

Magnetic Resonance Safety and Quality

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A Collaboration between the College of Radiology, Academy of
Medicine of Malaysia and the Ministry of Health, Malaysia

This document is to provide guidance to practitioners of Magnetic Resonance Imaging (MRI) for appropriate MRI practice that is as effective as possible and safe for the patient as well as for all those involved in the delivery of the MR service.

Whilst all are encouraged to strive for the best standard of care, these recommendations are not intended and should not be used for medico legal purposes. As always, practicalities as well as circumstances may warrant variations or adaptations of these recommendations yet, should not compromise the delivery of adequate and safe care to the patient.

The recommendations will be reviewed as and when the need arises or when new techniques, information, study results and technology emerges.

Magnetic Resonance (MR) Safety and Quality Assurance Programme Working Group

Chairperson

Dr. Subramani Venugopal

Consultant Radiologist & Head of Department
Hospital Tuanku Jaafar
Seremban
Negeri Sembilan Darul Khusus.

Members

Dato' Dr S.P. Sellaiah

Consultant Radiologist & Head of Department
Hospital Raja Permaisuri Bainun
Ipoh
Perak Darul Ridzuan

Dr. Ahmad Zalizan Zainul

Consultant Radiologist & Head of Department
Hospital Tuanku Fauziah
Kangar
Perlis

Pn. Nurul Faiezin Mohd Yusof

Medical Physicist
Hospital Tuanku Jaafar
Seremban
Negeri Sembilan Darul Khusus.

Dr. Pirunthavany Muthuvelu

Principal Assistant Director
Engineering Services Division
Ministry of Health Malaysia

Ir. Dr. Syed Mustafa Kamal Syed Aman,

Principal Assistant Director
Engineering Services Division
Ministry of Health Malaysia

Cik Martha James Jimponey

Medical Physicist
Assistant Director
Engineering Services Division
Ministry of Health Malaysia

Pn. Anita Suboh

Radiographer in charge MRI
Hospital Tuanku Ja'afar
Seremban
Negeri Sembilan Darul Khusus

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PART 1

MRI SAFETY GUIDELINES

1 INTRODUCTION

- i. This safety document provides a brief outline of the safety aspects to be considered in Malaysian Magnetic Resonance (MR) facilities.
- ii. This document has borrowed extensively from the references stated herein, especially from the American College of Radiology (ACR) guidance document for MR safety 2007, and is applicable for magnet strengths **up to 1.5 Tesla**.
- iii. Users are encouraged to refer to the various internationally accepted publications for further details and clarifications.
- iv. *Compliance with the guidelines set out in this document does not in itself confer immunity from legal proceedings.*

2 ORGANISATION

- i. Each MR facility, irrespective of magnet format or field strength, shall maintain MR safety policies, which shall then be reviewed whenever there is significant change to the hardware or software, but not later than annually.
- ii. The facility shall have an organisation chart with an MR Director (Radiologist) and an MR Manager (Radiographer).
- iii. The MR Director shall be the overall in-charge of the Magnetic Resonance Imaging (MRI) services for that facility, and his duties shall include, but not be limited to drawing up safety policies and review of such policies from time to time.
- iv. The Manager will be in charge of implementing the safety policies drawn up by the facility, in addition to other duties that the manager may have.
- v. There should be a list of staff privileged to work in the facility and records of their training shall be kept within the facility. (see MR personnel, item vii. below)
- vi. Any and all adverse events, MR safety incidents or 'near incidents' that occur, shall be reported to the MR Director within 24 hours, who shall then institute an investigation that is deemed appropriate for that event.

- vii. MR Personnel:
- a). Level 1 MR personnel: Those who have passed minimal safety education efforts to ensure their own safety as they work within Zone III(See Part 2, Section E) will be referred to henceforth as level 1 MR personnel.

 - b). Level 2 MR personnel: Those who have been more extensively trained and educated in the broader aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to henceforth as level 2 MR personnel. It is the responsibility of the MR Director not only to identify the necessary training, but also to identify those individuals who qualify as level 2 MR personnel.
It is understood that the MR Director will have the necessary education and experience in MR safety to qualify as level 2 MR personnel.

 - c). All those not having successfully complied with this MR safety instruction guidelines shall be referred to henceforth 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 director of that installation.

3 MRI SAFETY

MRI Safety can be broadly divided into:

- A) FACILITY SAFETY
- B) STAFF SAFETY
- C) PATIENT SAFETY
- D) 'PERSON ACCOMPANYING PATIENT ' (PAP) SAFETY
- E) PUBLIC SAFETY

A. FACILITY SAFETY

- i. The facility shall be designed and constructed with safety considerations. Internationally recommended 4 zone design layout is encouraged.
- ii. All areas within the MRI facility shall be clearly marked, and separated by appropriate barriers.
- iii. Ferromagnetic detection systems shall be used where appropriate.

- iv. All MR personnel should be classified as Level 1 or Level 2 personnel, trained accordingly, and records kept of such training. Minimum yearly refresher courses or briefings are recommended.
 - v. Non-MR personnel shall not be allowed free unrestricted access in Zones III and IV. Their movement in these zones must always be supervised by a Level 2 personnel.
- VI. Movement in the Control room and Magnet room shall be limited and strictly supervised.

MAGNET ROOM:

- a. No unauthorised personnel, patient nor visitor shall be allowed into this room without the clearance of the radiographer on duty.

MAGNET ROOM DOOR

- a. Clear signage in local languages shall be displayed on the magnet room door.
- b. The door shall always be locked during break times, after office hours and when the MR staff has to leave the control area unattended.

EQUIPMENT

- a. **Maintenance**
All equipment shall be maintained according to manufacturer's specifications and records kept of the same. (See section on Quality Control of equipment)
- b. **Magnet Quench**
Quenching the magnet is not recommended unless a person is in danger of bodily harm. Where a quench is inevitable, it should be remembered that a full quench can take a minute or more.

Specific References to be available in the facility:

The following be available and be referred to

Recommended:

- i) Reference manual for MR safety, Implants and Devices
Shellock ; - latest edition.
- ii) ACR Guidance Document for safe MR practices
-Kanal et all, (2007 or later)

Additional:

- i) Medical Devices Agency (UK)
Guidelines for MR equipment in clinical use;
(December 2002 or later)
- ii) RANZCR MRI Safety Guidelines;
(August 2005 or later)

Local Guidelines

All facilities shall have local safety policies published and circulated to their area of coverage.

B. STAFF SAFETY

B1.GENERAL

- 1.1) All radiographers who operate MRI equipment shall be given further training / refresher courses on equipment familiarisation and safety.
- 1.2) Only MR trained radiographers can operate MR equipment.
- 1.3) All medical officers in radiology and radiologists shall be given a briefing on MR safety relevant to that facility, by an appropriately trained person.
- 1.4) Other Allied Staff shall be given adequate safety training before being allowed access into the magnet room.
- 1.5) Support staff from cleaning services must be vetted and trained before being allowed into the MR facility. It is preferable to use the same trained people for such services.

B2.PREGNANT STAFF AND MRI

2.1) As yet, there are no known harmful biological effects of MRI on fetuses.

2.2) However, in line with International Practice Guidelines and Standards:

2.2.1 A pregnant employee can enter the magnet room for patient set up, but shall not remain inside the room during scanning.

2.2.2 Any pregnant employee who is worried or concerned about the effects of the magnetic fields on her fetus, may inform the MR Manager or MR Director, for further discussion.

B3.ANAESTHETISTS, DOCTORS AND OTHER MEDICAL SUPPORT STAFF

3.1) All staff from other departments shall be briefed and vetted each time they come to the MR suite.

3.2) Sedated patients and anaesthetised patients shall be connected to a continuous monitoring device.

3.3) At least one MR staff and one accompanying doctor must be “MR Ready” in case urgent magnet room intervention is necessary. (MR Ready is a state where the staff is ready to enter the magnet room at immediate notice, without further preparations)

3.4) Cardio pulmonary resuscitation, when necessary, is best performed outside the magnet room.

C. PATIENT SAFETY

C1. REQUESTS FOR EXAMINATIONS

1.1) All requests shall be accompanied by an MRI checklist.

1.2) The appropriate check list shall be filled and signed by the requesting clinician

1.3) Prior to the examination, the radiographer shall interview the patient and counter check the entries in the check list.

1.4) The radiographer shall then sign or initial the check list.

1.5) This check list shall be clipped to the MRI report and returned to the requesting doctor or filed in the department (as per local policy)

C2. PREGNANT PATIENT AND MRI

2.1) As yet, there are no known harmful biological effects of MRI on fetuses.

2.2) However, in line with International Practice Guidelines and Standards:

2.2.1) Whenever possible, the MR examination shall be delayed till after the first trimester.

2.2.2) All pregnant patients shall have written consent, where possible, taken prior to the examination. Consent shall be taken by the requesting doctor or by the doctor on duty in the MR room.

2.2.3) Gadolinium and/or other MR contrast agents are to be avoided throughout pregnancy.

Specific Notes:

- *If the information to be gained by MR would have required more invasive testing, MRI is acceptable..... FDA of USA.*
- *It might be prudent to exclude pregnant women during the first three months of pregnancy.....NRPB (UK) Extracted from: MRI in Practice. 3rd Edition. Westbrook, Roth and Talbot*

C3. SCANNING

3.1) All patients shall change into clothing provided by the MR facility, prior to scanning.

3.2) All patients shall be interviewed and double checked by the on-duty radiographer before they enter the magnet room. For unconscious patients and in those in whom no history is forthcoming, the radiographer should consider a skull radiograph (to exclude intracranial metallic clips) and a chest radiograph (to exclude pace makers)

3.3) All patients shall be briefed on relevant safety precautions before commencement of scanning.

3.4) An MR radiographer shall always be present at the console, when a patient is in the gantry room.

3.5) The patient shall preferably be withdrawn from the gantry tunnel before any staff enters the magnet room, during or after the procedure.

3.6) Normal level operating modes can safely be used. First level operating modes should be used with caution. Second level operating modes can only be used for research purposes, after obtaining ethical committee approval and patient / volunteer consent.

3.7) Sedated patients and anaesthetised patients shall be connected to a continuous monitoring device.

3.8) Cardio pulmonary, resuscitation, when necessary, is best performed outside the magnet room.

C4. MRI CONTRAST

4.1) Guidelines For Usage Of Gadolinium Based Contrast Media

4.1.1) All patients with asthma, a history of allergic respiratory disorders, prior iodinated or gadolinium-based contrast reactions and other relevant history, should be followed more closely as they are at a demonstrably higher risk of adverse reaction [1]

4.1.2) Patients who have previously reacted to one MR contrast agent can be injected with another agent if they are restudied, and at-risk patients can be premedicated with corticosteroids and, occasionally, antihistamines[1].

4.1.3) It is recommended that individuals with any level of kidney disease avoid using any type of Gadolinium based contrast agent when undergoing an MRI [1].

4.1.4) Caution is urged when administering any other type (non Gadolinium) of contrast agent to an individual with advanced kidney disease or kidney failure [1].

4.1.5) If a patient with advanced kidney disease does receive a Gadolinium based contrast agent, dialysis may be used to remove the Gadolinium from the body [1].

4.1.6) For a patient with moderate kidney disease, the risks of developing Nephrogenic Sclerosing Fibrosis (NSF) in their case should be weighed, before deciding either way [1].

4.1.7) If dialysis will be needed to remove the Gadolinium based contrast agent from the body, preparations should be made before the MRI contrast is administered, and dialysis should commence no later than 2 hours after the Gadolinium based contrast agent has been administered [1].

4.1.8) In patients diagnosed with NSF, Gadolinium based contrast agents should be avoided at all costs [1].

4.1.9) In pregnant patients, intravenous gadolinium should only be used if absolutely essential and only after discussion of risks and benefits with the patient and referring clinician and radiology faculty [9,15].

4.1.10) Lactating women who receive gadolinium can continue breast feeding without interruption. An informed decision to disrupt breast-feeding should be left up to the mother, who should be assured that this disruption need not last longer than 24 hours [9,10,11,12,13,14,15,16,17].

C5. CONSENT FOR MRI

5.1) Generally, a separate consent need not be taken for MR procedures.

5.2) Consent is considered necessary in the following instances:-

- Where parenteral contrast is to be administered
- Pregnant patients
- Interventional MR procedures
- Procedures under General Anaesthesia / sedation.
- Research procedures

D. PERSON ACCOMPANYING PATIENT (PAP) SAFETY

D1. PREGNANT 'PAP' AND MRI

1.1) Although as yet, there are no known harmful biological effects of MRI on fetuses, certain precautions shall be taken, in line with International Practice Guidelines and Standards

1.2) Whenever possible, a pregnant PAP (especially in the 1st trimester) should not stay in the magnet room during scanning.

D2. SCANNING

2.1) All PAP shall preferably change into clothing provided by the MR facility, prior to scanning.

2.2) All PAP shall be double checked by the on-duty radiographer before they enter the magnet room. Contraindications to entering a magnetic field would be the same as for patients.

2.3) All PAP shall be briefed on relevant safety precautions before commencement of scanning.

2.4) All PAP should be given adequate protection against acoustic noise.

E. PUBLIC SAFETY

- 1) No member of the general public shall be allowed access into the gantry room, at any time.
- 2) No member of the general public should be in the control area, without being directly supervised by an MR trained staff.

GENERAL SAFETY PRECAUTION:

No person, whether patient, staff, 'PAP' or other personnel, who has a cardiac pacemaker or other electromechanically activated device, should be allowed into the gantry room nor closer than the 5 gauss line (*unless he has been specially cleared and then only in exceptional circumstances*).

References to Part 1

1. Kanal et al; ACR Guidance Document for Safe MR Practices: 2007
2. Shellock; Reference manual for MRI safety, Implants and devices.
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6. RANZCR MRI Safety Guidelines, August 2005.
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16. ACR Committee on Drugs and Contrast Media. Manual on Contrast Media, Version 5.0. Reston, VA: American College of Radiology, 2004:4-68.
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PART 2

GUIDELINE ON SITE PLANNING FOR MAGNETIC RESONANCE IMAGING SYSTEMS

A. Introduction

MRI units use strong electromagnetic fields and radiofrequency (RF) radiation to translate hydrogen nuclei distribution in the body tissues into computer-generated images of anatomic structures.

The MRI unit consists of a magnet, shimming magnets, an RF transmitter/receiver system with an antenna coil, a gradient system, a patient table, a computer, display monitors, and an operator console.

B. MRI Suite

Site selection and preparation for a clinical MR installation require special considerations. An appropriate foundation and structure, the effects of the surrounding structure on magnetic field uniformity and the effect of the magnet's fringe fields on other devices must be considered.

The radiofrequency (RF) signals from the MR installation may affect equipment in adjacent facilities and electronic devices worn by patients in the MR facility or nearby areas. Conversely, and more likely, the RF radiation in the environment can have detrimental effects on the operation of the MR imager. There may also be consequences of locating two MR systems in the same vicinity.

A standard MRI suite comprises three main rooms; the procedure room (MRI magnet room); the equipment room, where computer equipment, signal generation equipment, and all the electronics needed to run the scanner are kept; and the control room.

The procedure room is surrounded by RF shielding to prevent interference from outside RF signals.

The suite should be equipped with MR-compatible or MR-safe equipment, defined as follows:

MR safe

Indicates that “the device, when used in the MR environment, has been demonstrated to present no additional risk to the patient, but may affect the quality of the diagnostic information”.

MR compatible

Indicates that “the device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device”.

MR environment

This term is used to describe the volume within the 5 Gauss (G) line around the scanner—that is, the perimeter around an MRI scanner within which the static magnetic field is higher than 5 G. A level ≤ 5 G is considered a “safe” level of static magnetic field exposure for the general public.

C. Design Considerations

Selection of the proper site of the MRI unit is very important and should be addressed in the early conceptual planning stages of an MRI suite. When locating an MRI unit, the large three-dimensional magnetic fringe fields may be one of the major limiting factors in MRI planning and site selection. These magnetic fields extend into space above, below and around the magnet and introduce some basic problems which may affect the functioning of the MRI unit.

Positioning the centre of the magnet is an important consideration for the quality of the images due to their dependency on maintaining a constant, homogeneous magnetic field in the centre of the magnet. The main magnetic field can be distorted when large fixed ferrous materials (such as steel frames, reinforcing rods and others) are present in the fringe field. Also, large moving masses, such as, elevators, carts, stretchers, motor vehicles, lawn mowers, and other magnetic objects within the 1-Gauss field can produce static magnetic field fluctuations that distort the images.

Considerations must be taken into account for the location and effective operation of a variety of the medical facility instruments and devices that may be affected by the magnetic fringe field generated by the MRI. For example, multi-format equipment, remote console, CT scanner, ultrasound equipment, patient monitoring equipment, cathode ray devices, computers, magnetic tapes and floppy discs.

The MRI system needs to be shielded from external sources of radiofrequency interference (RFI) and containment of the MRI radiofrequency signals. Penetrations into the gantry room must not reduce overall MRI system performance. The manufacturer/vendor and engineering service should be contacted for specific design requirements.

Consideration should be given to the delivery route of the magnet and any rigging equipment required to move the magnet during installation or if damaged due to a quench (condition when superconductive magnet becomes resistive, due to a break or crack, thus boiling off liquid helium). Wall openings, door allowances, corridor widths, ceiling heights and floor loading tolerances along the entire delivery route must be weighed during the planning stages.

Some manufacturers may require provisions for cooling their equipment which may include a chilled water supply line and a floor drain for flushing the system and/or a closed-loop cooling system that uses distilled, deionized water.

VAC (ventilation, and air-conditioning) equipment should not be located within the 3-Gauss line area. Duct systems should be constructed from non-ferrous material such as aluminium or polyvinyl chloride (PVC).

Soil pipes and floor drains of non-ferrous metal (PVC) is preferred and necessary in the control area, computer/equipment room, and gantry room.

Smoke detection shall be provided on the ceiling and will be required in the control area and computer/equipment room (Please refer to local building guidelines concerning fire protection requirements).

If provided, conductive connections for oxygen and medical vacuum in the gantry room are to be made outside the 5-Gauss area. All lines within the 5-Gauss area must be non-ferrous materials. Preference is to use non-ferrous portable equipment for oxygen and medical vacuum within the gantry area.

Electrical power supply for equipment, lighting and receptacles in the gantry room must pass through line filters.

Incandescent light fixtures with a DC (direct current) lighting system shall be provided within the gantry room.

All light fixtures and receptacles located within the 5-Gauss line field of influence should be made from non-ferrous material. Aluminium or PVC conduit must be used in lieu of steel conduit.

D. Space Requirement

Space requirements for an MRI suite will be determined on the basis of the MRI equipment selected and whether it will be located in a "self sustaining" structure, either attached or separated from the medical facility, or within a medical facility.

A typical MRI suite within a medical facility will contain a gantry room, control room, computer and equipment room, cryogen storage room, digital archival room, storage room, waiting area, dressing room, toilet (which includes modifications for the disabled), as well as examination, preparation, and recovery area.

E. Facility Layout

The MR facility must be designed within the constraints inherent in the technology of MR imaging. Magnetic fringe fields and cryogen storage are typical examples of the special considerations which must be made.

Annex1 Figure 1 lists some ideas on creating an ideal environment for magnetic resonance imaging.

The basic layouts of magnet installations do not usually differ drastically between different manufacturers who provide site planning guides listing the physical specifications of their equipment. The major factors influencing layout are magnet type, field strength and the type of building available or planned for the MR imaging area.

It is recommended to use the four zone concept to define various regions of the magnetic suite design. 5 Gauss line must be restricted within Zone 4.

Zone I

This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment

Zone II

This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Typically, patients are greeted in Zone II and are not free to move throughout Zone II at will, but are rather under the supervision of MR personnel. It is in Zone II that the answers to MR screening questions, patient history, medical insurance questions and other relevant information are typically obtained.

Zone III

This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the MR scanner's particular environment.

Zone IV

This area is synonymous with the MR scanner magnet room itself, that is, the physical confines of the room within which the MR scanner is located. Zone IV, by definition, will always be located within Zone III, as it is the MR magnet and its associated magnetic field that generates the existence of Zone III. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. The magnet area must be properly secured with locked entrances to keep out unauthorized persons and particularly to prevent inadvertent introduction of potentially hazardous metallic objects.

The design of the area must also provide adequate venting in the event that a superconducting magnet should quench.

F. Site Requirements

The site of the magnet must be such that during operation neither external influences affect the homogeneity of the magnetic field nor the safety of persons and/or the functioning of sensitive equipment can be affected by the stray magnetic field.

G. Magnetic field level warning signs in the control zone ≥ 0.5 mT

If the magnetic flux density in a given area exceeds 0.5 mT, it is necessary to display warning signs and restrict access in accordance with local regulations.

H. Magnetic room shielding

A magnetic room shielding must be taken into account and calculated.

I. Noise emission

If required, noise reduction should be realized based on the noise emission values as specified.

J. Disturbances caused by the magnetic stray field

All devices and systems with functions, which can be influenced by an external magnetic field must be taken into consideration. The maximum permissible magnetic flux density depends on the sensitivity of each system component and must be cross-checked with the equipment manufacturer, if necessary.

K. Disturbing influences on the magnetic field, causes and remedies

Static

E.g. iron girders, reinforcements, especially beneath the magnet.

Partially correctable by shimming of the magnet and/or compliance with minimum clearances or maximum weights.

Dynamic

E.g. moving ferromagnetic objects, electrical wiring, transformers.

Avoidable if minimum distances are kept. Minimum distances depend on moving direction and magnet orientation.

L. Site inspection

This inspection is exclusively concerned with the measurement of the magnetic and radiofrequency interference and building vibrations.

M. Transport

Identify transport dimensions of magnet and cabinet (without transport devices and safety distance).

N. Construction materials

To maintain magnet field homogeneity, the following specifications for materials are recommended:

N1. Floor

- a. The floors should be poured slab on grade with fibreglass impregnated or epoxy-reinforced concrete. Reinforcing bars or corrugated iron sheets should be avoided if possible, especially within the 50 gauss line.
- b. The floor in the vicinity of the magnet and patient table must be levelled to within tolerance.
- c. External vibration or shocks affecting the magnet may degrade image quality. In the 3 spatial orientations the **building vibration** must not exceed the following specification (manufacturer) as per example:

Building vibration specification: (typical)

$a_{\max} = -80 \text{ dB(g)}$ in the frequency range from 0 to 70Hz.

The requirement for a_{\max} is -80 dB(g) is measured as maximum rms value per frequency component (resolution $< 0.5 \text{ Hz}$) in the Fourier Transformation of the recorded signal (spectrum).

N2. Walls

The walls should be brick or concrete with minimum steel reinforcement or constructed of wood with standard nails, consistent with the national building code.

N3. Electrical conduit

Electrical conduit within 25 ft. (7.6 m) of magnet isocentre must be PVC or aluminium. In any case, do not use ferromagnetic material inside the exam room, since it could inadvertently become a projectile.

N4. Plumbing pipes and drains

Pipes and drains within 25 ft. (7.6 m) of magnet isocentre must be of nonferrous material such as PVC, copper or brass. Again, do not use ferromagnetic materials inside the examination room.

N5. Water installation

Please refer to manufacturer for specific requirements, i.e. whether using Chiller if no cooling water is available or using central hospital cooling water supply or if a local chiller is available.

For water quality specifications, please refer to the manufacturer.

N6. Electrical and mechanical considerations

N7. Environment (typical) - Please refer to the manufacturer's recommendations.

	Examination room	Equipment room	Control room/Evaluation
Room temperature	18 to 24 °C	15 to 30 °C	15 to 30 °C
Temperature gradient	n.a.	≤ 3 K / 5min.	n.a.
Relative humidity	40 to 60 %	40 to 80 %	40 to 80 %
Absolute humidity	< 11g / kg	< 11.5 g / kg	< 11.5 g / kg

The operation values should be set within these limits and the ventilation must be conforming to the local standards and regulations.

An air-conditioning system is required to meet the specified conditions.

N8. VAC

Ventilation and air conditioning equipment should not be located in the area inside the 10 gauss line.

N9. Transformers

Do not locate electrical distribution transformers inside the 3 Gauss line.

N10. Floor concrete

The finished layer of floor concrete should not be poured until the specific MR magnet/computer system is chosen. Final cable requirements and associated ducts will be specific to the particular type of system installed.

N11. Superconducting magnet requirements- Please refer to the manufacturer's recommendations**N12. Venting**

Venting for cryogen exhaust should be aluminium ducting capable of 350 ft³/min. (9.9 m³/min.)-- e.g., one 6-in. (15.24 cm) and one 2-in. (5.08 cm) non-magnetic vent pipe which is electrically isolated at the penetration points.

N13. A loading dock platform should be accessible to the magnet room for delivery of liquid helium/liquid nitrogen dewars. The loading platform should be placed beyond the 3 Gauss line. Without a loading dock, a forklift truck will be needed for unloading the dewars.

N14. General siting concerns

Exit from the magnet room should allow for rapid patient removal from the magnetic field to an area where patient monitoring and life support equipment will operate satisfactorily in case a medical emergency occurs. The main door to the magnet room shall open outwards.

A ferromagnetic detector should be used to screen for any ferrous objects on patients and medical personnel. Small ferrous objects can become dangerous projectiles in regions of high magnetic field gradients within 6.5 ft. (2 m) of the magnet.

RF shielding requires a minimum attenuation level of 100 db for electrical/plane waves in the frequency range of 10 KHz to 100 MHz.

N15. Power Supply

Mains requirements (typical) please refer to the manufacturer's recommendations.

Mains 3 phase, AC 415 V \pm 10 %, 50 Hz \pm 1 %
Connection value 110 kVA
Momentary power 125 kVA during measurement sequences < 5 sec.
Line to line unbalanced maximum 2 %
On-site circuit breaker minimum 160 A

The installation has to be done according to the local authority requirements.

N16. Sockets in the examination room

Hazardous conditions are created by the magnetic field when connecting devices made from magnetisable material to the receptacles installed in the examination room. The functionality of electrical devices, e.g. servo ventilators, may be affected by the magnetic field if the devices are not suitable for this type of operation.

The user is responsible for the installation and use of receptacles in the examination room as well as for damages caused by the above mentioned use.

In addition, the on-site electrical system has to conform to Group 2, if life-support systems are used in the examination room (refer to MS IEC 0100-710).

Sockets inside the examination room must be connected through extra RF filters and an insulation transformer if Group 2 is required.

N17. Room lighting in the examination room

The magnetic field adversely affects the operating life of light bulbs located in the immediate vicinity of the magnet. The filament in the light bulb oscillates with the frequency of the power supply.

It is therefore recommended to connect light fixtures in the vicinity of the magnet to a DC voltage supply. If room lighting is supplied with DC voltage, correct polarity of the sockets should be ensured during their installation. Residual AC ripple should be \leq 5 %. Phase light dimmer must not be used.

Please refer to Annex 2 for check list on design MRI installation

M. Quality Assurance(QA) programme

Audit of all the policies and procedures used in relation to the MR service should be a regular part of the broader QA programme.

All QA measurements whether at acceptance test levels or on a regular basis should be undertaken using good quality test objects. If using the manufacturer's own test objects, MR units should ensure that these are testing to a known level and that the results will allow trends to identify levels for action before image quality is compromised.

Please refer to MS IEC 62464 -1 (Magnetic resonance equipment for medical imaging – Part 1: Determination of essential image quality parameters)

Also refer to Phantom Test Guidance for the ACT MRI Accreditation program

References to Part 2

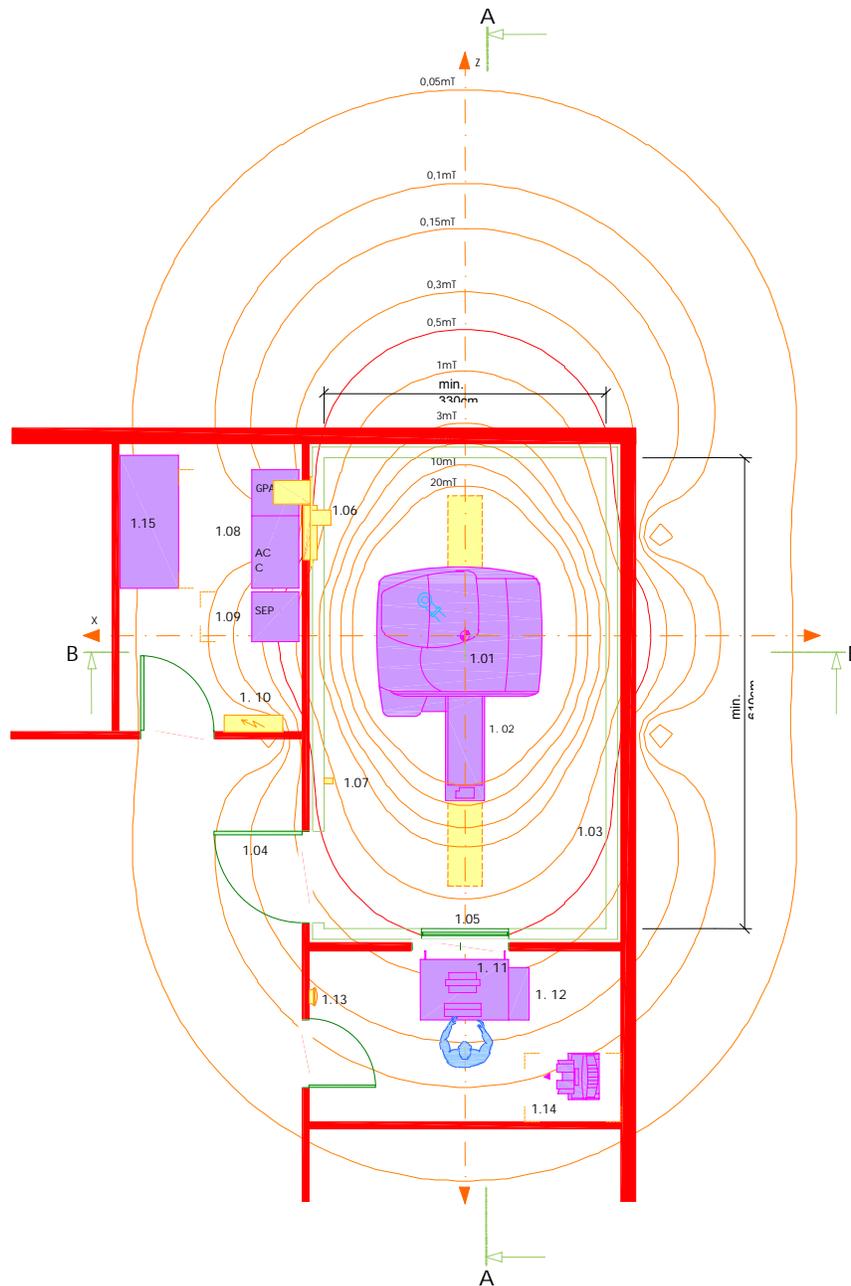
1. Magnetic Resonance Imaging (MRI) -VA Design Guide
2. Best Practices - Safety Considerations in the Design of Magnetic Resonance Imaging (AIA)
Contributed by Robert Paul Junk, AIA, and Tobias Gilk, Junk Architects, Kansas City, Missouri
3. Acceptance Testing Of Magnetic Resonance Imaging Systems - Report Of Task Group No. 6 AAPM
Nuclear Magnetic Resonance Committee
4. Quality Assurance Methods And Phantoms For Magnetic Resonance Imaging - Report Of Task Group
No. 1 AAPM Nuclear Magnetic Resonance Committee*

ANNEX 1

Figure 1: Planning example

Measurements are in centimetres and are not to scale.

For the legend and fringe field distribution, see next page.



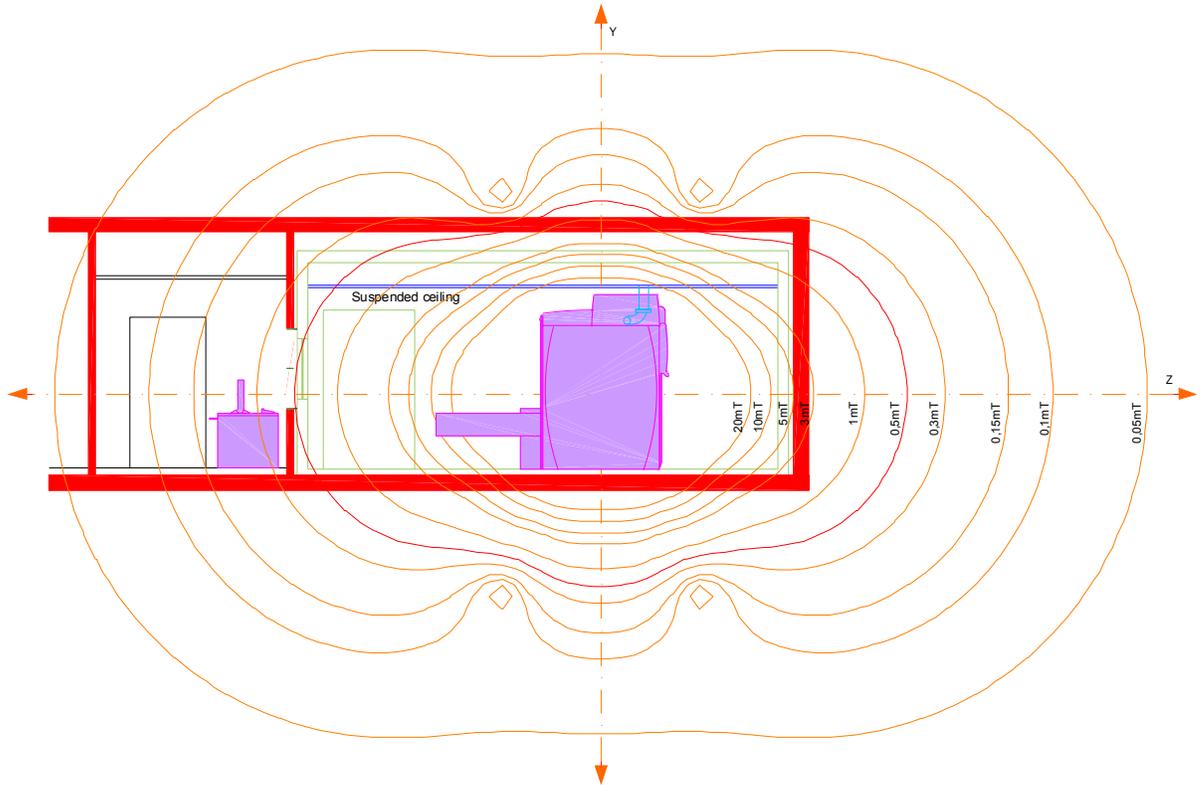
Equipment Legend				
Pos.	Description	Weight (kg), Heat dissipation to the air (W)		
		kg	W	Remarks
1.01	Magnet	5500	2750	#1/#2
1.02	Patient table	350		
1.03	RF-Cabin			
1.04	RF-Door			
1.05	RF-Window			
1.06	RF-Filter	110	250	
1.07	Magnet Stop			
1.08	Electronics cabinet GPA/ACC (water cooled)	1168	4000	#1
1.09	SEP cabinet	340	1000	#2/#3
1.10	Power distributor	52		
1.11	Control unit MRC Table	20 60	200	
1.12	Host PC MRC	22	700	
1.13	Alarm box	1		
1.14	Laser Printer	125	650	200 W stand by
1.15	Air conditioning cabinet			
	#1 Heat dissipation depending on measuring #2 Additional water cooling system necessary #3 The type of the cooling must be cleared with the manufacturer's project manager.			

Fringe field distribution

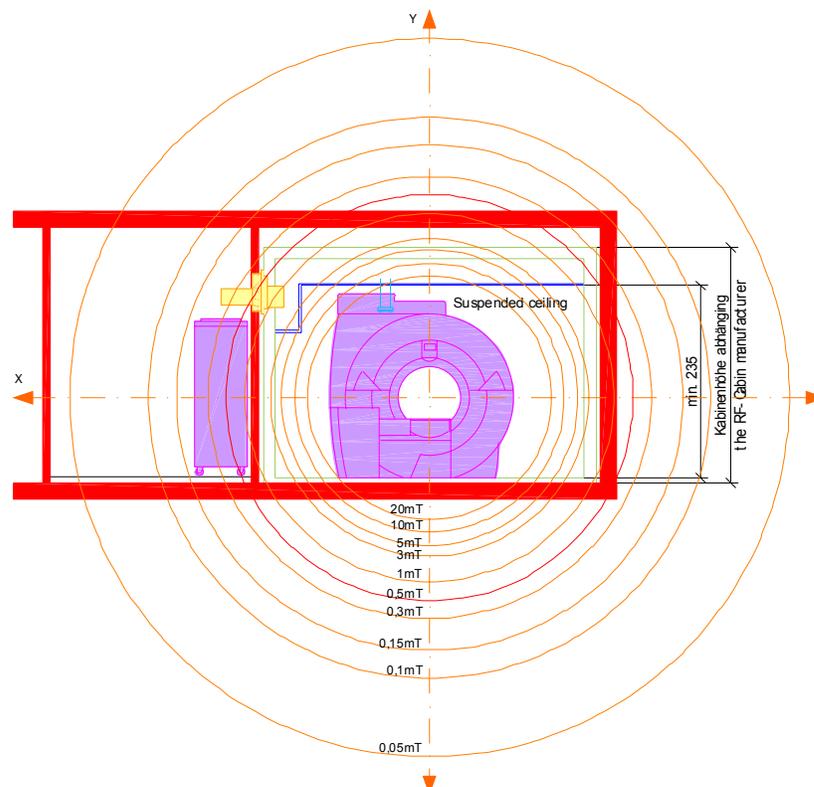
Fringe field	Distance from the magnetic centre in direction of		
	X axis	Y axis	Z axis
20 mT	1.6	1.6	2
10 mT	1.7	1.7	2.3
5 mT	1.9	1.9	2.6
3 mT	2	2	2.8
1 mT	2.3	2.3	3.5
0.5 mT	2.5	2.5	4.0
0.3 mT	2.8	2.8	4.6
0.2 mT	3.0	3.0	5.0
0.15 mT	3.2	3.2	6.0
0.1 mT	3.5	3.5	6.0
0.05 mT	4.5	4.5	7.2

Possible layouts as examples (Not to scale)

A.



B.



ANNEX 2

CHECK LIST ON MRI DESIGN INSTALLATION

The following lists are to be considered in designing an MR imaging facility. The list of functional areas can be used as the basis for estimating the area necessary once the functional requirements of a particular site are known.

A. Functional Areas

A1. The first group is normally required for an MR imaging facility:

- i. Scan Room
- ii. Control Room
- iii. Computer Equipment Room (include RF equipment and power supplies)
- iv. Reading Room (include physician's console)
- v. Cryogen Storage

A2. The second group is required adjacent to the MR imaging facility but some areas can be shared with other imaging services when necessary or when the joint space can be designed properly.

- i. Film Processing
- ii. Quality Control and Service
- iii. Patient Preparation, Recovery and Emergency Procedure Area
- iv. Patient Reception and Waiting Area
- v. Stretcher Holding Area
- vi. Storage (supplies, magnetic tapes, film, etc)
- vii. Washrooms
- viii. Soiled Utility
- ix. Clean Utility

A3. The third group lists additional functions, likely to be required, which can be both remote from the MR imager and shared with other services in extenuating circumstances.

- i. Secretarial and Transcription Services
- ii. Conference Area
- iii. Additional Storage (film library, magnetic tapes, DVD-R/RW)
- iv. Offices

B. Construction and Access Considerations

- i. Equipment transportation, unloading and installation access.
- ii. Floor loading (including access routes)
- iii. Floor levelness
- iv. Ceiling heights (especially magnet room and access route)
- v. Access for cryogenes.
- vi. Cryogen venting (normal and quench)
- vii. Controlled access to facility and well-controlled access to magnet room

C. Protecting Magnetic Field Homogeneity

- i. Location and amount of steel shielding
- ii. Other structural items of iron and steel
- iii. Large ferrous structures or objects
- iv. Symmetrical location of ferrous structures
- v. Moving ferrous objects
(eg, elevators, lift trucks and vehicular traffic within and outside the building)

D. Protecting Surrounding Environment from Magnetic Fields

A three-dimensional survey of magnetically sensitive devices and equipment should be undertaken. Tolerable distances from the centre of the magnet will depend on magnet field strength and shielding design. Use the field strengths as a guide.

E. Radiofrequency Shielding

Design appropriate RF shielding based on a site survey according to the manufacturer's specifications. Avoid light dimmers and fluorescent lighting ballasts within the magnet room.

F. Facility Environment

- i. Electrical supplies
 - voltages, current and phases
- ii. Air conditioning
 - general area, computer room (temperature, humidity and filtration)
- iii. Water supply and floor drains
 - include sink for phantom filling and draining
- iv. Chilled water supply
 - temperature, flow rate and tolerable temperature fluctuation
- v. Personnel protection
 - establish controlled areas and metal detection routines
- vi. Fire Detection and Safety
 - no sprinklers; non-ferrous extinguishers
- vii. Telephone Service
 - separate lines for operator, physician and service personnel (near computer)
- viii. Housekeeping
 - no ferrous cleaning tools or supplies

PART 3

MRI QUALITY CONTROL (QC) PROGRAM

Introduction

Quality Control (QC) is an integral part of the quality assurance (QA) programme and is a series of technical procedures that ensures high-quality diagnostic images. QC tests are required in acceptance testing, establishment of baseline performance of the equipment, detection of changes in equipment performance and in verifying that the causes of deterioration in equipment performance have been corrected. Acceptance testing should take place before the first patient is scanned and after major repairs of subsystem components. A baseline check should be carried out on the MRI system as a whole and on additional subsystems. All records should be kept at a central location near the MRI scanner. All staff, working within the MRI system including the radiologist, medical physicist and the radiographer, are responsible for ensuring good QC of the MRI system.

Responsibilities of the Radiologist

1. To ensure that radiographers have adequate training and continuing education in MRI
2. To provide an orientation program for radiographers based on a carefully established procedure manual
3. To ensure that an effective QC program exists for all MRI performed at the site. The radiologist should provide motivation, oversight and directions to all aspects of the QC program
4. To select the radiographer to be the primary QC personnel, performing the prescribed QC tests.
5. To ensure that appropriate test equipment and materials are available to perform the QC tests.
6. To arrange staffing and scheduling so that adequate time is available to carry out the QC tests and to record and interpret the results
7. To provide frequent and consistent positive and negative feedback to radiographers about clinical image quality and QC procedures.

8. To review the test results done by the radiographer at least every three months, or more frequently if consistency has not yet been achieved, to review the results of the medical physicist annually, or more frequently when needed
9. To oversee or designate a qualified individual to oversee the safety program for employees, patients and other individuals in the surrounding area
10. To ensure that records concerning employee qualifications, MRI protocols and procedures, QC, safety and protection are properly maintained and updated

Responsibilities of the Medical Physicist

To ensure and verify:

1. That the main equipment and all related essential accessories are up to date on QC tests, and PPM, as per manufacturers' recommendations.
2. Calibration for the coils (central frequency and transmitter gain)
3. Signal-to-noise ratio (SNR) and image uniformity in coils
4. Check of magnetic field gradient calibration (geometric distortion)
5. Film processor QC and hard copy fidelity
6. Physical and mechanical inspection
7. Magnetic Field Homogeneity
8. Slice Thickness and Position Accuracy
9. Image uniformity and SNR testing of all RF coils
10. Inter-Slice R.F. Interference
11. MRI phase stability

Part 4

MR CLINICAL AUDIT PROGRAMME

This section will only list the principles involved in a clinical audit programme and for specific details, please refer to the ACR as well as the RANZCR (Royal Australian and New Zealand College of Radiologists) materials.

1. A MR clinical audit programme involves clinical image review for each magnet/machine. These should be done by peers and eventually self-review. At least an annual review is recommended and when the review process has been established, more frequent reviews are encouraged.
2. Examinations for review should be chosen at random, after selecting a defined time period (eg a week). Actual parameters used should be recorded.
3. Each examination should be reviewed against a set criteria and there should be at least 2 reviewers and results recorded in writing.
4. The images of the examinations are evaluated for adequacy for clinical diagnosis. Failure of one criteria does not necessarily mean an inadequate study.
5. For images that are deemed non-diagnostic, there should be a review for potential causes and corrective action should be taken. There should be another clinical image review of similar examination/s after corrective action has been taken.
6. The clinical image review results with the written records of parameters and the images, either on film or electronic should be retained by the MR facility and available for review again when the need arises. This would be the case where accreditation of MR facilities has become established. Note that service schedule and records may be reviewed as well.

Examples of Examinations and Sequences to be included for review

1. Brain scan for suspected stroke (axial OR coronal long TR, long TE; and sagittal or coronal FLAIR or long TR, short TE sequence)
2. Cerebral MRA for assessment of stroke
3. Cervical spine MR for suspected radiculopathy – thin section axial images
4. Lumbar spine examination for sciatica (Sagittal, Axial long TR, long TE images)
5. Knee MR for suspected internal derangement – (One sagittal, one coronal sequence, at least one to show fluid with hyperintense signal)

Note: MR facilities for paediatric age group may select alternative examination sets and sequences.

(TO BE FILLED UP BY THE DOCTOR REQUESTING THE MRI EXAMINATION)

MRI PROCEDURE SCREENING FORM FOR PATIENTS (MRI CHECKLIST)

Name : _____
Age : _____
I/C No. : _____
RN No. : _____

Ward/clinic : _____
Weight: _____ kg

MRI procedure involves the use of a very strong magnetic field that may be hazardous to individuals entering the MR system room if they have certain metallic, electronic, magnetic or mechanical implants, devices or objects.

Please indicate in the appropriate column whether patient has any of the following

NO.		No	Yes	Comments
1	Cardiac pacemaker			
2	Internal wires or electrodes / implantable defibrillator			
3	Heart valve prosthesis			
4	Coronary artery bypass clips (CABG)			
5	Aneurysm clip / any vascular clips / intracranial clips			
6	Metallic stent, filter or coil			
7	Shunt (spinal or intraventricular)			
8	Surgical staples ,clips or metallic suture			
9	Vascular access port and / or catheter			
10	Biostimulator, neurostimulator system device			
11	Cochlear, otologic or any ear implant			
12	Hearing aid			
13	Dental implant, dentures, partial plates / braces			
14	Implantable pump (breast, penile, etc)			
15	Implanted drug infusion pump			
16	Magnetically-activated implant or device			
17	Other implants			
18	Bone / joint pin, screw , nail , wire , plate, etc			
19	Artificial limb or joint replacement or pins			
20	Any metallic fragment or foreign body in the eye			
21	Tattoo or permanent makeup			
22	IUCD, diaphragm or pessary			
23	Breathing problem or motion disorder			
24	Claustrophobia			
25	Any history of asthma, allergic reactions, respiratory disease or reaction to a contrast medium used for CT,MRI, or X-ray examination?			
26	Any allergies to medication or food ? If yes, please elaborate			
27	Urinary or bowel incontinence			
28	For female patients	Date of last menstrual period ____/____/____ Pregnant If yes, _____weeks Breastfeeding No <input type="checkbox"/> Yes <input type="checkbox"/>		

If yes, please describe in detail and list all surgical procedures (date and type)

Blood Urea _____ mmol/L

Serum Creatinine _____ umol/L

I verified that I have clearly explained to the patient / parents /guardian about the procedure and indication of the MR examination.

Signature / Name and chop of medical officer/ Specialist
Date: ____/____/____

Signature / Name of radiographer on duty

Date: ____/____/____



IMPORTANT INSTRUCTIONS

Before entering the MR environment or MR system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the MRI radiographer or radiologist if you have any question or concern BEFORE you enter the MR system room.

(TO BE FILLED UP BY STAFF WORKING IN THE MRI ROOM)

MR ENVIRONMENT SCREENING FORM FOR ACCOMPANYING INDIVIDUALS (MRI CHECKLIST)

Name : _____

Age : _____

No. IC : _____

MRI procedure involves the use of a very strong magnetic field that may be hazardous to individuals entering the MR system room if they have certain metallic, electronic, magnetic or mechanical implants, devices or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. Be advised, the MR system magnet is ALWAYS on.

Please indicate in the appropriate column whether patient has any of the following

NO.		No	Yes	Comments
1	Cardiac pacemaker			
2	Internal wires or electrodes / implantable defibrillator			
3	Heart valve prosthesis			
4	Coronary artery bypass clips (CABG)			
5	Aneurysm clip/any vascular clips/ intracranial clips			
6	Metallic stent, filter or coil			
7	Shunt (spinal or intraventricular)			
8	Surgical staples ,clips or metallic suture			
9	Vascular access port and / or catheter			
10	Biostimulator, neurostimulator system device			
11	Cochlear, otologic or any ear implant			
12	Hearing aid			
13	Dental implant, partial plates / braces			
14	Implantable pump (breast, penile, etc)			
15	Implanted drug infusion pump			
16	Magnetically-activated implant or device			
17	Other implants			
18	Bone / joint pin, screw , nail , wire , plate etc			
19	Artificial limb or joint replacement or pins			
20	Any metallic fragment or foreign body in the eye			
21	Tattoo or permanent makeup			
22	IUCD, diaphragm or pessary			
23	Breathing problem or motion disorder			
24	Claustrophobia			
25	Any history of asthma, allergic reactions, respiratory disease or reaction to a contrast medium used for CT,MRI, or X-ray examination?			
26	Any allergies to medication or food? If yes, please elaborate			
27	Urinary or bowel incontinence			
28	For female patients			Date of last menstrual period ____/____/____ Pregnant If yes, _____weeks Breastfeeding No <input type="checkbox"/> Yes <input type="checkbox"/>



IMPORTANT INSTRUCTIONS

Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys eyeglasses, hair pin, barrettes, jewellery (including body piercing jewellery), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens pocket knife, nail clipper, steel-toed boots/shoes and tools. Loose metallic objects are especially prohibited in the MR system and MR environment.

Please consult the MRI radiographer or radiologist if you have any question or concern BEFORE you enter the MR system room.

Name & / Signature of Radiographer on duty : _____

Date ____/____/____