tr>
<td>Reveal LINQ</td>
<td>Yes</td>
<td>Yes</td>
<td><strong>NO waiting period,</strong> Its best practice to send the data collected on the device before the MRI. Patients are able do this themselves if they have the MyCareLink Patient Monitor. If the patient doesn’t have it, there is no need to delay care. The technologist should continue with the MRI. For more information contact (800) 742-0884 ask for the representative in the area</td>
</tr>
</tbody>
</table>
Check the most up to date Specific MRI instructions on the site below or call 800 505 INFO

<table>
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</thead>
<tbody>
<tr>
<td>Scleral Buckle</td>
<td>AFTER WANDING</td>
<td>AFTER WANDING</td>
<td>Tantalum Clips used in scleral buckle surgery are acceptable on 1.5 and 3T Please Wand the orbital area with the ferromagnetic wand.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>1.5</th>
<th>3.0</th>
<th><strong>Comments Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Swanz-Ganz Catheters</td>
<td>Some models yes</td>
<td>Some models yes</td>
<td>Some brands are safe for 1.5 and 3T Check the manufacturers FDA approved guidelines Ex. Edwards Life Sciences model numbers Pedi catheter 040F4, 040HF4, 015F4, 015HF4 flow directed catheter 111F7, 114F7, 115F7, 123F6 are SAFE on 1.5 and 3T</td>
</tr>
</tbody>
</table>

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<tr>
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<th>3.0</th>
<th><strong>Comments Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Foley Catheters</td>
<td>Some models yes</td>
<td>Some models yes</td>
<td>Some brands are conditional for 1.5 and 3T Check the updated manufacturers FDA approved guidelines Ex. All Bard Temp Foleys are OK on 1.5 and 3T they should be ran straight down the center or the table no loops wires and disconnected from any temp monitoring devices</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>X-stop Vertebrae implant</td>
<td>Yes</td>
<td>Yes</td>
<td>May cause increased artifact</td>
</tr>
</tbody>
</table>
**Miscellaneous Surgical Objects safe on 1.5 and 3T**

Burr hole reservoir
Vicrly
Raney Clip
Pexy Clip
Neuro Hemo Clip
Weck Clip
Neuro Ligating Clip
Surgi Clip
Resolution Clip
Gastro Duodeno or Jejuno tube procedures
TIPPS Procedures
Retention disc
Retention ring
Screw Implant
Plate Implant
Omhya Reservoir

Surgicel
Surgiflo
DuraGen
Duraguard
Durepair
Burr hole cover
Prolene
PICC placement
Quinton
Hickman
Skin Staples
Catheters
Rickmans Reservoir
Zenith AAA Endovascular Graft
a.) Pregnant Health Care Employees:

All pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy. Although permitted to work in and around the MR environment, pregnant healthcare practitioners are requested not to remain within the MR scanner room during actual data acquisition.

b.) Pregnant Patients 1.5 and 3T

Pregnant patients may undergo MR scans at any stage of their pregnancy if the referring physician and the supervising radiologist determine that the risk-benefit ratio to the patient warrants that the study be performed.

1.) Pregnant patients may be allowed to have an MRI exam on a 3 Tesla magnet, if the area being imaged is a brain or extremity. Pelvis, abdomen or spine work should be on a 1.5

2.) The technologist is required to give the patient an information sheet about MRI’s and pregnancy. This should be documented.


3.) MR contrast agents should generally NOT be administered to pregnant patients, although exceptions may be made at the radiologist discretion.
c.) Possible Pregnant Patients and NON Contrast

Patients will not be given a urine hCG test unless getting contrast. In the event the patient is scheduled for a non-contrast exam and is unsure of pregnancy, the department will assume the patient is pregnant and follow those guidelines.

d.) Pregnant Companions

The companion will be given an information sheet on MRI and pregnancy. It is their choice to stay in the room during imaging. (Repeated occupational exposure to TVMF is not an issue).

e.) Pre procedure Pregnancy Testing

For Pre procedure Pregnancy Testing please follow the PATIENT RADIATION PROTECTION & SAFETY (INCLUDING PREGNANCY) policy located at:

https://ynhh.ellucid.com/documents/view/8470
Review of the literature shows no evidence to suggest that oral ingestion by an infant of the tiny amount of gadolinium contrast medium excreted into breast milk would cause toxic effects [8]. We believe, therefore, that the available data suggest that it is safe for the mother and infant to continue breast-feeding after receiving such an agent.

If the mother remains concerned about any potential ill effects, she should be given the opportunity to make an informed decision as to whether to continue or temporarily abstain from breast-feeding after receiving a gadolinium contrast medium. If the mother so desires, she may abstain from breast-feeding for 24 hours with active expression and discarding of breast milk from both breasts during that period. In anticipation of this, she may wish to use a breast pump to obtain milk before the contrast study to feed the infant during the 24-hour period following the examination.

References


IV Contrast Agents

No patient is to be administered MR contrast agents without orders from a licensed physician. Intravenous injection-qualified MR technologists may start and attend to peripheral intravenous lines if they have undergone the requisite training.

Injections may be performed through an appropriately sized IV line, which may be removed after the exam. The IV line will remain in place during the examination should IV drug therapy be required. This will apply to all patients.

For a patient with a history of contrast reactions please follow the premedication policy. If a patient experiences a contrast reaction the technologist should immediately contact the radiologist and nurse so that appropriate action may be taken. An incident report (R/L solution) is to be filled out via the intranet under Event Reporting. The FDA and the manufacturer of the contrast should also be contacted.

Oral Contrast

Please note for exams the patient may be asked to drink Volumen oral contrast. There are no significant contraindications for this agent and the agent can be given safely in
The ACR has categorized GBCA agents into groups of risk factors related to Nephrogenic System Fibrosis (NSF). Dotarem, Gadavist, Prohance and Multihance are Group II agents and Eovist is a Group III agent. Group I (highest risk) agents are not currently available/on formulary at YNHH. YNHH patient contrast screening policies has been tailored to the agents and the potential risk of adverse effect related to low eGFR values and risk of NSF when given standard weight based dosing. For a complete list of contrast agent groups and any additional info please visit the ACR website and read the current ACR Manual on Contrast Media https://www.acr.org/Quality-Safety/Resources/Contrast-Manual.

OUTPATIENTS

Contrast from Group II (such as Dotarem)

Outpatients receiving a GBCA from group II do not need to be screened for eGFR.

Contrast from Group III (Eovist)

Outpatients receiving a GBCA agent from groups III who answer YES to one or more of the contrast related questions on the MR Safety Screening Form (diabetic, hypertensive, and renal disease) will be screened for renal function. If an eGFR (or
Cr value to calculate eGFR) is on file < 6 weeks old this can be used otherwise a value will be obtained day of exam with Point of Care meter.

If valid eGFR is < 30 ml/min/1.73m² GBCA from group III will be administered only if all of the following conditions are met;

- Documented approval by the supervising radiologist by assigning/signing an appropriate protocol
- Informed consent obtained by supervising radiologist (or his/her designated resident/fellow) and signed by the patient. (Note: Informed consent and reason for exam should be documented in the report)

**INPATIENTS**

All inpatient requests for contrast-enhanced MRI exams require the ordering health professional to answer a series of ordering screen questions designed to identify patients who might be at risk for NSF. Risk factors include deteriorating renal function.

**Contrast from Group II (such as Dotarem)**

Inpatients receiving a GBCA from group II do not need to be screened for eGFR.

**Contrast from Group III (Eovist)**

A documented eGFR $\geq 30$ ml/min/1.73m² obtained within 48 hours prior GBCA administration is required.
If valid eGFR is < 30 ml/min/1.73m² Eovist will be administered only if all of the following conditions are met;

- Documented approval by the supervising radiologist by assigning and signing an appropriate protocol
- Informed consent obtained by supervising radiologist (or his/her designated resident/fellow) and signed by the patient. (Note: Informed consent and reason for exam should be documented in the report)

**Patients on Dialysis or with Acute Kidney Injury (AKI)**

If the patient is on dialysis or has known AKI, laboratory testing and calculation of eGFR is not useful or necessary (i.e., eGFR is not accurate in this setting).

**Contrast from Group II**

- Patients who are on dialysis or with AKI and receiving GBCA from group II do not need informed consent given that current data has not shown any unconfounded cases of NSF with these agents.
- Patients on dialysis should be scheduled for dialysis as close as possible following conclusion of the MRI exam. Hemodialysis is preferred over peritoneal dialysis whenever possible due presumed higher efficiency infiltration of GBCAs.

**Contrast from Group III (Eovist)**

- Patients who are on dialysis or with AKI and receiving GBCA from group III (Eovist) than informed consent should be obtained.

**Off Label Usage**
Radiologists commonly use contrast media for a clinical purpose not contained in the FDA labeling and thus commonly use contrast media off-label. Physicians have latitude in using gadolinium chelates off label as guided by clinical indication. This also includes pediatric usage in patients under the age of 2.

**Non-standard Contrast Dosing (ie- double dosing or multiple doses of contrast in 24 hours)**

1. Higher than standard weight based dosing

   This is occasionally needed for some group II agents is with some MR angiography, brain MRI, and cardiac MRI applications. In this setting, the Group II agent should be treated like a group III agent (where there is potential for NSF in at risk populations) as there is limited data on utilization of GBCA’s with non-standard dosing in this population. The rules of Group III agents as detailed above would apply in this setting.

2. Receiving more than one GBCA dose in 24 hours.

   Occasionally patients need more than one dose of GBCA within a 24-hour period. The NSF risk of more than one (standard) dose of a group II or III agents in patients is likely negligible in patients who have eGFR ≥ 30. If eGFR is < 30 (and patient is not on dialysis), than all non-stat or non-urgent studies should be delayed for 24 hours to allow for adequate clearance. If on dialysis, dialysis should be performed as soon as possible after the MRI. Therefore, there is no contraindication to undergoing an urgent or stat contrast enhanced MRI for a patient who has already been administered one dose of GBCA within a 24-hour period. Truly urgent or stat studies should not be delayed 24-
hours when eGFR <30 if benefits of exam outweigh NSF risks (radiologist-clinical team joint decision).

**Exceptions regarding Contrast Usage in Patients**

Exceptions to the above policies may be made at the discretion of the supervising radiologist, such as in the rare instance of an acute, life-threatening condition, and after consultation with the referring health care professional if consent can not be obtained from the patient or surrogate when needed. However, the rationale for the exception must be documented by the supervising radiologist.

**Documentation of Contrast Usage**

1. MRI technologists will record the specific GBCA and the dose administered to each patient by annotating the MRI exam and documenting dose in EPIC.
2. The radiologist reporting the exam will include the specific GBCA and dose in their report for every contrast-enhanced MRI procedure
**Gad Quick Reference Sheet**

**Who Needs eGFR testing?**

**OutPatients**

A patient receiving Eovist (group III agent) that answers yes to questions 19-23

eGFR Labs must be less than 6 weeks old and eGFR greater than 30
If eGFR less than 30 Radiologist needs to consent.

**InPatients:**

A patient receiving Eovist (group III agent)
eGFR must be less than 2 days old, and greater than 30
If eGFR is less than 30 Radiologist needs to consent.

**Patient getting higher than standard dose (ie. Double dosing) of group II/III agent (such as Dotarem or Eovist)**

Cardiac, Gamma Mets, Pelvis MRV Liver Combined

Policy for group III agents as above would apply in this setting as the patient may be at risk of NSF when eGFR under 30.

Information form link


**What do we do with prior Gadolinium "allergic-like" event?**

If a patient has had a prior reaction to a gadolinium agent but is approved to have a repeat scan with gadolinium (see pretreatment policy http://medicine.yale.edu/diagnosticradiology/patientcare/policies/ in contrast manual) effort should be made to determine which contrast agent the reaction occurred with. If unknown, Dotarem can be used. If with Dotarem, then Multihance should be used.

**Who needs a Hcg urine test?**

All females getting contrast who have started menses or are between ages 10-60

Adults (age 18+) can sign a waiver, peds (age 10-17) cannot sign waiver

For full policy and exceptions please see

http://radiology.yale.edu/patientcare/policies/pregnantpatientpolicy.asp
Yale New Haven Hospital Contrast Committee Contrast Reaction Policy

Staff follows the diagnostic radiology premedication policy that is located here:

For Physician Contrast coverage please follow the link below

https://ynhh.ellucid.com/documents/view/8472/35596/
All ED patients requiring an MRI will receive priority over an inpatient. If there are no available openings on the schedule, the Radiologist will look at the clinical needs of the inpatients scheduled and decide which patient to reschedule to accommodate the emergency.

There are multiple levels of “Stat” Ordered exams: *Life-Threatening* and *Urgent*:

A Stat patient that is considered *Life-Threatening* will be scheduled within 30 minutes of receipt of the order and the completed safety form. Scanning will begin within 2 hours.

A Stat patient that is considered *Urgent* will be scheduled within 30 minutes of receipt of the order and the completed safety form. Scanning will begin within 6 hours.

To schedule an ED MRI two important steps must be done before the patient will be given a scheduled time:

1. The order must be placed in EPIC
2. The inpatient screening process must be followed.

The next available time slot will be given to the ED requested patient and a call will be placed to the ED to alert them of the time. Patient transportation appointment will be scheduled in advance of scan time.
Yale Diagnostic Radiology
In-house MRI Requests:

October, 2012

- This document sets out the procedures/expectations for MRI requests
- MRI is available 24/7 although there are limited sub-specialized radiologists and technologists available after hours.
- Whilst radiologists and technologists are available after hours, it is important that the requests they respond to are appropriate and clinically indicated.
- MRI requests have therefore recently been divided into 4 categories as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Start time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life threatening</td>
<td>Imminent loss of life, limb or function</td>
<td>&lt;2hrs</td>
</tr>
<tr>
<td>Urgent</td>
<td>Delay in diagnosis could lead to inferior outcome</td>
<td>&lt;6hrs**</td>
</tr>
<tr>
<td>Routine</td>
<td></td>
<td>&lt;24hrs</td>
</tr>
<tr>
<td>Time Dependent</td>
<td>Specific timing necessity e.g. sedation, following a procedure etc.</td>
<td>As stipulated by requestor</td>
</tr>
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</table>

* *time from receipt of satisfactorily completed safety sheet.
** urgent requests received after 11:00 pm may be scheduled at 6:30 am.

- Life threatening MRI requests will be started within 2 hours of the safety sheet being received 24/7
- In collaboration with the orthopedic, neurology, general and neurosurgery departments, the following definition of life threatening indications have been agreed:

1) Mass Lesion with acute CNS deterioration
CT (or inadequate outside MRI) evidence of a mass lesion with significant neurologic deterioration over 24 hours where the condition is clinically expected to require either
   - further anatomic information (including additional MR sequences) in order to provide safe treatment
   - stereotaxy as a necessary part of providing safe operative care (CT-based stereotaxy being inadequate).

2) Acute Spinal Cord Injury or Deterioration
Acute injury or deterioration of spinal cord function including weakness and or sacral dysfunction due to a suspected mass lesion, discitis, osteomyelitis, cauda equina syndrome, or epidural abscess in the cervical/thoracic spine.
• Acute deterioration must have occurred over a short enough time such that rapid treatment is likely to result in restoration of function.

• A likely diagnosis of radiculopathy, sensory loss-only or fixed severe deficits of >48hrs duration are NOT deemed life threatening.

3) **Unstable Spine Correction**
For planning an unstable spine correction, particularly when an occult soft tissue component may compress neural elements upon deformity correction.

• Neurologic exam may be intact. e.g. bilateral jumped facets to rule out disc herniation.

4) **Stroke, if:**

   1) Diagnosis is uncertain.

   2) Time of onset is unclear.
      (MR perfusion/diffusion in attempt to define ischemic penumbra prior to intravenous lytics/catheter based intervention)

   3) Patient has a contrast allergy and needs angiography.

   4) Patient is of pediatric age group.

5) **Acute Aortic Dissection,** if there is a contraindication to iodinated contrast.

6) **Acute Appendicitis in Pregnancy,** if the general surgery attending consult deems the patient's condition to be life-threatening.
Selected acute stroke patients will undergo a stat MRI procedure to further assess cerebral ischemia and possible candidacy for thrombolysis or neuro-intervention. Indications include:

1. Patients with a suspected stroke syndrome (NIHSS ≥ 10)
2. Patients who present with an uncertain time of symptom onset
3. Patients with an uncertain diagnosis
4. Pediatric patients
5. Patients being considered for CTA but with a known contrast dye allergy
6. Patients suspected to be pregnant

1. The acute stroke team (resident/NP/attending) will enter the order (MRI - brain w and w/o contrast). It is the responsibility of the referring clinician to complete the on-line MRI safety sheet. Assistance will be provided by radiology to determine the presence of cochlear implants, orbital metal, pacemakers etc from previous imaging.

2. The acute stroke team (resident/NP/attending) will then contact the neuroradiology fellow on-call at 203-200-3181 to alert him/her of the acute stroke patient and MRI order.

3. The neuroradiology fellow will alert the MRI tech supervisor who will check for the completed safety sheet, schedule the case and notify the neuroradiology fellow to protocol the case.

4. Once the case is protocolled the MRI tech supervisor will call the acute stroke team at 203-688-7111 to accompany the patient to the MRI prep hold area. The acute stroke team will remain with the patient at MRI. The only exceptions to this would be if the patient is not found to have an acute stroke, and there are no hemodynamic or respiratory concerns, in which case the patient could be transported back to the ED/floor by standard transport.

- Hyperacute Stroke Protocol includes: Ax DWI, Ax FLAIR and Ax SWI sequences. Ax EPI perfusion will be added if the patient has separate IV access for gadolinium

Approved by Stroke Center and Dept. of Radiology: 4.10; 12.10; 05.11; 12.12; 03.13;
Process for overnight MR Cases:

1. The clinician places the order in EPIC, MR staff, Nurse or Clinician obtains and completes the MRI safety sheet via Encounters in EPIC.

2. The patient must be escorted to the MR Suite by an MD, PA, RN, for monitored cases.
Cleaning of the MRI suite to include the table, pads, coils, and the inside of the magnet bore is performed by the MRI staff to prevent the transmission of infections. Routine cleaning personnel are not allowed to enter the MRI suite because of the dangerous magnetic field strength that can cause potential catastrophic events harming personnel and the MRI system.

1. Gloves must always be worn when handling contaminated equipment and working with a cleaning disinfectant.

2. Cleaning of the table and pads is performed before and after each patient exam with a hospital approved disinfectant and all cleaning equipment must be MRI safe.

3. Periodic inspection of pads for fraying and tearing is done each month and replaced as necessary.

4. Patient contact inside the magnet bore of the MR unit can transmit infection so cleaning requires an MRI staff member to travel on the table inside the bore to sanitize and disinfect the tunnel walls.

5. MRI magnet room cleaning schedule listed below
   a. Ambulatory sites (North Haven, Guilford, Temple)- Monday
   b. YSC Smilow- Wednesday eve/ night
   c. YSC Howard Avenue- Friday eve
   d. SRC- Friday eve
If a patient has a latex allergy it should be documented in the patients chart. Latex allergic patient’s sensitivity may vary from a reaction only triggered by actual contact with a latex product to a severe reaction from airborne particles.

The MRI suites at YNHH Main Campus are latex free, accept for the Medrad endo-rectal coil. (All Invivo Products, O2 Tubing, suction catheters, gloves, Siemens Call ball are latex free)

For more information please see the Clinical Practice Manual Latex Precautions and Latex Allergies
MONITORING BY NURSING STAFF: CRITICAL CARE PATIENTS

This policy conforms fundamentally with the policy developed jointly by the Society of Critical Care Medicine and the American Association of Critical Care Nurses. Patients must be transported with the same level of monitoring required on the sending unit.

It is the responsibility of the health care team on the sending unit to assess the stability of the patient and assure personnel required for safe transportation.

- All ICU patients are to be transported to diagnostic procedures with a minimum of a RN and transporter
- All patients requiring cardiac monitoring are to be transported with a minimum of a RN and transporter
- Patients receiving blood or blood products must be accompanied by an RN
- Patients requiring restraints must be accompanied by an RN or PCA
- Any unstable patient who requires or is at risk for requiring acute intervention beyond the scope of nursing practice must be accompanied by an MD/LIP
- Non critical care personnel may provide transport for ICU patients deemed appropriate to travel without an RN or MD support. These patients must be transported without cardiac monitoring and a MD/LIP order is required indicating the patient may travel without cardiorespiratory monitoring
MONITORING BY MRI STAFF FOR THERMAL INJURY

Monitoring of patients is necessary in the MR scanner. The potential for thermal injury from possibly excessive radio frequency power deposition exists. Sedated, anesthetized and/or unconscious patients may not be able to express symptoms of such injury. Patients who require EKG monitoring and who are unconscious, sedated and/or anesthetized should be examined before scanning and after repositioning to ensure that MR safe EKG leads and any other electrically conductive material is not in contact with the patient or coiled so as to induce a current.
For workflow of staff members during a code procedure please follow this link: https://ynhh.ellucid.com/manuals/binder/916

The location of the Code Carts should be known by all MRI staff members. These will be checked daily by assigned MR staff for expired medications and functioning equipment.

1. It should be stressed that the magnetic field is **Always ON** As in any emergency; it is the responsibility of appropriately trained and knowledgeable MRI personnel to ensure the safety of all non MRI personnel as well as that of patients and family.

2. In the event of a code:

YNHH Main Campus:

- Outpatients call 155 for outpatients, and say: Code blue for an adult, Code white for a pediatric.
- Inpatients, 155
- North Haven Devine St call 911
- St Raphael Medical Campus call 155 and state location
- Temple Street Radiology 911
- Shoreline Medical Center call 911

Give the appropriate location:
3. The patient will be removed from the scan room immediately and the scan room door closed and locked MR staff members will get the code cart and start basic life support until the code team arrives.

4. Other MRI personnel can offer assistance, such as direct the code team to the right location.

5. The MRI physician should be notified that a code has been called.

6. While the code is in progress it is imperative that all scanner doors be closed and monitored by MRI personnel to prevent any accidental entry which could result in injury.

7. When the code team arrives they are responsible for the patient. MRI personnel will maintain the safety of all staff in the magnetic environment.

8. After the code it is the responsibility of the MRI staff to call the pharmacy so that the code cart can be restocked as soon as possible.

In a Quench or Emergency Situation

**What:**

RF Lindgren Door Release

**Where:**

Located on the inside and outside of every MRI door

**Why:**

The purpose of this door is to break the RF seal if needed.

**When:** In a quench situation, the pressure in the room could change and you might need to break the seal to get in or out of the room.

**How:** Press the red button and the seal become disengaged, twist it and the seal will reengage
**What:**
Emergency Hatch

**Where:**
All MRI rooms with doors that open IN have emergency hatches

**Why:**
To balance the pressure in a room with a open in door

**When:**
During a quench Situation if you are in the room the pressure in the room might be too great to pull the door open, hence the emergency hatch
1. Nursing care is provided to NP, WP and Fitkin MRI:

- Pediatric anesthesia patients admit, recover and discharge per Pedi-PACU Guidelines.
- Adult anesthesia patients admit, recover and discharge per PACU Guidelines.
- Admit, assess, monitor and recover adult moderate sedation patients, administer medications per orders of the physician in accordance with YNHH Clinical Administrative Policy C-11; Sedation/Analgesia for Diagnostic and Surgical Procedures Multi-Disciplinary Policy.
- Pacemaker patient admit and monitor per YNHH MRI Pacemaker policy
- Administer medication order from procedure protocol, such as urogram and enterography.

1.2 Taking care of patient with all kinds of special needs, monitor and manage patients with claustrophobia, pain, contrast agent reaction, extravasation, vaso vagal reaction and hyper/hypoglycemia. Document events and administer medication accordingly per physician order.

1.3 IV insertion, access/de-access central venous access device,
1.4 Assist ICU and ED nurses with their patients care in MRI setting, converting Smart iv pumps into MRI compatible iv pumps
1.5 Respond to requests of all patient care need from NP second floor departments; Nuclear Medicine, PET, CT, US, X-ray and reception areas.

2. Ensure MRI safety by helping MRI staff properly screen patients, family members and medical staff entering MRI scanner

3. Check all emergency equipment and documented via Intranet daily including weekends.

4. Perform Glucometer QC daily.
5. Physically inspect recovery area/induction room to ensure appropriate tubing, 02 flow meter attached, suction set-ups are all ready to use. Pediatric emergency supplies stocked-up and replaced when used.

6. Check Pyxis for any discrepancies, waste medication per YNHH pharmacy policy.

7. Coordinate with schedulers following guidelines in scheduling patients for adult moderate sedation, adult anesthesia cases, pacemaker patients and Pedi anesthesia add on cases. Ensure all appropriate papers scanned in Epic for outpatients and orders placed accordingly in Epic for inpatients.
   - MD requisition stating requiring moderate sedation.
   - Pre procedure phone call order

8. Perform and document pre procedure phone calls to out-patient adult conscious sedation cases before the appointment, screen and evaluate medical history of in and out patients scheduled for moderate sedation.

9. Perform and document patient follow-up phone calls to pediatric anesthesia, adult anesthesia, and conscious sedation cases the next business day.

10. Provide assistance to MRI staff to ensure efficient patient flow.

11. Review Epic for RN cases throughout the day. Check for any schedule changes, add on, and cancellations.

12. For Treprostinil protocols please follow The Treprostinil (Remodulin) Continuous Infusion policy. On page 7 is MRI related information.

https://ynhh.ellucid.com/documents/view/7474

Tehsiang Lam  
Assistant Patient Services Manager  

Maureen Perachio  
MRI Manager
In the event of a ferrous object in the MR scan room, an evaluation of the situation must be done immediately.

**If the object is inside the patient or in the imaging field:**

1. Stop the scan and speak with the patient. If the object is identified, and can be removed safely (i.e. a bobby pin) do so with caution.

2. If the object is unidentified or is unsafe for the MRI (i.e. undocumented aneurysm clip) **SLOWLY** move the patient out of the magnet and slide them on to a stretcher. The patient should not sit up, and all movements should be slow until outside of the MRI room.

**If the object is pinning a patient or staff member:**

1a. If the person is unconscious, bleeding profusely, at risk of losing a limb or extremity, or in severe pain, you must manually quench the magnet to bring down the field in order to release the object and the person.

1b. If the person is responsive and able to tell you they feel OK, you may be able to leave them in the position until a service engineer can respond and ramp the magnet down slowly to avoid a full quench. If you choose the latter, and the person then loses consciousness, or their condition worsens, immediately quench the magnet manually.

2. Once the person is released, get them out of the room and obtain medical help, code procedure pg 79. The MRI manager, safety officer and medical director should be informed immediately. The event should be reported on RL solutions via the intranet and the [www.fda.gov/medwatch](http://www.fda.gov/medwatch) website.

**If the object is solitary and not creating a life threatening situation:**

A service engineer can ramp the magnet down slowly to avoid a quench

Contrast Adverse Reaction Contact Info

[www.fda.gov/medwatch](http://www.fda.gov/medwatch) (800 FDA 1088)
Purpose: To outline the role and responsibilities required of the MRI safety officer in

Definitions: Responsibilities of the MR Safety Officer include, ensuring that MR safe
practice guidelines are established, implemented and enforced according to
ACR Accreditation Requirements and MR Safe Practice 2013 at all sites.

MR Safety Officer

- Coordinates with the development, implementation of the MRI Safety policies and procedures in compliance with the ACR MRI requirements and MRI Safe Practice 2013.

- Liaison as a consultant to the MR team regarding safety contraindications to ensure the MR unit is safe for patients, visitors, members of the public and staff.

- Coordinates with the MR medical director on revisions of MR safety policies and provides training.

- Develop, implement and enforce policies and procedures consistent with ACR’s Position Statement on Quality Control and Improvement, Safety, Infection control and Patient Education.

- Responsible for and submission of all materials, including clinical and phantom images, as appropriate, quality control data and such other information as required by the ACR MRI Accreditation Program.

- Responsible for reporting any MR safety incidents or "near misses" that occur in the MRI environment to the Manager, Medical Director and to the FDA via the Maude database.

- Provides Level 1 personnel training for ancillary departments to ensure all visitors are compliant with the MR Safety Manual.

- Active Participant in YNHH System MRI Safety Committee.
Purpose: To outline the role and responsibilities required of the medical director in

Definitions: MR medical director whose responsibilities will include ensuring that MR safe practice guidelines are established and maintained as current and appropriate for the site.

MR Director
- Responsible for the development and implementation of MR Safety policies and procedures in compliance with the most recent ACR White Paper on Magnetic Resonance (MR) Safety.
- Ensures that a physician is present and immediately available when contrast is administered to patients.
- Develop, implement and enforce policies and procedures consistent with ACR’s Position Statement on Quality Control and Improvement, Safety, Infection control, Patient and Staff Education.
- Be responsible for assuring compliance with the recommendations of the medical physicist.
- Be responsible for the oversight and submission of all materials, including clinical and phantom images, as appropriate, quality control data and such other information as required by the MRI Accreditation Program.
- Be responsible for notifying the ACR within 15 days of any changes in imaging equipment (units) or changes in the use of equipment that could affect clinical or phantom images.
- Takes a lead role in YNHH System MRI Safety Committee
- Provides personnel training for ancillary departments to ensure all staff are compliant with the MRI Safety Manual
Due to the presence of a powerful magnetic field, the MRI environment can be dangerous for patients and staff. Precautions must be taken to assure that ferromagnetic materials/devices do not get close enough to the MRI scanner to pose a danger.

Any loose metallic objects or devices will be placed in a locker or some designated secure space in Zone I or II.

Interrogation with a ferromagnetic detector is an important part of the screening process for all individuals entering the MRI environment.

All non-MR personnel, patients, visitors, ancillary facility members and anyone else MR staff deem necessary, need to be evaluated by thorough “wanding” with ferromagnetic detector in Zone II before given permission to enter Zone III or Zone IV. This group includes but is not limited to nurses and PCA staff accompanying patients, environmental services, cardiology and anesthesia staff”.

Employees who regularly work in MR do not need to be wanded. This group includes, but is not limited, to Radiologists, MR nursing, MR technologists and MR technical assistants.

All MR staff members can wand visitors, companions and facility staff members after appropriate training.

**Access to the MRI suite will be denied to any person who is not in compliance**
MRI Imaging with Ear Plugs:

The noise generated by scanning may reach a level in the scan room and in the bore of the magnet that can result in temporary (and occasionally) permanent hearing loss.

Properly inserted earplugs will limit the level of the noise that reached the inner ear.

Any patient who undergoes an MRI, as well as anyone in Zone 4 during a scan, **MUST** wear earplugs.

The earplugs will be inserted by the MRI staff. The earplugs are Latex Free and have an acceptable NNR rating.

In pediatric patients, and patients with unusual shaped ear canals, the earplugs may not fit properly to limit the noise level. In these instances, MRI staff will use another form of hearing protection such as headphones or ear muffs that will hold the earplugs in place and further dampen the noise level.

If a patient has their own custom ear plugs, designed for their ear canals it is acceptable to use after they have been wanded for metal. MR staff need to check they are inserted.
Dotarem (Guebert)

- Fill out form located here: https://ynhh.ellucid.com/documents/view/21771

Eovist (Bayer)

- 1-888-84bayer.

- Fill out form appendix B
I. **Purpose**
To standardize dosing of gadolinium-based contrast agents (GBCAs) in adult and pediatric patients to allow radiology technicians to administer GBCA when ordered by a provider. This protocol will be reviewed annually by the Yale New Haven Health System (YNHHS) Formulary Integration Radiology Subcommittee, local site Pharmacy and Therapeutics Committees and YNHHS Formulary Integration Committee.

II. **Background**
Gadolinium-based contrast agents (GBCAs) are intravenous drugs used in diagnostic imaging procedures to enhance the quality of magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA).

III. **Patient Population**
Adult and pediatric patients undergoing MRI procedures.

IV. **Procedure**
Provider shall order MRI procedure. Radiologist receiving procedure order will protocol the MRI. Once the procedure is protocoled by the Radiologist, the radiology technician will follow the Dosing Protocol outlined in the table below. All dosing will be in mL/kg.
Patients age 2 years and older undergoing MRI procedures will be administered gadolinium-based contrast (Dotarem®) according to the above dosing chart. Dotarem® dosing for patients weighing greater than 157 kg will be discussed with Attending Radiologist. Gadolinium contrast is administered at a rate of 1-2 mL/second, and line is flushed with normal saline after administration.

Pediatrics < 2 years old
Pediatric patients under the age of 2 years requiring gadolinium contrast:

**Weight 4 kg - 10 kg:** 0.025mM/kg of gadolinium containing contrast (Dotarem®) will be administered. **1cc of dotarem 4kg-9kg discussed via email with JP 8/8/17 9am**

**Weight < 4 kg:**
**0.5cc of dotarem**
For any pediatric patient weighing less than 4 kgs (10 lbs), approval must be obtained by Attending Radiologist. **Radiologist protocol counts as approval discussed with JP via email 8/8/17 9am**
REFERENCES:

1. Dotarem® (gadoterate meglumine) [prescribing information]. Bloomington, IN: Guerbet LLC; July 2016
American College of Radiology Committee on Drugs and Contrast Media. Manual on Contrast Media

Appendix B

Fax completed form to 973-709-2185
Spontaneous Adverse Event Report Form short version

<table>
<thead>
<tr>
<th>Sales Consultant:</th>
<th>Date informed of Adverse Event:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voicemail #:</td>
<td></td>
</tr>
<tr>
<td>Local case ID:</td>
<td>Date of receipt of information:</td>
</tr>
<tr>
<td></td>
<td>Initial report ☐ Follow-up report ☐</td>
</tr>
</tbody>
</table>

GIVE INFORMATION ON THE PATIENT WHO HAS EXPERIENCED THE ADVERSE EVENT.

<table>
<thead>
<tr>
<th>Initials</th>
<th>Gender</th>
<th>Age [years]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>male ☐</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FEMALE ☐</td>
<td></td>
</tr>
</tbody>
</table>

WHICH ADVERSE EVENT(S) HAS THE PATIENT EXPERIENCED?

<table>
<thead>
<tr>
<th>1.</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

Was the patient hospitalized? Yes ☐ No ☐ Did the patient die? Yes ☐ No ☐

DESCRIBE DETAILS OF THE ADVERSE EVENT(S).

For contrast agents, please describe the procedure. (e.g. MRI, CT)
**Which Bayer drug(s) were involved?**

<table>
<thead>
<tr>
<th>TRADE NAME/ Generic Name</th>
<th>Formulation</th>
<th>Total daily dose</th>
<th>Dose regime</th>
<th>Route of application</th>
<th>Lot number</th>
<th>Date from-to or duration</th>
<th>Indication for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: Testobay/Testofloxacin</td>
<td>Tablet</td>
<td>200 mg</td>
<td>2x100 mg</td>
<td>oral</td>
<td>678 9045</td>
<td>12 May 04</td>
<td>urinary tract infection</td>
</tr>
</tbody>
</table>

**Who has reported the Adverse Event(s)?**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Phone/Fax/E-Mail</th>
<th>Physician</th>
<th>Consumer</th>
<th>Other</th>
<th>specify:</th>
</tr>
</thead>
</table>

A Product Technical Complaint has been forwarded to Technical Complaints department □ Yes □ No

☐ If more detailed information are available fill in the full version of the spontaneous report form, please.

**Appendix C**

**MRI Safety Websites**

http://www.mrisafety.com
Includes “the List” updated yearly list of MR tested devices

http://www.imrser.org
MR Safety Papers, guidelines and information

http://cmemeded.com/mrisafety
MR Safety Courses

ACR website section on MRI Safety

http://enterprise.astm.org
ASTM standards for testing
Appendix D