

How to Determine the MRI Safety and Compatibility of an Implant or a Medical Device?

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Purpose

The purpose of this exhibit is to give an overview on how to determine the MRI safety and compatibility of an implant or a medical device.

MR Safety Considerations

Magnetic Resonance Imaging Tips for Scanning Patients with Implants

BEFORE

- Follow your site's process for screening the patient
- Identify the manufacturer and model of any implanted devices
- Locate the MRI safety information in the device manufacturer's labeling

Look for one of these icons:

MR

MR Safe. Patients with MR Safe devices have no scanning restrictions.

MR

MR Conditional. For patients with MR Conditional devices, implant conditions should be matched with the MR system information.

- Consult your MR system manual for MR system information
- Ensure that the MR system meets all conditions provided in the MR Conditional labeling
- If conditions are not met, the patient should not be scanned

MR

MR Unsafe. Patients with MR Unsafe devices should not be scanned. Assume any unidentified implant is MR Unsafe.

- Document device information in the medical record
- Consult a physician for any risk/benefit decisions

For MR Conditional devices:

- Follow all pre-scan conditions, such as special programming modes

DURING

- For MR Conditional devices, follow all scan conditions such as specific absorption rate (SAR) restrictions or patient positioning instructions
- Monitor the patient at all times

AFTER

- Assess the patient for discomfort or injuries
- Follow any post-scan conditions, such as device checks or programming

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Fig. 1 MRI safety considerations when scanning patients with implants or medical devices includes the knowledge of MRI safety labeling for implants, medical devices and other equipment: MRI Safety labels indicate MR Safe devices by a green and white icon. MR safe devices pose no known hazards in all MR environments. MR conditional devices do not pose known hazards in specific conditions of use and are labeled with "MR" inside of a yellow triangle. MR unsafe devices are unsafe in all MR environments and are labeled with a "MR" inside of a red circle with a bar through it. More details about MR Safety labeling is shown in Figure 2. Before scanning a patient with an implant or device the device information needs to be documented in the medical record and a consultation with a physician is necessary for any risk/benefit decisions. It should also be considered that MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device even if it is considered MR safe of MR conditional. Even non-ferromagnetic implants can cause heating due to eddy currents that propagate in metals exposed to oscillating magnetic fields. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

REFERENCES

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MR Safety Labeling

Understanding MRI Safety Labeling

The MR environment has unique safety hazards for patients with implants, external devices and accessory medical devices. Implants, medical devices and other equipment used in or near the MR environment should be labeled as **MR Unsafe**, **MR Conditional**, or **MR Safe**.

MR Unsafe items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.

MR Conditional items may safely enter the MRI scanner room only under the very specific conditions provided in the labeling. Patients should not be scanned unless the device can be positively identified as MR Conditional AND the conditions for safe use are met.

The conditions for safe use will be different based on the intended use of the device.

For items intended to enter the bore of the MRI system, the MRI Safety labeling should be matched with the MRI system for:

- Static field strength
- Maximum spatial field gradient
- dB/dt limitations (usually only applicable to active implants)
- SAR limits
- Any other conditions needed for safe use of the device, for example restrictions on the types of coils that may be used

When present, information about expected temperature rise and artifact extent may inform the risk/benefit decision of whether or not a patient should undergo an MRI examination. Expected temperature rise and artifact extent information are not conditions that must be met.

Items NOT intended to enter the bore of the MRI system usually have gauss line positioning restrictions or requirements to tether or affix the device to an unmovable part of the room.

MR Safe items pose no safety hazards in the MR environment. They may be placed anywhere in the MR environment. Patients with MR Safe devices have no scanning restrictions.

Fig. 2 Medical devices can be categorized into three categories: MR Safe, MR Conditional and MR Unsafe. MR Safe items pose no known hazards in all MR imaging environments. MR Conditional items have been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use: Field conditions including static magnetic field strength, spatial gradient, time rate of change of the magnetic field (dB/dt), RF fields, and specific absorption rate (SAR). MR Unsafe items pose hazards in all MR environments. Many implants, materials, devices, and objects have been tested with regard to MR procedures and the MR environment. Frank Shellock and his team have published an extensive online list to determine information about specific miscellaneous implants and devices assessed at different field strengths: http://www.mrsafety.com/TheList_search.asp

A proper preparation of each patient before an MRI exam is necessary to avoid burns even for patients without implants. The Guidelines to Prevent Excessive Heating and Burns Associated with MR Procedures recommend to:

- remove metallic objects contacting the patient's skin,
- use insulation material of 1 cm or thicker to prevent skin-to-skin contact and the formation of closed-loops from touching body parts,
- allow only devices, equipment, accessories (e.g., ECG leads, electrodes), and materials that have been thoroughly tested and determined to be MRI safe.

REFERENCES

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Decision Matrix for MR Safety Screening

A detailed MRI safety screening of implants and devices can prevent injuries. A detailed decision matrix with a step-by-step analysis to determine MR safety is displayed in Fig. 3.

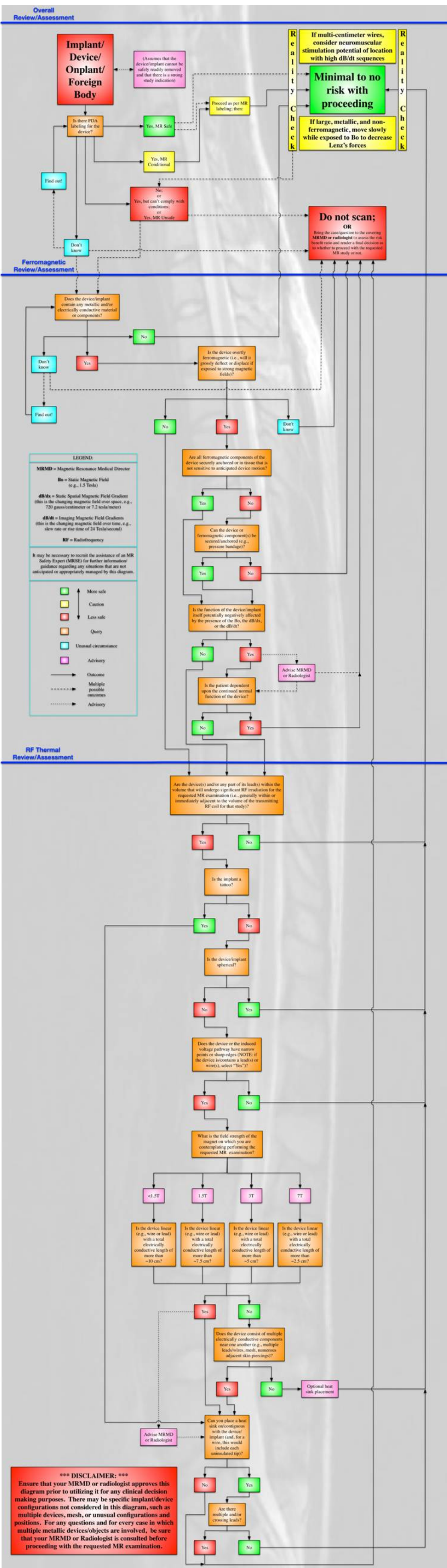


Fig. 3 Dr. Emanuel Kanal has developed a detailed decision matrix to determine the MR safety for implants and devices that are not listed in the literature or in on-line resources. This decision matrix includes a step-by-step analysis to determine the MR safety.

The decision to determine the MR safety of an implant or device is the responsibility of the Magnetic Resonance Medical Director (MRMD) who is a physician and legally liable for safety in the MRI environment and the safe execution of the magnetic resonance examination. The MRMD will establish MR safety policies and guidelines of the site and will oversee all decisions regarding MR site access and site access restriction decisions. An Magnetic Resonance Safety Officer (MRSO) will advise the MRMD and is charged with executing the MR safety practices as defined for the site by the MRMD. Additionally, a Magnetic Resonance Safety Expert (MRSE) can serve as a resource for the MRMD and MRSO in situations where the MRMD or MRSO need assistance with MR safety questions. The American Board of MR Safety offers Magnetic Resonance Safety Certified™ (MRSC™) credentials for professionals charged with overseeing the safety of clinical and/or research magnetic resonance sites who demonstrate that they satisfy ABMRS requirements for such certification and qualification.

All personnel working in the MR environment need to be trained with a comprehensive MRI safety course. For new employees who will work in the MR environment this course should be included in the employee orientation program and be repeated annually. The MRI safety training should include the presentation of technical and medical background of MRI safety. Hands-on demonstrations of missile effects of ferromagnetic objects can help to better understand and experience the dangers in an MRI suite. Detailed screening procedures of patients with a questionnaire for ferromagnetic objects, implants, devices, body piercing, allergies to MRI contrast agents, kidney disease, pregnancy, breast feeding and also the screening of patients that have a history injuries by a metallic foreign body such as bullets, shrapnel, or other type of metallic fragments help to avoid severe accidents in an MRI suite. An important topic to discuss in an MRI safety course are severe burn wounds that were experienced by patients when limbs or other body parts of the patients were in direct contact with transmit RF coils of the MR systems or when skin-to-skin contact points were responsible for these injuries. The safety course needs to warn about high acoustic noise levels of the gradient system during an MRI scan and the potential noise reduction with earplugs and headphones to avoid potential hearing damage. Videos from quenching magnets can help to understand how powerful a sudden loss of the superconductivity of the magnet might be and emergency procedures during a quench should be discussed. It is important that medical personal entering the MRI scanner room to evaluate the patient, administer medications or interventions need to be trained in emergency procedures in an MRI suite. Healthcare professionals need to know which objects can be brought into the different MRI zones in order to prevent fatal injuries and medical equipment failure and how to remove a patient from the MRI magnet room to resuscitate or treat the patient in emergency cases.

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Conclusion

Regular MRI safety training for staff, comprehensive screening forms and thorough patient evaluations, patient interviews before the exam, proper patient positioning, and constant visual and audio monitoring during the exam will improve the safety of patients and staff.

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