

Chapter 2

Magnetic Resonance Safety

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Abstract

The safe operation of both clinical and pre-clinical MR systems is critical. There are a wide range of potential MR hazards. This chapter covers both the theoretical background to issues of MR safety and the guidance on more practical issues. The main sources of information on national and international MR safety guidance and advice are discussed, as well as local safety policies which are required for all MR installations. The projectile effect and other MR safety issues due to static and time-varying magnetic fields are considered, such as peripheral nerve stimulation, tissue heating and RF burns. Finally, contrast agents, auditory effects and medical implants and devices are discussed, as well as the less thought about issue of biological safety of clinical and pre-clinical MR systems.

Key words: MR safety, MRI safety, MR safe, projectile effect, quench, SAR.

1. Legislation, Guidance and Best Practice

Legislation, guidance and best practice are all continually evolving within the field of MR safety, and there are often multiple sets of documents applicable within a single country (**Table 2.1**). This section cannot, therefore, be an exhaustive guide, and the reader is advised to consult local and national experts for the latest information.

Good sources of up-to-date information include the International Society of Magnetic Resonance in Medicine and European Society of Magnetic Resonance in Medicine and Biology web sites (www.ismrm.org/mr_sites.htm#Spotlight and www.esmrmb.org) and www.mrisafety.com maintained by Professor Sherlock. Regular MR safety updates are given at the ISMRM and ESMRMB annual conferences amongst others.

Table 2.1
Main hazards of MR imaging

MRI hazards	
Static magnetic field	<ul style="list-style-type: none"> • Projectiles • Medical devices • Rotational forces • Lenz effect • Cryogenic liquids (magnet quenches)
Field gradients	<ul style="list-style-type: none"> • Peripheral nerve and muscle stimulation • Acoustic noise
Radiofrequency pulses	<ul style="list-style-type: none"> • Thermal heating • Contact burns • Induced current burns
Contrast agents	<ul style="list-style-type: none"> • Gadolinium side effects
Biological hazards	<ul style="list-style-type: none"> • Transmission of bacteria and viruses

National and international radiology organisations also provide guidelines and advice. At the time of writing, current international advice on exposure limits for patients and volunteers is given in the ICNIRP (International Commission on Non-Ionizing Radiation Protection) publications on MR procedures (1–5), as well as the IEC (International Electrotechnical Commission) International Standard 60601-2-33 Edition 2.1, published in 2006 (6).

At a national level, the UK Health Protection Agency’s (HPA) published advice on “Protection of Patients and Volunteers Undergoing MRI Procedures” in 2008 (7), for example, is based on ICNIRP’s recommendations and focuses on their application in the UK. MHRA (Medicines and Healthcare products Regulatory Agency) has also produced guidelines based on UK and international MR safety advice (8). In the USA, the American College of Radiology produces guidance documents, the most recent one in 2007 (9). In addition, the FDA (Food and Drug Administration) publication entitled “Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices” contains advice on exposure limits (10).

Within the European Union EU Directive 2004/40/EC (11) contains a set of limits and action values affecting different frequencies of electromagnetic fields which initially stated that all EU member states should bring into force laws and regulations to comply with the directive by 30 April 2008. However, in an amendment to the directive (Directive 2008/46/EC (12)) this date was changed to 30 April 2012.

2. Local Safety Policies

All MR installations must have detailed local safety policies which are regularly reviewed and updated to reflect changes in working practices, updated safety guidance and national legislation. The requirements may differ slightly depending on whether the unit has been established for health care, human research or pre-clinical imaging, but the approaches to safety and the risks are the same.

Local safety policies need to be written to cover the work of departmental staff, occasional visitors, cleaners, maintenance and security staff as well as the emergency services. Training should be provided to each group of staff who are likely to need access to the MR scanning unit, tailored to their specific needs.

2.1. Controlled Area

Access to the MR scanning suite is typically defined with respect to controlled areas. Two levels of controlled areas are used to avoid accidents involving pacemakers and projectiles. Both of these areas are three-dimensional in nature, since the magnetic field in the vertical direction needs to be considered to include floors above and below the MRI suite.

- The *MR controlled area* includes all accessible areas where the magnetic field is above 5 G (0.5 mT). All entrances to the controlled area must have warning signs, and access should be restricted to authorised staff and screened patients (and their escorts). Other screened staff and screened visitors may also enter the controlled area if accompanied by an authorised member of staff. Persons with pacemakers or other medical implants must not enter this area.
- The *inner MR controlled area* is defined by the 30-G (3 mT) field contour, which is inside the scanner room. This is used to reduce the risk of projectiles. No ferromagnetic objects should be brought into this area.

2.2. Classification of Persons

The overall responsibility for the safety of all staff and members of the public lies with the *employer*. In an MRI department, this responsibility is delegated to the *responsible person*. The responsible person updates the operational and safety policies, ensures adequate training and is responsible for the maintenance of safety facilities.

The employer typically also appoints an *MR safety adviser*, who provides specialist advice on the scientific and technical issues relating to MR safety.

Authorised persons are members of staff who have completed an MR safety induction and are authorised to enter the controlled

area. The authorised person who is in control of the MR system at a given time is called the *MR operator*.

2.3. Local Rules

All MR departments should have a written set of local rules, which contain information about controlled areas, contingency plans, patient and equipment management and the names of the department’s responsible and authorised persons. The local rules are issued by the MR responsible person after full consultation with the MR safety advisor and representatives of all MR authorised personnel and should be reviewed and updated at regular intervals.

2.4. MR Safety Classification of Equipment

Items used in or near MR environments can be classified as MR safe, MR unsafe or MR conditional. The symbols and definitions of these terms are shown in **Fig. 2.1**.




	<p>MR safe An item which is marked MR safe poses no known hazards in all MR environments.</p>
	<p>MR unsafe An item marked MR unsafe is known to pose hazards in all MR environments.</p>
	<p>MR conditional Items marked MR conditional pose no known hazards in specified MR environments with specified conditions of use. For example, an item may be safe near a 1.5 T magnet, but not for 3.0 T.</p>

Fig. 2.1. MR safe, MR unsafe and MR conditional markings. The MR environment is defined as the volume within the 5-G field contour.

Marking items with the relevant symbol is an efficient way of reducing the risk of accidents. For example, a defibrillator may be marked as MR unsafe and an aluminium patient trolley with no ferromagnetic parts as MR safe.

2.5. Safety in Practice

Classification of areas, persons and equipment makes it easier to control access to MR areas and prevents accidents from happening. The controlled area for one MR unit is shown in **Fig. 2.2**. All rooms inside the bold outer line are part of the controlled area.

3. Safety Screening

All MR centres must have in place clear policies and procedures for screening anyone who may enter the MR environment.

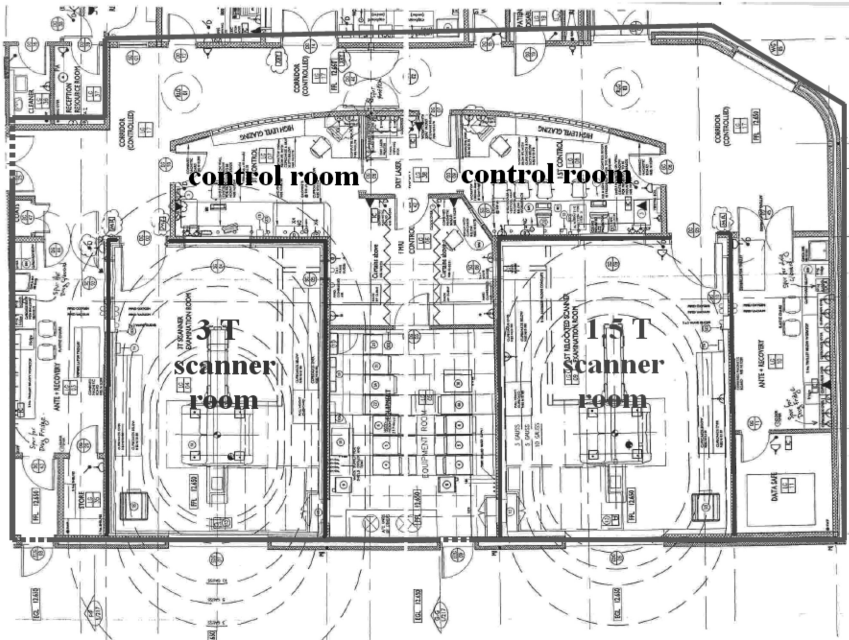


Fig. 2.2. Plan of MRI suite including control room, scanner room and equipment room with field lines.

Figure 2.3 gives an example of a form used to screen patients, research volunteers or staff to be scanned in a whole-body MR scanner. The form includes both questions designed to elucidate any safety queries and several questions designed to investigate the subject's likely tolerance for the MR scan.

In most instances, the form will be explained to the subject who will then fill in the form. An experienced member of staff will then go through the form with the subject, following up on any areas of concern and erring on the side of caution when deciding whether the subject can either enter the controlled areas or be scanned as appropriate.

4. Magnet-Related Safety Issues

4.1. Static Magnetic Field

The strength of the static magnetic field of a scanner is expressed in Tesla (T). One Tesla equals 10,000 G, and 1 G equals 0.1 mT. The earth's magnetic field is approximately 0.05 mT (0.5 G).

There are three principal types of MR magnets in use today.

- The most widely used are superconducting magnets which rely on liquid helium to cool the specially constructed coil windings to extremely low temperatures close to absolute zero.

SAFETY QUESTIONNAIRE FOR MRI

SURNAME..... FIRST NAMES
D.O.B..... HOME TEL:
ADDRESS:.....
.....

(Please circle correct response)

1. Have you had any Scans or X-rays here before? MRI / CT / X-rays / None

2. Do you have a pacemaker or artificial heart valve fitted? Y/N
Any other heart or chest operations? Y/N

3. Have you had any operations on your head, ears or spine? Y/N

4. Have you had any operations where metal might have been inserted into your body? Y/N
If 'Y', please give details

Have you had any other operations? Y/N
If 'Y', please give details

5. Do you have any foreign metallic bodies in your eyes? Y/N
Have you done any welding or metalwork? Y/N
Do you have any shrapnel in your body? Y/N

6. Do you have any of the following: Y/N
Dentures, dental plates or bridges Y/N False limb, calliper or brace Y/N
Tattoos / metallic make-up Y/N Hearing aid or ear implant Y/N
Body Piercings Y/N
Any implanted device that is electrically, magnetically or mechanically activated? Y/N

7. Do you have a history of (a) Seizures Y/N
(b) Diabetes Y/N
(c) Allergic reaction to drugs? Y/N
please state which drugs

8. Is there any chance that you may be pregnant? Y/N

9. Do you have a history of any problems with your heart or arteries? Y/N

10. Are you able to lie flat without becoming breathless? Y/N

11. How much do you weigh?

CLIENT SIGNATURE..... DATE

RADIOGRAPHER SIGNATURE

Fig. 2.3. Example MR screening form.

- Permanent magnets are similar in concept to bar magnets in that they do not require cooling or an electrical power source to operate.
- Resistive electromagnets require a permanent electrical source to operate. The magnetic field will cease once the power is turned off.

Typically most MR magnets (superconducting and permanent magnets) are permanently on, even in the event of a power failure. Permanent and resistive magnets are much less common than superconducting magnets.

One of the major MR safety issues relating to static magnetic fields is the projectile effect which happens when ferromagnetic materials are attracted by the main magnetic field. **Figure 2.2** shows the fringe magnetic field for a whole-body MR system. The magnetic field increases rapidly close to the magnet in a nonlinear manner dependent on the magnet design. Ferromagnetic materials should therefore not be brought into the MR scanner room.

Magnetophosphenes are flashes of light experienced by people in high magnetic fields which are thought to represent direct stimulation of the optic nerve and/or retina. They are generated by time-varying magnetic fields caused by movements of the head in a high magnetic field. They are not reported below 2.0 T but are experienced frequently at 4.0 T and above.

Another effect experienced in high magnetic fields is the generation of a metallic taste which again has been reported to be generated by movement in a magnetic field.

To date, there has been no conclusive evidence for irreversible or hazardous bioeffects of static magnetic fields, so the projectile effect for ferromagnetic materials remains the main safety concern for static magnetic fields.

4.2. Magnet Quenches

Although some low-field MR systems utilise permanent or resistive magnets, most high-field MR systems (1.5 T and above) use superconducting magnets. The magnet windings are cooled using liquid nitrogen or liquid helium in order to reach the low temperatures needed for superconductivity. Over time the amount of cryogenics will gradually decrease due to low levels of boil off. If the amount of cryogenics drops too low or the magnet begins to heat then an uncontrollable release of freezing gases termed a *quench* can occur. Modern MR systems should be fitted with an extraction system for these gases via an external piping system.

The MRI suite should be fitted with a number of oxygen monitors at critical locations in order to detect any increase in nitrogen or helium caused by a quench.

The volume of gas given off by an uncontrolled quench can be extremely large, and there is the potential for a patient to be lying on the scanner bed when a quench starts. Staff must be familiar with the procedures for evacuating a patient from the MR room full of freezing gases and should practise evacuation periodically. It is possible for high pressures to build up in MR rooms making it impossible to open the scanner door, so it may be necessary to break the viewing window to release the pressure.

It is important to remember that the only remaining sign of a quench occurring overnight or at weekends may be an oxygen

alarm ringing when staff start work the next day, indicating low levels of oxygen in the MR suite.

MR scanners are typically provided with an emergency quench button in order to turn off the magnetic field in the case of an emergency. Quenching the magnet in this way should only be considered in extreme cases, such as a person trapped against the side of the magnet by a ferromagnetic item.

5. Time-Varying Gradient Fields

Time-varying gradient fields are a key and integral part of MRI. Gradients are turned on and off rapidly, for varying durations and with varying maximum strength, depending on the pulse sequence and scanner under consideration. This has two main effects: peripheral nerve and muscle stimulation and acoustic noise.

The induced current density J in a circular loop of radius r placed in a time-varying field B is given by

$$J = \sigma \times \frac{r}{2} \times \frac{dB}{dt}$$

where σ is the conductivity of the material, in this case the type of tissue carrying the current.

Faraday's law of induction means that a time-varying magnetic field induces a voltage in a conductor and the induced voltage can lead to an induced current. The rate of change of the gradient field is termed dB/dt , and this can vary greatly depending on the scanner, pulse sequence and application.

The time-varying gradient fields have negligible thermal effects, but strong time-varying gradient fields could potentially lead to seizures, magnetophosphenes, changes in nerve conduction, peripheral nerve stimulation, cardiac arrhythmias or cardiac arrest.

Peripheral nerve stimulation (PNS) and muscle stimulation can occur when a time-varying magnetic field induces electric currents in nerve and muscle cells. Peripheral nerve stimulation occurs at up to 5 kHz. At frequencies of about 10–100 Hz, cardiac muscle stimulation may lead to ventricular fibrillation. The threshold current density for this is about 1.2 A/m^2 , so it can be avoided by keeping the current densities below 0.4 A/m^2 .

The maximum gradient strength has increased substantially over the last two decades with improvements in engineering and applications such as echo planar imaging and diffusion imaging which both rely on strong rapidly switching gradients. The

threshold for nerve excitation in the human body varies greatly with the lowest threshold being for retinal neurones, then large-diameter peripheral nerves, small-diameter peripheral nerves and finally cardiac muscle. The strongest concern focuses around cardiac excitation in the impaired patient. Clinical scanners are designed with restrictions to ensure that only peripheral nerve excitation, if at all, is possible. With the patient's nose at isocentre, large-diameter peripheral nerve excitation tends to occur in the lower back, while with the patient's naval at isocentre, excitation is mostly likely to occur at the shoulder. The y -gradient tends to be most effective in producing excitation, and the shape of the radiofrequency pulses used is important (13).

6. Radiofrequency Effects

The radiofrequency (RF) fields used to manipulate the magnetisation lead to induced currents in the body, which in turn causes power dissipation, i.e. heating. The amount of heating that is acceptable for any particular organ depends on its blood flow, since blood carries the heat away and spreads it through the body. In general, human tissues can tolerate a rise of about 1°C.

Concern here is most focused on compromised patients and on organs without thermoregulation, such as the eyes, or those that are particularly heat sensitive, such as the reproductive organs.

The quantity used to measure RF exposure is the specific absorption rate (SAR), defined as

$$\text{SAR} = \frac{\sigma \times E^2}{2\rho}$$

where σ is the conductivity, E is the induced electric field and ρ is the density of the tissue. The factor of $1/2$ comes from averaging over time for an alternating field. SAR is measured in units of W/kg.

There are limits on whole-body SAR for different operating modes of the scanner, which are calculated from limits on temperature rises (*see Table 2.2*).

For patients with metallic implants, heating is more of a concern because the metal will absorb more energy (since they have higher conductivity than tissue), and this heat will spread to surrounding tissues.

Another heating effect of RF pulses is RF burns. These burns are caused by highly concentrated absorption of RF energy at a single point, resulting in local increases in temperature and (if

Table 2.2
SAR values averaged over 6 min

Operating mode	Limit on core temperature rise (°C)	Whole-body SAR limit (W/kg)
Normal	0.7	2
First-level controlled	1	4
Second-level controlled	>1	>4

the temperature is high enough) tissue burning. RF burns occur when there is a conductive loop. The risk can be minimised by avoiding loops of conductor, e.g. keeping ECG leads from forming a loop. Loops in the patient’s body should also be avoided, such as clasped hands. Padding can be used to position the patient correctly.

7. Use-Related Safety Concerns

7.1. Contrast Agents

Contrast agents are often used for clinical MRI imaging and are also used less frequently for some research applications, such as dynamic susceptibility contrast MRI to measure perfusion and contrast-enhanced MR angiography. For example, gadolinium-based contrast agents are widely used for brain and spine imaging, as well as for contrast-enhanced MR angiography. There are also a variety of organ-specific contrast agents, such as liver contrast agents.

Side effects from MR contrast agents are generally low, for example often showing no significant difference between an injection of a gadolinium-based contrast agent and a placebo injection of saline. Side effects in small numbers of patients may include nausea, headache, vomiting and hives. Anaphylactic reactions may occur in 1 in 500,000 subjects, and the MR unit must be prepared for the possibility of this.

One major side effect of some gadolinium-based contrast agents is nephrogenic systemic fibrosis (NSF) which can affect patients with kidney disease. This leads to swelling and tightening of the skin with large areas of hardened skin. Glomerular filtration rate should be measured for all patients with kidney disease prior to deciding on the use of gadolinium contrast agents.

7.2. Auditory Effects

Sound is produced by Lorentz forces acting on the MR gradient coils. Noise levels as high as 135 dB have been measured in

MR systems. Fast pulse sequences and higher field MR systems in particular can lead to higher levels of noise in MRI systems.

Sound levels are a safety issue for both patients and staff. Wearing ear plugs typically reduces noise by 10–20 dB and MR-compatible headphones by more than this. Staff should always wear headphones when in the MR scanner room while the scanner is operating, and patients should be provided with effective ear protection matched to the application in hand.

7.3. Implants and Devices

Some patients or staff will have an implant or device, such as an aneurysm clip, cardiac pacemaker or metal screw, used to fix a broken bone. A particularly good resource is a book by Frank G. Shellock entitled *Reference Manual for MR Safety, Implants and Devices* which is updated annually, the latest version at the time of writing being the 2009 edition (14). Over 2,300 objects have been tested in the MR environment and are reported in the book, typically at a field strength of 1.5 T. Approximately 900 of these have additionally been tested at 3 T.

Manufacturers of implants will often produce many types of an implant, such as an aneurysm clip over time, some of which may be MR unsafe, while others may be MR safe. MR conditional implants may be safe with a particular combination of field strength, maximum spatial gradient and RF coil position but unsafe with other combinations.

The static magnetic field can exert a rotational force on non-spherical ferromagnetic objects. Some implanted clips, such as aneurysm clips, can twist inside the patient causing injury or death. The static magnetic field can also interact with implanted medical devices, such as pacemakers and defibrillators. Even at low fields of about 1 mT, the magnetic field can alter the operating mode of some pacemakers.

7.4. Biological Safety

There is often a strong emphasis on MR-specific safety issues in relation to MR scanners and peripheral equipment, such as MR-compatible patient monitors. It is important, however, to ensure that biological safety is also considered for MR installations. Like any other area of a hospital or pre-clinical facility, there is the potential for the transmission of bacteria, viruses and other biological hazards. The scanner bore, control panels, MR door handles and the scanner room must be cleaned regularly according to facility guidelines, using appropriate cleaning techniques and MR safe cleaning equipment.

7.5. Physiological Monitoring

Physiological monitoring is important for three key reasons in MRI. First, respiratory and cardiac/peripheral monitoring is a requirement for some MR applications. Second, physiological monitoring is necessary for some research applications. Lastly, physiological monitoring is required for some patients,

particularly those who are impaired in some way or are under general anaesthetic. Specific MR-compatible physiological monitoring equipment may be required for these applications.

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