MRI Safety Policy of PolyU Human MRI Lab

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1. Facilities

The Magnetic Resonance Imaging (MRI) Facility at The Hong Kong Polytechnic University (PolyU) houses a state-of-the-art research-dedicated whole-body 3.0T Siemens Prisma scanner. The system is equipped with:

- a high-performance gradient system (80 mT/m @ 200 T/m/s simultaneously, on all three axes) with an advanced cooling system;
- a standard integrated whole-body coil, 20- and 64-channel head/neck coils, 32channel head coil, 18-channel body coil, 15-channel knee coil, 32-channel spine coil, 4-channel large flexible coil, and 4-channel small flexible coil;
- several MR-compatible peripheral devices, including an fMRI package (Sinorad), an eye tracker (EyeLink 1000 Plus), an EEG (BrainAmp), a tES (Soterix), and a physiological monitor (BIOPAC), for multi-modal imaging.

The scanner shall only be used for research, and the research subjects shall be volunteers only. The scanner shall not be used for clinical tests (excluding clinical research).

2. Contact Information

Address:

The University Research Facility in Behavioural and Systems Neuroscience The Hong Kong Polytechnic University Room ZB216, LG2, Block Z, Phase 8 181 Chatham Road South Hung Hom, Kowloon, Hong Kong

Open Hours: Monday - Friday 9:00 - 18:00 Saturdays, Sundays and Public Holidays - Closed

Phone Number: 27665384 (enquiry)

Email: ubsn.enquiry@polyu.edu.hk

3. Site Access and Restrictions

3.1 Hours of Operation

Typically, scanning can only take place during open hours (Mon - Fri 9:00 - 18:00). Should you need to scan outside these hours, prior arrangement must be made with the University Research Facility in Behavioural and Systems Neuroscience (UBSN) staff.

3.2 Safety Zones

The MRI lab is divided into four safety zones, as indicated on the floorplan of the facility. The layout of the MRI lab is shown in Figure 1. Four zones are labelled 1-4, and each zone is progressively more restrictive.

Zone 1: Public Area

This zone is freely accessible to the general public.

Zone 2: First Access/Contact Points between MR Subjects and MR Staff

This is the area where subjects will be screened, change into a patient gown, do the assessment (if needed), and wait to enter the magnet. Subjects and other non-MR personnel must be accompanied by MR personnel. MR personnel are those who have undertaken safety educational efforts to ensure their safety and that of others working within Zones 3 and 4, including secondary users, primary users, the project radiologist, radiographers, and UBSN staff in charge of the MRI.

Zone 3: Control Room and Equipment Room

Only MR personnel and pre-screened non-MR personnel may enter this zone. To perform the MRI examination, at least two MR personnel must be available in Zone 3. The non-MR personnel cannot enter Zone 3 alone.

Zone 4: Scanner Room

Zone 4 is the highest risk zone and is always located within Zone 3. The same training and screening requirements apply to Zones 3 and 4. Any subject or non-MR personnel entering Zone 4 must be supervised by a primary user or the radiographer. Never bring any unapproved devices or objects into Zone 4.

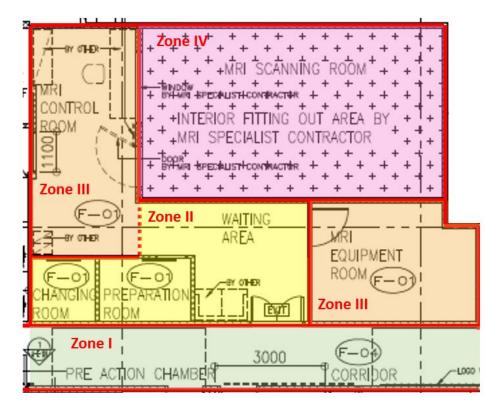


Figure 1 MRI Lab Layout

3.3 Signage

Warning signs are posted at all entry points to Zones 2-4. Additionally, Zone 4 areas are marked as potentially hazardous due to the presence of a strong magnetic field. At the entrance to the magnet room is a red light stating "The Magnet Is On".

3.4 Card Access

Access to the MRI lab (i.e., Zone 2) is controlled by card key access. Authorization for card key access to the MRI lab requires successfully completing safety training and having an MRI safety screening form (Annexes 2 and 3) for control room and scanner access (Zones 3 and 4). Access must be approved by UBSN staff. The emergency door in the control room should always be closed except in the event of an emergency.

4. Definitions and Responsibilities of Different Personnel

MR medical director

He/she is ultimately responsible for ensuring that MR safe practice guidelines are established and maintained as current and appropriate for the site. All adverse events, MR safety incidents, or "near incidents" that occur in the MR centre need to be reported to the MR medical director in a timely manner.

MR advisory committee

The MR advisory committee is an external committee of the UBSN that reviews and develops MRI safety policy and plays a consulting role for the operation of the PolyU MRI lab. Members are appointed by the director of the UBSN.

MR safety officer

He/she is responsible for (1) day-to-day supervision of the issues pertaining to the safe operation of the MRI system and (2) ensuring all safety policies are well implemented and complied with. He/she should be readily accessible and available (e.g., to the operators of the MR system) at all times that the MR facility is accessible.

Radiographer

He/she is responsible for (1) scanning participants, (2) training users and giving an assessment to users, (3) setting up standard scan protocols, and (4) conducting regular quality checks and quality assurance.

Primary user

He/she is qualified to operate the MRI system with the minimum supervision from UBSN.¹ When performing an MRI examination, he/she is responsible for the safety of the subject and MRI system.

Secondary user

¹ Please refer to Annex 1 for a description of the reasonability of setting a primary user to operate the MRI system individually.

He/she is responsible for assisting the primary user/radiographer/radiologist in subject screening, scan preparation, and operating the MRI system. The specific task should be based on his/her experience and be assigned by the primary user/radiographer/radiologist.

General Workers

Cleaners/janitors, A/C maintenance workers and other non-academic/non-UBSN staff who need to work in Zones 3 and 4 (control room and scanner room).

Project Radiologist/Radiographer (if needed)

For projects involving invasive procedures or extra-care subjects, the research team must hire a radiographer or radiologist (for the invasive procedure only), who is responsible for (1) supervising and/or conducting the whole MRI examination procedure and (2) ensuring the safety of the subject and the MRI system.

5. MRI Safety Training Procedure

Operation of the Siemens MRI scanner requires approval by the MR medical director in all circumstances. The following training policy has been established to provide a safe environment for non-MRI personnel to become trained to safely operate the MRI scanner (primary user), or to be proficient in MRI safety rules and able to assist a primary user (secondary user).

Please contact Celia Dong (celia.dong@polyu.edu.hk) to complete the following training procedures.

Please note any research student, faculty, or staff member can become a primary and secondary user. Undergraduate students cannot become primary and secondary users.

To become a secondary user, you must contact UBSN staff to complete the following:

Step 1: Watch an MRI safety video.

Step 2: Attend classroom MRI safety and system operation training provided by the UBSN.

Step 3: Tour the MRI lab.

Step 4: Demonstrate familiarity with emergency procedures at the MRI lab.

Step 5: Complete an assessment of practical MRI safety knowledge provided by a radiographer, and fill in the MRI safety screening form (Annexes 2 and 3).

Step 6: Complete an online MRI safety quiz with more than 80% accuracy (the quiz can be started at any time after step 1).

Step 7: Be approved as secondary user by the MR medical director.

<u>**To become a primary user**</u>, you must hold a valid CPR+AED certificate and complete the following:

Step 1: Become a secondary user.

Step 2: Attend on-site training for MRI system operation.

Step 3: Assist a radiographer for at least 20 hours in subject screening, scan preparation, and operating the MRI system.

Step 4: Set up and perform at least three scan sessions with human subjects supervised by a radiographer.

Step 5: Complete a practical evaluation test administered by a radiographer. This practical evaluation test consists of completing a scanning session autonomously, without any help from the radiographer who is present as an observer.

Step 6: Be approved as a primary user by the MR medical director.

6. Safety Requirements for Subject Safety Screening

The purpose of safety screening is to ensure that no one enters the control room (Zone 3) or the scanner room (Zone 4) with ferromagnetic objects in their bodies, on their bodies, or as part of any materials or equipment brought into the magnet room. Safety screening of ALL individuals entering these zones is a cornerstone of keeping the MRI environment safe.

6.1 Subject Safety Screening

During subject recruitment, researchers should inform subjects that people with any metal implants/fragments, metal eye injury, implanted electronic devices or their residual parts, surgery or tattooing (including make-up tattoos) within the previous six weeks cannot be scanned. Subjects with tattoos should be preapproved by the radiographer for undergoing the MRI examination. Pregnant subjects are also not allowed to be scanned. Should researchers be uncertain about any cases during recruitment, they must consult the scientific officer or radiographer directly.

Everyone entering the control room and the scanner room is required to undergo safety screening by MR personnel, including completing and signing a safety screening form (Annexes 2 and 3), and must undergo a verbal screening. If any possible contraindications are revealed or if there is uncertainty regarding a person's screening status, access will be denied. A radiologist or MR medical director should be consulted, and their decision will be final. It may be necessary for health record documentation and MR device labelling to be obtained for the radiologist/MR medical director to make a final decision.

Individuals (not limited to subjects) entering the scanner room are required to remove all electronic devices and key cards with magnetic strips, metallic projectile hazards such as

piercings, dentures, and removable bridges, and eye make-up. To avoid allergic reactions, individuals are not allowed to apply any scented body products (perfume, cologne, aftershave, aromatherapy, hair spray, etc). Before entering the scanner room, all individuals must check with the ferromagnetic screening system to ensure safety procedures are adhered to.

Any equipment or object entering the scanner room must be preapproved by the scientific officer or radiographer, and labelled and signed by the approver. Any equipment for use in the research in the scanner room must be referenced in the research proposal for the study.

6.2 Contraindications

- Subjects with any metallic implants/fragments or certain medical conditions will NOT be scanned.
- Subjects who screen positive for implanted electronic devices will NOT be scanned under any circumstances. Examples of such exclusionary devices include but are not limited to pacemakers, neurostimulators, insulin pumps, and intraocular pressure monitoring contact lenses.
- Subjects with the residual parts of such devices will NOT be scanned under any circumstances.
- Subjects who have undergone surgery or tattooing (including make-up tattoos) within the previous six weeks will NOT be scanned under any circumstances. Any subject with a glow-in-the-dark tattoo will NOT be scanned under any circumstances. Subjects with large or dark tattoos should be approved by the radiographer.
- Pregnant subjects will NOT be scanned under any circumstances. Pregnant women (visitors, guests, adult monitors, etc.) are NOT allowed to enter the scanner room (Zone 4).
- Where the radiographer or project radiologist has any doubts about the veracity of the information provided about implants, the ability of the prospective subject or their representative to provide said information, or the compatibility and safety of implants in a prospective subject, the subject will NOT be scanned under any circumstances.
- Subjects with certain classes of implants, such as cardiac stents, carotid stents, heart valve replacements, knee replacements, internal bone or joint pins or screws may be scanned six weeks after device implantation. The device name, manufacturer, and model number may be required to document its MRI compatibility and safety. The project radiologist is needed to supervise the whole MRI examination procedure. Each subject's particular circumstances will be judged on a case-by-case basis. The final decision to scan a subject with implants rests solely with the project radiologist or MR

medical director. If either of these personnel declines to scan the subject, the subject will NOT be scanned under any circumstances.

Researchers are advised to obtain as much information about the implant (such as date of implant, device name, manufacturer, and model number) before enrolling the subject in a study and to consult with the staff radiographer or radiologist to determine whether the subject could be eligible for scanning at the MRI lab.

6.3 Informed Consent

All subjects that undergo an MRI for an experiment or testing must have signed an informed consent and/or assent; minors must be accompanied by their parent or legal guardian. Minors must have their parent or legal guardian fill out the safety screening form (Annexes 2 and 3) and a consent form. Individuals with diminished cognitive or communication capacity may only be scanned if they are accompanied by a caregiver duly authorized to act on their behalf.

7. Invasive Procedures

The UBSN does not recommend performing any invasive procedures at the PolyU MRI lab.

7.1 Injectable Contrast Agents

The scanning of subjects that require injecting contrast agents is not permitted at the PolyU MRI lab.

7.2 Anaesthesia and Sedation

The scanning of subjects that require anaesthesia or sedation is not permitted at the PolyU MRI lab.

8. Safety Requirements and Important Matters for MRI Examination

8.1 Exam Attire

Since the prevalence of fabrics containing non-detectable metallic microfibers has increased, the risks of burns occurring should the subject wear such items of clothing into the scanner will be explained to the subject by the MRI operator.² Subjects should change into UBSN-provided patient gowns for the duration of their scan. As a matter of routine study procedure, operators should inform subjects that the most suitable items of clothing to wear for their scan are those made of cotton or cotton/polyester blends. Subjects will not be scanned should their garments be or become damp or wet. Should this happen during

² MRI operator: The person who operates the MRI system.

the course of scanning, all scanning must cease immediately and the subject must be removed from the scanner.

8.2 Claustrophobia

Subjects undergoing MR imaging will be screened for known claustrophobia about undergoing imaging. Subjects wishing to undergo MR imaging will first be offered an opportunity to practice in the MR environment.

Claustrophobia may also occur without prior awareness. To minimize this occurrence, all aspects of the exam that could ultimately become a cause for subject concern must be explained, for example, the length of the exam, the loud gradient-induced noises, etc.

Additional steps that will mitigate the risk are:

- Maintenance of verbal contact
- Use of MR-compatible headphones to provide calming music
- Positioning the patient prone or feet first if possible
- Provision of special mirrors to enable the patient to see out of the bore
- Illuminating the gantry quite brightly
- Insurance of adequate air movement through the bore

All subjects must be informed that they may terminate the exam at any time they wish.

8.3 Communication during Scanning

• Intercom System

The MR personnel will verbally check on subjects in between sequences, using the intercom to access their comfort and anxiety levels. If a subject is uncomfortable, the scan will be stopped and the subject will be moved out of the scanner to discuss whether or not to terminate the scan.

• Squeeze Ball

The squeeze ball allows subjects to set off an alarm to gain the attention of the MRI personnel. It

will be given to all subjects and they will be instructed to use the alarm in case of any concerns or discomfort during the MRI examination.

8.4 Scanner Noise

Echo Planar Imaging (EPI) and other fast gradient sequences commonly used in the MRI examination produce high levels of noise. Anyone to be scanned must be provided with hearing protection that lowers noise to at least 99dB. Accompanying personnel in the scanner room must be provided with hearing protection that lowers noise levels to at least 85dB.

9. Scanning Extra-care Subjects

Extra-care subjects include but are not limited to children, people with diminished cognitive capacity, people with diminished communication abilities, and people requiring mental or physical assistance. A radiographer is required for scanning extra-care subjects. An adult monitor can accompany those subjects in the scanner room if needed. The monitor may be MR personnel who has completed safety training, is familiar with the use of the squeeze ball, the use of the motorized scanner bed, and the manual release on the scanner bed. Should the subject be more comfortable with non-MR personnel (such as parents, primary caregiver) as the monitor, the monitor must complete a safety screening questionnaire with no contraindications for the MR imaging. They are required to wear appropriate exam attire and be familiarized with the use of the emergency squeeze ball. The adult monitor must wear appropriate hearing protection at all times. During vetting of MRI project application, the reviewers will decide if the subjects are regarded as extra-care subjects. More details of MRI project application can be found in the MRI project policy of the human MRI lab.

9.1 Children

Children can be accompanied by an adult monitor while they are inside the scanner. This adult monitor must remain with the child at all times while the child is inside the scanner room. All children should be asked whether or not they want to be accompanied by an adult monitor while they are inside the scanner as part of a routine study procedure. Any child, irrespective of age, who displays signs of anxiety or who requests to be accompanied while they are inside the scanner must be accompanied by an adult monitor. If there is any doubt about the ability of a child to follow safety instructions, they must be accompanied by an adult monitor.

In situations where there is more than one child (e.g., a sibling of the child being scanned) in the MRI lab, the child must be accompanied by an adult at all times to monitor their activities and ensure their safety.

MR personnel must inform parents and/or primary caregivers that only clothing made of cotton or primarily cotton/polyester blends is permissible. This may require the inspection of clothing labels, which may only be done by the radiographer in the presence of the parent or primary caregiver.

9.2 Diminished Cognitive Capacity

Any subject who exhibits diminished cognitive capacity and may not be able to follow safety instructions must be accompanied by an adult monitor at all times while the subject is in the scanner room.

9.3 Diminished Communication Abilities

Any subject who exhibits diminished ability to communicate, for example through deafness, or an inability to speak must be accompanied by an adult monitor who has the ability to communicate with the subject.

9.4 People Requiring Mental or Physical Assistance

Any subject requiring mental assistance can be accompanied by an adult monitor at all times while the subject is inside the scanner room. All subjects should be asked whether or not they want to be accompanied by an adult monitor while they are inside the scanner as part of a routine study procedure. If the subject displays signs of anxiety or other unstable emotions, the MRI examination should be stopped immediately.

Where scanning subjects rely on mobility assistive devices (e.g., wheelchairs, walking frames, walking canes), only assistive devices constructed of MR-safe material are permitted in the scanner room. For assistance, the UBSN offers an MR-safe foldable wheelchair. Before arranging to scan such research participants, researchers should contact the UBSN in advance to ensure that appropriate MR-safe mobility assistive devices are available for the safe movement of the research participant in the scanner room. Such subjects should be asked whether or not they want to be accompanied by an adult monitor while they are inside the scanner as part of a routine study procedure.

10. Potential Risks and Their Mitigation

10.1 Static Magnetic Field

Translational Forces

The most immediate danger of the main magnetic field is projectiles. Both small and large ferromagnetic items introduced into the scanner room pose a serious threat to the health and life of those in the room, as well as the potential to destroy millions of dollars' worth of equipment. All items that are brought into the scanner room for research studies must be checked with the ferromagnetic metal detector (Zone 3).

The intensity of the static magnetic field around an MRI system varies with respect to the distance from the scanner. This fringe field of the MRI system creates a spatial gradient magnetic field that increases in strength as you move closer to the scanner. The opening of the bore of the magnet is where (accessible) this force is the greatest.

The static magnetic field can affect ferromagnetic and conductive metal within a person's body as well. Vigilant metal screening procedures are vital to a safe MRI environment. A ferromagnetic metal detector is provided as a secondary screening source but is not a substitute for a written and verbal metal screening questionnaire. In the research environment, the risk of scanning volunteers with implants strongly outweighs the benefits, and so no volunteer with an implant will be allowed to participate.

The safe fringe field for a person with a pacemaker is at the 5 Gauss line, or just inside the control room door. For this reason, no person with electronic devices either on or in their body may enter the control room (Zone 3).

Rotational Forces

Rotational force, or torque, in a static magnetic field is the force exerted on an elongated ferromagnetic object, so that it aligns in the same direction as the static magnetic field. This force is the greatest at the isocentre.

Lenz Forces

Lenz's Law states that the current induced in a circuit due to a change or a motion in a magnetic field is so directed as to oppose the change in flux and to exert a mechanical force opposing the motion. A non-ferromagnetic conductive metal, like aluminium, will experience a pushing force that is the opposite of the scanner's magnetic field.

If you need to introduce a piece of non-ferromagnetic metal equipment into the scanner room, such as an MR conditional fire extinguisher, or research equipment, move slowly into the scanner room. If you move quickly with a large item, you may "run into" the opposing force.

Biological Effects

Biological effects of the static magnetic field are caused by the static field interacting with fluid in the body. Dizziness and vertigo may be caused by the disruption of the flow potentials in the semicircular canals, which are the gyroscope of the body. This is resolved by moving slowly away from the magnet.

Magnetophosphenes in the eye can cause flashes of light as they move through the magnetic field.

The magneto hydrodynamic effect is a slight change in the cardiac output, caused by blood in the aorta flowing perpendicular to the magnetic field, which alters the conductivity in the heart. For this reason, ECG patterns will be altered in the magnet. This effect is not significant at the 3T field strength level.

10.2 Time-varying Magnetic Field: The Gradient

Gradients in the magnetic field are created by coils of wire inside the magnet. The strength of the gradients is measured in terms of the change in the field strength per unit of distance. The rapid switching of these field gradients can cause peripheral nerve stimulation (PNS) as they induce a voltage in nerve tissue. This stimulation is the greatest at the furthest distance from the isocentre within the bore and Echo Planar Imaging (EPI) sequences create the highest amount of PNS.

PNS is not dangerous, however, the FDA limits it when it is sufficient to produce severe discomfort or pain. All subjects are warned of PNS and told to notify researchers by using the alarm bell if it becomes uncomfortable or painful.

As the gradients are turned on and off during a scan by switching the direction of large currents that flow through the wires inside the scanner, a force is exerted on the wires. The current oscillates at audible frequencies and the greater the current, the greater the sound—in the range of 126 - 131 dB on a 3T system (Foster et al., 2000; Hattori et al., 2007) during

EPI sequences. The FDA has recommended that safe audible levels are no more than 99 dB(A) (US Food and Drug Administration, 2014). Therefore, anyone in the magnet room while it is in operation is required to correctly wear earplugs.

10.3 Radiofrequency Fields (RF)

Tissue Heating

In contrast to the main static magnetic field, radiofrequency (RF) pulses are only present during scanning. The RF field is greatest at the isocentre and is negligible outside of the bore. RF energy is exchanged with the subject in order to create MR images. As these fields pass through the conductive tissues of the body they generate electrical currents that circulate within body tissues. The body tissues are resistive, however, so that the circulating current loses energy to the body in the form of heat.

A powerful amplifier (43.2 kW peak power) (Siemens Healthcare, 2015b, p. 9 Technical Data) generates this energy and scanner software limits the absorption rate in those being scanned. Entering the correct weight and height of a subject during registration will enable this software to correctly estimate the absorption rate for each sequence.

The effects of RF absorption are the heating of the tissue and the subject's ability to cool through evaporation, convection, conduction and radiation. If the input is greater than the output, tissue heating will result. This can be expressed in terms of the specific absorption rate (SAR), which is the FDA limit for RF exposure and is primarily set to avoid warming of the subject.

According to the FDA (US Food and Drug Administration, 2014), the recommended SAR level for MR imaging is 4W/kg (whole-body), 3.2W/Kg (head). If scanning in normal mode, the whole-body SAR is maintained at 2W/kg and at first level, 4 W/kg (IEC 60601-2-33:2010, 2010). Each subject's weight must be entered accurately in the scanner control computer as it is an integral component of correct SAR calculation. *This is a critical safety step*. Any subject whose weight cannot be accurately established cannot be scanned.

Certain individuals are at much higher risk of problems from SAR. This includes, but is not limited to, subjects with diabetes, obesity, cardiovascular disease, reduced ability to perspire, hypertension, and old age. These subjects may become warm more quickly than healthy subjects and may have reduced ability to disperse heat. These subjects will be carefully monitored for heating and comfort and may only be scanned under the supervision of a radiographer or radiologist.

Metal in the Bore

There is potential for thermal injury from excessive RF power deposited as a result of conductive metal in the bore heating. MR conditional equipment used in MRI research must be carefully placed.

In order to avoid creating large loops with the conductive material, we will:

- Maintain sufficient distance between any wires or cables and the subject's skin by using padding.
- Make sure that cables are run in straight lines to avoid crossing or looping.
- Make sure that cables are run parallel to the magnetic field.
- Make sure that cables from different components, such as ECG, RF and EEG, are kept separated.

Proximity Burns

Proximity burns are burns where focused RF energy is deposited on areas of skin that are touching the bore of the magnet. To eliminate the possibility of proximity burns, pads will be used to ensure that the subject's tissues do not directly come into contact with the inner bore of the magnet during the MR imaging process.

Pads are provided for this purpose. It is also important that the patient's own tissues do not form large conductive loops.

RF burns can occur where very small areas of skin-to-skin contact take place, usually medial calves lightly touching, lateral thigh where fingers lightly touch and also heels lightly touching. These areas create large loops in the body and energy focuses through the loop; when skin is lightly touching, the elevated energy is deposited in a very small area, as opposed to being dispersed into a large area.

These concerns are greatest on high field scanners and have been known to cause substantial burns. Accordingly, looped conductors within the bore must be avoided at all costs.

Care should be taken to ensure that the patient's arms and legs are not positioned in such a way as to form a large calibre loop within the bore. For this reason, it is preferable to instruct subjects not to touch their thighs, calves or heels in the MRI scanner. To help mitigate the possibility of these burns, we will use scrubs to reduce skin-to-skin contact and use cushions to prevent skin-to-bore contact.

10.4 Tattoos

While not all tattoos are contraindicated, questions regarding the type of tattoo ink used during the screening process are warranted. Many different kinds of metal oxides exist that are used in tattoo ink. Creating a heat sink in the form of an ice pack on tattoos mitigates tissue heating. However, we will not scan subjects with glow-in-the-dark tattoos, as this is the most reactive ink.

10.5 Thermal Control

The condition of the air within the MRI scanner room will affect the rate of cooling of the subject. Subject scanning will be performed when the room temperature is below 22°C and the relative humidity is between 40% and 60% to ensure excessive heating does not occur (Siemens Healthcare, 2015b, p. 24 Technical Data). Thermostats for the control room and

the scanner room in addition to a hygrometer are located on the wall to the right as you enter the control room.

Blankets will be provided to subjects who are cold. However, the MRI operator will explain that they should squeeze the alarm bell if they become too warm. The MRI operator will stay in verbal contact with subjects in between series over the intercom to ensure that they are not becoming too warm.

11. Devices

Any behavioural, physiological or other equipment to be brought into the scanner room must be screened for MR compatibility. The device must bear a tag indicating its compatibility. If deemed MR compatible, any subsequent modifications to the device will necessitate its rescreening. All such devices must be brought into and be positioned in the scanner room BEFORE the subject is allowed to enter the scanner room. To arrange a screening of a device for MR compatibility, please email ubsn.enquiry@polyu.edu.hk.

12. Incidence Reporting

It is the responsibility of all MRI personnel to report all adverse events, MR safety incidents, or "near incidents" to UBSN staff in a timely manner, even if there is no injury to people or damage to equipment. UBSN staff will judge if it needs to be reported to HSEO and fill in the Accident/Incident Report Form.

13. Emergency

The static magnetic field in the 3T MRI facility is always present. All those entering the facility must be made aware of the presence of the field, as it cannot be felt, seen or smelled.

The major risk in the facility is related to individuals entering the MRI facility who are unfamiliar with the MRI environment and its hazards. MR personnel working in the centre will be constantly vigilant of who is entering the control room and the scanner room. Especially in emergency situations, MR personnel will ensure that no one without proper training or screening enters the scanner room and that those individuals who do enter have removed all ferrous material.

For MRI studies involving human subjects, there will be at least two MR personnel present whenever a subject is in the scanner room. This policy is in place to facilitate expeditious responses to emergencies.

13.1 Emergency and Safety Training

ALL users (both secondary and primary) must take the up-to-date safety training and renew their user qualification annually. These individuals must also be fully aware of the current procedures for both medical emergencies and facility emergencies.

13.2 AED and First Aid Kits

The MRI lab is equipped with an AED and a first aid kits, which are located in the control room. **Please note that the AED and the first aid kits are not MR-safe.** No components may be brought into the scanner room.

13.3 Fire Extinguisher

As part of the Zone 3 and Zone 4 restrictions, the MRI lab has a readily accessible, clearly marked, MR-conditional fire extinguisher available. Additionally, there is a smoke detector system and a sprinkler system that will be automatically activated in case of smoke or fire, respectively. The fire evacuation plan is posted in the control room and in the Safety Training presentation.

13.4 Emergency Procedures

*** In case of a life-threatening emergency, please call 999 directly***

Physical Location:

Room ZB216, LG2, Block Z,	九龍紅磡
The Hong Kong Polytechnic University Phase 8	漆咸道南181號
181, Chatham Road South	香港理工大學第八期
Hung Hom, Kowloon	Z座,地下二層,216室

Hung Hom, Kowloon

13.5 Fire Emergency

If there is a fire or equipment failure such as sparking wires or signs of smoke:

Step 1: Stop all scanning.

Step 2: Press the Emergency Shut-down switch immediately.

Step 3: Remove the subject from the scanner and lead the subject out to a safe area.

Step 4: Activate the fire alarm by breaking the fire break glass to initiate a building evacuation.

Step 5: Extinguish the fire (only if safe). If the fire cannot be contained and is uncontrollable, quench the magnet (follow 13.7 Emergency Quench Procedure).

Step 6: CLOSE THE DOOR OF THE SCANNER ROOM.

Step 7. Leave the building by the nearest fire escape route. Use stairs and do not take the lift.

Step 8. After you have left the building and reached a safe place, call the Campus Control Centre (CCC Emergency Tel. No.: 2766 7999 or Ext. 7999 on the PABX system) for immediate assistance.

Step 9: Wait for security to arrive.

Step 10: If the fire department is called, wait for them to arrive so that they can take appropriate actions immediately. You must remind the firefighters of the presence of the magnetic field and warn them not to enter the MRI scanner room with non-MR compatible equipment.

13.6 Medical Emergency

In case of a medical emergency:

Step 1: Stop all scanning.

Step 2: Remove the subject from the scanner room to the waiting area for treatment.

Step 3: CLOSE THE SCANNER ROOM DOOR.

Step 4: Call 999 for the ambulance service if it is a life-threatening emergency.

Step 5: Notify the 24-hour manned Campus Control Centre (CCC) at P111 (Emergency Tel. No.: 2766 7999 or Ext. 7999 on the PABX system) and UBSN staff for immediate assistance.

Step 6: The operator (radiographer or primary user) should provide immediate care to the subject. For minor injuries, please make use of the first aid kits, which are located in the cabinet beside the changing room.

Step 7: Wait for security or paramedic (if 999 is called) to evaluate the incident and provide a professional first aid service. Do not let the injured person leave even if he/she feels better and never consider that assistance is no longer required.

Step 8: The scientific officer will make an internal record of the incident and report it to the MR medical director.

13.7 Emergency Quench Procedure

There are **ONLY 2** situations requiring a quench:

1. If there is a fire in the magnet room that cannot be put out using a non-magnetic fire extinguisher and requires the assistance of the fire department.

2. If an individual is pinned to the magnet, trapped or in a life-threatening situation by a non-removable ferrous object.

Step1: Please inform UBSN staff when you think the quench is needed, and follow the instructions from UBSN staff.

Step 2: Evacuate the scanner room but leave the door open.

Step 3: Press one of the **Magnet Stop switches** to start the quench. This action is irreversible and has several consequences.

Step 4: The WARNING LED will light up and an alarm signal will sound.

Step 5: Do not touch the helium ducts in the scanner room.

Step 6: Notify Siemens for ad hoc service.

Step 7: Police, fire, and other emergency personnel should be restricted from entering the scanner room with their axes, oxygen tanks, etc., until it can be confirmed that the magnetic field has dissipated.

NOTE: In the absence of a major emergency, users should never quench the magnet.

13.8 Spontaneous Quench Procedure

The sudden appearance of white clouds or fog around or above the MRI scanner indicates that cryogenic gases have vented partially or completely in the scanner room.

Step 1: In the event of a spontaneous system quench, it is imperative that all personnel and subjects be evacuated from the scanner room, as quickly and safely as possible.

Step 2: If anyone is inside the scanner room while a quench occurs, OPEN the scanner room door immediately for ventilation as there is potential for the person to suffocate. If you cannot open the door, break the window to vent the room.

Step 3: Inform UBSN staff at the first opportunity when you are safe.

Step 3: Do not touch the helium ducts in the scanner room.

Step 4: Staff should turn off power to the scanner using the **Emergency Shut-down** switch.

Step 5: There may also still be a considerable residual static magnetic field despite a quench or partial quench of the magnet.

Step 6: Site access should be immediately restricted until the arrival of Siemens equipment service personnel.

13.9 Coolant Accidents (Frostbite)

Direct contact with sub-zero liquids, gases, and surfaces (e.g. pipes) may lead to frostbite. The eyes and mucous membranes are especially vulnerable.

Step 1: Call 999 if it is life-threatening.

Step 2: Notify CCC and UBSN staff.

Step 3: Remove clothing carefully from the locations involved.

Step 4: Rinse frostbitten skin with lukewarm water.

Step 5: Cover frostbitten skin with sterile bandages.

Step 6: Do not apply powder or creams.

Step 7: Wait for first aider or go to UHS/hospital/clinic.

13.10 Power Outage Procedures

If the power goes out while a subject is inside the scanner, use the manual table release to remove him/her from the scanner.

If there is a scheduled power suspension, please refer to the to-do list in Annex 4.

13.11 Scanner Room Door Failure

In the event of a power failure or a failure of the pneumatic system in the scanner room door, it may be necessary to press the emergency door open button. Buttons are located in the scanner room and in the control room.

Annex 1

Legitimacy of MRI System Operator Not Being a Licenced Radiographer

Some parties question the necessity and safety of allowing unlicensed people to operate the MRI system with minimum supervision from UBSN. Below is the response.

The UBSN only recruited a part-time licenced radiographer for MRI. The primary responsibilities of the radiographer are (1) to train users and (2) to perform MRI experiments. The UBSN will train our own system operator (primary user) so that the MRI system can be used when the part-time radiographer is unavailable.

To guarantee safety, the UBSN set a very high standard for being a primary user, including (1) holding a CPR+AED certificate, (2) more than 20 hours of operation experience, and (3) successfully performing MRI experiments at least four times without any help. Unlike a clinical MRI centre, the research group will only focus on one or certain organs (mostly the brain), and invasive procedures (injection of CA and anaesthesia) are prohibited. Less physiological knowledge and experimental experience are required compared to a licenced radiographer in a clinical MRI centre. We believe our training is sufficient for them to complete their experiments safely.

Although the radiographer will not be on site when a primary user is performing experiments, the scientific officer is always available and capable of handling emergencies. Also, primary users are able to provide basic life support to subjects.

In Hong Kong, there is no regulation which requires the MRI operator to be licensed. According to the Radiation Ordinance (Cap. 303, Laws of Hong Kong), radiographers serve to "control the import, export, possession and use of radioactive substances and irradiating apparatus...". However, since MRI is non-radioactive, it is not covered under the Radiation Ordinance, and hence radiographers are not needed (https://www.rbhk.org.hk/eng/function.html). There should be no other governing bodies in HK that regulate the use of MRI.

In the US, MRI technologists (perform the same duties as radiographers in HK) are only required to be licensed in New Hampshire, New Mexico, North Dakota, Oregon, Tennessee, and West Virginia. Most states do not have any licensing or certification requirements for MRI technologists (https://www.medicaltechnologyschools.com/mri-technologist/how-to-become-mri-tech). For example, at Purdue University (Indiana), users are able to operate the MRI scanner after successfully completing the MRI safety training and passing the practical evaluation test administered by the operations manager or one of the directors in the MRI centre (https://www.purdue.edu/hhs/mri/Training/ApprovalProcedures.html).

In conclusion, we believe that allowing a primary user to perform experiments is necessary and safe for the UBSN human MRI centre.

Annex 2	
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MRI SAFETY SCREENING FORM*

Section A: Project Information Exam Date:						
Oper	rator's Name:	Secondary User's Name:		Tel. N	No.:	
Pl's l	Name:	Project No.:		Subject N	No.:	
Secti	on B: Subject Information					
Nam	e:	H	HKID / Passp	ort No.:		(First 4 digits)
Sex:	M / F Date of Birth:	(DD/MM/YY)	Height:		Weight:	
Secti	on C: Safety Questionnaire					
Your answ		Please carefully read the follo	owing questi	ons and m	ark the c	orresponding
LIST a	all prior surgical operations and	a their respective time:				
List a	any history of Chronic Illness: _					
List a	any history of MRI and other re	elated imaging exam:				
Indic	ate if you have a history of:	🗌 Brain Surgery 🗌 Str	oke 🗌	Cancer		Asthma
Indic	ate if you: 🔲 Need Walking	Aids Have Difficulty in	Lying Flat or	n your Bac	k	
Pleas	se indicate if you have or have	had any of the following:				
the a p im	ARNING: Certain implants, deve MR procedure. You will be repatient gown. Do not enter M plant, device, or object. Consu om. Please note that the MR S	equired to remove clothing th RI restricted area if you have ult the MRI operator or UBSN	at is not 100 e any questi I staff BEFO	0% cotton ons or co	, and to oncerns re	change into egarding an
				Yes	No	Not Sure
1	Eye Injury by Metal					
2	Body Injury by Metallic Object	ct (e.g. Bullet, Shrapnel, etc.)				
3	Brain Aneurysm Clip					
4	Cardiac Pacemaker / Defibril	lator				
5	Neurostimulator	o a Dill com Infusion Dumn))			
7	Electronic Device / Implant (Shunt	e.g. Pill Calli, illusion Pullip, e	-((.)			
8	Stent / Filter / Coil					
9	Cochlear (Middle Ear) Implar	nt				
10	Hearing Aid					
11	Eye Implant / Eyelid Spring /	Wire				

*Personal Information Collection Statement: The personal information collected is for your examination registration. It will be kept confidential, and only authorised staff members of PolyU will have access to and handle your personal data. No information will be disclosed or transferred to others without your written permission, except (1) if necessary to protect your rights or welfare, and (2) if required by law.





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		Yes	No	Not Sure
12	Metal Rod / Pin / Screw / Joint Replacement			
13	Prosthesis (e.g. Artificial Heart Valve, Eye, Limb, Penile, etc.)			
14	Breast Tissue Expander			
15	Glucose Monitoring Sensor / Medication Patch			
16	IUD / Contraceptive Diaphragm / Vaginal Pessary			
17	Tattoo / Permanent Makeup			
18	Denture / Dental Retainer / Dental Brace / Dental Implant			
19	Accessory / Body Piercing / Wig			
20	Cosmetic Colored Contact Lenses			
21	Known / Possible Pregnancy			
21	(First day of the Last Menstrual Period: DD/MM/YY)			
22	Claustrophobia			

If **YES**, please give information (e.g. type of material, how long ago):

Section D: Important Instructions

Before entering the MRI scanning room, you must **remove all metallic objects** including, but not limited to, hearing aids, dentures, keys, beepers, cell phones, eyeglasses, hair pins, jewellery, watches, safety pins, paperclips, money clips, credit cards, bank cards, magnetic strip cards, coins, pens, pocketknives, nail clippers, tools, and clothing with metallic threads.

Please consult the MRI operator or UBSN staff if you have any questions or concerns BEFORE you enter the scanning room.

Section E: Declaration

I voluntarily provide the above information and attest that it is correct to the best of my knowledge.

I have **read and understand** the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Subject/ Parent/ Guardian's Signature:	Subject/ Parent/ Guardian's Name:
	Relationship: Subject / Father/ Mother / Guardian
Screener's Signature (Secondary User):	Primary User's Signature:
Radiologist's Signature (if applicable):	Date:

(DD/MM/YY)

|--|





磁力共振成像安全篩查表格*

甲部	:項目資料			實驗日期	:			
主要	操作員姓名:	次要操作員姓名:		聯繫電話	· ·			
導師	姓名:	項目編號:	受討	式者編號:				
乙部	:受試者資料							
姓名	:	香港身份	}證 / 護照號	蒊:		(首四個字)		
性別	:男/女 出生日期:	(日/月/年)	身高:	,	體重:_			
丙部	:安全問卷							
	物品在磁力共振環境下是 禁 的安全對我們非常重要。請							
請列	明所有手術史及其日期:							
請列	明長期病患史:							
請列	明磁力共振及其他相關掃描	史:						
閣下	閣下曾否有以下情況: □ 腦部手術 □ 中風 □ 癌症 □ 哮喘							
閣下是否有以下情況: □ 需要助行工具 □ 躺臥困難								
請指	出閣下是否有以下任意一項	:						
純相控制	告:特定體內植入物,設備 帛的衣服,並換上病人服。 制區。請在進入磁力共振掃 統中 強磁場始終存在 。	如果對植入物,設備或物品	有任何疑問]或疑慮,	請勿進入	磁力共振		
				是	否	不確定		
1	眼睛曾被金屬物料傷害							
2	身體曾被金屬物體(例如: 腦動脈瘤夾	: 子彈,彈片等) 傷害						
4	過動脈瘤炎 心臟起搏器/除顫器							
5	神經刺激器							
6	電子設備/植入物(例如:	膠囊內窺鏡,輸液泵等)						
7	分流器							
8	支架 / 過濾器 / 線圈							
9	人工耳蝸 (中耳)							
10	助聽器	1日 44						
11	眼部植入物/眼瞼彈簧/金	廣線						

*個人資料收集聲明:所收集的個人資料用作閣下的檢查登記。香港理工大學神經科學中心實驗室(以下簡稱為「理大」)會對有關資料保密,只有經授權的人士方可准許查閱及處理閣下之個人資料。除(1)為保障閣下的權利或福利所需及(2)法律規定外,未經閣下書面同意,理大不會向他人披露或轉移任何資料。附註:本中文譯本僅供參考。如有歧義, 須以英文版本為準。





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		是	否	不確定
12	金屬棒/針/螺釘/關節置換物			
13	人工假體(例如:人工心臟瓣膜,眼球,義肢,陰莖等)			
14	乳房組織擴張器			
15	血糖監測感測器 / 藥貼			
16	宮內節育器 / 子宮隔膜 / 子宮托			
17	紋身/永久妝			
18	假牙 / 牙齒固定器 / 牙套 / 種植牙			
19	飾物配件/體環/假髮			
20	有色隱形眼鏡			
21	懷孕/可能懷孕 (最近經期第一日:日/月/年)			
22	幽閉恐懼症			
<i>l.</i>				

如是,請提供資料(例如:物料、時間):

丁部:重要提示

進入磁力共振掃描室之前,閣下必須**脫下所有金屬物品**,包括但不限於:助聽器、假牙、鑰匙、傳 呼機、手機、眼鏡、髮夾、珠寶、手錶、安全別針、回形針、錢夾、信用卡、銀行卡、磁卡、硬幣、 鋼筆、小刀、指甲剪、工具、帶有金屬線的衣服。

如閣下有任何疑慮,請在進入磁力共振掃描室之前諮詢操作員或實驗中心工作人員。

戊部:聲明

□ 我自願提供上述資料並確認上述資訊全部屬實。

□ 我閱讀並理解了此表格的內容,並有機會就此表格中的資訊以及我將要接受的磁力共振掃描提 出問題。

受試者/受試者的父母/監護人簽名:

受試者/受試者的父母/監護人姓名:

關係:□受試者/□父/□母/□監護人

篩查人簽名(次要操作員):

主要操作員簽名:

放射科醫生簽名(如適用):

日期:

(日/月/年)

Annex 4

To-do List for Power Suspension (For UBSN staff only)

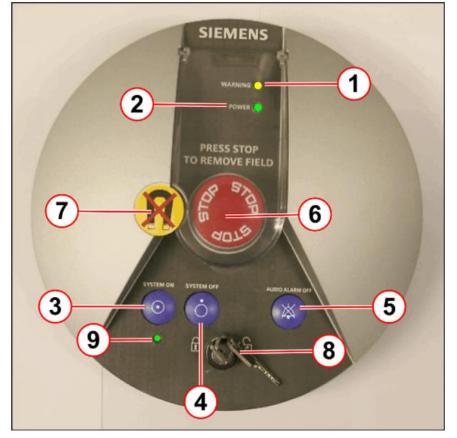
Before power suspension:

- 1. Inform Siemens.
- 2. Check liquid Helium level and make sure it is enough for the power suspension period.
- 3. Shut down MRI and all other devices.

After power resumed:

- 1. Check if the main power LED 2 (green) is on.
- 2. Warning LED 1 (yellow) will flash or alarm sound on. Press silence to mute.
- 3. Yellow 2 (LED) will be off if all faults are cleared.
- 4. Mute the alarm of the oxygen monitor (if any).
- 5. Check if cold head running with normal sound.
- 6. Check if the temperature of scanner room is normal ($\sim 22^{\circ}$ C).
- 7. Turn on MRI system and check if there is any error message shown.
- 8. If any abnormality is found, call Siemens hotline (28707500) to clarify with the engineer on duty. (Charge will apply for support out of contact/office hour)

Fig. 65 Alarm box - LEDs and buttons



- (1) LED WARNING = yellow
- (2) LED POWER = green
- (3) Button SYSTEM ON
- (4) Button SYSTEM OFF
- (5) Button AUDIO ALARM OFF
- (6) Button MAGNET STOP (ERDU)
- (7) Tamper-proof seal
- (8) Power switch locking key
- (9) SYSTEM ON LED = green