

MRI FACILITY

Standard Operating Procedures

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Table of Contents

1	MR Hazards and Safety Procedures.....	6
1.1	Static Magnetic Field	6
1.2	Projectile Risk	6
1.3	Implantable Medical Devices	6
1.4	Third party equipment.....	6
1.5	Biological Effects.....	7
1.6	Exposure Limits for Volunteers	7
1.7	Occupational Exposure Limits	9
1.8	Exposure Limits for General Public.....	10
1.9	Time-varying Magnetic Field Gradients (dB/dt)	11
1.9.1	Biological Effects	11
1.9.2	Exposure Limits for Volunteers	11
1.9.3	Occupational Exposure Limits.....	12
1.9.4	Exposure Limits for General Public	12
1.10	Acoustic Noise	13
1.10.1	Hazards.....	13
1.10.2	Exposure Limits for Participants	13
1.10.3	Occupational Exposure Limits	13
1.10.4	Exposure Limits for General Public.....	13
1.11	Radiofrequency Magnetic Fields (B ₁)	14
1.11.1	Heat Stress.....	14
1.11.2	Induced Current Burns	14
1.11.3	Contact Burns	14
1.11.4	Exposure Limits for Volunteers.....	15
1.11.5	Occupational Exposure Limits	15
1.11.6	Exposure Limits for General Public.....	15
1.12	Cryogenics	17
1.12.1	Asphyxiation	17
1.12.2	Cold Burns, Frostbite and Hypothermia	17
1.12.3	Handling Cryogenics.....	17
1.12.4	Over-pressurisation of the MR Environment	18
1.13	Other potential hazards	19
1.13.1	Laser Light Localizer	19
1.13.2	MR Phantoms	19
2	Management of the MRI Facility.....	20
2.1	Responsibility and Organisation	20
2.2	Key Personnel	20
2.2.1	External MR Safety Advisor	21
2.2.2	MRI Management Committee	22
2.2.3	Access for Personnel	22
2.3	MR Controlled Access Area	23
2.3.1	Definitions	23
2.3.2	Access to MR Controlled Access Area	23
2.3.3	Warning signs.....	23
2.4	Access Control.....	25
2.4.1	Access for Personnel	25
2.4.2	Responsibilities of Authorised Personnel	25
2.4.3	Categories of Authorised Personnel	26
2.4.4	Required Staffing Levels for Scanning	26

2.5	Categories of Exposed Persons	27
2.5.1	Participants	27
2.5.2	Staff	27
2.5.3	General Public	27
2.5.4	Cleaning and Maintenance Staff	27
2.5.5	MR Maintenance Engineers	27
2.6	Control of Equipment	28
2.6.1	Equipment Policy	28
2.6.2	Responsibility for Entry	28
2.7	Volunteer Management: General Considerations	29
2.7.1	Volunteers	29
2.7.2	Pre-requisites for MR Examination	29
2.7.3	Medications	30
2.7.4	Responsibility for Volunteers whilst in the MR Controlled Access Area	30
2.7.5	MRC Indemnity Arrangements for Volunteers	30
2.7.6	Pregnant Women	30
2.7.7	Implanted Medical Devices	31
2.7.8	Metallic Foreign Bodies	31
2.7.9	Spectacles and Hearing Aids	32
2.7.10	Transdermal Patches	32
2.7.11	Tattoos, Makeup	32
2.7.12	Body Piercings	32
2.7.13	Silver impregnated garments	32
2.8	Volunteer Management	33
2.8.1	Scanning	33
2.8.2	Preparation	33
2.8.3	Screening	33
2.8.4	Positioning	33
2.8.5	Hearing Protection	34
2.8.6	Comfort	34
2.9	Communication	35
2.9.1	Panic Alarm	35
2.9.2	Volunteer Monitoring	35
2.9.3	Maximum Time in the Scanner	35
2.10	Data Management	36
2.10.1	Minimum Data Required	36
2.10.2	Scan Logs	36
2.10.3	Data Protection and Confidentiality	36
2.10.4	Abnormal (Incidental) Findings	36
2.11	Staff Training	38
2.12	Accident/Incident Reporting and Investigation	39
2.13	Booking policy	40

3	Emergency Procedures	41
3.1	General Considerations	41
3.2	Emergency Switches	42
3.2.1	Location	42
3.2.2	Magnet Quench Switch	42
3.2.3	Power Stop Button	42
3.2.4	Patient Table Stop Button	42
3.3	Location of Rescue Equipment	43
3.4	Evacuation and Access Routes	44
3.4.1	Evacuation of the MRI Facility, Escape Routes.	44
3.4.2	Access Routes for Rescue Vehicles	44
3.5	Medical Emergencies	45
3.5.1	General Consideration	45
3.5.2	Emergency Procedures	45

3.6	Major Equipment Failure	46
3.6.1	General Consideration	46
3.6.2	Emergency Procedures	46
3.7	Spontaneous Magnet Quench	47
3.7.1	General Consideration	47
3.7.2	Emergency Procedures	47
3.8	Deliberate Magnet Quench	49
3.8.1	General Consideration	49
3.8.2	Emergency Procedures	49
3.9	Fire	50
3.9.1	General Considerations	50
3.9.2	Emergency Procedures	50
3.10	Emergency Contact Numbers	52
4	References.....	53
5	Appendices.....	54
5.1	Appendix A: Controlled Access Area	54
5.2	Appendix B: Emergency switches.....	55
5.3	Appendix C: Participant Information Sheet	56
5.4	Appendix D: Screening forms	57
5.5	Appendix E: MRI Consent Form	59
5.6	Appendix F: Emergency evacuation map	60
		60
5.7	Appendix G: Risk assessment of magnetic field exposure	61
5.8	Appendix H: Statement of conformity	64
5.9	Appendix I: Definition of Terms.....	65
5.10	Appendix J: Near Miss Form	67
5.11	Appendix K: SOP Receipt	68
5.12	Appendix L: Recommended Pre-Screening.....	69
5.13	Appendix M: Occupational exposure to electromagnetic fields (EMF)	72
5.14	Appendix N: MRI Authorisation Procedure	76
5.15	Appendix O: Use of Unlabelled Equipment in MRI environment.....	77

Introduction

This documentation is intended to provide a basic review of safety issues in magnetic resonance imaging (MRI) and how these affect the day-to-day practice of performing MRI scans at the MRC Cognition and Brain Sciences Unit (CBU).

It is based on the recommendations of the Medicines and Healthcare products Regulatory Agency (MHRA) [8], the National Radiological Protection Board (NRPB)/Health Protection Agency (HPA) and now Public Health England (PHE), the International Electrotechnical Commission (IEC), the International Commission on Non-Ionising Radiation Protection (ICNIRP), and the Siemens Magnetom Prisma^{fit} Operating Instructions.

1 MR Hazards and Safety Procedures

1.1 Static Magnetic Field

Safety issues to consider with a strong static field, B_0 , are projectile effects, implantable medical device safety and compatibility, peripheral equipment compatibility, and biological effects.

1.2 Projectile Risk

The projectile risk applies to devices, which contain ferromagnetic components. These can be passive devices such as keys and coins or active devices such as infusion pumps. Magnetic objects experience a strong attracting force in the fringe field of the magnet. Therefore, even small magnetic objects such as coins can turn into dangerous projectiles, which may cause serious injury to people. The force on an object depends on the rate of the change in magnetic field (the magnetic field gradient). The potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field is therefore a serious concern in MR units.

CBU Health and Safety procedures

- Only authorised personnel will have free access to the MR Environment (cf. 2.3). Authorisation of personnel includes a training course during which the projectile hazard is discussed in detail.
- All other persons entering the MR Environment must be screened for metallic objects (cf. 2.7.8 and Appendix D: Screening forms).

1.3 Implantable Medical Devices

The strong static magnetic field can affect implantable medical devices in exposed people (staff and volunteer). Any ferromagnetic component within an implantable medical device may experience both an attractive force (i.e. the device will try to move to the isocentre) and a torque force (i.e. the device will try to turn to line up with field lines). Both of these effects can cause tissue damage and/or damage to the implantable medical device. Examples of implantable medical devices are stents, clips, prostheses, pacemakers and neuro-stimulators.

CBU Health and Safety procedures

- A test of the 0.5 mT (5 Gauss) contour was undertaken independent of the manufacturer, confirming that the 0.5 mT is contained within the MR Controlled Access Area.
- Only Authorised MR Personnel have free access to the MR Controlled Access Area.
- Authorisation of personnel includes both screening and a training procedure during which the potential hazards of implantable medical devices are discussed in detail. This is subject to annual review.
- All other persons must be screened for implantable medical devices (cf. 2.7.7 and Appendix D: Screening forms).

1.4 Third party equipment

The static field can affect any equipment that has ferromagnetic components. Firstly, the function of the equipment could be affected.

Secondly, all equipment with ferromagnetic components has the potential to be a projectile hazard.

CBU Health and Safety procedures

- Any equipment which is taken into the MR Environment must be labelled as MR Safe or MR Conditional (cf. 2.6). Labelling of devices for MR safety is done by the manufacturer or following an internal certification procedure. MR Unsafe equipment must not be brought into the MR Environment, beyond the MR Projectile Zone.
- Only Authorised Personnel can take third party equipment into the MR Environment. Authorisation of personnel includes a training course during which the potential hazards of third party equipment are discussed in detail.

1.5 Biological Effects

The principal interactions of a static magnetic field, B_0 , with the body and its functions are the creation of electrical potentials and resulting currents generated by body movements (a 'dynamo effect') and the possible displacement of naturally generated currents within the body by B_0 (a 'motor effect').

There is very little evidence to suggest any adverse biological effects of static magnetic fields. A change in the T wave on an ECG trace may be observed in the magnet but this is due to a change in the charge distribution in the blood, not to any blood flow changes or cardiac rhythm changes. No noticeable effects on nerve conduction have been found at field of 3T. Some subjects and workers report nausea or a metallic taste in the mouth when in the field but this seems to be more associated with head movements in a magnetic field than due to the field itself and seems to be worse when entering the bore 'face down'. It is therefore advisable to push subjects slowly into the field and to take care when working in the magnet bore.

CBU Health and Safety procedures

- All participants will be informed about possible biological effects (cf. Appendix C: Participant Information Sheet)
- Continuous physiological monitoring (e.g. pulse) will be performed during scanning when necessary
- Supervision of participants will be provided by a MR Operator.

A two-way intercom will be used for communication between a participant in the scanner and the MR Operator. As an additional measure of precaution, an emergency squeeze bulb will be provided.

1.6 Exposure Limits for Volunteers

The primary source of information for exposure limits for patients and volunteers in the UK is the 2008 HPA report [8], the 2010 IEC standard [2] and the ICNIRP 2004 and 2009 [1]. All three organisations recommend an approach based on the restriction levels shown in the table below.

	Normal mode	Controlled mode	Research/ Experimental mode	Movement dB/dt limit
HPA	$\leq 4T$	4 – 8T	$> 8T$	$1Ts^{-1}$
IEC 2010	$\leq 3T$	3 – 4T	$> 4T$	$3Ts^{-1}$
ICNIRP 2009	$\leq 4T$	4 – 8T	$> 8T$	$1Ts^{-1}$

At the CBU we define the operating modes as follows:

Normal mode: Routine scans (Siemens sequences and Work in Progress or third party sequences imported from partner sites part of a C2P agreement) in healthy volunteers. No physiological monitoring required.

Controlled mode: Routine scans in healthy volunteers with MR conditional implants (or Patients w/o MR conditional) implants or with psychological considerations like anxiety. Pulse monitoring necessary.

Research/Experimental mode: Scans using in-house developed sequences (sequences that are completely redesigned particularly the RF and gradients) for the purpose of testing. Should be validated

on phantoms (with real-time temperature monitoring) before using in participants. Pulse monitoring and specific ethical approval necessary.

We mostly run in Normal mode but enter Controlled mode when scanning patients.

CBU Health and Safety procedures:

- Continuous physiological monitoring (e.g. pulse) will be performed during scanning when necessary
- Supervision of participants will be provided by an MR Operator

In an Emergency:

In order to offer life-saving treatment as soon as possible after an incident, an Automatic External Defibrillators (AEDs) is located in the kitchen of the MRI Facility. Alternatively, there is another one situated in the 'Elbow' at the top of the South Wing of the main building (see map).

- The MR Operators are trained on how to use the AEDs, as well as the Unit's First Aiders.
- In an emergency there is one internal telephone number (66166) that calls all first aiders simultaneously. This ensures that help is provided at the scene as quickly as possible.
- First aiders have attended a 'First Aid at Work' course which is renewed regularly. MR Operators have attend the Statutory and Mandatory Training Programme offered by the NHS (<https://www.e-lfh.org.uk/programmes/statutory-and-mandatory-training/>).
- We have a comprehensive first aid kit (including a burns kit) based in the kitchen of the Imaging Facility. The first aid equipment in the MRI Facility is inspected and replenished regularly. A poster displaying the updated list of first aiders' names and phone numbers as well as the internal emergency number is displayed in various locations inside the MRI Facility.
- It is CBU policy that all casualties will be treated outside of the MR Environment, in the reception area of the MRI Facility, unless the nature of the emergency prevents this (see below the procedure in this scenario). All CBU first aiders will have automatic access to the reception area (after completion of the appropriate authorization procedure).
- The patient table is removable to aid the emergency removal of a participant from the MR Environment. All staff who obtain authorization to enter the MR Environment will undergo patient table operating training as part of the authorization procedure.

CBU Policy on administering First Aid in the MR Environment:

The CBU policy is that no first aid is to be administered in the MR Environment. Casualties are to be removed to a 'safe' area – Reception of the MRI Facility in the first instance.

However, in an incident where for some reason it is **absolutely impossible to remove a casualty from the MR Environment**, the **MR Operator** or **Authorised Person** present must make a decision about what action is to take place. At least, they should bring the subject outside of the MR Projectile Zone.

As complete units, the first aid kits are MR Unsafe. However, the kit can be safely used in the MR Environment providing that it stays away from the MR Projectile Zone.

Similarly, the Laerdal face mask and/or Blue Dot resuscitation face mask are both MR Safe and could be used in the MR Environment in an incident where there was no choice but to resuscitate in that area. **Under no circumstances is a defibrillator or oxygen cylinder to be taken into the MR Environment, unless these are clearly marked 'MR Safe'.**

Warning: None of the CBU AEDs are MR Safe. CBU has no oxygen cylinders and assume Emergency Services carry unsafe cylinders.

1.7 Occupational Exposure Limits

The occupationally exposed population consists of adults who are generally exposed under known conditions and are trained to be aware of the potential risk and to take appropriate precautions. At the CBU, this will include authorised personnel only, as only these members of staff will have access to the MR Controlled Access Area (cf. Appendix A: Controlled Access Area).

Occupational exposure is covered in the UK by the Health and Safety Executive (HSE) following the EU Directive 2013/35/EU [4] and, internationally, by the ICNIRP [1]. The regulations generally require employers to ensure that worker exposure to EMFs does not exceed certain exposure limit values (ELVs). However, under Regulation 4(3) (b), this requirement does not apply to “the development, testing, installation, use and maintenance of, or research related to, magnetic resonance imaging equipment for patients in the health sector”. The HSE published a Certificate of Exemption available from: <http://www.hse.gov.uk/radiation/nonionising/emf-exemption-certificate.pdf> that includes “the use of magnetic resonance imaging equipment other than for patients in the health sector”. There are two conditions set out in the CEMFAW Regulations for these exemptions:

- (i) the exposure of employees to EMFs is as low as is reasonably practicable and
- (ii) employees are protected against any health effects and safety risks related to that exposure.

To satisfy condition (i) a risk assessment has been carried out and attached in Appendix M (5.13). The organisation of the MRI Facility, the SOPs, appropriate staff training, incorporation of safety considerations into the design of the MRI Facility and control of access to the MRI Environment including robust screening procedures and labelling of equipment assure the compliance with condition (ii).

EMFs at different frequencies affect the human body in different ways, causing sensory and health effects; see table below. Indirect effects can also happen; indirect effects are caused by the presence of an object in an EMF which may become the cause of a health and safety hazard. One example would be the risk of injury from ferromagnetic objects in a large static magnetic field being attracted to the magnets and hitting anyone in the way. Table 1 provides examples of effects which may be produced by work activities and equipment in the different frequency ranges; in most cases, it will only be the highest power instances that may lead to effects being experienced.

Examples of possible effects of EMFs in relation to MRI

Field and frequency range	Effects	MRI equipment
Static electric and static magnetic fields 0–1 Hz	Indirect effects: Uncontrolled attraction of ferromagnetic objects, i.e. the risk of injury from objects in a large static magnetic field being attracted to magnets in the workplace and hitting anyone in the way Sensory effects: Nausea, vertigo, metallic taste in the mouth, flickering sensations (magnetophosphenes) in peripheral vision Health effects: Micro shocks	Main magnet
Low frequency magnetic and electric fields: 1 Hz–10 MHz	Indirect effects: Interference with active or passive implanted or body-worn medical devices, electric shocks Sensory effects: Nausea, vertigo, metallic taste in the mouth, flickering sensations (magnetophosphenes) Health effects: Nerve stimulation, effects on the central and peripheral nervous system of the body: tingling, muscle contraction, heart arrhythmia	Switched gradient fields
High frequency fields: 100 kHz–300 GHz	Indirect effects: Interference with active or passive implanted or body-worn medical devices Health effects: Thermal stress, heating effects leading to a rise in core body temperature or localised limb heating (eg knees or ankles)	RF coils

Contact with charged conducting bodies can lead to RF shock or deep tissue burns

CBU health and safety procedures

Magnetic field measurements were performed in the Control Room, the MR Environment as well as in the Technical Room for a detailed risk assessment. The 2T field contour was demonstrated to be contained within the magnet bore. Authorised personnel will therefore not be exposed to magnetic field strength greater than 2T during normal operating procedures. The estimated average exposure for different groups of Authorised Personnel are summarised in the table below (cf. Appendix G: Risk assessment of magnetic field exposure). In each case, the estimated exposure values (averaged over 24 hours) are well below 200 mT (0.2 T).

Category of Authorised Personnel	Average field strength over 24h	
	Typical	Worst case
MR Operator	8.3 mT	52.4 mT
Authorised Researcher (Level 1)	8.3 mT	52.4 mT
Authorised Researcher (Level 2)	81.6 mT	177 mT
Authorised Technician	3.6 mT	13.3 mT

Authorised personnel will be informed about the aforementioned recommendations during the MR safety training course which is part of the CBU MRI Authorisation Procedure (cf. 2.3.2).

1.8 Exposure Limits for General Public

The general public comprises individuals of all ages and of varying health status and may include particularly susceptible groups or individuals. Moreover, individual members of the public cannot reasonably be expected to take precautions to minimise or avoid exposure.

The table below summarises the basic restrictions for general public exposure to static magnetic fields as recommended by the ICNIRP [1].

General Public	ICNIRP 98 upper limit (mT)
Without pacemakers	400
With pacemakers	0.5

CBU Health and Safety procedures

- A measurement of the 0.5 mT (5 Gauss) contour was undertaken confirming that the 0.5 mT is contained within the MR Controlled Access Area. Moreover, the contour extends very little outside the MR Environment and it is physically impossible for members of the public to be exposed to magnetic fields greater than the 0.5 mT safety limit.
- Access to the MR Environment will be possible by authorised personnel only.

Members of the general public who wish to access the MR Environment (e.g. visitors) must be screened like volunteers (cf. 2.7 and Appendix D: Screening forms).

1.9 Time-varying Magnetic Field Gradients (dB/dt)

The safety concerns with the time-varying magnetic field gradients are biological effects such as peripheral nerve and muscle stimulation, and acoustic noise generated by gradient switching. The latter is discussed in a separate section (cf. 1.10).

In MR, three orthogonal magnetic field gradients are switched on and off to select the region of diagnostic interest and to spatially encode the MR signals. As a general guide, the faster the imaging or spectroscopy sequence or higher the resolution, the greater the rate of change of the gradient fields used and the resultant current density induced in the tissue.

1.9.1 Biological Effects

Time-varying magnetic fields induce electric currents that could be sufficiently large in tissues to interfere with the normal function of nerve cells and muscle fibres. A well-established example of this is the sensation of flashes of light, 'the magnetic phosphenes', caused by induced electric currents stimulating the retina. However, this effect has not been shown to be hazardous.

Peripheral nerve stimulation can occur in the body when exposed to high switching magnetic fields (both strong and fast). This manifests itself as a twitching or sensation in the region concerned and can in extreme cases cause pain or injury. Our system is safe guarded by a gradient supervisor unit that will disable the gradient system when the switching rate exceeds a set maximum. The gradient supervisor unit is calibrated, tested, and maintained by the manufacturer.

CBU Health and Safety procedures

- All participants will be informed about possible biological effects (cf. Appendix C: Participant Information Sheet).
- Continuous physiological monitoring (e.g. pulse) will be performed during scanning in Controlled Mode
- Supervision of volunteers will be provided by the MR Operator

A two-way intercom will be used for communication between volunteer in the scanner and the MR Operator. As an additional measure of precaution, an emergency squeeze bulb will be provided.

1.9.2 Exposure Limits for Volunteers

The IEC provides a very comprehensive explanation on the restrictions for time-varying magnetic field gradients to be incorporated in MR scanners (IEC 60601-2-33) [2]; it is too detailed to present in full here. Fundamentally, the IEC states that the system must not have gradient output that exceeds the limit for peripheral nerve stimulation (PNS). This will protect against cardiac fibrillation. The PNS threshold may be determined from numerical modelling or from human studies. For the controlled mode of operation the IEC recommends that the gradient system shall operate at a level that does not exceed 100% of the directly determined mean threshold PNS.

CBU Health and Safety procedures

- The time varying magnetic field produced by the gradient system (dB/dt) is automatically calculated for each MR sequence by the scanner operating system and the MR Operator is warned if the critical threshold for PNS is exceeded.
- dB/dt is continuously monitored during scanning by an independent hardware component (gradient supervisor unit) which will inform the MR Operator about the current level and disable the gradient unit if the critical threshold for PNS is exceeded.

Manufacturer's statement of conformity with IEC 60601-2-33 (cf. Appendix H: Statement of conformity).

1.9.3 Occupational Exposure Limits

The occupational exposure to time-varying magnetic field gradients must satisfy the two conditions set out in the HSE Certificate of Exemption. The risk assessment done at CBU covers all occupational exposure.

CBU Health and Safety procedures

Given the nature of the MRI studies performed at the CBU, the presence of personnel in the MR Environment during a scan is not anticipated. Personnel will therefore not be exposed to time-varying magnetic fields during the normal use of the equipment. In situations when there is a need for staff to be present in the MR Environment during the operation of the equipment, the person should keep as far as reasonable possible from the mouth of the bore.

1.9.4 Exposure Limits for General Public

The corresponding exposure limits for general public exposure to time-varying magnetic fields are summarised in the table below.

Frequency range	Magnetic flux density (T)
0 – 8 Hz	$4 \times 10^{-2} / f^2$
8 – 25 Hz	$5 \times 10^{-3} / f$
25 – 50 Hz	2×10^{-4}
50 -400 Hz	2×10^{-4}
400 Hz – 3 kHz	$8 \times 10^{-2} / f$
3 kHz – 10 MHz	2.7×10^{-5}

The MHRA understands that it is difficult for an MR unit to measure these parameters but recommend that sites ask for confirmation from the manufacturer that staff will not be exposed to levels above these during the normal use of equipment.

CBU Health and Safety procedures

Members of the general public will not normally be allowed in the MR Environment during a scan and will therefore not be exposed to time-varying magnetic fields during the normal use of the equipment. However, there are certain situations when children need to be accompanied during the scan by one parent or carer. They are advised to keep a safe distance from the bore of the magnet (outside the MR Projectile Zone), and usually sit on the chair next to the door.

1.10 Acoustic Noise

1.10.1 Hazards

A characteristic of the switching gradient fields is the production of acoustic noise. When the alternating low-frequency currents flow through the gradient coils, which are immersed in the high static magnetic field B_0 , forces are exerted on the gradient coils that move like a loudspeaker coil and generate sound waves. The level of this acoustic noise at the location of the patient or volunteer can reach an unacceptable and even dangerous level [5].

CBU Health and Safety procedures

- Earplugs, ear defenders, or other means of hearing protection will be used when scanning a participant
- Adequate staff training in the use of ear protection.

1.10.2 Exposure Limits for Participants

The Control of Noise at Work Regulations 2005 are to ensure that all hearing is protected from excessive noise. As the scanner is capable of generating noise levels in use which are greater than the lower daily exposure level 80dB (A weighted), suitable hearing protection must be used with all participants. Extra care must be taken with young age participants.

CBU Health and Safety procedures

- Standard headphones and hearing protection recommended by the manufacturer will be used.
- Staff will be trained in the selection and fitting of hearing protection.

For all other equipment (e.g. headphones obtained from suppliers other than the manufacturer) a risk assessment will be performed. To this end, information about the maximum sound pressure level produced by the scanner will be obtained from the manufacturer and the type of hearing protection will be chosen to ensure that the noise level at the eardrum is less than the above figure taking into account the frequency spectrum of the MR system in use.

1.10.3 Occupational Exposure Limits

The Noise at Work Regulations 2005 requires that employers must make hearing protection freely available to employees when noise exposure exceeds 80 dBA. The regulations also state hearing protection must be worn by all employees when noise exposure exceeds 85 dBA. The type of hearing protection must be chosen to ensure that the noise level at the eardrum is less than the above figure. Note that these limits do not vary with age.

CBU Health and Safety procedures

Given the nature of the MRI studies performed at the CBU, the presence of personnel in the MR Environment during a scan is not anticipated. However, should someone be within the MR Environment during a scan, other than the participant, suitable hearing protection will be provided and must be worn. The maximum sound pressure level outside the MR Environment is well below 80dBA during the normal use of the equipment, as confirmed by acoustic noise measurements.

1.10.4 Exposure Limits for General Public

CBU Health and Safety procedures

Members of the general public will not normally be allowed in the MR Environment during a scan. In situations when the presence of additional people is necessary in the MR Environment i.e. parent/carer accompanying participant, they will receive noise reduction earplugs and ear defenders. The maximum sound pressure level outside the MR Environment is well below 80dBA during the normal use of the equipment, as confirmed by acoustic noise measurements.

1.11 Radiofrequency Magnetic Fields (B₁)

The main safety issues for radiofrequency (RF) fields used in MR are thermal heating leading to heat stress and induced current burns and/or contact burns.

Absorption of energy from radiofrequency fields used in MR results in the increased oscillation of molecules and the generation of heat. If this occurs in human tissue, a compensatory dilation of blood vessels results in an increase in blood flow and the removal of the excess heat, which is dissipated mainly through the skin.

Limbs will disperse thermal energy more rapidly than internal parts of the abdomen. The electromagnetic and thermal characteristics of different organs and parts of organs will differ. The eyes are an example of organs that have very little blood flow. In fact, the lens of the eye has none, and therefore takes time to disperse thermal energy. The testes are organs separated from the main volume of the body and regarded as heat sensitive. Normally their temperature is a few degrees below body temperature. A rise of 1°C is in general very acceptable to a normal healthy body. The actual temperature rise at any time will depend on the balance between the energy absorbed and the energy transferred from the region of the body concerned. The ambient temperature and humidity will play a major role in the rate of dissipation. The lower the ambient temperature and the lower the humidity, the greater the transfer.

1.11.1 Heat Stress

Heat stress is of particular concern for some patients, such as those suffering from hypertension, or pregnant women, or those on drugs such as diuretics or vasodilators that may compromise these responses. Other potentially vulnerable groups include those with neurodegenerative disease, and nerve damage from medical conditions such as diabetes, or old age.

One fundamental issue is excessive cardiovascular strain resulting from thermoregulatory responses to body temperatures raised over a short period of time by more than 0.5°C in vulnerable people. The temperature rise is a function of the Specific Absorption Rate (SAR), health factors and medication.

CBU Health and Safety procedures

- Pregnant women will not be scanned at our unit.
- Potentially vulnerable people (e.g. on hypertensive drugs) must be monitored closely, including pulse rate.

1.11.2 Induced Current Burns

There have been reports of burns that have occurred when the arms or the legs have been positioned in such a way as to create a conductive loop pathway [6]. The RF burns have occurred where the arms or thighs meet.

CBU Health and Safety procedures

- Adequate positioning of volunteers to avoid conductive loops (cf. 2.8.4).
- Positioning of participants will be conducted or supervised by an MR Operator.

1.11.3 Contact Burns

Contact burns are the most often reported adverse incident in MR. A review of burns in MR is given in [7]. The radiofrequency field will induce currents in conductors and can raise their temperature significantly.

Examples of causes are contact with metal in clothing, coils, coil leads, ECG connectors. Part three of these guidelines discusses how to screen and set up patients to avoid this hazard.

CBU Health and Safety procedures

- Burns to volunteers and patients from contact with such metallic objects must be avoided by the careful positioning and set up within the bore of the magnet (cf. 2.8.4).
- Positioning of participants will be conducted or supervised by a MR Operator

A burns kit and a roll of cling film have been incorporated into the first aid kit.

1.11.4 Exposure Limits for Volunteers

The IEC standard information on specific absorption rate (SAR) limits and monitoring is too detailed to list here. It is recommended that sites make themselves familiar with the SAR limits used by their system from both the IEC standard [2] and the manufacturer's user manual.

The IEC SAR limits are set assuming moderate environmental conditions of relative humidity i.e. < 60%, and ambient temperature < 24°C. The MHRA recommends that the MR unit ensures that these environmental conditions are monitored.

The MHRA also recommends that a clear statement should be obtained from the supplier of the maximum operating values for all exposure types that the equipment will provide in normal operation, and the maximum values that could occur in a fault condition.

CBU Health and Safety procedures

- Environmental conditions (ambient temperature, relative humidity) are controlled by an air conditioning system.
- The specific absorption rate (SAR) is automatically calculated for each imaging sequence by the scanner operating system. A scan cannot be started if it exceeds the SAR limit.
- The SAR is continuously monitored during a scan by an independent hardware component (radiofrequency supervisor unit). The radiofrequency supervisor unit immediately stops a scan if the SAR limit is exceeded.
- As SAR calculations depend on the body weight and height, the participant's weight and height must be determined before the scan and recorded at the participant registration..

Manufacturer's statement of conformity with IEC 60601-2-33 (cf. Appendix H: Statement of conformity).

1.11.5 Occupational Exposure LimitsCBU Health and Safety procedures

Given the nature of the MRI studies performed at the CBU, the presence of personnel in the MR Environment during a scan is not anticipated. Personnel will therefore not be exposed to radiofrequency magnetic fields during the normal use of the equipment. In situations when there is a need for staff to be present in the MR Environment during the operation of the equipment, the person should keep as far as reasonable possible from the mouth of the bore.

1.11.6 Exposure Limits for General PublicCBU Health and Safety procedures

Members of the general public will not be normally allowed in the MR Environment during a scan and will therefore not be exposed to RF magnetic fields during the normal use of the equipment. In situations

when the presence of additional people is necessary in the MR Environment i.e. parent/carer accompanying participant they will sit in locations that are far from the RF source to minimise exposure.

1.12 Cryogenics

There should be no hazards from cryogenics providing adequate attention has been paid to the provision of venting directly to the outside of the building of all potential sources of helium and nitrogen following normal boil-off or in the event of a pressure release valve bursting. However, for completeness and as a warning, reference is made to some of the potential hazards.

The hazards in the use of low temperature liquefied gases for MR systems are:

- Asphyxiation in oxygen-deficient atmospheres.
- Cold burns, frostbite and hypothermia from the intense cold.
- Over-pressurisation from the large volume expansion of the liquid following evaporation.

1.12.1 Asphyxiation

Nitrogen and helium may produce local oxygen deficient atmospheres, which will produce asphyxia if breathed. Atmospheres containing less than 18% oxygen are potentially dangerous and entry into atmospheres containing less than 20% oxygen is not recommended. Atmospheres containing less than 10% oxygen can result in brain damage and death.

Asphyxia due to oxygen deficiency is often rapid with no prior warning and the victim may not be aware of the asphyxia. Typical symptoms are:

- Rapid breathing and gasping for breath
- Rapid fatigue
- Nausea
- Vomiting
- Collapse or inability to move
- Unusual behaviour

1.12.2 Cold Burns, Frostbite and Hypothermia

Liquid helium and nitrogen or even their cold gases can damage the skin producing an effect similar to a heat burn. Unprotected parts of the skin that come into contact with uninsulated items of cold equipment may also stick fast to skin, the flesh being torn on removal.

The cold vapours from liquefied gases may cause frostbite given prolonged or severe exposure to unprotected parts. A symptom is local pain but sometimes no pain is felt, or it is short-lived.

Transient exposure to very cold gas produces discomfort in breathing and can provoke an attack of asthma in susceptible people.

1.12.3 Handling Cryogenics

CBU Health and Safety procedures

- The CBU staff is not involved with handling cryogenics so there is minimal risk from cryogenics during normal operation.
- In the event of unusual venting, possible during a quench, Siemens and the helium supplier needs to be informed immediately.

No unauthorised person, at any time, should operate or tamper with cryogenics, valves, etc.

1.12.4 Over-pressurisation of the MR Environment

In the unlikely event of a quench when the helium venting happens towards the inside of the MR Environment (due to an obstructed ducting), there is the potential for over-pressurisation of the room. Because the RF door is opening towards the inside of the room this poses a high risk that the 'air pressure' is so high that the door will not open.

CBU Health and Safety procedures

The manufacturer of the MR system is inspecting regularly and, if necessary, clearing the ducting of the helium venting.

1.13 Other potential hazards

1.13.1 Laser Light Localizer

The laser light localizer on the magnet facilitates correct patient positioning. It contains two Class II lasers. Direct exposure of the eyes to the laser beam may result in injury of the eye (cornea).

CBU Health and Safety procedures

- Strictly adhere to the operating procedures provided by the manufacturer
- Inform patients of this risk and ask them to keep their eyes closed during the positioning procedure.
- Check that the laser light localizer appears in the form of crosshairs on the patient table. If the laser light localizer takes the form of a spot, switch the laser light localizer off and notify the manufacturer.

Have the laser light localizer checked regularly by the manufacturer.

1.13.2 MR Phantoms

When measurement phantoms are used as intended within the scope of quality measurement of RF coils, there is no physical contact with measurement phantom fluids. The fluids are sealed in the measurement phantoms.

Phantoms are filled with water-based nickel sulphate solutions or oil. Other components may include sodium chloride, sodium phosphate buffers, as well as lactates, acetates, or dye.

If phantom fluid has escaped, aerosols containing nickel may form in the event of a fire or atomization caused by strong air currents. Carcinogenic effects cannot be ruled out if these aerosols are absorbed by the body.

Home-made MR phantoms are also used for MR safety testing and MR Spectroscopy. These are formulated using tested recipes found in literature.

The manufacturer of the MR system checks regularly all the standard MR phantoms and will replace any damaged ones or top-up the fluid.

CBU Health and Safety procedures

- Do not use damaged phantoms.
- Avoid skin contact with phantom fluid.
- Wear appropriate personal protective equipment (PPE) when making phantom (gloves, work coat, and goggles).
- Wear a mask with a filter for inorganic vapours if aerosols are formed.
- Change contaminated clothing immediately.
- Do not eat, drink, or smoke.
- Ensure that phantom fluid does not enter the waste water.

Dispose of phantom fluid in compliance with local and national regulations.

2 Management of the MRI Facility

2.1 Responsibility and Organisation

2.2 Key Personnel

CBU Director

Prof. Matthew A. Lambon Ralph
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Tel: 01223 7767754
Email: matt.lambon-ralph@mrc-cbu.cam.ac.uk

Responsibility: General management of health and safety related issues at the Cognition and Brain Sciences Unit. Chair of the Unit Management Committee (UMC) which has overall responsibility for Unit policy and management.

CBU Deputy Director: Neuroimaging

Dr Richard Henson
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Telephone: 01223 767591
Email: rik.henson@mrc-cbu.cam.ac.uk

Responsibility: Implementation, supervision and maintenance of health and safety procedures related to neuroimaging at CBU. Chair of the Imaging Management Committee (IMC) which has overall responsibility for general neuroimaging policy and management at the CBU, within the framework laid down by the Director and the UMC.

CBU Head of MRI (MR Safety Expert)

Dr Marta Correia
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Tel: 01223 767737
Email: marta.correia@mrc-cbu.cam.ac.uk

Responsibility: Implementation, supervision and maintenance of health and safety procedures related to MRI. Chair of the MRI Management Committee which has responsibility for the implementation, supervision and maintenance of health and safety procedures specific to the CBU MRI Facility.

CBU Health and Safety Coordinator

Mr Gary Chandler
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Tel: 01223 767752
Email: gary.chandler@mrc-cbu.cam.ac.uk

Responsibility: Implementation, supervision and maintenance of general health and safety procedures at the CBU as required by the *UK Health and Safety at Work etc Act 1974*.

Senior Radiographer (MR Responsible Person)

Dr Marius Mada
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Tel: 01223 767747
Email: marius.mada@mrc-cbu.cam.ac.uk

Responsibility: Day to day management of the radiography team at the CBU MRI Facility. Implementation, monitoring and maintenance of health and safety procedures related to MRI, including training of MRI Operators.

Medical Monitor

Dr James Rowe
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Email: james.rowe@mrc-cbu.cam.ac.uk
Tel: 01223 767697

Responsibility: For referring an adult for further clinical investigation in the event that a scan is flagged as abnormal (eg. an abnormality is noticed in a brain scan by a radiographer).

Paediatric Medical Monitor

Dr Anna Maw
Consultant Paediatric Neurologist
Cambridge University Hospitals NHS Trust
Child Development Centre,
Box 107, Addenbrookes Hospital
Cambridge, CB2 2QQ
Tel: 01223 216662 | Fax: 01223 242171
anna.maw@addenbrookes.nhs.uk

Responsibility: For referring a child for further clinical investigation in the event that a scan is flagged as abnormal (e.g. an abnormality is noticed in a brain scan by a radiographer).

Facility Administrator

Mr Matthew Sharrock
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Tel: 01223 769603
Email: mri.admin@mrc-cbu.cam.ac.uk

Responsibility: Overall responsibility for administration of the CBU MRI Facility within the wider Unit administrative framework. Note mri.admin@mrc-cbu.cam.ac.uk is accessed by both MRI Admin and Radiographers.

2.2.1 External MR Safety Advisor**Professor Steve Williams**

Professor of Imaging Sciences
Institute of Psychiatry
King's College London
De Crespigny Park, London, SE5 8AF
Email: steve.williams@kcl.ac.uk

2.2.2 MRI Management Committee

The MRI Management Committee shall consist of

- The Head of MRI (chair)
- The Facility Administrator
- Senior Radiographer

The committee will review and update local MRI Facility issues, including health and safety policy.

Any changes or crucial updates to policy that are needed in between these meetings can be made via Chairman's action.

2.2.3 Access for Personnel

The MR scanner and the related equipment are contained within the MR Controlled Access Area (cf. Appendix A: Controlled Access Area). Access to the MR Controlled Access Area shall be given only to authorised personnel (please see section 2.4.3 for categories of authorised personnel). Only Authorised Person Supervisors will have free access to the MR Controlled Access Area.

Unauthorised personnel shall have access only if accompanied by an Authorised Person who will take on the full responsibility for the presence of the unauthorised person or persons for the duration of their presence in the MR Controlled Access Area .

The MR Responsible Person shall formally approve certification of a member of staff as an authorised person when the member of staff has satisfactorily completed training in their responsibilities and the safety requirements of MR equipment.

2.3 MR Controlled Access Area

2.3.1 Definitions

The **MR Controlled Access Area** is characterised by the MHRA as follows: “A locally defined area of such a size to contain the MR Environment. Access to this area should be restricted and controlled by suitable control methods (e.g. keypad entry) with suitable warning signs displayed at all entrances.” [8]

At the CBU, the MR Controlled Access Area starts at the end of the hallway, at the door near the entrance to the Staff Kitchen (see Appendix A). The MR Controlled Access Area consists of two zones:

- Zone 1: Room containing the MR scanner, Control Room, Back office
- Zone 2: Technical Room

The **MR Environment** is defined by the MHRA as “the three-dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.5mT field contour (5 Gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.” [8]

The **MR Projectile Zone** is situated inside the MR Environment and is defined as the volume containing the full extent of the 3 mT magnetic field contour around the MRI scanner. No MR Unsafe devices are to enter this zone.

At the CBU, the MR Projectile Zone extends to the end of the patient table. This allows the use of ferromagnetic tools along the west wall of the scanner room (the one with the glass) e.g. fire-fighters can fight fires inside the MR Environment using standard gear.

Note: At the CBU, the MR Environment extends slightly outside the MR scanner room both in the Control Room and the Technical Room (see Appendix A). Access to the extent of the 5G line inside the Control Room is physically restricted by the presence of the desk. The Technical Room is locked, and access is for Authorised Person Supervisors only.

2.3.2 Access to MR Controlled Access Area

Access to the MR Controlled Access Area is provided by self-locking doors or key. The devices for operating the locks are:

- Zone 1: Access card (plus MR Environment by key)
- Zone 2: key

Keys for the Zones 1 and 2 are kept in a numbered safe in the Control Room. Only Authorised MR Environment person or above have access to this safe and they are responsible for keeping this code confidential. Disclosure of this code is permitted in an emergency after which the code must be changed.

2.3.3 Warning signs

Following the standard procedures and recommendations of the manufacturer (Siemens Healthineers, Erlangen, Germany) the following warning signs are in use.

	
Strong Magnetic Field	Radio Frequency Field
	
Wear hearing protection	Laser light

 No entry to persons with implants which may be affected by electromagnetic fields, e.g. cardiac pacemakers, defibrillators, hearing aids, insulin pumps, drug pumps	 No entry to persons with implants made of metal or other metal objects in the body
 No entry with mechanical watches, electronic data carriers such as pocket calculators, digital watches, etc.	 No entry with fire extinguishers made of ferrous metal
 No entry with metallic parts of any kind	 No entry with data carriers such as credit cards, identification cards with magnet strips, magnetic tapes, etc.
 No open fire. Smoking prohibited	

2.4 Access Control

Entry to the MRI Facility is controlled by access card. Access privileges will be upgraded to include the MRI Facility upon completion of the relevant training courses. Those completing the relevant training and without a Unit card will be assigned a temporary one whilst they carry out their research at the CBU.

2.4.1 Access for Personnel

The Authorised Person is a suitably trained member of staff authorised to have access to the MR Controlled Access Area and also, depending on their role, access to the MR environment. All authorised persons must:

- be certified by the MR Responsible Person following completion of satisfactory training (cf Appendix N: MRI Authorisation Procedure)
- be listed on a certified list
- keep an appropriate record of their MR training; an annual screening of all authorised persons is to be kept by the MR Responsible Person
- complete and pass a screening questionnaire annually
- satisfy themselves at all times that they conform to the requirements of the screening process.

The MHRA defines access and supervision rights of MR authorised personnel as follows [8]:

Staff group	MR Environment	MR Controlled Access Area Outside MR Environment
Authorised person Non-MR environment e.g. clerical staff, management staff, non-trained technical staff	May not enter without supervision	May enter and supervise
Authorised person MR environment e.g. researchers, trained technical staff	May enter and supervise (NO participants)	May enter and supervise
Authorised person Supervisor e.g. MR operator	May enter and supervise (incl. participants)	May enter and supervise

The local MRI Authorisation Procedure includes:

- An MRI Safety Training course available as a Moodle course on me.cam.ac.uk
- A tour of the MRI Facility including a practical demonstration of the projectile risk, effect of the magnetic field on non-ferrous conductors and practical demonstrations of emergency procedures

2.4.2 Responsibilities of Authorised Personnel

- On entering the MR Controlled Access Area, all personnel must at all times comply with the CBU Standard Operating Procedures.
- All unauthorised personnel, which will include visitors, patients and unauthorised staff, shall have access only if accompanied by an Authorised person.
- The Authorised person will take on the full responsibility for the presence of the unauthorised person or persons for the duration of their presence in the MR Controlled Access Area.
- All authorised personnel who act as volunteers for scanning must conform to the appropriate requirements referred to in the sections about volunteer management (cf. 2.7).

- Authorised Person MR Environment can screen workmen, cleaners, engineers and other visitors for entry to the MR Environment but not participants for scanning.
- Only an Authorised Person Supervisor e.g. MR Operator can screen participants for scanning.

Lost or mislaid cards must be reported to the MRI Facility Administrator immediately so that all access privileges on the card can be suspended.

2.4.3 Categories of Authorised Personnel

The MHRA guidelines define the following categories of Authorised Personnel.

MR Responsible Person

The MR responsible person:

- has day-to-day responsibility for safety in the MRI centre
- is required to have sufficient MRI expertise and safety knowledge to ensure that appropriate levels of MRI safety and training are delivered and updated to relevant staff
- is delegated as responsible person by the Head of MRI

MR Safety Expert (MRSE)

The MRSE:

- provides scientific advice to the MRI Facility
- has expert knowledge of the physical principles of MRI and detailed knowledge of MRI techniques

MR Operator

The MR Operator is:

- an authorised person who is deemed to have sufficient experience and appropriate training and is responsible for operating the scanner in a safe and appropriate manner
- responsible at all times for the safety of participants (and accompanying carers/parents/guardians) who are undergoing MRI
- responsible for ensuring that any equipment taken into the MR Environment for the examination is suitable

MR Operators at CBU are normally HCPC Registered Diagnostic Radiographers with relevant MR training. They are classified as Authorised Person Supervisors. Any Authorised MR Environment Person can become an MR Operator following the procedures and requirements included in the document "**MR Operator Training at the CBU**".

2.4.4 Required Staffing Levels for Scanning

For **scanning participants during CBU Opening Hours** (Appendix I: Definition of Terms) of the CBU, the minimum requirement is one MR Operator and at least one other authorised person e.g. the study researcher.

For **scanning participants outside CBU Opening Hours** of the CBU the minimum requirement is one MR Operator and at least two other authorised persons e.g. the study researcher and another authorised MR Environment person/Supervisor

For **scanning phantoms**, the minimum requirement is one MR Operator provided that this person does not enter the MR Environment. Otherwise, at least one other authorised person must be present.

2.5 Categories of Exposed Persons

2.5.1 Participants

It is not anticipated that any MRI for diagnostic purposes will be performed at the MRC Cognition and Brain Sciences Unit. Most studies will be on healthy control participants who are volunteers and will have been pre-screened for any neurological illnesses as well as any history of head injury, psychiatric disturbance or substance abuse.

However, increasingly more studies are recruiting 'stable' patients; that is, participants who have a neurological history, but who do not require ongoing medical attention and for whom MRI poses no significant risks over and above those that apply to a normal healthy participant. Possible groups include stable ex-stroke patients, mild Parkinson's disease and early stage Alzheimer's Disease.

The scanning of healthy volunteers would require prior approval from Cambridge Psychology Research Ethics Committee (CPREC) or Local Research Ethics Committee (LREC). These studies would involve standard cognitive neuroscience paradigms which have been used previously on similar volunteers outside the scanner, and will be undertaken within the guidelines laid out by the Standard Operating Procedures.

Scanning studies involving patients or drugs would require prior approval from the Local Research Ethics Committee (LREC). These studies would be undertaken within the guidelines laid out by the Standard Operating Procedures.

All participants must be screened before exposure (cf. 2.7 and Appendix D: Screening forms).

Only MR Operators are allowed to scan participants.

Written informed consent must be obtained from all participants.

2.5.2 Staff

Only Authorised MR Environment Persons and above shall have free access to the MR Controlled Access Area. Unauthorised staff shall be subject to the procedures for the general public (see below).

2.5.3 General Public

All unauthorised personnel, including unauthorised staff and the general public, must be screened for a wide range of factors (cf. 2.7 and Appendix D: Screening forms) and seek authority to enter the MR Controlled Access Area.

2.5.4 Cleaning and Maintenance Staff

Cleaning and maintenance staff (e.g. estates and engineering staff) requiring access to the MR Environment may only do so as unauthorised personnel and must undergo screening (cf. 2.7 and Appendix D: Screening forms). They may only gain access to the MR Environment under direct supervision of an Authorised MR Environment Supervisor. A request for access needs to be made through the MRI Facility Administrator and requires approval of the MR Responsible Person. All items required to be used in the MR Environment must be demonstrated to be MR Safe. Cleaning equipment to be used in the MR Environment must be clearly labelled and stored appropriately.

2.5.5 MR Maintenance Engineers

All access of MR related engineers i.e. MR maintenance, helium refill needs to be organised by the MRI Facility Administrator and authorised by the MR Responsible Person. An authorised MR Environment Person/Supervisor has to supervise the MR engineer/s, particularly when working in the MR Environment.

2.6 Control of Equipment

2.6.1 Equipment Policy

All equipment taken into the MR Environment must be MR Safe or MR Conditional. If MR Conditional, the label must clearly display the conditions for safe operation.

MR Safe	'An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic'
MR Conditional	'An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.'
MR Unsafe	'An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.'



Only equipment may be taken into the MR Environment if:

- classified as MR Safe or MR Conditional by the manufacturer
- labelled MR Safe or MR Conditional by an Authorised member of staff, following adequate testing. Testing and labelling must be approved by the MR Responsible Person and the MR Safety Expert, and a written record must be kept.
- labelled MR Safe or MR Conditional by an authorised member of staff at the Wolfson Brain Imaging Centre (WBIC) or the Radiology Department, Addenbrooke's Hospital. The conditions for cross-sites testing are outlined in Appendix O: Use of Unlabelled Equipment in MRI environment.

A re-examination of each device's MR safety will be required whenever changes are made to the MR environment or device.

2.6.2 Responsibility for Entry

Control of equipment entering the MR Environment on a day-to-day basis is the responsibility of the MR Operator (cf. 2.6.2) responsible for the examination at the time. Only equipment that is known to be MR Safe or Conditional should be taken into the MR Environment.

2.7 Volunteer Management: General Considerations

2.7.1 Volunteers

The means of volunteer recruitment must be approved by the relevant Research Ethics Committee (REC).

In addition to screening onsite before the scan (see below), it is recommended that volunteers are pre-screened before attending the MRC CBU, to save time and prevent a potential volunteer being sent home because not suitable. Some recommended questions are given in Appendix L: Recommended Pre-Screening. These questions can be asked over the phone, though researchers might want to consider posting a version and getting a signed response before booking the scan, to have a record of responses (in case a volunteer complains about being sent home) – though ethical approval will be needed for this. Note that the answers to these questions can include personal information, so anything written down that includes PID should be stored safely in accord with the ethics approval and the CBU's data protection policies.

Members of staff are permitted to be scanned under the supervision of the MR Operator.

The term volunteer shall include:

- Healthy members of the public volunteering for a MR study.
- 'Stable patients' volunteering for a MR study.

2.7.2 Pre-requisites for MR Examination

For all MR examinations of volunteers the following prerequisites must be fulfilled:

- Ethical approval for scanning volunteers must be obtained from the relevant Research Ethics Committee prior to the MR examination.
- Written MR information must be made available to all volunteers before they consent to scanning, as defined in the study protocol approved by the research ethics committee.
- Written informed consent must be obtained before examination (Appendix E: MRI Consent Form).
- All volunteers must be screened before exposure (Appendix D: Screening forms)

The following additional considerations will apply to the MR examination of volunteers under the age of 18 years:

- Ethical approval for scanning volunteers must be obtained from the relevant Research Ethics Committee prior to the MR examination.
- Written MR information must be made available to the participant and their parent/legal guardian before they consent to scanning, as defined in the study protocol approved by the research ethics committee.
- A demonstration and introduction session should be made available for the participants and their parent/legal guardian prior to the scanning session, and the details of such a "desensitisation" process must be approved by the Imaging Management Committee.
- A parent/legal guardian must accompany the participant at all times (except in the MRI room itself); they cannot be supervising other dependents.
- Participants under 16 must give informed verbal assent, and signed informed consent must be obtained from the parent/guardian before the examination (Appendix D: Screening forms).
- The MRI Screening Form (Appendix D: Screening forms) must be completed before the examination in the presence of the participant and signed by their parent/legal guardian.
- Participants aged 16 and over may be exempt from the above need for parental/guardian participation in the study and in the consent/screening process, where the relevant Research Ethics Committee approves such exemptions within the study protocol. In this case, such participants would complete the form (Appendix D: Screening forms), giving their own signed, consent.
- A parent/legal guardian will need to complete a visitor's screening form (Appendix D: Screening forms), and they will also need full screening if they accompany the participant in the MRI room during the scan

2.7.3 Medications

There are medicines that might interfere with the thermoregulation mechanisms in certain participants e.g. participants suffering from high blood pressure. As a precaution all patient volunteers and those aged 60 and above should be monitored i.e. pulse. The researcher accompanying the volunteer will identify the participants at risk.

The MR Operators will not be responsible for screening participants for medication or use of recreational drugs that might influence the data quality e.g. affect the neurovascular coupling for fMRI, such as caffeine. This is the responsibility of the researcher to decide eligibility.

2.7.4 Responsibility for Volunteers whilst in the MR Controlled Access Area

The MR Operator will remain responsible for the safety, health and well-being of the volunteer throughout the period that the volunteer is within the MR Controlled Access Area.

2.7.5 MRC Indemnity Arrangements for Volunteers

Studies sponsored by the MRC:

The MRC provides indemnity where it is the Sponsor or has entered into a written agreement to provide indemnity for all or part of a study:

Negligent Harm. This will be covered by the MRC for MRC sponsored studies involving a member of the CBU.

Non-negligent Harm. The MRC does not provide cover for non-negligent harm. However, it takes a sympathetic view of non-negligent claims.

A copy of the MRC's indemnity policy statement can be obtained by emailing mri.admin@mrc-cbu.cam.ac.uk.

Studies not sponsored by the MRC:

Where the MRC is not the sponsor, then the researcher must provide written confirmation of any insurance or indemnity arrangements made in line with the terms and conditions agreed with their parent organisation. The insurance or indemnity arrangements must be as defined in the LREC/CPREC approval for the study.

Medical Doctors:

Medical doctors are advised to arrange adequate personal insurance against claims for negligent and non-negligent harm. They are advised that even non-remunerated research may be regarded as private practice (non-NHS practice) by some medical insurers.

2.7.6 Pregnant Women

There is currently no convincing evidence that electromagnetic fields that would be experienced in the normal operating mode can cause any detrimental effect to the well-being of the foetus, however a precautionary approach is recommended.

We therefore exclude from scanning all women who are or may be pregnant as a general measure of precaution.

2.7.7 Implanted Medical Devices

Implanted medical or non-medical devices fall into two main categories:

- Active implanted medical devices - such as pacemakers, defibrillators, neurostimulators, cochlear implants and drug pumps, where functionality is dependent upon an energy source such as electrical, mechanical or pneumatic power.
- Non-active implanted medical devices - which are passive in that they require no power source for their function, for example hip/knee joint replacements, heart valves, aneurysm clips, coronary stents and breast implants.

Active implanted medical devices can contain metallic components which render the device incompatible with MR in that MR may be unsafe and therefore contraindicated by the implant manufacturer or may cause artefacts which can affect image quality.

No active implanted medical or non-medical devices are to be scanned at the CBU.

Some non-active implanted medical devices are inherently not MR safe, and would prevent scanning under all circumstances like aneurysm clips

Some non-active medical devices are not associated with significant MR risks and may be scanned, including

- Knee and hip replacements
- Bone fixation plates
- Dental implants

Some non-active implanted medical devices may have an unknown risk. As a precautionary measure, further specific information would be required about the MR safety of a particular device prior to scanning. If sufficient information and advice from the manufacturer can be obtained about MR safety at 3T, it would be permitted to scan the person. Examples include: Vascular stents, cardiac valves.

Some non-active devices may be MR safe but nonetheless unsuitable for MR in view of the large interference with the MR signal. Examples in this category include

- Jaw or maxillary reconstruction metalwork
- Metallic shoulder prostheses

Scanning of MR Conditional non-active implanted medical devices has to be authorised by the MR Responsible Person or the MR Safety Expert.

2.7.8 Metallic Foreign Bodies

The presence of metallic objects such as bullets, pellets, shrapnel, or other types of metallic fragments, in particular ferromagnetic objects, is a particular hazard both external and internal to the body. This is of particular relevance to volunteers who are or have been involved in the manufacture of metal products. The embedded metal fragments may heat up and/or move, or become dislodged. The potential for injury is greater if the object is near soft tissue structures and/or significant vessels e.g. aorta or carotid artery.

We therefore exclude all volunteers with such metallic foreign bodies as a general measure of precaution.

Should any artifact, indicating a metallic foreign body, appears at any point during the scan, scan should be stopped immediately and investigate the source. Should the metal be outside the body i.e. hair clip, the scan can be resumed after the object was removed, outside the MR Environment.

2.7.9 Spectacles and Hearing Aids

Metallic orthoses such as spectacles and hearing aids must be removed before scanning. MR safe spectacles are provided that match as much as possible the volunteer's prescription.

2.7.10 Transdermal Patches

A transdermal patch is a medicated adhesive pad that is placed on the skin to deliver a time-release dose of medication through the skin into the bloodstream.

Burns have been reported to the MHRA associated with transdermal patches due to the presence of some metallic backing.

Transdermal patches containing metal must be removed. A list of known MR unsafe patches is displayed in the MR control room

2.7.11 Tattoos, Makeup

Tattoos may contain iron oxide or other metallic substances that are conductive. As with any conductive material in MR there is the risk of heating due to RF energy deposition. There is no evidence to predict tattoo behaviour in MR but considering the worst case scenario i.e. burns due to tattoo on face **CBU will not scan volunteers with tattoo on the face. During scanning, patients should be asked to report any discomfort immediately.**

Volunteers may be asked to remove any makeup as some products contain large amounts of paramagnetic substances that affect the image quality

2.7.12 Body Piercings

Metallic body piercings might heat up and may move or become dislodged, which may lead to injury. Also, they could cause artifacts on the MR images.

All body piercings must therefore be removed before the volunteer enters the MR Controlled Access Area .

2.7.13 Silver impregnated garments

There are more frequent reports in the literature of burns due to metal impregnated garments. Should the volunteer disclose the use of these items these need to be removed and replaced with MR safe ones available in the MR Facility Reception area.

2.8 Volunteer Management

2.8.1 Scanning

2.8.2 Preparation

Identification: The MR Operator must ensure that the volunteer is correctly identified. This is done by checking their name, date of birth and address.

Volunteer weight and height: It is important that a current weight and height measurement is available at the time of scanning in order for the MR equipment to calculate the SAR levels to which the volunteer will be exposed. If the current weight and height is not known, the volunteer must be weighed and height measured before scanning.

Reassurance and explanation: A suitably trained person should describe the examination to the volunteer, explaining the sights, sounds and experiences to be anticipated, and predicting the likely length of examination.

2.8.3 Screening

Before booking in volunteers for an examination they will obtain an information sheet that covers major safety questions such as pacemakers, implants, and pregnancy. Participants under 18 will be offered a demonstration and familiarisation session prior to the scanning session.

Before booking in volunteers for an examination, volunteers will be pre-screened in order to prevent an inappropriate examination being booked. The pre-screening interview will cover major safety questions such as pacemakers, aneurysm clips, electronic implants and pregnancy.

On arrival in the unit volunteers will be asked to complete a screening form (Appendix D: Screening forms). A MR Operator will then review the screening form with the volunteer.

The screening form must be signed by the volunteer (or parent/legal guardian) and the MR Operator. The parent/legal guardian will be asked to complete a screening form if their presence in the MR Environment is necessary. A MR Operator will then prepare the volunteer for the MR examination. This includes the removal of all unsafe items from the volunteers body/clothes (e.g. watches, credit cards, jewellery, hairpins, body piercings, hearing aids, spectacles, etc). The volunteers will be asked to store these items in one of the lockers provided.

Before entering the MR Environment, the MR Operator must ensure that the volunteer to be scanned has completed the screening form and that he/she has no unsafe items on him/her. The use of a hand-held metal detector will facilitate this procedure.

2.8.4 Positioning

Two issues are important here: volunteer comfort and volunteer safety. Time taken to ensure that the volunteer is comfortable will lead to greater volunteer compliance with the scan. With regard to volunteer safety, the prevention of burns is the major concern. Poor positioning of the volunteer and associated cables, leads and sensors, have been the cause of many burns reported to the MHRA.

To avoid burns caused by RF heating [ECRI. *Safety concerns in the MR environment: unique environment, unique risks. Health Devices 30(12), 2001, p. 422-444.*]:

- Ensure that insulation is placed between the cable and the volunteer if contact cannot be avoided.
- Do not loop conductive cables or allow cables to cross one another.
- Do not pass cables diagonally across the patient.

- Ensure that cables run parallel to the bore of the magnet and as close to the centre of the bore as possible.
- Ensure that cables do not touch the bore of the magnet.
- Ensure that cables exit the bore of the magnet as close to the centre as possible.
- Ensure that the volunteer's skin does not touch the bore of the magnet.
- Use MR Safe insulation foam pads if necessary.
- Ensure that no conductive loops form with any parts of the volunteer's body i.e. avoid skin-to-skin contact. Foam pads can be placed between the thighs, between the arm or hand and the trunk and between the ankles to avoid the formation of any conductive loops.
- Ensure that sensors are placed outside the scanning area whenever possible, as well as away from RF coils.
- Ensure that regular checks for damage are made on all coils, cables and leads for damage and do not use if damage is seen.
- Use only high impedance leads; fibre optic leads are preferred.
- Ensure that the volunteer is instructed to inform staff immediately if they feel any warming.
- Ensure that the sites of all sensors are regularly checked for any evidence of heating if the volunteer is unconscious or for any reason unresponsive.

Ensure that you are familiar with and follow the manufacturer's instructions at all times. This includes using only the monitoring equipment, ECG wires, leads, electrodes and accessories recommended by the MR system manufacturer.

2.8.5 Hearing Protection

The time-varying magnetic field gradients used in MRI may produce loud noise within the magnet interior. Volunteers should be clearly warned of this. With fast imaging sequences (such as EPI) the noise level may exceed 85 dBA.

All volunteers being scanned must therefore wear suitable hearing protection (e.g. earplugs and/or ear defenders). Staff and others remaining in the MR Environment during an examination, must also wear suitable hearing protection.

2.8.6 Comfort

Adequate lighting and ventilation in the magnet interior are important. Care should be taken if pillows, blankets or covers are used to ensure that they are MR Safe and that heat loss is not inhibited. At all times during scanning the volunteer should be in a position to make contact with the operator and give warning of any discomfort or concern.

2.9 Communication

For communication between the volunteer and the person who is scanning, a two-way intercom is available. Recorded music or narrative of the volunteer's choice can be made available during structural brain scans and during the set-up period.

2.9.1 Panic Alarm

An alarm / panic button will be provided at all times. The device will be given to all volunteers with an explanation of its intended use. This has to be tested before scanning of each volunteer.

2.9.2 Volunteer Monitoring

Pulse monitoring is necessary when scanning in the Control or Research Mode or for patient volunteers and volunteers over the age of 60.

Visual and audio contact with the subject should be maintained throughout the scanning session.

The MR Operator must not leave the Control Room whilst a volunteer is being scanned unless it is to enter the MR Environment.

2.9.3 Maximum Time in the Scanner

There is no guidance on the duration of MRI sessions so currently there is no limit providing the SAR limits are not reached.

2.10 Data Management

Currently, there is evidence to support the view that, provided the recommendations referring to the exposure limits (cf.1.6 and 1.8) are followed by all those associated with MR diagnostic equipment and its operation, the risk of short or long term deleterious effects is very low.

However, it is in the interest of the individual and the population as a whole, that records are maintained of all MR scans of all volunteers.

2.10.1 Minimum Data Required

The following is regarded as the minimum scan data that should be retained:

- Equipment reference including update status and static magnetic field intensity.
- The subject's name or reference, sex and age.
- Date of scan.
- The approximate time spent in the magnet.

This information should be held with a copy of the patient/volunteer consent form, including a signed statement showing confirmation of full explanation given and medical screening conducted.

2.10.2 Scan Logs

Scan logs are in electronic form via the subject data management system provided by the manufacturer.

All volumes of the scan log, all the volunteers' records should be held in safe keeping for a period that ensures compliance with the current guidance from the Department of Health and the Medical Research Council. It should be in a form from which full details can be retrieved within this period if required.

2.10.3 Data Protection and Confidentiality

Access to Personally-Identifiable Data (PID) will be restricted to members of the research team, as defined by their ethical approval, and to the CBU radiographers and CBU panel management team (for members of our volunteer panel, as approved by separate ethics). All PID will be stored securely and in line with CBU Data Protection policy (<http://intranet.mrc-cbu.cam.ac.uk/administration/data-protection/>) and the University of Cambridge's policies (e.g, GDPR: <https://www.information-compliance.admin.cam.ac.uk/data-protection/general-data-protection-regulation>). The MRC and University of Cambridge comply with the requirements of the EU General Data Protection Regulations 2016 and the Data Protection Act 2018 with regard to the collection, storage, processing and disclosure of personal information and is committed to upholding the Acts core Data Protection Principles.

If participants give their consent (e.g, as on standard CBU Consent Form), then their anonymised data may be shared with other researchers. In the case of MRI images that include the face, though this is not currently regarded as PID, it is recommended that the face is removed before sharing.

2.10.4 Abnormal (Incidental) Findings

The Cognition and Brain Sciences Unit is a cognitive neuroscience research unit and does not provide any diagnostic services and seeks to avoid harm from implicit but unproven public-health screening. This policy will be clearly stated on the volunteer information sheet. Example wording is given in Appendix C.

Even though we do not provide a diagnostic service, as stated for participants in our information sheets, we have a duty-of-care. This duty-of-care includes the need to act on potentially serious problems that are noticed during the course of volunteers' participation in a study, but also the need to avoid harm directly (eg distress, anxiety, mental well-being) or indirectly (by invasive further investigations; or by loss of employment and financial well-being) as a result of a false-positive findings. Therefore, if a potential abnormality is noticed on a brain scan (e.g, by a radiographer during acquisition or by a researcher during analysis), this will be brought to the attention of the CBU Medical Monitor, who is responsible for acting on this information. Formal review of every scan by a radiologist, or review of every scan by a radiographer trained for diagnostic reporting, is not warranted.

It may be necessary to exclude such participants from the study for scientific but not medical reasons, in which case the reasons for the exclusion will not be fed back to the researcher. The Medical Monitor will determine whether referring the individual for further clinical evaluation is appropriate, either directly in the event of life-threatening abnormalities, or via the General Practitioner. If the incidental finding is from an individual under 18 years of age, the findings will be referred to the Paediatric Medical Monitor. Note that, if a volunteer later contacts a researcher to ask about possible abnormal findings, the researcher should only take their contact details, and then tell the Medical Monitor and Radiographers, one of whom will contact the volunteer. A researcher should not try to give any medical or quasi-diagnostic feedback to the volunteer.

It is important that the participant gives permission to be informed of any incidental finding (otherwise detection of one puts radiographers/researchers in a difficult position). Example wording is given in Appendix E. Therefore, we cannot scan an individual who refuses to be informed of such a finding. All participants should be encouraged to provide their GP's details in case an incidental finding is made, though in some situations a participant may not wish to, or may not know their GP's details; a scan can continue in such situations.

2.11 Staff Training

To avoid accidents, it is essential that all personnel associated with MR equipment be adequately trained.

The training of all appropriate categories of staff in terms of their normal duties and those in the event of an emergency is essential before installation and for all new staff subsequent to installation. Regular reviews of the training status as well as updates and refresher courses for all staff will be required during the operating life of the MR diagnostic unit.

A particular area of concern is that of an emergency which can relate to the safety of the person scanned and the staff, or of an environmental emergency such as a fire. Careful consideration must be given to setting up the correct form of training for the specialist staff who may be involved in any form of emergency which needs their entry into the MR Controlled Access Area and the necessary liaison with the appropriate groups both within and outside the establishment.

The MRI Management Committee (cf. 2.2.2) will ensure that the necessary responsibilities are established and carried out. Furthermore, it will review and update the unit's health and safety policy at regular intervals.

2.12 Accident/Incident Reporting and Investigation

All accidents and near misses, however minor, must be reported to the relevant line manager and the MR Responsible Person or Head of MRI, and recorded (Appendix J: Near Miss Form).

All accidents and near misses will be investigated by the relevant line manager and the MR Responsible Person or Head of MRI to establish the root cause and introduce management action to prevent a recurrence.

All notifiable accidents, dangerous occurrences and cases of occupational related ill health, as defined by The Reporting of Injuries, Diseases and Dangerous Occurrences Regulation 1995, must be reported to the Safety Co-ordinator who will ensure the Director, the local Health and Safety Executive Office and the Health and Safety Section at Head Office are informed.

2.13 Booking policy

All MRI projects must be approved by the Imaging Management Committee (IMC), and then booked through the MRI Facility Administrator. Procedures for this process are on the CBU wiki and in the Minutes of the IMC.

- Pilots are charged and will be used to review the slot time requirements for the rest of the project
- Users are charged for the total slot time rather than the total EPI time
- Cancellations must be given at least 10 working days notice.
- Cancellation of an entire project of slots will require at least 4 weeks notice.
- Any cancellations with less notice than 10 working days notice will be charged to the groups QQ and more slots will need to be requested through the IMC. Any exceptions to this rule will need to be approved by the IMC before the project commences. Exceptions include patients or special populations cancelling, who cannot be replaced with backups. If late cancellations are due to researcher error (e.g. researcher forgot to cancel scan or did not have a backup volunteer in place) the cancellation policy will be enforced.
- It is the researcher's responsibility to pre-screen volunteers for the suitability for the scan and make sure a backup is in place. If the volunteer or patient cannot participate due to reasons that should have been revealed in the screening of the volunteer / patient, e.g. piercings, claustrophobia, then the slot will be charged. Other exceptional considerations, such as head movement, will be treated on a case by case basis by the IMC.
- If for any reason the participant or researcher is late for the scan slot, the MR Operator will have the right to terminate the session.
- If a fault is found with CBU equipment causing the data to be invalid, then a slot will not be charged.

3 Emergency Procedures

3.1 General Considerations

Caution In an emergency access to the MR Environment must be subject to the direct supervision of an Authorised MR Environment Person/Supervisor.

Caution Consideration will need to be given to the provision of the necessary supervision and control should an emergency such as a fire occur out of hours.

Caution No ferromagnetic material of any kind must enter the MR Projectile Zone. All personnel must be adequately screened for ferromagnetic material being carried on their person, hairgrips, key rings, scissors, knives, etc., beyond the 3 mT static magnetic field level. There can be only one exception to this rule, which is if the magnet has been de-energised (quenched).

3.2 Emergency Switches

3.2.1 Location

There are three different types of emergency shutdown switches: the **Magnet Quench** switch, the **Power Stop** switch, and the **Patient Table Stop** switch. The location of these switches is shown on the floor plan in Appendix B: Emergency switches.

3.2.2 Magnet Quench Switch

There are two Magnet Quench switches, one in the Control Room, the other one in the MR room (Appendix B: Emergency switches).

The Magnet Quench switch is used to de-energise (quench) the magnet.

This will quickly reduce the field strength of the magnet to a low level. As a result, magnetic field energy is converted into heat energy. The helium coolant boils off abruptly and is released through an exhaust line. This generates a considerable amount of noise (hissing, etc.) because large amounts of helium gas are released into the open.

Lowering the magnetic field strength to 20 mT takes less than 20 seconds.

The rapid release of the magnet's stored energy, is moderately violent, and may cause permanent damage to the magnet. It can cause weeks of downtime and thousands of £ worth of helium.

A deliberate Magnet Quench may only be initiated if there is:

- An uncontrollable fire in the MR Environment which requires the use of ferromagnetic fire-fighting equipment.
- A life-threatening accident where the victim is pinned to the magnet.

3.2.3 Power Stop Button

There are three Power Stop switches, located in the Control Room, the MR room, and the Technical Room (Appendix B: Emergency switches).

The Power Stop switch is used to for an emergency shutdown of the complete MR system (except the magnet). This will immediately cut electrical power to all components of the MRI system except the magnet.

One of the Power Stop buttons must be pressed if there is

- A fire or
- An electricity-based accident

3.2.4 Patient Table Stop Button

There are three Table Stop buttons: two are located on the control units on the right and left side of the patient table at the magnet, and one on top of the patient intercom in the Control Room (cf. Appendix B).

The Patient Table Stop button is used for stopping the motor-powered movement of the patient table in case of emergency.

Push the Patient Table Stop button in case of accident or risk of injury due to table movements. The Patient Table Stop symbol will appear on the table display. The brakes are released and the patient table may be moved horizontally by hand.

3.3 Location of Rescue Equipment

An AED is located in the kitchen of the MRI Facility, along with a comprehensive first aid kit (including a burns kit) and a first aid blanket. The kitchen door carries appropriate signage.

A second AED, along with an oxygen cylinder is situated in the 'Elbow' at the top end of the south wing of the main CBU building. In an emergency within the MRI Facility the second AED, along with the oxygen cylinder, will be brought to the Reception Area by one of the first aiders.

Most CBU first aid staff will have had training in using the AED equipment. They are summoned, on the internal telephone network by calling reception on 66166

3.4 Evacuation and Access Routes

3.4.1 Evacuation of the MRI Facility, Escape Routes.

In the event of the fire alarms sounding, the member of staff in charge of the building at that time e.g. an MR Operator:

- ensure everyone in the scanner building evacuates by a fire escape and makes their way to an assembly point, where they must remain until instructed otherwise.
- check all rooms (including technical and plant room, Mock scanner) are empty of people.
- collect the AED, first aid kit and first aid blanket, if safe to do so.
- make their way to the main entrance of the CBU in the front car park and report to the head fire officer attending.

Fire extinguishers should not be the first defence in tackling fires, always evacuate first if possible and only if a person's life is in imminent danger use fire extinguishers to fight a fire. The fire extinguishers at CBU are MR Safe and can be taken into the MR Environment.

3.4.2 Access Routes for Rescue Vehicles

Turn left into the MRC site from Chaucer Road, once in the front car park keep left and follow the access road through the black gates and down the full length of the South Wing. At the bottom turn right and the scanner building is directly in front (Appendix F: Emergency evacuation map).

3.5 Medical Emergencies

3.5.1 General Consideration

In the event of a medical emergency (e.g. cardiac arrest), the scan should be terminated immediately. The patient/volunteer should be removed from the MR Environment at the first opportunity. Under no circumstances should ferromagnetic resuscitation equipment be brought into the MR Projectile Zone.

3.5.2 Emergency Procedures

MR Operator

- Terminate scan
- Remove volunteer from bore of the magnet
- Check condition of participant and make an assessment as to whether urgent additional help is needed.
- Escort the volunteer to the 'safe area' (MRI Facility reception) and stay with them.

IF THIS IS AN EMERGENCY AND URGENT HELP IS NEEDED:

- MR Operator and other Authorised MR Environment Person to remove the volunteer from the MR Environment to the 'safe area' (MRI Facility reception) using the patient table, if required.
- **Call 999 out of working hours or when an ambulance is needed.**
- **Call 66166 from internal phone** to summon CBU first aiders to the MRI Facility **(during Unit working hours only)**

Report our location

- MRI Facility
MRC Cognition and Brain Sciences Unit
15 Chaucer Road, Cambridge, CB2 7EF
Emergency Telephone 01223 273677

Report what has happened

Details of the medical emergency (e.g. suspected cardiac arrest)

Details of the patient (e.g. female approx 25 years old)

- **DURING UNIT WORKING HOURS:** inform Reception on **67772** and ask them to send somebody outside to wait for the ambulance and direct it where to go.
- **OUTSIDE OF UNIT WORKING HOURS:** a person should be dispatched to the front car park to direct the ambulance.

Report incident

Inform at least one of the following persons:

- Head of MRI
- MR Responsible Person
- Deputy Director Neuroimaging
- Director

3.6 Major Equipment Failure

3.6.1 General Consideration

In the event of a major equipment failure, resulting in serious malfunction or electric shock, the electrical power to the MR system should be switched off by pressing the Power Stop buttons (Appendix B: Emergency switches). The participant can then be safely evacuated. Note! The patient table will not be powered; you will have to manually remove the table (See instructions on how to manually remove the table add reference). Scanning may not be resumed before a qualified Siemens Service Engineer has inspected the system and certified it for safe use. The Head of MRI and/or MR Responsible Person must be informed immediately of any such failures.

3.6.2 Emergency Procedures

MR Operator

- Press one of the **Power Stop** buttons.
- Manually remove patient from bore of the magnet
- Speak to the volunteer and make an assessment of their condition, explaining the situation

In case of a medical emergency

- Call **999 out of working hours or when an ambulance is needed.**
- Call **66166** to summon CBU first aiders to the MRI Facility (**during Unit working hours only**).

Report our location

- **MRI Facility**
MRC Cognition and Brain Sciences Unit
15 Chaucer Road, Cambridge, CB2 7EF
Emergency Telephone: 01223 273677

Report what has happened

Details of the medical emergency (e.g. suspected cardiac arrest)

Details of the patient (e.g. female approx 25 years old)

- **DURING UNIT WORKING HOURS:** inform Reception on **67772** and ask them to send somebody outside to wait for the ambulance and direct it where to go.
- **OUTSIDE OF UNIT WORKING HOURS:** a person should be dispatched to the front car park to direct the ambulance

Report incident

Inform at least one of the following persons:

- Head of MRI
- MR Responsible Person
- Deputy Director Neuroimaging
- Director

3.7 Spontaneous Magnet Quench

3.7.1 General Consideration

During a quench, the super-conductivity of the magnet is suspended. The liquid helium boils off during this process and is released via the exhaust vent line. The energy of the magnetic field is converted into heat.

A quench may be triggered by:

- the Magnet Quench switch.
- an accident (earthquake, fire, etc.)

A magnet quench generates a considerable amount of noise (hissing, etc.) because large amounts of helium gas are released into the open.

Caution!

When the helium venting happens towards the inside of the MR Environment (due to an obstructed ducting), there is the potential for over-pressurisation of the room. Because the RF door is opening towards the inside of the room this poses a high risk that the 'air pressure' is so high that the door will not open.

Warning: Frostbite may be caused by touching the exhaust vent line. Keep clear of the exhaust vent lines.

In the event of the magnet quenching, the MRI Facility should be evacuated until a suitably qualified person or a representative of the supplier authorised by the MR Responsible Person has inspected the system.

If the oxygen alarm is activated Do not enter the MR Environment.

3.7.2 Emergency Procedures

- Terminate the scan.
- Remove participant immediately using the patient table if needed. Be aware that the door might be stuck.

• Evacuate the MRI Facility (shouting "Evacuate Quench")

- All occupants must immediately make their way to the fire assembly point in the rear garden.
- Staff with participants/visitors should escort them to the assembly point.
- The MR Responsible Person or their deputy (other Authorised MR Environment Person/Supervisor) will be responsible for collecting the AED and first aid equipment on route if safe to do so and checking that all of the rooms are empty on their way out.
- Assemble at the meeting point in the rear garden and do not re-enter the building until it has been declared safe by a suitably qualified person.
- When reasonable to do so report the incident to at least one of the following: Head of MRI, Deputy Director Neuroimaging, Director

In case of a medical emergency

- **Call 999 out of working hours or when an ambulance is needed.**
- **Call 66166** to summon CBU first aid staff to the MRI Facility (**during Unit working hours only**).

Report our location

- **MRI Facility**
MRC Cognition and Brain Sciences Unit
15 Chaucer Road, Cambridge, CB2 7EF
Emergency Telephone: 01223 273677

- **DURING UNIT WORKING HOURS:** inform Reception on **67772** and ask them to send somebody outside to wait for the ambulance and direct it where to go.
OUTSIDE OF UNIT WORKING HOURS: a person should be dispatched to the front car park to direct the ambulance

Report what has happened

Details of the medical emergency (e.g. suspected cardiac arrest)

Details of the patient (e.g. female approx 25 years old)

3.8 Deliberate Magnet Quench

3.8.1 General Consideration

A deliberate magnet quench may only be initiated if there is a life-threatening accident when the victim is pinned to the magnet

3.8.2 Emergency Procedures

Check

- The decision to initiate the quench should be made by the Head of MRI or the MR Responsible Person, if available. In a life-threatening situation where none of these persons are available, the MR Operator or other Authorised MR Environment Person/Supervisor will make the decision.
- In the event of a person being trapped by a ferromagnetic object, it will be necessary to support the object when the quench is initiated. Do not bring any further ferromagnetic objects into the MR Environment. Only authorised staff should enter the MR Environment.
- If a person has an impalement injury by a sharp object, the magnet should be quenched before attempting to remove the patient to prevent further injury. (Do not attempt to remove the impaled object as this can lead to profuse blood loss).

Caution!

When the helium venting happens towards the inside of the MR Environment (due to an obstructed ducting), there is the potential for over-pressurisation of the room. Because the RF door is opening towards the inside of the room this poses a high risk that the 'air pressure' is so high that the door will not open.

Evacuation

- All occupants must immediately make their way the fire assembly point in the rear garden.
- Staff with volunteers/patients/visitors should escort them to the assembly point.
- The MR Operator or other Authorised MR Environment Person/Supervisor will be responsible for collecting the AED and first aid equipment on route if safe to do so and checking that all of the rooms are empty on their way out.
- Assemble at the meeting point in the rear garden and do not re-enter the building until it has been declared safe by a suitably qualified person.
- When reasonable to do so report the incident to at least one of the following: Head of MRI, Deputy Director Neuroimaging, Director

Quench

To initiate a magnet quench, lift the flap on the **Magnet Stop Switch** (Appendix B: Emergency switches) and press it. The magnet will quench. **Note!** Make sure to reset the quench button as this will help with the recovery of the magnet.

3.9 Fire

3.9.1 General Considerations

All fire alarms in the main Unit and the MRI Facility are automatically linked to the Fire Station. Breaking the glass at one of the alarm points will result in the fire brigade being directed to the Unit.

In the event of fire, the fire has to be extinguished with methods appropriate to the surroundings. Fire fighters have to be able to take appropriate actions immediately. For this purpose, the fire department has to be familiar with the MR system and its location.

Before initial start-up of the MR system, the fire department must be informed about the MR system and the structural conditions on site.

The Fire Brigade can normally fight the fire from outside the MR Projectile Zone, without the need to quench the magnet. A decision to quench the magnet needs to be made by the Head of MRI or the MR Responsible Person.

3.9.2 Emergency Procedures

ON DISCOVERING A FIRE:

- On discovering a fire in the MRI Facility, raise the fire alarm by breaking the glass on one of the fire alarm points.
- Terminate all MR procedures
- Remove the participant from the MR Environment
- Press the **Power Stop** button
- **Evacuate** (see *Evacuation* below)

ON HEARING THE FIRE ALARM:

- Terminate all MR procedures
- Remove the participant from the MR Environment
- **Evacuate** (see *Evacuation* below)

Evacuation

- All occupants must immediately make their way the fire assembly point in the rear garden.
- Staff with participant/visitors should escort them to the assembly point.
- The MR Operator or other Authorised MR Environment Person/Supervisor will be responsible for collecting the AED and first aid equipment on route if safe to do so and checking that all of the rooms are empty on their way out.
- Assemble at the meeting point in the rear garden and do not re-enter the building until it has been declared safe by a suitably qualified person.
- When reasonable to do so report the incident to at least one of the following: Head of MRI, Deputy Director Neuroimaging, Director

In the event of a fire within the MR Environment

- Terminate all MR procedures
- Remove the participant from the MR Environment
- Press the **Power Stop** button
- **Evacuate** (see *Evacuation* above)
- Only fire extinguishers clearly marked as MR Safe may be brought into the MR Environment.
- In the event of a serious fire in the MR Environment that requires additional fire-fighting equipment to be brought into MR Environment, the decision to quench the magnet needs to be made by the Head of MRI or the MR Responsible Person. This is normally not necessary as the fire can be fought from a

safe distance, with normal fire-fighting equipment. **Note!** There is enough space in the MR Environment, outside the MR Projectile Zone, to use standard fire-fighting gear.

3.10 Emergency Contact Numbers

In an emergency outside of working hours, assistance is available from Scanner One, the on-call emergency service co-ordinated by Authorised Personnel. This service provides a line of communication with an authorised person out of hours and will if necessary arrange for an Authorised MR Environment Person/Supervisor to be on site to help resolve a problem, meet an engineer or meet the emergency services.

Scanner One (07890 365906).

University of Cambridge Security Office (01223 331818)

Please note that University Maintenance, University Security or Hyline Security, the Police and the Fire-brigade **WILL NOT enter the MRI Facility** until a member of staff is on the scene. This needs to be an Authorised MR Environment Person/Supervisor.

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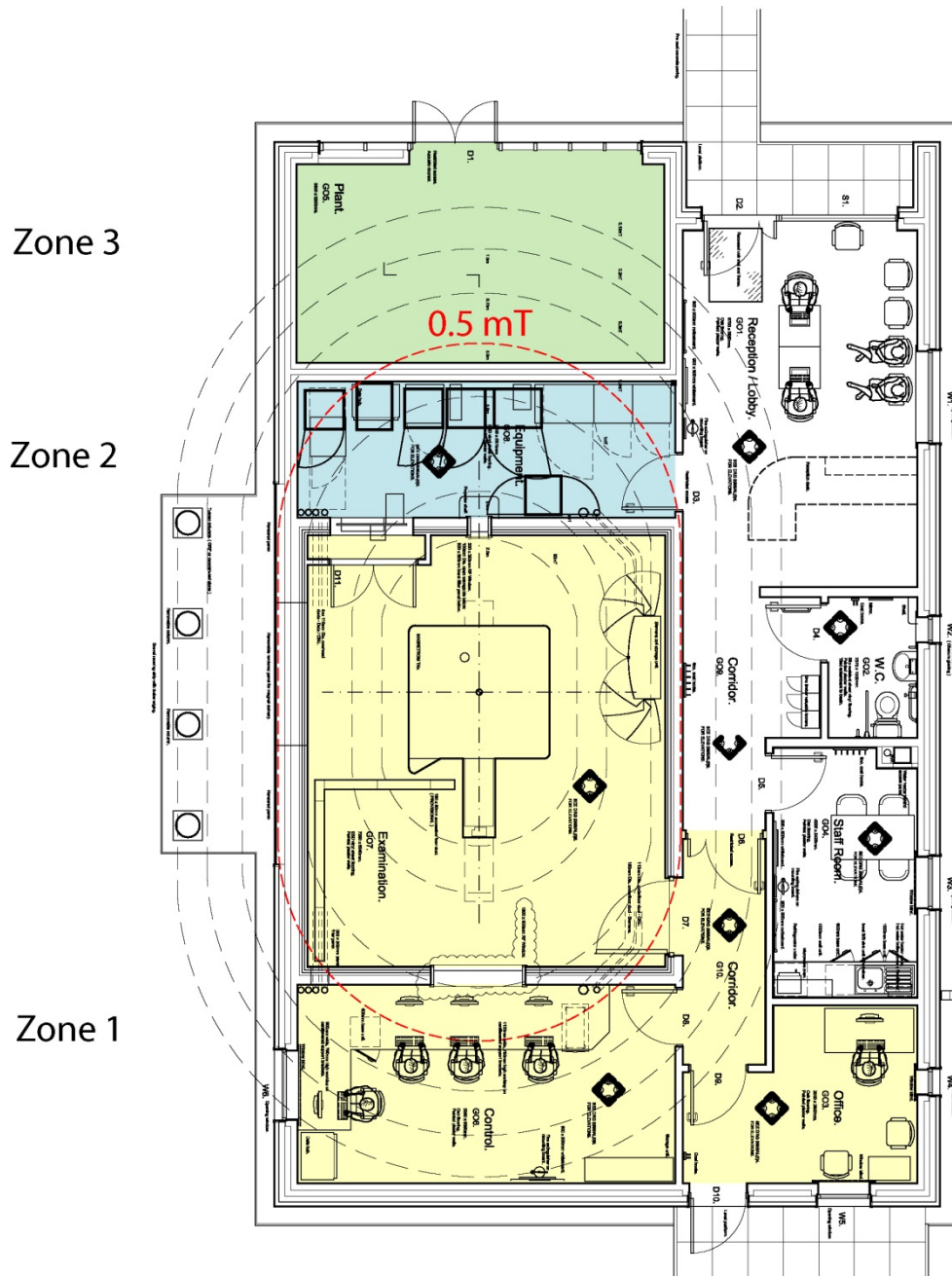
Dempsey MF, Condon B and Hadley DM. Investigation of the factors responsible for burns during MRI. Journal of Magnetic Resonance Imaging 13(4), 2001, p. 627-631.

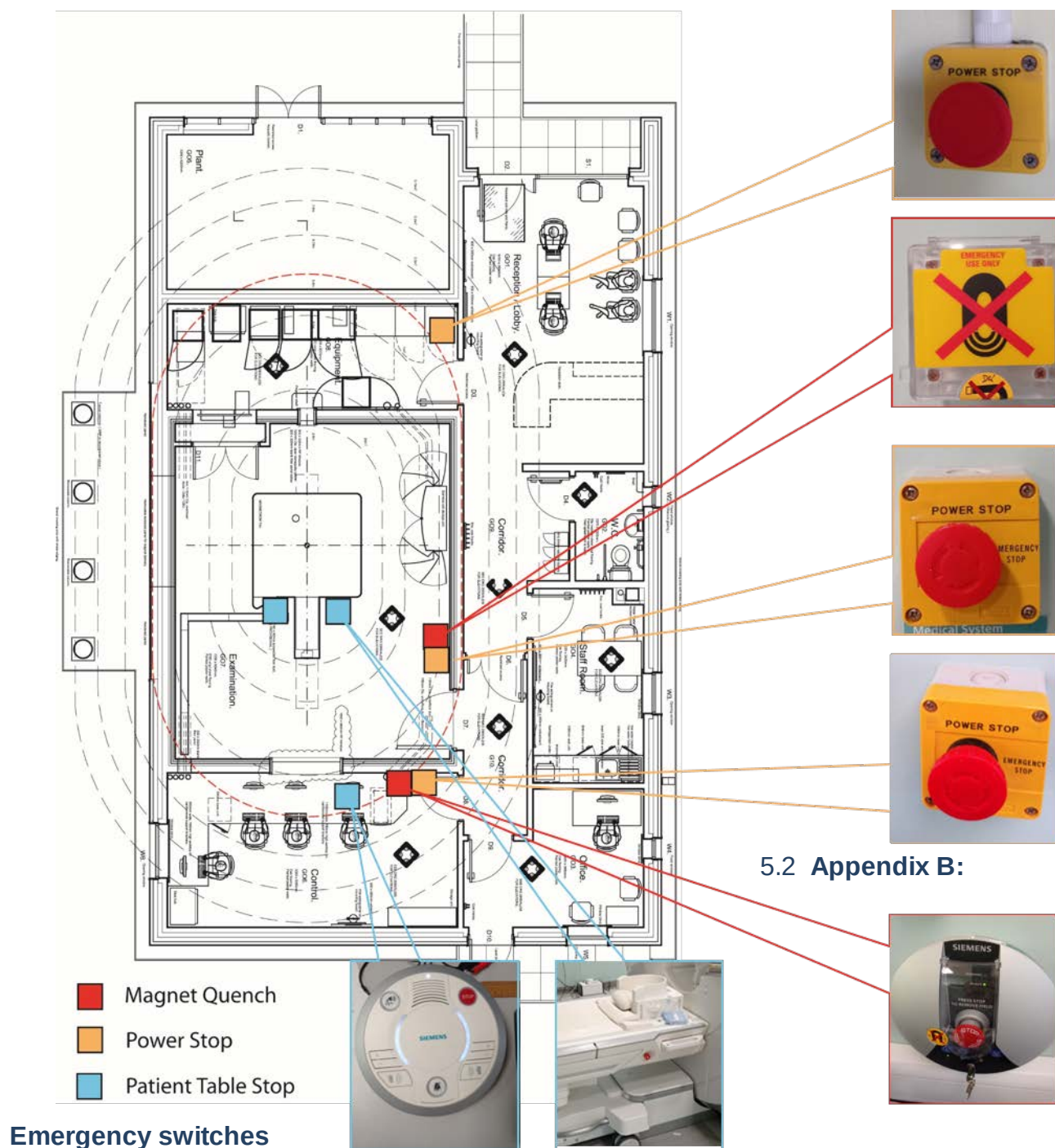
[8] MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, 2015 v4.2

[9] Health Protection Agency. Protection of Patients and Volunteers Undergoing MRI Procedures. Documents of the Health Protection Agency Radiation, Chemical and Environmental Hazards August 2008. RCE-7

5 Appendices

5.1 Appendix A: Controlled Access Area





5.3 **Appendix C: Participant Information Sheet**

<http://intranet.mrc-cbu.cam.ac.uk/home/participant-information-sheet-template/>

5.4 Appendix D: Screening forms

MRC MRC Cognition and Brain Sciences Unit

UNIVERSITY OF CAMBRIDGE

MRI Safety Screening Form

VOLUNTEER

Last Name

DOB / /

Address

First Name

Email

Postcode

Telephone

Weight

Height

GP's Name & Address

Please answer the following questions as best as you can. Some of the items on the list are contraindications for MRI or require additional information. If you answered Yes to any of the questions, please give more information to the radiographer. Use the diagram to indicate the location of the surgery/implant/device. Failure to disclose information could result in serious injury.

		Yes	No	
Any surgery or other invasive procedures in the last six weeks	☐			
Any injury to your eye involving metallic fragments	☐			
Any possibility you may be pregnant/fertility treatment	☐			
Cardiac pacemaker	☐			
Internal Cardiac Defibrillator	☐			
Pacing wires	☐			
Aneurysm or other type of blood vessel clips	☐			
Cochlear or other type of ear implant	☐			
Deep brain stimulator	☐			
Implanted insulin or other drug delivery pump	☐			
Spinal fusion stimulator	☐			
Shrapnel, shot or bullet	☐			
Intraventricular or spinal shunt	☐			
Artificial heart valve/ Annuloplasty Rings/ Sternal Suture Wires	☐			
Venous umbrella/filter	☐			
Vascular stents	☐			
Embolisation coils	☐			
Vascular access port or catheter	☐			
Loop recorder (event monitor)	☐			
Harrington rods (spinal rods)	☐			
Eye/orbital prosthesis e.g. intraocular lens, eye buckle	☐			
Artificial limb or joint	☐			
Intrauterine device (IUD)	☐			
Tattoos (including any semi permanent makeup)	☐			
Orthopaedic devices (pins, screws, wires or plates)	☐			
Penile/breast or other tissue expanders/implants	☐			
Patches for drug delivery e.g. nicotine	☐			
Other implanted device/foreign body not listed above	☐			
Metallic body piercing/jewellery (Remove before entry)	☐			
Hearing aid and/or Dentures (Remove before entry)	☐			

University of Cambridge, MRC Cognition and Brain Sciences Unit, 15 Chaucer Road, Cambridge, CB2 7EF
 radiographers@mrc-cbu.cam.ac.uk 01223767747



MRI Safety Screening Form

VISITOR

Last Name		First Name	
Institution/Company			
Job title			
Purpose of entry			

You are entering an MR environment. Please remove all metallic objects before entering the magnet room including: keys, coins, cards, phones, jewellery, watch, belt etc. Lockers are available to secure your personal belongings. The items on the list below are not safe in the MR environment. If you answered Yes to any of the questions, you will be refused entrance. Failure to disclose information could result in serious injury.

	Yes	No		Yes	No
Cardiac pacemaker	☐	☐	Implanted insulin/other drug delivery pump	☐	☐
Internal Cardiac Defibrillator	☐	☐	Loop recorder (event monitor)	☐	☐
Aneurysm/other type of blood vessel clips	☐	☐	Shrapnel, shot or bullet	☐	☐
Cochlear or other type of ear implant	☐	☐	Other implanted device/foreign body not listed above	☐	☐
Deep brain stimulator	☐	☐	Ferrous/MR unsafe tools	☐	☐

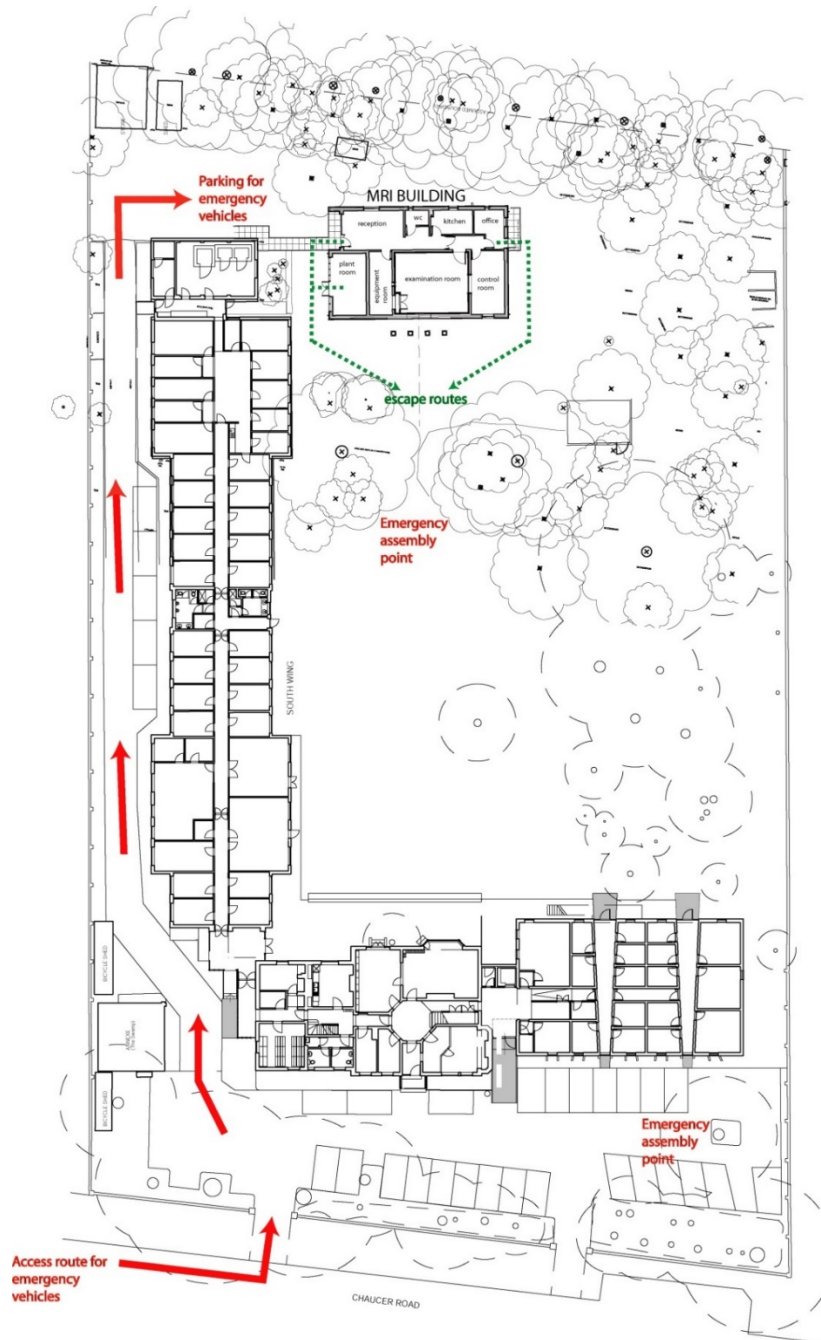
☐ I am aware of the risks of the MR environment and I declare I have nothing in or on me that was not cleared by the Radiographer as safe (Please tick).

Your name		Your Signature	
Radiographer name		Radiographer signature	
Date	/ /		

5.5 Appendix E: MRI Consent Form

<http://intranet.mrc-cbu.cam.ac.uk/wp-content/uploads/2013/02/CBU-Adult-Volunteer-Study-Specific-Consent-Form-CPREC-approved-PRE.2017.046-2.docx>

5.6 Appendix F: Emergency evacuation map



5.7 Appendix G: Risk assessment of magnetic field exposure

The aim of this risk assessment was to estimate the magnetic field exposure averaged over a period of 24 hours. This analysis was based on typical tasks performed by different categories of Authorised Personnel, taking into account the location of the area where each task is performed, as well as the corresponding field strengths and duration of the exposure. To this end, the maximum magnetic field was measured in six reference areas (A1-A6, cf. Fig. G-1) located within the MR Controlled Access Area. The results of this analysis are summarised in Table G-1.

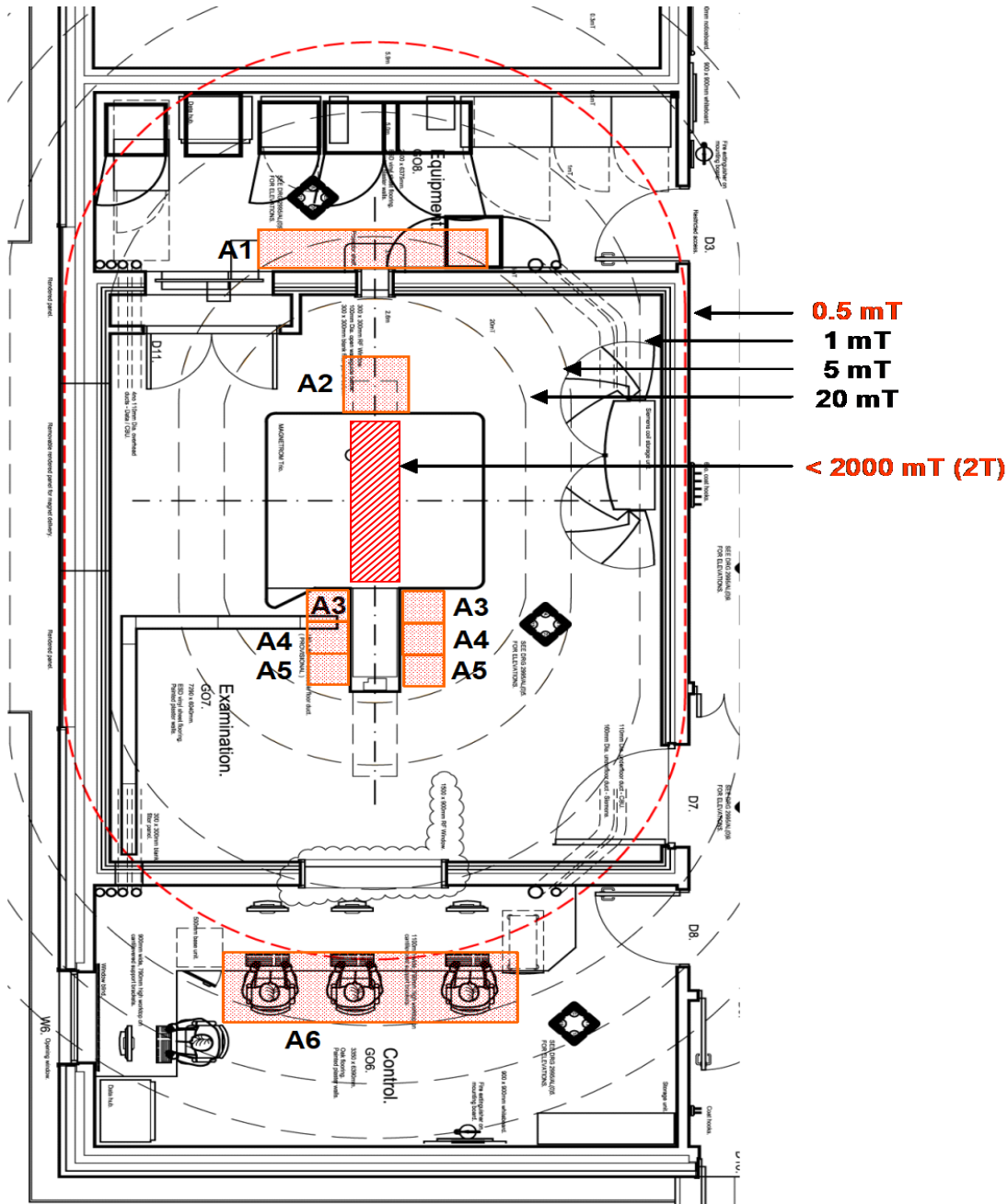


Fig. G-1. Location of the reference areas

Table G-1. Magnetic field exposure during typical tasks

Area	Max. Field Strength ¹⁾	Typical Tasks	Who	Duration ²⁾ Typical	Duration ²⁾ Worst case
A1	8.0 mT	Adjustment of projector	R, AR1, AR2	5 min	15 min
		Maintenance of projector	T	30 min	8 h
A2	1000 mT	Adjustment of screen Maintenance work on screen	R, AR1, AR2, T	5 min	15 min
A3	500 mT	Positioning and preparation of participants or phantoms	R, AR1	-	2 h
		Interaction with participant	AR2	3 h	8 h
A4	110 mT	Positioning and preparation of participants or phantoms	R, AR1	1 h	-
		Interaction with participant	AR2	2.5 h	-
A5	40 mT	Positioning and preparation of participants or phantoms	R, AR1	-	-
		Interaction with participant	AR2	2.5h	-
A6	0.5 mT	Scanning; Control of ancillary equipment; Data Analysis	R, AR1	8 h	10 h
		Maintenance work	T	30 min	8 h

¹⁾ Measured using a calibrated Gaussmeter

²⁾ Per day

R = Radiographer or MR Operator

AR1 = Authorised Researcher (Level 1)

AR2 = Authorised Researcher (Level 2)

AT = Authorised Technician

The magnetic field exposure averaged over a period of 24 hours was calculated for different categories of Authorised Personnel using the reference values listed in Table G-1 for both typical and worst case conditions (cf. Table G-2). The analysis was based on the following assumptions:

Radiographer or MR Operator. Positioning and preparation of participants or phantoms is done in area A4. This takes 5-10 min per subject, which gives about 1h for 8 subjects per day. The worst case condition assumes this task being performed in area A3 located close to the magnet bore (total exposure time: 2h).

Authorised Researcher (Level 1): Typically stays within the Control Room, but assists with adjusting the projector or the screen. The worst case condition assumes an Authorised Researcher additionally helping with positioning and preparation of participants or phantoms in area A3 (total exposure time: 2h).

Authorised Researcher (Level 2): This refers to researchers who are present in the MR Environment during the entire scanning session. The maximum period of time is limited to 8h per 24h interval. Typically the researcher would move in areas A3-A5. The worst case assumption is that the researcher stays in area A3 all the time.

Authorised Technician. The average magnetic field exposure was calculated for maintenance work in areas A1, A2 and A6, carried out under both typical and worst case conditions.

Table G-2. *Average magnetic field exposure*

Category of Authorised Personnel	Average field strength over 24h	
	Typical	Worst case
Radiographer or MR Operator	8.3 mT	52.4 mT
Authorised Researcher (Level 1)	8.3 mT	52.4 mT
Authorised Researcher (Level 2)	81.6 mT	177 mT
Authorised Technician	3.6 mT	13.3 mT

5.8 Appendix H: Statement of conformity

SIEMENS

CONFORMITY with Standards and Regulations for MR Systems

Manufacturer	Siemens Aktiengesellschaft Medical Solutions
Division	Magnetic Resonance (MR)
Address	Henkestraße 127, D-91052 Erlangen, Germany
Medical device	<u>MAGNETOM Trio</u>

The following standards and regulations were observed during the developing process for the MR-Systems MAGNETOM Espree for the technical requirements of each system.

IEC 60601-1	Medical electrical equipment: General requirements for safety
IEC 60601-1-1	Safety requirements for medical electrical systems
IEC 60601-1-2	Electromagnetic compatibility, requirements and tests
IEC 60601-1-4	Programmable electrical medical systems
IEC 60601-2-33	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
EN 30993 - 1	Biological evaluation of medical devices: Part 1 Guidance on selection of tests
EN 30993 - 5	Part 5 Tests for cytotoxicity: in vitro methods
EN 30993 - 10	Part 10: Tests for irritation and sensitization.
IEC 60825-1	Safety of laser products - Part 1: Equipment classification requirements and user's guide

Place and date	Erlangen, <u>2005-06-10</u>
----------------	-----------------------------

Name	V. Schmidt, MR Global Regulatory Support
------	--

Signature



5.9 Appendix I: Definition of Terms

Authorised Person	A person who has free access to the MR Controlled Access Area . The selection and certification of a person for authorisation rests with the MR Responsible Person and must be endorsed by the Head of MRI. Certification of an individual shall only be authorised after satisfactory completion of the local MRI Authorisation Procedure.
Control Room	The location of the MR control console and all computers used for stimulation and monitoring control. The Control Room is part of the MR Controlled Access Area .
Technical Room	The room housing the Siemens MRI hardware and ancillary equipment. The Technical Room is part of the MR Controlled Access Area and only accessible via a key lock.
MR Environment	the three-dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.5mT field contour (5 Gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories. The MR Environment is part of the MR Controlled Access Area .
MR Controlled Access Area	A locally defined area of such a size to contain the MR Environment. Access to this area should be restricted and controlled by suitable control methods (e.g. keypad entry) with suitable warning signs displayed at all entrances. [8] At the CBU, the MR Controlled Access Area starts at the end of the hallway, at the door near the entrance to the Staff Kitchen (see Appendix A). The MR Controlled Access Area consists of two zones: Zone 1 (Room containing the MR scanner, Control Room, Back office) and Zone 2 (Technical Room)
MR Conditional	An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
MR Safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic
MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment
CBU Opening Hours	The official Opening Hours of the CBU are: Mon-Thu 9:00-17:30 and Fri 9:00-16:30
MRI Facility Opening Hours	The official Opening Hours of the MRI Facility are: Mon-Fri 8:00-20:00 and Sat 08:00-18:00.
MR Operator	An authorised person who is deemed to have sufficient experience and appropriate training and is responsible for operating the scanner in a safe and appropriate manner. He/she is responsible at all times for the safety of participants (and accompanying carers/parents/guardians) who are

	undergoing MRI and is responsible for ensuring that any equipment taken into the MR Environment for the examination is suitable. MR Operators at CBU are normally HCPC Registered Diagnostic Radiographers with relevant MR training. They are classified as Authorised Person Supervisors. Any Authorised MR Environment Person can become an MR Operator following the procedures and requirements included in the document "MR Operator Training at the CBU".
--	--

5.10 Appendix J: Near Miss Form

<u>NEAR MISS REPORT</u>		Ref No.....
Name		
MRC Staff	☐	Employee Number.....
Other Staff	☐	
Student	☐	
Visitor/Member of public	☐	
Contractor/Engineer	☐	
Occupation.....		
Date/ Time of Incident		Location
Date/Time reported to Safety Co-ordinator		
Report Completed by.....		
Description/Details of incident		
Signature		Date

5.11 Appendix K: SOP Receipt

**Please read the declaration below, initial and sign the form.
Please return this signed page only to MRI Administrator at CBU.**

Initial

I have received and understand the Standard Operating Procedures.

I undertake to follow the procedures recommended to prevent damage to property, injury or ill health to myself and others.

I have attended the MRI Training Stage One (Video and Safety Presentation) and the MRI Training Stage Two (Practical Session - Screening & Site Tour).

SIGNED:

**NAME:
(PLEASE PRINT)**

**UNIT/DEPARTMENT/
UNIVERSITY**

DATE:

5.12 Appendix L: Recommended Pre-Screening

Structured phone interview for screening Panel volunteers and other volunteers for fMRI

[[Experimenters should thoroughly familiarise themselves with this sheet, especially the notes sections under each question, before ringing up potential volunteers for the first time. If there are any doubts over the suitability of a volunteer, experimenters should clarify the situation with a radiographer]]

Name of volunteer Date

Introduction and brief explanation

1. Introduce yourself, and describe why you are phoning. As an introduction to MRI, you might like to say something similar to: "As you may know, MRI is an acronym for 'Magnetic Resonance Imaging'. MRI can be used to examine both brain structure and the 'brain at work'. It is safe and non-invasive, and allows us to examine how different parts of the brain may be involved in language, hearing, vision, movement, memory, thought and emotion."

2. [Assuming volunteer is interested in taking part following intro] Have you taken part in a research MRI scan before, either here at the CBU or at the Wolfson Brain Imaging Centre. YES/NO
[[If YES, proceed to section B, otherwise go to section A]]

SECTION A (if new):

General

3. Are you right handed? YES/NO

[[Most studies scan only right handers to keep the data as homogeneous as possible, though decision up to researcher]]

4. How old are you?

[[Volunteers have to be at least 18. (We do scan children, but only with parental consent, and for advice about talking to parents, please consult an experienced researcher.)]]

5. What is your approximate height?

6. What is your approximate weight?

[[Potential volunteers with very high weight/size may feel unduly uncomfortable in the scanner, and should therefore be excluded]]

Study Specific

7. Ask any experiment specific questions here.

[[E.g. Do they need to be native English speaker, have normal hearing, or not taken part in similar study before?]]

Claustrophobia

8. Volunteers lie on a bed that slides, so that the head and much of the body is inside a tunnel; in the large magnet. People who don't like small spaces might find this uncomfortable - would this be a problem for you?
YES/NO

[[Lying in the MRI scanner involves one's whole body being enclosed in a relatively narrow tube. Claustrophobia would make it difficult for the volunteer to remain comfortable during this. Significant claustrophobia could be grounds for dismissing the volunteer from suitability for fMRI.]]

Vision

9. [Only if visual component] Will you need glasses to look at a computer screen in the scanner? YES/NO

[[If YES, suggest that volunteer wears contact lenses instead, if they have them. If they require glasses, but don't have contact lenses, explain that a non-metallic glasses substitute will be provided, but that it would help if the volunteer brought with their latest glasses prescription.]]

Lying still

10. Volunteers are typically in the scanner for an hour, during which time they have to lie fairly still on their back on the scanner bed. Would this be a problem for you, for instance due to back problems? YES/NO

[[Given that volunteers might have to lie on their backs without moving their heads constantly in the fMRI scanner for over an hour, any bladder, neck or back problems might make it very uncomfortable for the volunteer. They might also exacerbate existing neck problems. Also, volunteers need to be able to move independently, and get on/off a bed on their own, unless you have special help for them.]]

Metal

11. Because MRI requires volunteers to be in a strong magnetic field, we have to be very careful to ask about metal in the body, since these metallic bits could move or heat up, causing discomfort or damage. Do you have any metal implants, not including normal fillings? YES/NO

[[Any ferromagnetic metal in the volunteer's body could potentially do serious damage to that volunteer if s/he goes into the MRI scanner, so it is important to make sure there is absolutely nothing in the volunteer's body of this sort (except for dental fillings --- although if there are many fillings, this might cause an artefact in a non-brain area of the scan, but won't be dangerous for the volunteer). Any implants may contain metal, even if the volunteer believes they are made from another material. Check with radiographer if not clear. If the volunteer has ever worked with metal, such as welding, or any job where metal shards might have flown into the volunteer's skin or eyes, then this could be a problem. If the volunteer has worn eye and other protection, this may still mean there are some shards under finger-nails, etc. If in doubt, then it is possible to have an x-ray of the danger area of the body before MRI scanning, to make sure things are safe. Ask the radiographers for the feasibility of this. Obviously for an fMRI scan, exclusion on metal grounds means exclusion from all studies and this information needs to be passed on to the panel manager.]]

12. Do you have a pacemaker? YES/NO

13. Have you ever broken a bone that required a pin or plate or something similar to be put in? YES/NO

14. Do you have any piercings? YES/NO

If YES, are they removable?

15. Do you have any extensive experience of metalworking, or any accidents involving metal (splinters in the eye, for example?) YES/NO

General health

[[A volunteer who is not healthy may make scanning a problem (e.g. severe asthmatic). Any problems with health may underlie other considerations (see metal notes above and other notes in this section). Of course, health exclusion criteria are a judgement call (except when metal implants are an issue), but careful consideration should be given before scanning anyone with a history of convulsions/epilepsy (except febrile convulsions, which are quite common in infancy and have no known long-term neurological consequences), loss of consciousness of more than a couple of hours, or psychoactive medication. Migraine is only a factor if very frequent, i.e. more than one per week, or accompanied by visual loss or hemiparesis, which is very rare.]]

16. I need to ask you some questions about your general health. Have you ever been in hospital or had an operation? YES/NO

If so, why?

[[Pay particular attention to: convulsions, head injury, ischaemia/stroke, cardiac/respiratory problems, operations in which there is ANY chance of a metal clip/pin/plate/ having been inserted]]

17. Have you ever even been knocked out? If so, for how long?

[[There is no evidence that loss of consciousness for a few minutes necessarily causes detectable brain damage. If they have lost consciousness for several hours at any point and have been admitted to hospital for more than overnight observation (which used to be quite common with concussion), then it is worth considering excluding them. Any more serious brain injury than concussion normally excludes a participant from any study of healthy participants. Remember that volunteers might not think of combat sports, such as boxing, kick-boxing, martial arts, etc. as causing brain injury, but in any sport where there are repeated blows to the head are probably grounds for exclusion, for similar reasons.]]

18. Have you ever had an MR scan on any part of your body? YES/NO

[[Again to check for implants, primarily. Also, may reveal head injury or implant considerations, as well as revealing other problems. E.g. any physical disability will cause difficulties in getting in the scanner.]]

19. Are you on any medication currently, not including (if female) the contraceptive pill? YES/NO

If yes, what? (And what is it for?)

[[If volunteer is currently on psychiatric medication such as anti-depressants, neuroleptics, tranquillisers, or anything else, then it is probably best to exclude them, although final judgement rests with the experimenter and depends on the study questions and the ethical approval. If they are no longer on such medication but have been in the past, then whether or not to exclude them would depend on the why they were taking the medication, how long they took it for, and how long ago this was. You should also be aware that some medications can affect data quality, e.g., by affecting the neurovascular coupling in fMRI. If unsure, ask a more experienced experimenter or the radiographers.]]

Rules to explain to volunteer

There are some other things you should know:

(if female): we do not scan women if they are pregnant, or trying to become pregnant.

(again, if female) If you have a contraceptive coil, you cannot be scanned for at least 6 weeks after insertion.

(again, if female) If you have a coil we need to know the make / type, as not all coils are MRI compatible.

We do not scan people under the influence of alcohol. [[You may also want to discourage high levels of caffeine prior to scanning]]

We do not recommend that you are scanned with a hangover.

[[Make sure the volunteer doesn't have a hangover at the time of the scan, which would make things unpleasant for him/her and, probably, interfere with task performance. Alcoholism or other substance abuse would be a clear reason for exclusion for a study of healthy volunteers.]]

The scanner makes a banging noise when it is working, and this can be loud. You will be given earplugs, which will block some of the noise, and headphones.

SECTION B (if scanned before):

20. When were you last scanned?

[[We discourage volunteers from being scanned on more than one study per week, unless necessary, eg part of a study design]]

B2) Have you had any operations or accidents since?

[[If YES, then carefully ask questions 16 to 19]]

B3) Ask any experiment specific questions here

[[E.g. Do they need to be native English speaker, right handed, have good hearing, or not taken part in similar study before?]]

[END OF QUESTIONNAIRE]

5.13 Appendix M: Occupational exposure to electromagnetic fields (EMF)



RISK ASSESSMENT RECORD FORM		
Section 1: Administrative Details		
Name of Assessor: Gary Chandler	Job Title: Lab Manager	Date of Assessment: 01/06/2017
Section 2: Activity/Task		
Activity /Task Provision of MRI testing at the CBSU		
Risk: Occupational exposure to electromagnetic fields (EMF)		
Area affected: MRI Building		

Source of Risk (Background):

Three types of electromagnetic field are employed in MRI, and each is associated with physiological effects.

- Exposure to strong static magnetic fields, particularly when there is rapid motion of the head, is associated with transient sensory effects such as vertigo, nausea, and a metallic taste. These effects resolve once the movement stops or the affected person is removed from the field. There are no known longer-term health consequences. These effects can only occur if an individual is very close to the magnet.
- Exposure to the switched magnetic field gradients used in MRI can result in peripheral nerve stimulation, which at sufficiently high levels of exposure can result in intolerable pain. This can only occur if an individual is inside the scanner or very close to the bore of the magnet (within 0.5-1 m) while imaging is taking place
- Exposure to RF magnetic fields can result in excessive tissue heating. In practical terms, this can only occur if an individual is inside the scanner during imaging.

The Control of Electromagnetic Fields at Work Regulations 2016 [1] place an obligation on employers to assess occupational EMF exposure, perform risk assessments, put appropriate control measures in place, and provide workers with appropriate information and training.

The Regulations contain exposure limit values (ELVs) for occupational exposure to EMFs, but the development, testing, installation, use and maintenance of, or research related to, MRI equipment for patients in the health sector is exempted from these ELVs, subject to certain conditions. The HSE has also exempted certain MRI activities that do not fall within this definition.

The conditions that apply to the exemptions are as follows.

- The exposure of employees is reduced to the lowest level reasonably practicable*; and
- Employees are protected against the health effects and safety risks arising from their exposure to electromagnetic fields.

There is copious evidence (e.g. Capstick et al 2008) [2] to show that MR workers can exceed the ELVs for time varying magnetic fields when they move around in the vicinity of the MR scanner and if they are close to the scanner (within 0.5-1.0 m) while images are being acquired. There may be exceptional circumstances in which the limits for exposure to RF fields may be exceeded.

*Since the transient physiological effects encountered in MRI only occur above a particular exposure threshold (although this threshold may vary somewhat between individuals), there is no need for further

reduction of exposure below that level. Thus ALARP effectively only applies at exposure levels at which effects may occur, which only arise within approximately 0.5-1 m from the scanner.

Supporting Evidence:

Published data on hazards and EMF exposure (e.g. [2]) in MRI. MHRA guidelines on safe use of MRI [3]. HSE guidance on The Control of Electromagnetic Fields at Work Regulations 2016.

Factors the risk contains: *(if for COSHH include route of exposure, length of exposure time and exposure limits)*
Electromagnetic fields.

Potential Consequence if risk is realised:

- Transient physiological effects.

Section 3: Current Control Measures

The employees at particular risk where the ALs and ELVs can be exceeded are the MRI Radiographers and trained operators.

The CBSU MRI SOPs are in place and are followed

To minimise where the ELVs are exceeded MR staff only remain in the scanner room where absolutely necessary and only approach with 1 metre of the scanner when needed to prepare the volunteer, testing or essential cleaning.

MRI staff are screened for anything that might put them at a higher risk from exposure to EMFs such as being pregnant or those with medical implanted devices. MRI staff are protected against the health effects and safety risks posed, by their training and the sharing of information about the risk and how to avoid them.

The indirect effect of ferromagnetic materials becoming projectiles in the vicinity of the static field are also covered in the SOPs with careful screening and thorough testing of any equipment used in the MRI room.

Where an employee reports experiencing a health effect and that employee is believed to have been exposed to EMFs exceeding any ELV, health surveillance and any medical examinations would be provided as appropriate.

The MRI equipment is fully maintained and updated by the manufacturer and we will consider the availability of alternative equipment or equipment designed to reduce the level of exposure as they become available where practicable. The manufacturer, Siemens, has produced a statement of Conformity with IEC 6060601-2-33 for the safe use of its equipment within current guidelines

The system is safe guarded by a gradient supervisor unit that will disable the gradient system when the switching rate exceeds a set maximum.

The gradient supervisor unit is calibrated, tested, and maintained by the manufacturer.

The time varying magnetic field produced by the gradient system (dB/dt) is automatically calculated for each imaging sequence by the scanner operating system and the Scanner Operator is warned if the critical threshold for peripheral nerve stimulation PNS is exceeded.

dB/dt is continuously monitored during scanning by an independent hardware component (gradient supervisor unit) which will inform the Scanner Operator about the current level and disable the gradient unit if the critical threshold for PNS is exceeded.



Section 8: Review	
Risk Owner: Gary Chandler	
<i>G Chandler</i>	
Planned Review Date: 01/06/2018 reviewed no change	
Next Review Date 01/06/2019	
Reference	
[1]	The Control of Electromagnetic Fields at Work Regulations 2016.
[2]	Capstick M, McRobbie D, Hand J, Christ A, Kühn S, Hansson Mild K, Cabot E, Li Y, Melzer A, Papadaki A, Prüssmann K, Quest R, Rea M, Ryf S, Oberle M, Kuster N. An investigation into occupational exposure to electromagnetic fields for personnel working with and around medical magnetic resonance imaging equipment. Employment, Social Affairs and Equal Opportunities DG, European Commission, 2008. Available at: http://www.itis.ethz.ch/assets/Downloads/PapersReports/Reports/VT2007017FinalReportv04.pdf .
[3]	D. Grainger, "Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use," Medicines and Healthcare Products Regulatory Agency, Mar. 2015.

5.14 Appendix N: MRI Authorisation Procedure



MRI Authorisation Procedure

(Obtaining MRI researcher status)

We aim to achieve efficient training procedures that guarantee the safety of researchers, participants and equipment whilst also allowing researchers to prepare for an MRI project at the unit.

MRI Researcher training (achievable within a week):

1. Read SOPs, and read information on our [intranet](#) / [wiki-pages](#)
2. **MRI safety training session:** Introduction to the MRI unit and the procedures. Demonstrate awareness of General responsibilities, H&S guidelines and emergency procedures.
3. **Shadow at least three MRI sessions.** (The neuroimaging administrator can suggest sessions for you to shadow) *Candidates are encouraged to ask questions during these sessions and to observe the following processes:*
Screening of participant; appropriate RAS and consent paperwork; controlled area measures; stim computer delivery; communicating with participant in scanner; observing different methods, sequences and protocols. Mock scanner training
4. Once Training is complete and this form has been handed back to the neuroimaging administrator, MRI access will be added to the candidate's swipe card.

CHECKLIST to be signed by Radiographers and neuroimaging administrator

MRI candidate Name	
MRI objectives (please give any details about your potential MRI project)	

Procedure	Initials of radiographer / admin
READ SOPS	(researcher initials)
Have Undertaken MRI SAFETY TRAINING and passed multiple-choice test.	(radiographer initials)
Shadow session 1 Observe Screening of participant; appropriate RAS and consent paperwork; controlled area compliance.	(radiographer initials)
Shadow session 2 Stim computer delivery; communicating with participant; observe different sequences and protocols.	(radiographer initials)
Shadow session 3 Stim computer delivery; communicating with participant; observe different sequences and protocols; mock scanner awareness.	(radiographer initials)
Meet with neuroimaging administrator	(Administrator initials)

5.15 Appendix O: Use of Unlabelled Equipment in MRI environment

The below text represents a joint policy for use across the three human imaging sites in Cambridge Health Imaging. It aims to ensure a consistency of approach across the campus and to clarify the responsibilities of both the physics teams and the researchers involved.

Items of ancillary equipment that are sold for use in an MRI environment should be labelled using the standard terms of "MR Safe" (in which case they can be used unconditionally within the scanner) or "MR Conditional" (in which case they labelling should be carefully checked to identify whether they can be used in way that has been demonstrated to be safe by the manufacturer). When use cases comply with these conditions then the devices can be used for studies although it may be necessary to write an SOP for their safe use.

However, some equipment may need to be used for a research study beyond the restrictions that the manufacturer has identified as safe, or no testing may have taken place. In these circumstances, the local imaging site will need to test the equipment under the operating conditions needed for the research study in the MRI environment, and also ensure that it passes electrical safety tests. The use of such ancillary devices is only appropriate for research studies with appropriate research consent: it is not allowed to use such devices for clinical studies.

The current standard used in testing for commercial products is published by the ASTM (American Society for Testing and Materials) and tests the projectile effect, torque, RF induced heating and image artefacts. The local site testing will summarise the perceived risks under each of these headings. If practical, the design and results of the tests will be discussed with staff across other sites within Cambridge Health Imaging (CBSU, Imaging, WBIC) to provide oversight and consistency of practice across the University.

Once the testing is complete the testing site will provide a report to the investigator who has requested the use of the device, detailing the conclusions. If there are adverse conclusions that in the opinion of the local MR Safety Expert render the device a risk to the health or safety of participants it will not be possible to use the device. This decision will be final and only reconsidered on the basis of further information or adaptations to the device or its proposed use.

It is more likely that a reasonable degree of testing will have shown that the device is safe, but that no definitive conclusion can be reached on the basis of the testing for all circumstances. The relative risk of proceeding will be detailed. As well as the test results, further information that will be considered is the demonstrated safe use of the device at other sites (either through published results or documented personal communication).

It will be the responsibility of the investigator to consider and respond to the report: depending on the strength of conclusion they may decide to review information about the relevant risks in the participant information sheet, or consult the relevant ethics committee and the study's insurers. It is the responsibility of the investigator to ensure that the participant is fully informed about the risks and any mitigations (e.g. the presence of clinically qualified staff). These documents may need to be re-reviewed by the local approvals committee (e.g. IMC – Imaging Management Committee, WRAC – WBIC Resource Allocation Committee) in light of the test results.