INFECTIOUS OR REGULATED MEDICAL WASTE

Each MR facility must abide by federal, state and local regulations regarding the collection and disposal of infectious waste or regulated medical waste (RMW).

RMW must be collected, transported, stored, packed, labeled, treated and disposed in a manner that minimizes exposure to team members, patients, the public and the environment to disease-causing agents.

DEVICE AND OBJECT SCREENING

Whenever practical, ferrous objects, including those brought by patients, visitors, engineers, etc., should be restricted from entering Zone III and prohibited in Zone IV. Each facility should have ready access to a strong handheld magnet ≥ 1000 Gauss (Figure 7) and/or a handheld ferromagnetic detection device (Figure 8). This will afford the technologists the means to test external and even some superficial internal devices or implants for the presence of grossly ferromagnetic attractive forces.

Hand-Held Magnets ≠ Ferromagnetic Detectors

At many MR facilities, high strength handheld magnets (like the one shown in Figure 7) are used to test objects for their magnetic field hazards. However, these magnets are ***not*** comparable to ferromagnetic detectors. While they can help MR personnel differentiate ferrous from non-ferrous objects, their extraordinary strength introduces concerns that limit their use:

1. The handheld magnetic must NEVER be taken into Zone IV as the interaction between it and the MR scanner could result in serious injury or death to anyone in the vicinity.
2. Their magnetic field drops off sharply hence they are useful for distinguishing ferromagnetic materials only at or near the surface of an object. Ferromagnetic components below the surface may go undetected.
3. Because shallow ferromagnetic material within the body of a patient could be moved by these very strong handheld magnets, they are *poorly* suited for patient screening.
4. The strong magnetic field could adversely affect the proper operation of cardiac or other pacemakers and other electrically or magnetically or mechanically activated devices on or in patients. Accordingly, the magnet should not be brought into the vicinity of patients with cardiac or other pacemakers, automated external defibrillators (AEDs), hearing aids, cochlear implants, or other externally or internally affixed or implanted magnetically or mechanically activated devices.
5. Some medical equipment designed for use in Zone IV may have maximum allowable static and dynamic magnetic field values. The hand-held magnet should not be used to test or brought into the vicinity of the equipment as it could impair the device.
6. The handheld magnet should be kept away from all magnetic media such as computers, computer monitors, hard disks, portable magnetic media (including floppy disks and zip disks), and magnetic stripes on credit cards, bank cards, and some airline tickets.

Figure 7. Hand-held test magnet (available from Newmatic Medical, Caledonia, MI). ***NOT MR SAFE.***

Figure 8. Hand-held ferromagnetic detector Safescan® Target Scanner (available from Mednovus™, Palos Verdes, CA). ***NOT MR SAFE.***

The Safescan Target Scanner (Figure 8) is not a substitute for conscientious medical screening but rather a second line of defense for maximizing patient and team member MR safety after the patient has been medically cleared to enter Zone IV.

To use the device:

1. Turn on the scanner and allow it to self-calibrate. An audio sound at low frequency will be followed by a higher frequency tone – and then a low-frequency continuously sounds. Furthermore, the blinking red alarm lights will turn off when the device is ready for use.
2. Position it as closely as possible to the person or object being screened.
3. To optimize its sensitivity, move it briskly in small circles while carefully screening the person or object.
4. Turn the device off after every use.

Ferromagnetic detection systems are not intended to replace thorough screening methods by the MR technologist. Because they are intended as an *adjunct* to comprehensive screening of persons and devices approaching Zone IV, they should be used after a patient has been medically cleared for the MR procedure.

1. The Safescan Target Scanner (Figure 8) must NEVER be taken into Zone IV as the interaction between it and the MR scanner could result in serious injury or death to anyone in the vicinity.
2. While screening of the patient's head area is advised, ever rub the scanner directly against the patient's eye/eyelid.
3. While screening of the patient's chest area is advised (to confirm the absence of a pacemaker or defibrillator), do no rest the Target Scanner on the chest of an individual for prolonged periods of time

MR Safety Labeling

Released in 2005 by the MR Task Group of the ASTM International Committee F04 on Medical and Surgical Materials and Devices, Standard ASTM F2503 defined the MR labeling terms and associated icons that are currently recognized by FDA. There are three categories for objects (including implants) that may be permitted into the MR environment. These categories are based upon one, two, or all three of the primary hazards in MR: the static magnetic field (B_o), the RF fields (B_1), and the gradient magnetic fields (dB/dt).

The MR technologist should never assume the MR safety of a device if it is not clearly labeled. All unknown external objects or devices considered for entry into Zone III or IV must be tested with the strong handheld magnet or ferromagnetic detector. The results of such testing – as well as the test date, time, tester name, and method – should be documented in writing. **If a device has not been tested or if its MR safety status is unknown, it must *not* be taken into to Zone III or IV.**

All devices, including portable metallic or partially metallic objects, brought into Zones III and IV must be properly identified and labeled using the current FDA labeling criteria developed by the American Society for Testing and Materials (ASTM).

MR Safe

An "MR Safe" item poses no known hazards in all MR imaging environments. With this terminology, **MR safe items are *non-conducting, non-metallic, and non-magnetic*** items, such as a plastic Petri dish or an all plastic cataract-replacement lens. An item may be determined to be MR safe by providing a scientifically based rationale rather than test data.

MR Safe

Only those objects that eliminate the primary MR hazards (i.e., B_o, RF, and dB/dt) are deemed "MR Safe." These objects are completely non-magnetic, non-electrically conductive, and non-RF reactive.

A square green "MR Safe" label should be affixed to MR safe objects.

MR Conditional

An "MR Conditional" item has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the MR environment include static magnetic field strength, spatial gradient (dB/dx), time rate of change of the magnetic field (dB/dt), 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.

MR Conditional

"MR Conditional" objects may contain magnetic, electrically conductive, or RF-reactive components. However, they may be safe in proximity to the MR scanner – provided the conditions for safe operation or use are defined and observed for the device itself and the MR scanner.

Objects with an MR conditional rating should be labeled with a triangular yellow "MR Conditional" label. These objects, however, should be taken into Zone IV *only if* the MR technologist has confirmed that the conditions defined for the object are indeed met in the MR environment for that particular scanner.

MR conditional items labeling includes results of testing sufficient to characterize the behavior of the item in the MR environment. Such testing for items that may be placed in the MR environment should address magnetically induced displacement force and torque as well as RF heating. Other possible safety issues include but are not limited to thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, the safe functioning of the item, and the safe operation of the MR system. Any parameter that affects the safety of the item should be listed and any condition that is known to produce an unsafe condition must be described (Woods 2007).

MR Unsafe

An "MR Unsafe" item poses hazards in all MR environments. MR unsafe items include magnetic items such as a pair of ferromagnetic scissors.

MR Unsafe

Objects that are significantly ferromagnetic and pose a direct threat to persons and/or equipment in the scanner room are deemed "MR Unsafe."

Such objects should be clearly labeled with a round red "MR Unsafe" label.

MR Conditional Devices in Zones III and IV

When an MR Conditional device or piece of equipment is exposed to conditions that exceed its conditional rating threshold, its normal or safe operation may be disrupted.

To prevent device or equipment failure, the facility should identify the allowable conditions for all MR Conditional devices or equipment that may be brought into Zones III and IV. Such equipment includes (but is not limited to) patient monitoring systems, ventilators, medication pumps, anesthesia machines, monitoring devices, and biopsy equipment.

As shown in Figure 9, the location of critical isogauss line(s) should be identified for MR Conditional devices and equipment and marked on the floor and/or walls of Zone IV to facilitate and assure safe operation of the device or equipment. In fact, facilities should consider providing physical indications of critical gauss lines in the construction of any new magnet room (Figure 10).

All devices or equipment taken into Zone III or IV must be clearly labeled either **MR Safe** or **MR Conditional**. Appropriate descriptive text that specifies the condition(s) should be included on MR Conditional labels.

Fire Extinguishers

All fire extinguishers potentially used in the MR Department must be MR Conditional and must be readily available to MR personnel for use in Zones III and IV.

Oxygen Tanks, Gauges, and Carts

Only MR Safe or MR Conditional oxygen tanks, gauges, and carts are permitted in Zones III and IV.

Patient Monitoring Systems

Physiological monitoring of patients during MR procedures is sometime necessary and methods must be chosen carefully. Because electrical current is generated in cables or leads during the MR procedure, the use of standard electrodes, leads, and cables is prohibited as they may cause excessive heating that could burn the patient. Furthermore, monitors that contain microprocessors or other similar components may leak RF, producing electromagnetic interference that can substantially alter MR images.

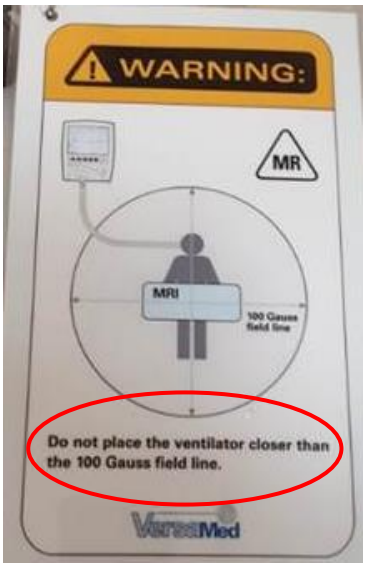
Only MR Safe or MR Conditional monitoring systems can be used for MR procedures. Such equipment must be clearly labeled as it normally resides within Zones III and IV.

MR technologists must undergo competency training before using MR Safe or MR Conditional monitoring systems. (Radiology Administration is responsible for providing this training and maintaining the related documentation.)

Visual monitoring or record keeping of the physiologic display is the responsibility of the patient's nurse or designated healthcare provider.

Sedated, anesthetized, or unconscious patients may not be able to express discomfort or symptoms of injury.

If the patient is sedated, anesthetized, unconscious, or unresponsive, all attached leads that will be in or partly in the volume undergoing RF irradiation should be covered with a cold compress or ice pack wrapped in a dry towel at the attachment site of the lead for the duration of the MR exam.



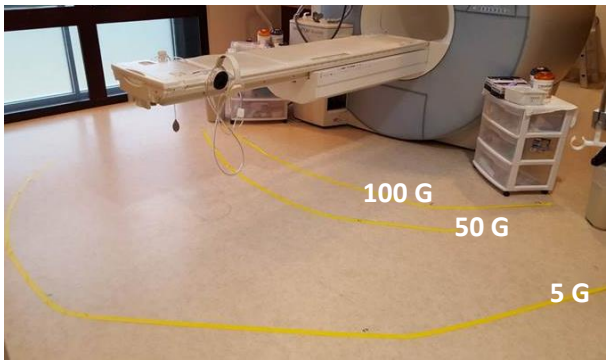


Figure 9. Floor marked with tape 5, 50, and 100 Gauss lines (measured by physicist) to ensure safe use of MR Conditional Versamed ventilator. Ventilator must not be placed closer than 100 G line. Pole tethered to wall to maintain safe distance from scanner. (Tressler 2016.)

Continuous Infusion Pumps

Continuous infusion of medication during an MR procedure can be achieved only through the use of MR Safe or MR Conditional infusion pumps. Such infusion pumps must be clearly labeled and those belonging to the MR Department will normally reside within the MR Department ONLY.

Figure 10. Examples of demarcation of 100 G lines in newly constructed MR scanner rooms. (White 2017).

1. Use only electrically conductive devices, equipment, accessories (e.g., ECG leads, electrodes, etc.), and materials that have been thoroughly tested and determined to be MR Safe or MR Conditions.
2. Whenever possible, place physiological monitoring sensors (e.g., pulse/oximeter) outside the scanning area as well as away from RF coils.
3. Electrical devices that are not functioning properly during the scan should be removed immediately.

MR staff must undergo competency training before using the infusion pumps. (Radiology Administration is responsible for providing this training and maintaining the related documentation.)