

MRI Safety Manual for Operators

Version 6

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Document History

Version	Comments	Author(s)	Date
6.0	Added rules for pregnant individuals	A Gouws	October 2019
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3.0	Updated to reflect new definitions of Level 1, 2 and 3 operators	A Gouws	October 2016
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Referenced Documents:

Title	Type
Safety Questionnaire and Consent for Participants: Modality - MRI	Form
YNI Patient Safety Questionnaire	Form
YNiC Clinical Diagnostic Policy	Web Policy
MRI Local Rules for Operators	Document
MRI Safety Questionnaire Explanation for Operators	Document
MRI Training Scheme for Level 0, Level 1 and Level 2 Operators	Document
MHRA Guidelines	External Document

Table of Contents

Document History.....	1
Referenced Documents:.....	1
1. Introduction.....	3
2. Designation of the Controlled Areas.....	3
3. Working Procedures: General Rules.....	4
4. Working Procedures: MRI-Specific Rules.....	4
4.1. Control of Access.....	4
5. System Failure.....	7
Appendix A. Plan of MRI Unit.....	10
Appendix B. Personnel and Responsibilities.....	11
MRI Responsible Person.....	11
Categories of Staff.....	11
Operators at level 0,1,2 and 3.....	12
Equipment Manufacturers.....	12
Appendix C: Administration of Screening Forms.....	13
Appendix D: Emergency Procedures and Quench.....	14
Quenching Procedure.....	14
Appendix E: Safety and hazard information in MRI.....	15
E.1. Static magnetic field.....	15
E.2. Time-varying magnetic fields.....	17
E.3. Radiofrequency fields.....	18
E.4. Acoustic Noise created by MRI.....	19
E.5. Cryogens within MRI.....	19
E.6. MRI phantoms.....	20
E.7. MRI laser localiser.....	20
E.8. Use of the patient table within MRI.....	21

1. Introduction

This document governs all use of the magnetic resonance (MR) scanners installed in York Neuroimaging Centre, University of York.

Although there are no known adverse effects to humans from the static or time-varying electromagnetic fields used in MR scanning, there is a need for caution for a number of reasons:

- The static field can cause pacemakers or other implanted devices to malfunction and cause other metal implants or shards to move.
- The static magnetic field can cause loose ferromagnetic articles to become projectile causing injury or death to persons near or in the magnet bore.
- The static field can cause damage to personal possessions such as analogue watches and credit cards.
- In addition to the static magnetic field, smaller, moving magnetic fields are used to control data acquisition during scans. At higher field strengths, the movement of these smaller fields sometimes produces a tingling sensation due to peripheral nerve stimulation. Although this peripheral nerve stimulation is not inherently dangerous, the sensation can be uncomfortable for the patient/volunteer.
- Radiofrequency (RF) exposure can heat tissue, particularly if any metallic implants or objects are present.

The MRI scanners therefore can pose a dangerous environment unless operated according to strict safety protocols.

This document outlines the rules that MR scanners operators **must** adhere to, in order to ensure the safety of themselves, colleagues and participants. It has been drawn up by YNiC Staff and approved by the Research and Governance Committee.

All users of the scanner, whatever their affiliations, **must** adhere strictly to its provisions.

This document is compiled from all the currently available safety literature, the main reference source being the “*GUIDELINES FOR MAGNETIC RESONANCE DIAGNOSTIC EQUIPMENT IN CLINICAL USE, WITH PARTICULAR REFERENCE TO SAFETY (Medicines and Healthcare Products Regulatory Agency MHRA)*” which is readily available on the internet.

As with all Health and Safety directives, all personnel have a responsibility to behave responsibly to ensure the well-being of themselves, their colleagues, patients and participants in MRI examinations and any other visitors. Certain categories of staff (identified in Appendix B) have additional responsibilities;

2. Designation of the Controlled Areas

- A plan of the MRI unit is shown in Appendix A. Within the unit there exists two scanning suites for different scanners, each with a Controlled Area (comprising the MRI control room, MRI Scanner, MRI Equipment and Chemistry). The extent of the controlled areas are shown in Appendix A.
- Access to a controlled area is controlled by electronic security fob to prevent unauthorised access.
- Within a Controlled Area is the Inner Controlled Area (MRI Scan room) which totally encloses the 5 Gauss magnetic field contour.

- All objects and equipment **must** be screened and/or tested by a Level 3 MR operator prior to being taken into the inner controlled area.
- All personnel including staff and visitors whose work does not normally require them to operate within the inner controlled area, **must** be screened using an MR safety questionnaire, prior to entering the inner controlled area, and **must** be supervised by a level 1, level 2 or level 3 operator at all times whilst within the inner controlled area. As part of the final screening procedure at the scan room entrance door, a metal detector screening of anyone entering the room should be undertaken by a trained operator.

3. Working Procedures: General Rules

These rules are in addition to and can be seen as an extension of the Health and Safety at Work Act. This clearly lays down the mandatory responsibilities and statutory requirements of the employer, employees and visitors who have access to the place of work. All the terms of the Act **must** be adhered to, including that persons **must** behave in a responsible and considerate manner in order not to endanger themselves or others and to maintain a good working atmosphere.

- No person or object should be permitted to enter the inner controlled area without being screened or tested by level 1, level 2 or level 3 operator.
- Only trained and competent personnel are permitted to operate the equipment.
- Equipment **must** be properly used, serviced and maintained in a good state of repair.
- Faults **must** be reported promptly see *MRI Local rules* section 8.
- Working areas and exits **must** be kept clean, tidy and free from obstruction.
- Any accident, incident or near miss **must** be reported immediately see *MRI local rules* section 8.
- If a fault or incident may have rendered the equipment unsafe it **must** be taken out of service until appropriate tests have been performed.
- In the event of an emergency such as fire, local procedures **must** be followed (see *MRI Local Rules* section 4). All personnel should know the location of fire alarms and escape routes (see Appendix A).

4. Working Procedures: MRI-Specific Rules

4.1. Control of Access

Access to a controlled area is restricted via electronic fob with permissions based on individuals working requirements. No screening is required to enter the Controlled area.

Access to the Inner Controlled Area is restricted to Category A staff and persons under the direct supervision of Category A staff.

The person is responsible for all personnel in the controlled area. He/she needs, therefore, to consider the various risk factors before proceeding with any activity in the controlled area.

All people **must** be “screened” by a level 1, level 2 or level 3 operator before access to the inner controlled area is permitted. Any object not normally present in the inner controlled area **must** be assessed/screened by a level 3 operator before being taken into the inner controlled area.

The outer door to the MRI control room **must** be kept closed at all times.

Only level 1, level 2 or level 3 operators will have fob access to the MRI suite (i.e. access to the outer and inner MRI controlled areas). Level 0's are not allowed into either the inner or outer MRI controlled areas without the presence of at least a level 1 operator in the suite.

During scanning, at least two operators must remain in the controlled areas while the participant or patient is in the inner controlled area. Thus, at no point should there be fewer than two qualified operators (one of whom is at least a level 1 operator) in the MRI suite if there is a person being scanned. Following a scan, if the participant / patient has been safely removed from the inner controlled area (scan room), the level 0 operator can leave the MRI suite to prepare the next participant so long as the previous participant is being debriefed in the outer controlled area by the level 1 (or higher) operator.

When the MRI unit is not in use, the following doors are kept on fob-access only (these doors are identified in Appendix A):

- MRI control room outer door
- Chemistry laboratory
- MRI equipment room

Note

When the scanner is not in use, the door the MRI scan room is locked.
The key **must** be kept in the top drawer of the pedestal under the MRI console bench.

4.2.1 Screening People

All screening of patients, participants, staff and visitors **must** be performed using the latest version of the appropriate safety questionnaire.

For clinical patients scanned by York Diagnostic Imaging, the *Patient safety questionnaire* is used.

For YNiC research scans, the *Safety Questionnaire and Consent for Participants: Modality - MRI* is used along with *General Consent* form. Both forms **must** be present and signed for research scans before the operator proceeds.

In general all persons having an MR examination should be screened twice. In the case of patients this is performed by admin staff at the time of booking the scan and then by the Radiographer immediately prior to the scan. In the case of participants the should be done by the PI (or their representative) and then by the level 1, level 2 or level 3 operator performing the scan. The operator performing the scan is responsible for the safety of the individual having the scan and **must** satisfy themselves it is safe to proceed.

Visitors entering a scan room but not having a scan need only be screened once but this **must** be performed by a level 3 operator.

All patients, research participants and visitors who are escorted into the inner controlled area (scan room) must complete a screening questionnaire and must undergo a final screening check at the scan room entrance, to include metal detector screening by a trained operator.

4.2.2 Screening equipment

Occasionally small items of equipment (e.g. photometers and other optical equipment) need be taken into the controlled area for specific purposes or studies. This is permitted only after an

appropriate risk assessment is performed and express permission is granted by the MRI Responsible Person or his/her deputy. The activity/procedure **must** be directly supervised by a level 3 operator who assumes responsibility for the safety of all personnel within the controlled area.

4.3. MRI Examination

Clinical scans **must** only be performed by an HPC registered radiographer.

Clinical scans **must** only be performed upon receipt of an appropriate referral from a registered healthcare professional. Referrals deemed inappropriate will be returned to the referrer. Clinical scans will only be performed providing the Radiographer is satisfied it is safe to proceed.

Research scans **must** only be performed by level 1, level 2 or level 3 operators.

Participants may only be scanned as part of a research project with appropriate ethical approval or for protocol/technique development as approved by the Director or Deputy Director of the centre.

Patients and participants can only be scanned providing appropriate documentation (safety and consent forms have been completed) in accordance with the *MRI local rules* sections 6 & 7.

A record **must** be maintained of all persons who are scanned (see the *MRI Local Rules*).

A record **must** be maintained of the *YNiC Safety Questionnaire and Scan Consent forms* as well as *General Consent Forms* for all persons entering the inner controlled area. These **must** be treated as confidential and returned to YNiC reception for scanning and filing as appropriate.

Suitable earplugs or sound-attenuating ear defenders **must** be provided to all persons undergoing an MRI scan. Where any person refuses to wear the hearing protection provided, they **must not** be scanned. Earplugs **must** be of disposable type and discarded after a single use. Where ear defenders are used these should be adequately maintained and inspected on a regular basis, and cleaned after each use. Any damage to the earphones **must** be reported immediately to the MRI Responsible Person or his/her deputy.

Persons **must not** be examined during scanner servicing or be in position in the scanner during switch on/off of the magnet (except in an emergency).

Only equipment that has been adequately tested and shown to be safe may be connected to the MR scanner or used within the controlled area

If any patient/participant is unable to position him/herself on the bed unaided the operator should assess the level of assistance required, and only if they are confident that they can safely assist should the assistance be given. .

The outer door to the MRI control room **must** be kept closed at all times.

Only level 1, level 2 or level 3 operators will have fob access to the MRI suite (i.e. access to the outer and inner MRI controlled areas). Level 0's are not allowed into either the inner or outer MRI controlled areas without the presence of at least a level 1 operator in the suite.

During scanning, at least two operators must remain in the controlled areas while the participant or patient is in the inner controlled area. Thus, at no point should there be fewer than two qualified operators (one of whom is at least a level 1 operator) in the MRI suite if there is a person being scanned. Following a scan, if the participant / patient has been safely removed from the inner controlled area (scan room), the level 0 operator can leave the MRI suite to prepare the next participant so long as the previous participant is being debriefed in the outer controlled area by the level 1 (or higher) operator.

4.4. Results of Examination

Results of clinical scans will be returned to the referring clinician or the patients GP if the reporting radiologist deems it to be in the patients interest. No member of staff will offer any opinion to the patient in respect of their examination.

Scanning of human participants for research purposes normally uses volunteers who are either healthy or have a known, previously documented neurological abnormality which does not present a contraindication for MRI (i.e. patients may be scanned for research projects but not diagnostic purposes).

In the event that a scan reveals a suspected abnormality that was unknown to the operator in charge of the scan and which they suspect might require treatment, the *YNiC Clinical Diagnostic Policy* (<https://www.YNiC.york.ac.uk/information/policies>) **must** be followed.

1. So as to avoid distress to participants arising from false alarms, staff **must not** disclose their concerns to the participant.
2. The operator involved **must**, without delay, report his/her concerns to the MRI Responsible Person.
3. In the interests of participant confidentiality, the operator concerned should not discuss the situation with colleagues or other participants.

4.5. Exposure Limits

Full detail of the exposure limits in MR are detailed in MHRA guidelines. The MRI system in YNiC is fully compliant with those guidelines. For all practical purposes the following exposure limits are imposed.

Patients/Participants

- The exposure of any one person to the static magnetic field **must not** exceed an average of 0.2 Tesla, averaged over any 24-hour period. Therefore the time spent in the magnet by any one person should not exceed 90 minutes in any 24-hour period.
- Other than this, there is no restriction on the frequency with which a screened person may be scanned.

Staff

- The exposure of any one person to the static magnetic field **must not** exceed an average of 0.2 Tesla, averaged over any 24-hour period. At the side of the bore opening staff experience approximately 0.5T it is unlikely therefore that any person could exceed the exposure limit under normal circumstances.

5. System Failure

Should any part of the system fail that may endanger patients/participants, staff or equipment, the examination **must** stop and the patient/participant **must** be removed from the scanner. If there is a risk of damage to the equipment, the operator **must** turn off the power to the equipment by pressing one of the red 'stop' buttons in the MRI Scan or MRI Control room. No further scanning is permitted to take place until the fault has been corrected.

5.1. Magnet Quenching

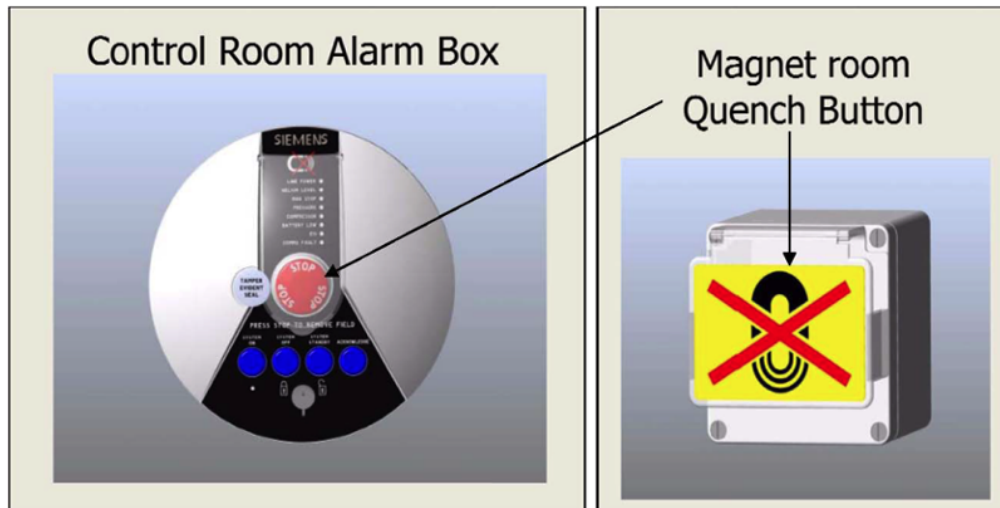
Quenching should only be performed by Category A staff.

QUENCHING refers to the loss of absolute zero in the magnet coils. If the temperature rises, the coils cease to be superconducting and become resistive. Heat is then generated, resulting in boil-off of helium, and the field strength falls sharply. It is essential that due consideration is given to the position of the trapped person and the object trapping them as once the field is removed the object will fall and may cause further injury. Quenching can be manually instigated in an emergency. Re-establishing the static field after quenching is an expensive, specialist procedure. In addition, the magnet may be permanently damaged. A quench should only be performed if a person being is in a life-threatening situation due to the magnetic field i.e. someone is pinned against the magnet by a heavy object.

Procedure

- Manually quench the magnet by pressing one of the quench buttons.
 - **For the GE 3T Signa excite:** The quench buttons can be found both inside (white box) and outside (red box) the MRI scan room by the door. Raise the plastic guard on the box to access the quench button.

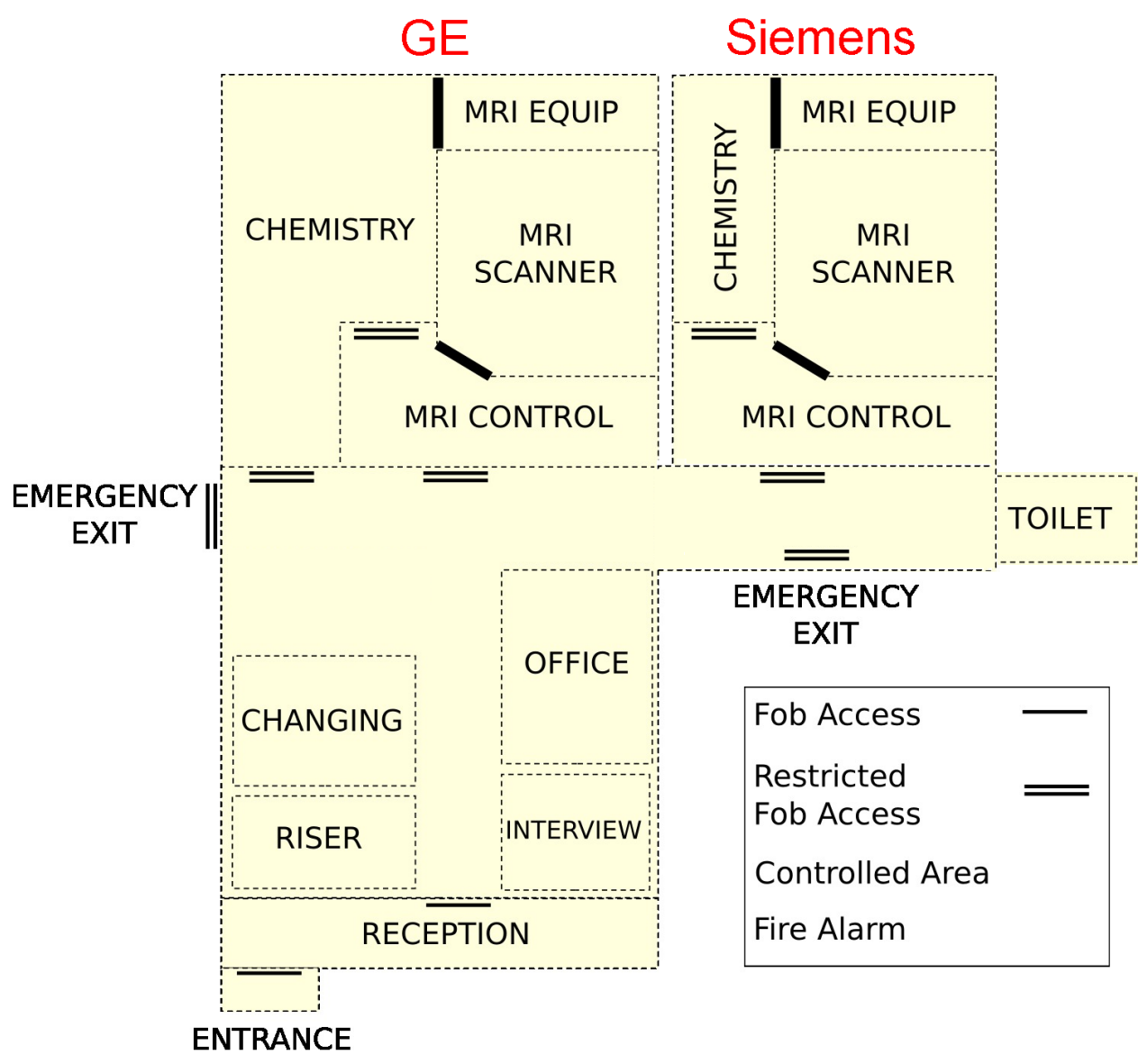
- **For the Siemens Prisma:** The quench buttons can be found both inside (small plastic box 1m to the right of the scan room door as you enter the scan room) and outside (round control panel on the wall just to the top left of the operator console) the MRI. Raise the plastic guard on the box to access the quench button.



- The DOOR to the MRI Scan room **must** be OPEN during quenching. Manually quenching may be performed only by an operator who **must** first have given due consideration to the relative risks (see Note above)
- Dial 9-323-333 and call for an ambulance.
- Do not attempt to remove the participant from the scanner if they are pinned against the magnet.

Appendix A. Plan of MRI Unit

Figure A.1. Plan of MRI Unit



This picture is a schematic and is not to scale

Appendix B. Personnel and Responsibilities

MRI Responsible Person

This person is responsible for ensuring that the rules and procedures set out in this document are adhered to at all times. He/she also carries responsibility for keeping abreast of any new legislation or external guidelines that may be relevant to internal procedures. In times of absence, he/she may appoint a deputy who **must** previously have been approved by the Research and Governance Committee.

Categories of Staff

Following MHRA recommendations YNiC recognises three categories of Staff

Category (A)

MR OPERATOR: Those staff who to operate, maintain or modify the MRI equipment such as radiographers, radiographic assistant practitioners, scientific staff, technical staff, MRI service engineers and suitably qualified and trained research staff. Within Category A YNiC recognise 4 levels of operator.

- *Level 3 Operator:* Fully independent operator with permission to construct and amend protocols and trouble shoot system failures.
- *Level 2 Operator:* An operator who has gained significant experience performing the duties defined for a Level 1 operator, and is considered qualified to train other operators to Level 0 or Level 1 standard.
- *Level 1 Operator:* Independent operator with permission to run specific pre-prepared protocols unsupervised. They are not permitted to create or amend protocols and are not permitted to troubleshoot system failures.
- *Level 0 Operator:* Persons in training to be a level 1 operator. Persons whose duties may require them to enter the inner controlled. Most work under the direct supervision of a Level 1, Level 2 or Level 3 operator whilst in the inner controlled area.

Category (B)

Personnel who do not fall into category (A) but are present with a volunteer or patient during scanning such as chaperones, family members.

Category (C)

All other staff who may be required to enter the MR CONTROLLED AREA when scanning is not taking place .

Training requirements	A	B	C
Full training and instructions in the use of the equipment, its hazards and what action to take in the case of an emergency. Level 3 Operators should form the basis of the team training subsequent members of this category	✓		
Must understand the safety aspects relating to: <ul style="list-style-type: none"> The electrical safety of the equipment. The main static magnetic field and associated equipment. Radio-frequency (RF) fields and associated equipment. Gradient magnetic fields and associated equipment. 	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	
They must understand departmental emergency procedures.	✓	✓	✓
They must read understand the local rules and procedures in connection with the MR equipment.	✓		
They must understand the significance of the MR CONTROLLED AREA and the INNER MR CONTROLLED AREA and be able to differentiate clearly between them. In particular they must be fully conversant with: <ul style="list-style-type: none"> The projectile effect. The effect of magnetic field upon implants and prostheses. The effect of magnetic fields upon personal effects such as credit cards and watches. 	✓ ✓ ✓	✓	
They must understand the consequences and effects of quenching of superconducting magnets	✓		
They must be fully aware of the recommendations on exposure to MR.	✓		
They must have had full instruction in, and must understand the consequences of, the correct selection, fitting, and use of ear protection.	✓	✓	

Operators at level 0,1,2 and 3

These are staff who have undergone specific training and are conversant with, and are able to put into practice all the rules and emergency practices outlined in this document. They are responsible for screening participants and other visitors to ensure that it is safe for them to enter the inner controlled area. They are responsible for supervision all non MR trained persons within the inner controlled area. The Research and Governance Committee grant Operator status. This Committee will maintain a list of current Operators at all times and will immediately inform the MRI Responsible Person of any alterations to it. Before a person can be listed as an operator they **must** complete training and testing commensurate with their responsibilities (see *MRI Training Scheme for Level 0 and Level 1 Operators* for details).

Equipment Manufacturers

Trained service personnel or representatives of scanner manufacturers can operate the equipment for quality control testing, servicing and demonstration purposes. Such people may be admitted to the controlled area on production of identification (and normally by arrangement).

Appendix C: Administration of Screening Forms

All persons entering the inner controlled area are required to complete a safety/consent form.

For clinical patients these forms are scanned and stored in the patients unique folder on the YNi Ltd server.

For participants, *Session Safety and Consent Forms* are scanned and stored electronically whilst *General Consent forms* are also held in paper format in a locked filing cabinet in reception.

If the answer to any question on these forms casts doubt on either their safety or their full consent the scan **must not** be performed until such time as the doubt has been resolved to the complete satisfaction of the Operator performing the scan.

Appendix D: Emergency Procedures and Quench

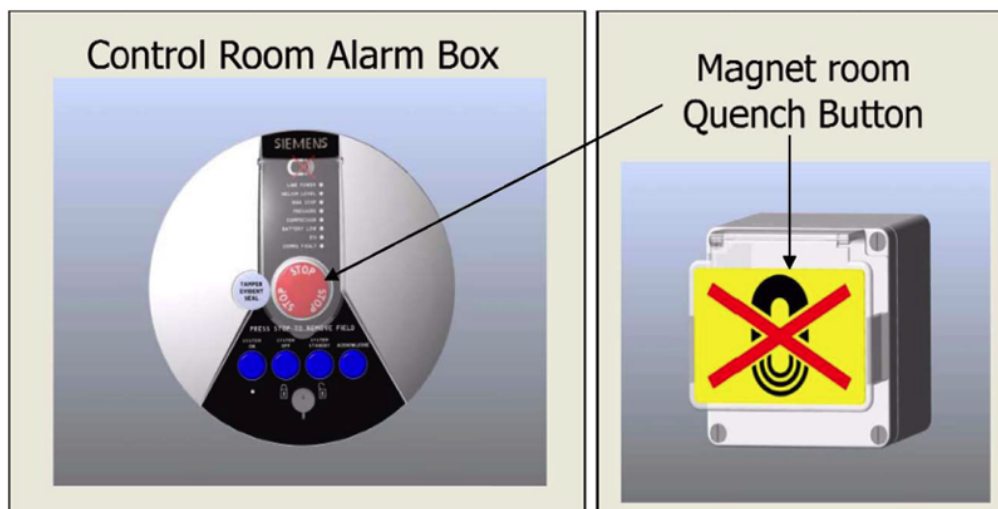
QUENCHING refers to the loss of absolute zero in the magnet coils. If the temperature rises, the coils cease to be superconducting and become resistive. Heat is then generated, resulting in boil-off of helium, and the field strength falls sharply. Quenching can be manually instigated in an emergency. Re-establishing the static field after quenching is an expensive, specialist procedure. In addition, the magnet may be permanently damaged.

Quenching Procedure

This procedure is to be used in the event of a person being in a life-threatening situation due to the magnetic field (i.e. someone is pinned against the magnet by a heavy object).

Procedure

- Manually quench the magnet by pressing one of the quench buttons.
 - **For the GE 3T Signa excite:** The quench buttons can be found both inside (white box) and outside (red box) the MRI scan room by the door. Raise the plastic guard on the box to access the quench button.
 - **For the Siemens Prisma:** The quench buttons can be found both inside (small plastic box 1m to the right of the scan room door as you enter the scan room) and outside (round control panel on the wall just to the top left of the operator console) the MRI. Raise the plastic guard on the box to access the quench button.



- The DOOR to the MRI Scan room **must** be OPEN during quenching. Manually quenching may be performed only by an operator who **must** first have given due consideration to the relative risks (see Note above)
- Dial 9-323-333 and call for an ambulance.
- Do not attempt to remove the participant from the scanner if they are pinned against the magnet.

Appendix E: Safety and hazard information in MRI

This section list and describes the hazards in MRI and the risk assessment information associated with these.

A wide variety of hazards are addressed in the following sections, including:

- Static Magnetic Field
- Time Varying Magnetic Fields
- Radiofrequency fields
- Acoustic Noise created by MRI
- Cryogenics within MRI
- MRI phantoms
- MRI laser localiser
- Use of the patient table within MRI

E.1. Static magnetic field

The magnetic resonance imaging devices in the YNiC MRI magnet rooms have a 3 Tesla static magnetic field (B0) which is present all the time. They are NEVER switched off. The magnitude of this field is such that a number of risks have to be considered. These include the effects on implanted medical devices, risks of objects becoming projectiles within the field, the effects on physiological monitoring equipment and possible biological effects.

The MRI magnet rooms have been designed to be of sufficient floor area such that the field strength has fallen to 0.5mTesla at the edge of the magnet room. Testing has confirmed that the 0.5mT contour is contained within the 'inner controlled area' that is the MRI magnet room.

E.1.1. Risks

The following are extracts from MHRA guidelines, for further information please refer to the MHRA guidelines.

1. Medical devices

The static magnetic field may affect a medical device. The compatibility of any medical device **must** be ascertained and verified as safe or verified that the conditional status is satisfied before being allowed into the inner controlled area including implanted devices such as pacemakers, stents, clips, neurostimulators, hearing aids,

2. Projectile Risks

Any item that contains magnetic material can be attracted to the MRI magnet. The force and the associated acceleration may be very large and even small items, such as coins or keys, may cause serious injury or death. All magnetic objects **must** be considered as potential projectile hazards until proven otherwise.

3. Monitoring equipment

All physiological monitoring equipment **must** be treated as any other item that may be taken into the MRI magnet room. Monitoring equipment **must** be treated as a potential projectile risk and also that its function may be adversely affected by the static magnetic field.

4. Biological effects

No adverse biological effects have been described (see Review of the Scientific Evidence for Limiting Exposure to Electromagnetic Fields, 0-300GHz, published by the National Radiological

E.1.2. Limits

Please see MHRA guidelines for full information regarding exposure limits.

1. Exposure limits for staff

Table E.1.

	Staff upper limit Tesla	Average field strength (T) over 24hours
Body	2.0T	0.2
Limbs	5.0T	0.2

An estimate of exposure for YNiC staff working within the MRI area can be tabulated as follows:

Table E.2.

Staff member	Typical field average (T) over 24 hours	Estimated maximum average (T) over 24 hour
MRI operator (Radiographer)	0.008	0.05
Approved Researcher	0.004	0.05
Administrative staff	0.002	0.002

In addition to the MHRA limits above, approaches to limiting exposure of pregnant individuals are specified in the MRI Local Rules for Operators.

2. Exposure limits for Patients/participants

The NRPB static field exposure limits for volunteers and patients (participants) are recommended to be:

Mode	Field Strength (T)
Normal operating mode	< 2.5
Controlled operating mode	2.5 - 4

The YNiC scanners can be considered to be operating within the NRPB definition of upper level of controlled operating mode. The MHRA recommends that units develop their own protocols for the 'medical supervision' of patients when scanning in controlled mode and that in most cases visual monitoring of the patient by the MR operator will be sufficient to ensure patient safety. Given that YNiC is primarily involved in the scanning of 'normal' healthy volunteers or ambulant out patients and does not accept patients/participants whose conscious level is compromised YNiC policy is that participants/patients are monitored visually and through verbal communication by the MR Operator at the end of each scan sequence. In the event of any change in the apparent medical condition of any patient or participant scanning will be terminated immediately and medical assistance summoned if necessary.

3. Exposure limits for patients/accompanying persons (the general public)

The general public may, on occasion, have reason to enter the MRI areas so as to accompany a person who is being scanned. YNiC policy is that a person accompanying someone having a scan **must** satisfy the same safety constraints as if they were having the scan themselves.

E.2. Time-varying magnetic fields

During MRI scans, the magnetic gradient within the bore of the main magnet can be varied in three principal directions (X, Y and Z axes of the magnet). These gradients can be switched rapidly and are primarily necessary for the spatial decoding of the MRI signals within the body of the participant.

E.2.1. Risks

Time varying fields can induce electric currents in conducting material. Therefore there are risks associated with the possible induction of current within biological tissues. The biological effects include peripheral nerve stimulation, muscle stimulation, perception of phosphenes and in extreme situations, pain. The sensitivity of individuals is known to be person specific and can vary. Particular individuals such as those suffering from epilepsy, those taking tricyclic antidepressants, other neuroleptic agents or drugs that are known to lower seizure thresholds are more likely to be affected by rapidly changing magnetic fields. Although the evidence is limited, it is possible that the developing brain in the neonate and young children may be more sensitive to changing magnetic fields. Current YNiC policy is that no child under the age of six, or any person who may be pregnant or is pregnant may be scanned for either research or clinical reasons.

E.2.2. Limits

The IEC sets strict limits on the gradient outputs of MRI scanners. The scanners at YNiC have a manufacturer's statement of conformity with IEC 60601-2-33. This limits the time varying fields produced by the gradient systems within the scanner and warnings are issued, by the computer controlling the MRI system, if an attempt is made to exceed these limits. The hardware controller physically prevents the limits being exceeded.

The exposure limits for all those who are authorised to enter the MRI inner controlled area are within the guidelines suggested by the 1993 NRPB report:

Although the limits are given in current density, there is some evidence that the magnitude of the induced electric field may be more relevant. This is difficult to calculate and will vary from person to person and within tissues. The YNiC policy is to conform to the NRPB guidelines until the MDA, EU or other organisation changes the recommendations. The manufacturer's limits are strictly adhered to.

1. Exposure limits for staff

YNiC staff are not expected to be present within the scan room whilst any MRI scans are performed. Therefore no occupational exposure to time-varying fields should be experienced. The manufacturer's limits also ensure that staff will not be exposed to current densities that exceed the NRPB guidelines.

2. Exposure limits for participants

The limits for time varying fields are set by the MRI hardware, monitored by a hardware gradient supervisor unit and are within those recommended by the NRPB.

3. Exposure limits for patients/accompanying persons (the general public)

The limits for time varying fields are set by the MRI hardware, monitored by a hardware gradient supervisor unit and are within those recommended by the NRPB.

E.3. Radiofrequency fields

Bursts of radiofrequency electromagnetic radiation between 25MHz and 130MHz are used in MRI to change the spin state of nuclei within the body. The radiofrequencies are only transmitted within the MRI magnet room as the whole room is enclosed within a Faraday cage manufactured by Imedco Ltd. A manufacturer's certificate of conformance of the ability of the cage to prevent ingress or egress of radiofrequency fields has been issued.

E.3.1. Risks

The risks associated with the use of radiofrequency (RF) fields in MRI are that the absorption of the RF energy may cause the generation of heat. It is also possible for the RF fields to induce current burns and/or contact burns through a part of the body or an external component that acts a conductive loop. These RF burns have been reported where the arms or legs have been positioned to effect a conductive path and the RF burns occur where the arms or legs touch.

Contact burns are the most frequently reported incidents in MRI to the MHRA. These burns occur where a part of the body is in contact with metal in clothing, coils, ECG leads, EEG leads, physiological monitoring probes and other equipment brought into the MRI magnet room.

The YNiC policies on supervision of what may be taken into the scan room apply (see section under static magnetic fields and the operational policies at the end of section 5). All participants/patients to be scanned **must** be screened for objects that may give rise to RF burns. All participants/patients **must** be placed in the scanner by a trained Operator to avoid conductive loop RF burns. No equipment **must** be taken into the MRI magnet room without approval of a level 3 operator.

The other major biological risks of using radiofrequency fields are due to heat generated within the participant/patient. The specific absorption rate (SAR) is automatically calculated for each MRI procedure for each participant/patient. As the SAR limit is dependent upon the weight of the participant, all participants' weights **must** be determined before scanning and the correct value **must** be entered at the MRI console. Scanning is not possible if the SAR limit is exceeded as the MRI hardware and software prevent the scan sequence being initiated. SAR is also monitored throughout a scan by an independent hardware component. This SAR monitoring unit automatically stops a scan if the SAR limit is reached.

Heat stress is a risk in certain groups where their normal physiological mechanisms for temperature control are impaired. These include neonates, those on drugs such as diuretics, vasodilators, those suffering from hypertension and women during pregnancy. Cardiovascular stress in the elderly, caused by thermoregulatory demands, is a particular issue that has to be considered. The ambient temperature and humidity also play a role in the ability of the body to dissipate heat.

YNiC policy is not to scan any individual who may be at risk of heat stress without express medical authorisation and direct medical supervision. No pregnant person may be scanned at YNiC.

All YNiC rooms are controlled in terms of temperature and humidity. The MRI areas are on separate controllers and the temperature and humidity of the MRI magnet room are set to be below 21 degrees Celsius and 40% humidity which is below the limits recommended by the MDA (24 degrees and 60% respectively). The environmental conditions are routinely monitored by the MRI operator. Within the bore of the magnet, a flow of cool air is also used for participant/patient comfort.

E.3.2. Limits

1. Exposure limits for staff

The NRPB (1993) states occupational exposure guideline limits for radiofrequency electromagnetic fields in terms of the SAR (specific absorption rate). These limits are enforced by the MRI hardware and software. As staff are not expected to be in the magnet room during a scan, it is not envisaged that an occupational exposure will be encountered.

2. Exposure limits for participants and for patients/accompanying persons

The SAR limits for participants/patients depends on a number of factors including the specific MRI protocol to be used. The IEC and NRPB guidelines are detailed and too long to list here. YNiC policy is that the manufacturer's limits are strictly adhered to (they actually cannot be modified or overcome by any YNiC user or operator).

E.4. Acoustic Noise created by MRI

All MRI systems generate loud noises during scanning. These sounds are created by the alternating currents flowing within the gradient coils. As these coils are contained within a large static magnetic field, forces are exerted on the gradient coils causing them to vibrate and therefore to generate pressure changes which are heard as sound.

E.4.1. Risks

The levels of these sounds can reach very high levels above 120dBA and are therefore hazardous. It is strict YNiC policy that any individual who is to be in the magnet room during scanning **must** wear adequate hearing protection in the form of earplugs or ear defenders. It is the responsibility of the MRI operator to ensure that auditory protection is in place before scanning proceeds.

fMRI experiments that use sound as a stimulus may add to the noise exposure of the participant. All fMRI experiments that use sound **must** estimate the noise exposure of the participant before carrying out scanning and have explicit permission from the Ethics committee to carry out any scans using that noise level.

E.4.2. Limits

The Noise at Work Regulations 1989, state that hearing protection must be available to individuals liable to be exposed to sound levels that reach 85dBA and **must** be worn when levels exceed 95dBA. Although the IEC standard 60601-2-23 states that for patients and participants this level may be increased by 9dBA if the exposure is less than one hour, and that it may be increased by a further 5dBA if exposure is only once, the sound level in YNiC magnet room can still exceed 99dBA for any participant and therefore all persons who are to be in the scan room during a procedure **must** wear hearing protection.

E.5. Cryogenics within MRI

Under normal circumstances there is no reason why any individual should have exposure to the cryogenics within the MRI facility. Annual refilling of the cryogenics is carried out by the manufacturers. Small amounts of Helium can boil off in the event of a failure of the Helium compressor or cryocooler. These small amounts are normally vented to the outside world through a specific helium vent to the roof of the MRI building.

If the normal mechanisms for containing the liquid Helium at cryogenic temperatures fail, then large amounts of Helium gas can escape and the volumes are so large that normal air constituents may be physically displaced. As the main risks associated with escape of cryogenics are due to a lack of oxygen, an alarmed oxygen meter is present within the MRI facility. This meter monitors the oxygen level within the MRI magnet room and sounds an alarm in the MRI control room if the

oxygen level drops below 18%. If this were to occur then the emergency evacuation procedure would be activated.

E.5.1. Risks

The main risks due to the cryogenics are those that arise if the Magnet were to 'Quench' and then the liquid helium would rapidly boil off and form a freezing gas, most of which would be vented to the outside, but some can vent into the magnet room. In the case of a quench then the risks are through asphyxiation, cold-burns, frostbite and hypothermia. A further risk is overpressure forming in the magnet room preventing the opening of the MRI door. Even transient exposure to freezing gases can cause respiratory distress and may trigger asthmatic attacks in susceptible individuals. It should be noted that severe cold burns may not be associated with any pain due to tissue damage. No individual should touch any material that has been exposed to cryogenics or to freezing gases.

The magnet in YNiC has the gradient coils in a vacuum. Although this does decrease the level of noise in the magnet room when scanning is in progress, it is not sufficient to warrant any person being scanned without hearing protection.

E.5.2. Handling of cryogenics in MRI

Any use of cryogenics within the MRI area by manufacturer engineers, such as would occur during the normal refilling procedure, **must** be sanctioned by the Safety Officer for YNiC and also by the MRI operator. No other person is authorised to allow the transfer or handling of cryogenics within YNiC. No persons other than the Safety officer or the MRI operator may be present. A least one other person than the manufacturer engineer **must** be present during cryogen handling.

E.6. MRI phantoms

MRI phantoms are essential for the calibration and testing of the MRI equipment. Although they contain MRI chemicals that may be hazardous, they are all sealed containers. Only Level 3 MRI operators and manufacturer engineers should normally use the MRI phantoms.

E.6.1. Risks

There are two main classes of risk; (a) manual handling risks (b) effects due to leakage of phantom material.

MRI phantoms can contain fluids which are water solutions containing Nickel Sulfates, oils, and/or a mixture of components that could include Sodium Chloride, Sodium Phosphate, buffers, lactates, acetates, Gadolinium compounds or dyes. These substances can be released following damage to a phantom. The released substances may come into contact with the surface of the body or may be inhaled.

E.6.2. Manual handling of MRI phantoms

This **must** only be performed by trained MRI operators or a manufacturer engineer.

COSHH procedures are in place (see COSHH folder in MRI Control room) for dealing with an accident that causes a release of the contents of a MRI phantom.

E.7. MRI laser localiser

The localisation of a participant/patient within the MRI magnet depends on knowing the accurate

position of a fiducial point (normally the nasion if head imaging is performed). This localisation is carried out with the aid of class II laser attached to the front of the MRI magnet.

E.7.1. Risks

The class II laser is of sufficient power to cause damage to the cornea of the eye.

E.7.2. Use of the laser localiser

This **must** only be carried out by the MRI operator. The operator **must** ensure that the patient/participant's eyes are closed during the use of the laser localiser. The laser light is checked by a manufacturer engineer four times per year.

E.8. Use of the patient table within MRI

E.8.1. Risks

The patient/participant table for MRI is dockable and height adjustable. In this respect there is a risk that an attempt might be made to mount the table when it is undocked and it could move. A further risk is that an individual attempts to mount or demount the table when it is in the raised position. Secondary risks are that a person may fall from the table if the side barriers are not raised or the participant restraint straps are not used.

E.9.2. Limits

The weight limit for the safe operation of the patient table is 159Kg. No participant who weighs more than 159Kg may be scanned.

Use of the patient table in MRI: This **must** only be carried out by an operator. The operator **must** ensure that the table is in the locked docked position before use, that the table is at an acceptable height for the patient /participant to mount or demount the table and that safety restraints are used when appropriate. Participants **must not** be left on the table unattended when the table been moved out of the bore of the magnet.