Work and Safety Procedures in the MRI Unit

Introduction
The Edmond and Lily Safra Centre for Brain Sciences was established at the end of 2009 as a multi-discipline study centre for brain science research. It was formed based on the ICNC following the recommendation of an international committee regarding its expansion, with the support of the Edmond J. Safra philanthropic fund and others. The brain imaging centre which includes a Magnetic Resonance Imaging (MRI) scanner is used for conducting advanced brain science research.

Personnel
Prof. Moshe Gomori – Medical Director
Prof. Leon Deouell – Academic Director
Mr. Eldad Joffe – ELSC Executive Director
Dr. Yuval Porat – Unit Manager
Lee Ashkenazi – Administrative Assistant, Unit Helsinki Coordinator
Dr. Gaby Pell – Advising Physicist
Asaf Yohalashet, – Radiology Technicians
Nizar Abed – IT Support

Imaging Unit Committee
The committee includes the Medical and Academic Directors, the ELSC Executive Director, and the Unit Manager.

The committee shall peruse applications for human experiments before they are submitted to the Helsinki Committee and shall approve/reject experiment applications. The committee shall verify that there are no technical or safety hindrances to the experiment, and that the experiment protocol is applicable in the available unit conditions. The committee shall also refer to ethical aspects if required, but does not replace the need for study approval by the appropriate ethics committees as per university procedures and the approval of the Helsinki committee.

The committee shall discuss routine matters dealing with running and promoting the imaging centre so that it will be able to provide optimal service to the researchers, and will remain up-to-date in regards to developments in the field of functional imaging.
Unit Work Principals

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

Experiment Run Approval

Running experiments is stipulated in the approval of the Imaging Unit Committee, the Helsinki committee, and fulfilling the Hebrew University Procedures (or, in cases of researchers from other establishments – fulfilling the procedures of the relevant research establishment).

1. Receiving the Approval of the Imaging Unit Committee

Principal Researchers interested in using the scanner shall apply for experiment run (the experiment protocol, as submitted to the Helsinki Committee) to the Unit Manager for preliminary perusal in the unit. The application shall then be examined by the Imaging Unit Committee. The application shall be examined for technical and safety aspects, to ensure the proposal is within the practical scope of the unit and its work principals, and in order to assist the researcher with the required documents and authorisations. The approval of the unit committee has to be received before the application is submitted to the Helsinki Committee, to prevent the need for retrospective correction of the Helsinki Protocol should changes be required as per the unit committee’s conclusions. This step is obligatory and the protocol must be written according to the unit’s Work and Safety Procedures. In addition, it has to be noted in each protocol submitted to the Helsinki Committee that the protocol was written in accordance with the Work and Safety Procedures file, and to add this file as an appendix with each submission of the protocol to the committee.

2. Receiving the Approval of the Helsinki Committee

a. Each run shall be based on the appropriate Helsinki Committee approval, in which there is a direct, explicit reference and the approval for use of the unit scanner. As per the Ministry of Health procedures, the Principal Researcher shall be a doctor/researcher in a hospital.

b. In experiments for which Prof. Moshe Gomori is the principal researcher, the experiment initiator in the Helsinki application shall be the head of the research group. Prof. Gomori is fully responsible for following the approved protocol and the Clinical Research Protocol of the Ministry of Health in full.

c. In experiments in which Prof. Moshe Gomori is the principal researcher, the unit shall assist with the logistics of the accessibility process opposite all relevant authorities in the Hasassah Ein-Kerem Hospital. The Helsinki coordinator shall be in contact with a representative from the research group, responsible for submitting their group’s application.
d. Once the approval of the Helsinki Committee is given, a copy of the entire approved application shall be submitted to the unit's Helsinki Coordinator, and the approval shall be given an internal-use serial number.

e. The Helsinki Coordinator may perform inspections as regarding to fulfilling of regulations, without impinging on the full responsibility of the initiator, as defined in section b.

f. Actual runs shall be performed only by the secondary researchers noted in the Helsinki Approval.

g. Each subject, including in cases of "Pilot" experiments and other tests, shall sign a consent form approved by the Helsinki Committee.

h. Each researcher must have the unit's experiment run procedures in the research file, signed by the Initiator and the secondary researchers.

**Experiment protocol approval** – an "experiment" is defined as a run of a group of subjects in a set and detailed procedure (including definition of the population, experiment procedure, scan sequences and order, etc.) in order to answer a scientific hypothesis. Before starting a new experiment, a detailed description shall be submitted to the unit manager, in which the precise procedure shall be defined, including the sequences to be used. The Unit Manager and the unit Academic Director shall approve the experiment and add it to the appropriate Helsinki approval. The approval refers to the technical, safety, and ethical aspects and shall not contain an evaluation of scientific importance or probability. Should the protocol be similar to a previous protocol already approved, this shall be noted and the differences be emphasized. This approval is in any case subject to the Helsinki Committee's approval.

**Insurance**

The imaging centre is insured for research performance. The policy only covers runs under experiments approved by the Helsinki Committee.

**Training and Authorising Users**

User – someone who has undergone safety training and received a user diploma subject to preliminary inquiry and approval by the Unit Manager to invalidating contraindications (such as metals in body). A user is permitted to assist in running the experiment but is not permitted to operate the MRI scanner. A user will undergo safety training as set by the Unit Manager. Safety training shall include general aspects of MRI safety as well as being familiarised with the unit's

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1 Running experiments includes all activities requiring presence in the operator or magnet rooms
unique safety protocols. The user must undergo a test at the end of their training, passing with a grade of 100. Safety training refresher course and user’s authorisation shall be performed once every two years. The responsibility for obtaining and refreshing the user's authorisation is the researcher's.

- Users must undergo basic CPR training and learn how to use the unit defibrillator.
- Users must undergo human experiments' ethics course as per the Hebrew University’s procedures.
- Users must be included in the secondary researchers’ list of the Helsinki Committee.
- If needed, use of peripheral equipment training shall be provided by the Unit Manager or by any experienced user.

Unit Entry Policy

The unit is divided into zones I-IV as per the recommendations of the American College of Radiology. Zone I is outside the building, Zone II is inside the building, Zone III is the operator and machine rooms, Zone IV is the magnet room, over 5 gauss.

Visitor/Volunteer – shall be escorted to all zones. Technical and administrative staff or invited visitors shall be allowed into these zones escorted by the Unit Manager or anyone on their behalf who had undergone safety training.

User – permitted to be in zones II or III. A user may also enter zone IV (magnet room) under supervision of a Radiology Technician/Unit Manager. Any activity inside the magnet room requires reservation via the reservation system/applying to the Unit Manager. Entering the operator room outside reserved time or working hours must be coordinated with the Unit Manager.

Radiology Technician/Unit Manager/Siemens Engineers – permitted to stay in all sections with access to the scanner’s operating system and operating the scanner, at all working hours, as per the unit procedures.

Experiment Run Procedure

1. **Researcher presence**

Running an experiment requires the presence of a Radiology Technician, being in charge of the test. The person in charge is responsible for all aspects of subject safety, proper operation of the MRI scanner, maintaining the unit procedures by all present, keeping the unit equipment intact and the state of the facility in order. Together with the technician there shall be a user (researcher-student) who has initiated the experiment.

Scanning a person requires the presence of at least two users (excluding the subject, see section 4 in this list).
2. Subjects

- Minimum age for scan is 18, a scan under 8 requires specific insurance.
- No pregnant women may be scanned.
- No subjects with permanent makeup, tattoos on face, neck, head or subjects with extensive tattoos (more than 10% of skin) may be scanned.
- Activate cooling ventilation system if needed.

3. Before the experiment

Waiting: a subject arriving at the unit must wait in the waiting room only; the operator room door must be locked.

Registration and preparation of subject for test: the technician and user shall escort the subject from the waiting room to the registration room in order to:

- Give information regarding the MRI scan.
- Fill demographic data form.
- Fill and question metals form and decide whether the subject is fit for the test (detailed criteria for subject unfitness for the scan are detailed in the unit safety procedures and will be given during the safety training).
- Sign the Helsinki approval consent form for the experiment and sending the scans for analysis by a Hadassah Ein Kerem radiologist. The user – a secondary researcher of the research group is responsible for bringing the consent forms with them, giving the subject information regarding the specific experiment, and verifying the Helsinki consent form is signed.
- All subject paperwork is to be filed in a temporary file on which the names of the head of the research group, the technician, and the user, the ID and name of the subject, and the test date shall be noted.
- The subject shall remove all objects with magnetic properties and shall give them to the person responsible for the test, including clothes containing clips/metal beads and underwire bras. All of the subject's pockets must be empty.
- The subject's belongings are to be kept in a locked drawer in the registration room.
- The subject shall enter the operator room clear of all metals, the person in charge of the scan shall enter the magnet room clear of all metals.
- All registration and preparation steps must be performed even if the subject has already been scanned in the past.
- The researcher has full and exclusive responsibility for keeping the relevant paperwork and filing them in the research file, as well as giving a copy of the consent form to the subject as per the Ministry of Health human experiment procedure. Copies of the metal questionnaire and consent form shall be filed in the unit archive by the person responsible for the scan.
It is the researcher's responsibility to question the subject before arriving for the scan regarding their fitness for undergoing an MRI scan, as well as briefing regarding appropriate clothes for the scan.

Registration and preparation of subject for test – tattoos:

- The participant will declare the existence of a tattoo, its size, location on body, and the place of making the tattoos in writing as part of the metal questionnaire.
- In addition to written information, the participant will report orally to the RT about any tattoos or permanent makeup. The location, size and color of the tattoo must be reported as well.
- The participant will be given all information about the potential risks associated with scanning tattoos. This information will be given both orally and as part of the informed consent form that was approved by the Helsinki committee.
- The participant will be instructed to immediately report any heat/pain or abnormal sensation in the area of the tattoo. The participant should explicitly be told that they should press the stress button (and thus stop the exam) at any time during the exam if they fell heat in the area of the tattoo.
- Subjects with tattoo will be monitored closely, while maintaining auditory and/or visual contact throughout the exam.

4. Bringing the subject to the experiment run and run process

- The subject shall go from the registration room to the operator room and scanner accompanied by the technician/user.
- The subject must be registered in the unit scan log.
- The subject shall enter the scanner only after it was verified once more that they have no metallic object on their person that may have magnetic properties.
- The person in charge of the scan must verify the bed is clean before a new subject is entered.
- The subject must remove their shoes before entering the scanner.
- The scanner shall be operated by a Radiology Technician only
- As long as the scan is in process and the subject is in the scanner, at least two people shall be present in the operator room: the Radiology Technician – "the person in charge" and a researching user. At least one of them must be registered as a secondary researcher in the Helsinki approval. Their role is to verify the scan runs properly, there is constant contact with the subject, there are no safety issues, the subject is not in distress.
- Each subject shall be briefed before the scan starts regarding mode of action in cases of lack of communication or distress. Bidirectional communication with the subject through the operator room's intercom and earphones shall be verified before the scan starts. The subject shall be provided with a distress button; its use shall be tested and practiced before the scan starts.
- During the scan no person, other than the subject, technician, or users who have something to do with the experiment, may enter the operator or magnet room.
The subject's well-being is to be determined between scans (via conversation or requesting the subject to press a certain response button in response to yes-no questions). If the subject shows signs of distress or is unwilling to continue the scan, they must immediately be taken out of the magnet.

- No FIRST LEVEL MODE scans may be run without the preapproval of a Physicist and the Unit Manager.

- In any medical emergency, basic first aid shall be given using the first aid kit in the unit and the subject is to be evacuated to the ER. After basic first aid and evacuation, a report form must be filled and given to the Unit Manager (see details in the Unit Safety Procedures) within one day. The Unit Manager shall pass the report on to the Medical Director.

5. Medical Analysis of Test Data

- The scan results are confidential and for research purposes only. No use shall be made of scan results without the explicit permission of the subjects. The scan results for each subject per year, shall be given to the Medical Director or anyone on their behalf, for initial review in order to discover any obvious pathologies. This review is not meant as a medical opinion and does not replace a certified clinical exam.

- Scan analysis – data shall be sent for analysis in the Hadassah Ein Kerem hospital. Analysis shall be sent by the Medical Director to the subject and their attending doctor, based on the details filled in the 'Demographic Details' form within a month from the scan.

- Inquiry regarding scan analysis shall be by the attending doctor to Prof. Gomori, no inquiries from the subject or the scanning researcher shall be accepted. In addition, the unit is not certified to deal with this matter.

- The imaging unit does not give a CD with the scan data to the subjects; the researcher is responsible for giving the CD to the subject.

- In cases in which any unusual findings are discovered by the Radiology Technician, requiring immediate medical attention, the Radiology Technician shall give the subject the scan data (CD) and will instruct them to go immediately to their attending doctor with said data, or if not possible, go to the ER. In addition, the Radiology Technician shall report to the Unit Medical Director, or the Neuroradiology unit on-call in the Hadassah hospital and the unit should send the scan data for analysis within 48 hours from the scan. If there is suspicion of a medical emergency, the Technician shall work as per emergency protocol. When the event has been initially dealt with, the Technician must report to the ENU Manager.

6. End of scan

- At the end of the scan transfer of data to the PACS server must be verified, and scan process must be entered into the scan log.
The person in charge must burn the CD for the Medical Director including anatomic scans (including reconstruction of all axes), and one functional experiment scan. The CD shall be kept in the designated place in the unit offices.

The subject is not required to stay after the MRI scan is completed but may stay if it is required, as long as the secondary researcher is present.

At the end of the experiment the person in charge must:
1. Put the magnet and operator rooms in order.
2. Put the peripheral equipment into place and turn off the equipment.
3. Turn off the scanner system (if this is the last scan of the day).
4. Lock the unit and starting the alarm system (if this is the last scan of the day).

**Working with Peripheral Equipment**

- The equipment was purchased by the unit and is there for the experimenter, equipment must be kept in order and the Unit Manager must be informed any problem.
- At the end of the experiment, the equipment must be turned off and put back in place.
- Peripheral equipment might be dangerous or make noise in scans. No peripheral equipment of any kind may be used without explicit approval of the Unit Manager, whether it is in the magnet room or in the operator room and is attached to the RF panel. No cable may be attached to the RF panel without approval.

**Bringing New experiment equipment**

In order to start using new equipment inside the magnet room, the researcher must follow these steps in the following order:

1. The researcher must bring documents from the manufacturer that show the safe distance for placing the equipment within a 3T field. Note: Equipment that is safe for 1.5T field is not necessarily safe for 3T field!
2. To prevent interactions with the magnetic field that can lead to serious burns or electrification, the researcher must make sure that the equipment is properly isolated, and does not have any exposed wires.
3. The researchers, together with the MR technician, will perform a phantom test run with the new equipment, to make sure it causes no artifacts or distortions.
4. The researchers will must present documents allowing the use of the equipment in experiments with human subjects.
5. Finally, installation of any new equipment has to be explicitly approved by the unit manager.

**Reporting and Documenting Scanner Malfunctions**

The person in charge and the user shall record any malfunction in the malfunction log found in the operator room and shall call the relevant authorities. Also, they must immediately report any unusual event or malfunction to the Unit Manager.
Reporting Structure Malfunctions, Events, and Accidents
The person in charge/users shall immediately report any unusual event or malfunction to the Unit Manager and fill a report form (as per unit safety procedures).

Reservation Policy
Unit use slots can be reserved through the unit reservation system:

- Primary researchers, with at least one user in their group, shall receive login and password for the research group for the unit reservation system.
- Any use, including tests, installations, etc. requires slot reservation.
- Use slot shall be defined in half-hour increments, minimum reservation time for Radiology Technician – two hours. Technician availability shall be displayed in the reservation system.
- Each time slot in the scanner shall be ascribed to a research group user, to the budget number from which use fees shall be collected, and to the Helsinki approval for a subject run.
- Slots can be reserved in the unit for a subject experiment 24 hours ahead, as per technician availability. Technician working hours are entered by the technician by the 23rd of each month for the following month, and may be updated throughout the month.
- Cancellation – can be done 72 hours in advance with no charge. Cancellation within 72 hours of the reserved slot shall be fully charged. In this case, the user can mark the time slot as it is for "adoption" by another user. If it shall not be adopted by another user, the slot shall be charged in full.
- Reserved slots must include all stages of experiment from receiving the subject, phantom run if needed, and the CD burned by the technician for analysis. At the end of the allotted time the room must be cleared for the next user.

Usage Charge
Charging is performed for the hours reserved by the researcher, even if they were not fully utilised.

If there is need for extra experiment time and the Radiology Technician has agreed to stay beyond the reserved time slot, charges shall be updated according to the time actually used.

No charge fees shall be collected in the following cases:

- Experiment-start delay due to technician tardiness or if the technician has not shown up.
- Malfunction of scanner.
- Bad weather conditions rendering work impossible, as per Unit Manager's decision.
- Cancellation at least 48 hours before time.
Charge Fees

Budget number must be entered into the reservation system. Payment request (form 29) shall be sent in advance on X amount.

charge fee for Hebrew University researchers per hour is $80.

For Hadassah Ein-Kerem researchers: $150/hr

For other academic establishments researchers: $200/hr.

* Use charges are subject to change according to unit policies.

* Use charges are set for weekdays, Sunday-Thursday. Weekend and holiday eve tariffs are yet to be set.

Safety Procedures – ELSC Neuroimaging Unit

1. General information

Location: the unit is located in the Hi-tech village, bitan 13/3, Safra campus. The unit has a 3T Siemens magnet used for magnetic resonance imaging of human subjects.

Essential phone numbers:

Security centre 7/24, 85000, 02-6585000

Campus head safety engineer – Ami Davidian 86912

Siemens service centre 7/24, 03-9151599

Dr. Yuval Porat, unit manager (room 2), 02-5494016, 054-8820582

Operator room (room 1) – 02-5494003

General Office (room 3) – 02-5494799

Beit Hakerem taxis – 02-5000101

2. Unit description
The unit includes the magnet room, operator room, waiting room + kitchenette, three offices, and a machine room. Outside the structure is the chiller unit. The unit has two emergency exits (figure 1).

**Security system** – the unit has a Moked-Mikud security system, including volume detector, cameras, and entrance control system. The operator room has a distress button dialing to the security centre. Exiting the emergency exit by the chiller activates the alarm and calls the security centre.

**Fire detection system** – the unit has smoke detectors, connected to the fire system in the lobby. There is no automated sprinkler system. There are two MRI-compatible aluminium fire extinguishers, found at the entrance to the magnet room and in the lobby. A non-MRI-compatible fire extinguisher is found by the machine room. In addition, there are manual buttons (red box) by the emergency exits for manual fire alarm activation. In case of fire alarm the security centre is alerted.

The unit is divided into Zones I-IV as per the College of Radiology (ACR) definitions for control of entrance authorisation to the different areas of the unit, as per their distance from the magnet (figure 2).

**Zone I** – areas freely accessed by the general public, outside the imaging unit building.

**Zone II** – intermediate areas between areas freely accessed by the general public and controlled areas zone III and zone IV. Visitors to this area must be under supervision of unit or research personnel. This area includes the waiting room, toilets, kitchenette, and subject registration offices.

**Zone III** – an area from which there is free access to a high risk area due to magnet presence (zone IV). This area contains but can be beyond the highest risk area, and may contain slippage of the 5
gauss field lines. In the unit this zone is defined as operator and machine rooms. Access to this zone must be physically controlled. Entrance to the control room is to be performed only after all metals have been removed from the subject.

**Zone IV** – highest risk zone, containing the magnet. Passage into this zone is always through zone III. The entrance to this zone must be marked by the 5 gauss line on the floor and clear warning signs. Main risk factors originate in this zone: constant strong static magnetic field, changing magnetic fields, and RF electromagnetic field during the scan.

![Figure 2: Unit zone division](image)

### 3. People in the unit
1. Visitor – subject, escort, service people.
2. User/operator – permitted to run experiments in the scanner, approved by the unit.
3. Siemens engineers – engineers Vadim Zachernich, Deror Elimelch, may enter any zone at any time.
4. Campus security personnel – in emergencies security guards who had undergone safety briefing may enter up to zone III. In life saving situations, they may enter zone IV.

The unit shall have an updated list of people who are authorised to enter and the date in which they had undergone safety course/briefing. Personnel must undergo safety refresher course/briefing every two years.

### Table 1: Entrance authorisations according to zone.
4. Unit hazard factors

The unit has various hazard factors. The unit-specific hazard factors are: the existence of a constant, strong magnetic field, hazard factors for subject and operator during the scan, high-voltage electricity, cryogenic and chemical hazards. In addition, there are general hazard factors – fire, earthquake, missile attack, harassment, sabotage. In the safety procedures there shall be reference to unit-specific hazards. The Hebrew University safety procedures apply for general hazards.

Table 2 details the unit-specific hazards and the appropriate prevention methods.

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Location</th>
<th>Person at risk</th>
<th>Description</th>
<th>Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static 3T magnetic field</td>
<td>Zone IV</td>
<td>Anyone/anything beyond the 5 gauss line carrying metallic objects</td>
<td>1. Pulling of magnetisable metallic objects 2. Induction of eddy current on non-magnetisable metallic objects.</td>
<td>- Warning signs on the entrance door, warning against bringing in metals  - Red 5 gauss line marking in the magnet room  - Code door before the operator room entrance  - Official operator, user, and permanent service providers (cleaners, maintenance, security) safety training  - Subject metals questionnaire and removing any metallic object from the subject, including emptying pockets in the waiting room-office  - Manufacturer instructions must be fulfilled when using any equipment inside the magnet room</td>
</tr>
<tr>
<td>Time Varying magnetic fields – gradients</td>
<td>Zone IV – magnet bed</td>
<td>Subject</td>
<td>Peripheral nerve stimulation</td>
<td>- Informing the subject before the scan and giving them a distress button. - Instructing the subject not to cross hands/feet - Monitoring the subject after each scan and during breaks in the experiment</td>
</tr>
<tr>
<td>Time Varying magnetic fields - gradients</td>
<td>Zone IV 0 magnet bed when scanner is working</td>
<td>Subject/operator</td>
<td>Acoustic noise</td>
<td>- For the subject – earplugs, 30dB with earphones. - For the operator in the magnet room – earplugs, 30dB</td>
</tr>
<tr>
<td>RF electromagnetic field</td>
<td>Zone IV – magnet bed when the scanner is working</td>
<td>subject</td>
<td>Tissue heating up to burn</td>
<td>- Informing the subject before the scan and giving them a distress button. - Excluding subjects with metals in their bodies or medically incompatible - Signing an extra consent form by tattooed people - In cases of sequence programming – it is forbidden to run sequences beyond FDA SAR on any subject. - Removing any conducting metallic object from the bore area, including unused coils, cables, or wires, before the scan - Fulfilling all Manufacturer instructions when working with any peripheral equipment.</td>
</tr>
<tr>
<td>Hazard</td>
<td>Biological contamination</td>
<td>Laser radiation – Class 2M</td>
<td>Siemens Phantoms and cooling liquid containers</td>
<td>High voltage power</td>
</tr>
<tr>
<td>---------------------</td>
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<td>-----------------------------</td>
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<td>-------------------</td>
</tr>
<tr>
<td>Location</td>
<td>Zone IV – magnet body, magnet cold head, zone III – machine room, compressor area</td>
<td>Zone IV – subject bed, coils, magnet body, and any other surface in contact with the subject</td>
<td>Zone IV – magnet bed</td>
<td>Zone III – zone IV</td>
</tr>
<tr>
<td>Person at risk</td>
<td>Anyone in any area of the unit, particularly in the magnet room</td>
<td>Subject/operator</td>
<td>Anyone around the phantom</td>
<td>Anyone in the vicinity of the Siemens power cabinet</td>
</tr>
<tr>
<td>Description</td>
<td>Direct contact frost bites contamination blindness Skin burn in case of direct contact with the phantom liquids or cooling liquids</td>
<td>Electrocuition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevention</td>
<td>Sensor systems inside the magnet and system alarm means</td>
<td>- Cleaning surfaces with antiseptic materials as per Manufacturer instructions before bringing in any subject - Excluding subjects with active contagious disease</td>
<td>- Instructing the subject to close eyes when the laser is on.</td>
<td>- Warning stickers on the cabinet and at the entrance of the machine room</td>
</tr>
</tbody>
</table>

5. **Safety protocols according to unit hazards**

5.1. **3T static magnetic field**

a. No magnetisable objects may be brought into the magnet room. Any object containing metal shall be considered a magnetisable object.

The operator must be clear of metals and ready to enter the magnet room at any given time. The operators have a drawer for personal equipment in the operator room. The subject cannot enter the magnetic field beyond the 5 gauss line without being scanned for metals or any medical contraindication that may be affected by the magnetic field.

A pregnant operator may run experiments in the magnet room.

**Criteria for entering the static magnetic field:**

The subject must undergo thorough questioning regarding the presence of metals in their body by the operator and sign the metals form.

**Questioning instructions:**

- Initial questioning shall be done by phone.
- Second questioning is performed in offices 3 or 4. The metals form is supplied by the unit and shall be updated as needed. After the questionnaire is filled by the subject, it is necessary to go over
each section and ask the subject about surgery history, car accidents involvement, or bombings.

- A third questioning shall be performed orally before entering the magnet room.
- A returning subject is to undergo the full questioning.

**Detailed Criteria for scan performance:**

- The subject must be clear of any metals (magnetisable or non-magnetisable) at all parts of their body.
  - People with pacemakers cannot undergo the scan.
  - If there are other implants or surgery history inquiry must be performed before the subject comes for a scan. If needed, the radiology technician shall go to Prof. Gomori for authorisation.
  - Presence of metal after orthodontics treatment, mouth implants, and false teeth – there is no safety risk in performing the scan but artefacts may be introduced into the images.
- Pregnant women may not be scanned.
- People with permanent makeup may not be scanned.
- No subjects with permanent makeup, tattoos on face, neck, head or subjects with extensive tattoos (more than 10% of skin) may be scanned

**Rule of Thumb:** if there is doubt regarding fitness, the scan may not be performed.

The subject must be fit for the scan even before entering the operator room (zone III).

The 5 gauss line is marked in red at the entrance to the magnet room and does not slip into the operator room. There is 5 gauss line slippage into the machine room (figure 2), therefore there is a red mark on the floor at the entrance of the machine room. All entering the machine room must be questioned regarding the existence of a pace maker.

**Criteria for bringing equipment into the static magnetic field**

Many everyday objects contain metals or may be damaged by the magnetic field, for example (partial list): wristwatches, cell phones, keys, writing implements, office supplies, measuring equipment, belts, glasses, brooms, hairpins, zippers, coins, magnetic cards. Even wood/plastic/aluminium objects may contain metal bolts. Steel contains iron. Any metal-containing object shall be considered a magnetisable object. No magnetisable object may be brought into the magnet room.
There are non-magnetisable metals, but since we cannot know everything regarding the manufacturing process, no equipment may be brought into the magnet room without the approval of the Unit Manager and without being accordingly marked.

Object used in the unit shall be labelled and marked as:

- MR-safe – safe for bringing into the magnet room.
- MR-not safe – not safe for bringing into the magnet room.

b. Moving quickly inside the magnet room or shaking heads inside the bore is not permitted. Report any sensitivity to high magnetic fields such as metallic taste, vertigo, and dizziness when moving head close to the magnet bore.

5.2. Time Varying Magnetic Fields – gradients

a. Peripheral nerve stimulation – rapid varying of gradients, such as in the EPI (Echo Planar Imaging) scan may cause currents to go through the subject's body and cause Peripheral Nerve Stimulation (PNS). There are reports of tingling sensations, muscle twitching, and discomfort. It is rare to have visual flashes. The scan computer evaluates the probability of PNS based on the subject's data and the pulse sequence.

Dangerous conduction circuits may be created when body parts are touching or when the subject's skin comes into contact with the bore channel cover or with the coil cables.

**Instructions for preventing conduction circuits:**

- The subject must be instructed not to cross hands and legs, not to put their hands in direct contacts with the sides of their body or with the bore channel cover, at least 5mm distance should be kept between body parts.
- The subject must not wear any garments with conduction ability (underwire bras, metals parts, or wet/damp clothes).
- A minimum 5mm distance must be kept between the subject's body and the bore channel cover; only sponges, paper, or cotton/linen blanket may be used for this purpose. All said means must be dry.
- Manufacturer instructions must be fulfilled when using peripheral equipment and no loops may exist in metal cables.
- No unused coils may be left on the magnet bed.
- The scan may not be performed if the coils are exposed.
In any case in which the subject experiences discomfort, they shall inform the operator, who shall stop the scan.

b. **Acoustic noise** – a result of the gradients during the scan.

   - **In the magnet bed** – scan operation noise can reach 120dB.
   - **In the magnet room** – scan operation noise can reach 88.3dB.
   - **In the operator room** – the noise comes through apertures in the Faraday cage. The magnet room's door must be closed during a scan.

The operator shall verify before the scan starts that the subject has disposable earplugs or noise-dampening earphones or uses designated earphones that dampen environmental noise at about 30dB. In addition to the earplugs, the subject must put on earphones used for communication during the scan. An operator in the magnet room must put in earplugs.

**Important!** Verify the earplugs are correctly applied – the earplug must be inserted into the inner ear canal with only the very end outside it.

5.3. **RF field**

When the scanner works electromagnetic pulses are emitted at a frequency of 123MHz via an RF coil inside the magnet body (body coil). Exposure to RF radiation may cause tissue heating through current induction in conductive elements of the body. FDA regulation defines SAR = Specific Absorption Rate in Watt/kg units. SAR takes into consideration various factors such as run parameters (transmission frequency, pulse type, transmission coil, scan duration, etc.), subject parameters (weight, height, age, position in magnet, imaging tissue volume), and temperature conditions in the magnet room. In each scan the scanner calculates the SAR value in normal perfusion conditions of the subject and does not enable running a scan beyond the permitted SAR value. SAR is also computed according to whole-body-averaged and does not assume local heating (e.g., due to tattoos or metallic jewellery). Therefore, even if the scanner enables running an experiment in SAR conditions, it is possible that a burn shall occur.

**Instructions for prevention of biological affects caused by RF radiation:**

- Meticulously fill in the subject data when registering them into the scan computer.
- Fill instructions for prevention of conduction circuits as noted in section 5.2.
- Exclude subjects with permanent makeup, tattoos on face, neck, head or subjects with extensive tattoos (more than 10% of skin).
- Activate cooling ventilation system if needed.
- In any case of experiencing heat, the subject shall inform the operator who will stop the scan.
6. **Emergency Instructions**

As per management provision 069-05, in any case of emergency in the unit, a "Notification of dangerous situation/accident" form, found in offices 3-4 is to be filled and given to the unit manager.

6.1. **Pulling metallic objects towards the magnet** - when a magnetisable object senses a magnetic field, its long axis aligns itself with the field and the object shall be pulled towards the high field. The object shall move towards the centre of the magnet, and shall accelerate until it reaches the field's homogenous area, there is will approximately stop (at the centre of the magnet). The object's speed depends on various factors, including mass and geometry. In a 3T field the speed can reach up to 100 kph. The object will hit anything in its way with great force.

It is important to note that there is no single action protocol when a magnetisable object is brought into the magnet room and is pulled into it. Each case has to be evaluated separately, before an action is to be taken.

Cases in which the magnetic field is to be turned off (Quench) action is to be taken are cases in which there is danger to the subject's life or wellbeing.

In general, the magnet has to be quenched when one of two cases occur:

1. When a magnetisable metallic object pins the subject to the magnet without any possibility of extracting them safely.
2. When a sharp metallic object penetrates the subject's body and significantly endangers any organ.

In any other case, in which the object penetrates an area that does not endanger life or limb, operator's discretion is required.

The danger of removing the subject from the bed/room must be evaluated. The bed must not be removed if its movement may move the object. Consider pulling the subject by pulling his feet without moving the bed and coil if such action is safe.

**If there is any doubt regarding subject removal safety, perform Quench.**

The moment the subject is outside the magnet area and out of danger, all present must leave the magnet room and any close access to the magnet (including of security) must be prevented.
Do not attempt removal of object from the magnet! Such action may result with damage to personnel or magnet. The magnet room must be locked, and a large warning note must be put on the door. The unit manager and Siemens service centre must be notified.

Quenching is done by pressing the QUENCH button on the wall to the left of the operator window. A second button is found inside the magnet room, in the inner side of the operator window. Pressing the QUENCH button drops the field to 20mT within 20 seconds, the liquid helium is released as gas through the QUENCH tube passing through the ceiling and outside the building, and a loud noise is heard. Only after 20 seconds have passed can the subject be evacuated and removed from the magnet room.

In extreme emergency in which the magnet must be abandoned and rescue forces not from campus must enter the area, quenching must be performed.

When quenching the magnetic field, failing of the quench pipeline may cause leaking of gaseous helium into the magnet room. The hazards are:

- **Asphyxiation** – one litre of liquid helium turns into 700 litres of gaseous helium, the gaseous helium shall rapidly replace the oxygen and may cause asphyxiation.
- **Rise in air pressure in the magnet room** – in case of rise in air pressure in the magnet room, the magnet room door opens to the outside of the room by pressing the handle.
- **Frostbites** – the gaseous helium is at a temperature of -250°C, therefore anything that comes in contact with it shall freeze immediately and there is danger of frostbite.

In any case where white vapour is seen in the magnet room evacuate immediately and clear the building.

The unit does not have an oxygen detector.

6.2. **Sudden Quench** – strong vibration, such as though of earthquakes may cause sudden quench. Spontaneous quench is rare and its dangers are similar to those of manual quench – replacing oxygen with helium and frostbites caused by the gaseous helium. If there is suspicion of quench, safely evacuate the room and building.

6.3. **Minor helium leak** – in any cases of cooling system malfunction, liquid helium may evaporate through the quench pipeline. If white vapour is seen in the magnet room, clear the magnet room immediately. The gaseous helium pipeline goes through the machine room as well, so if white vapour is seen in the machine room, immediately clear the building.
6.4. **Peripheral Nerve Stimulation** – The scan must be stopped and the subject must be evacuated from the magnet room.

6.5. **Heat burns**
- Immediately stop the scan and evacuate the subject from the magnet room.
- Give basic first aid (wash the area in running water) and evacuate to the hospital if needed.

6.6. **Fire**

**Examples for fire sources in the unit**: short circuit in the scanner system, incandescent lamps.

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**Behaviour during fire in the MRI unit**

- **Inform the security centre**: 6585000

- **Cut off the main electricity current to the building**: the main button is in the electricity cupboard next to the inner side of the entrance. Immediately evacuate the subject out of the scanner and the magnet room (using discretion and removing any metallic objects from body).

- **Activate the alarm**: press the red alarm button next to the entrance/emergency exit

- **Escape the building via the closest free exit**

- **Extinguishing the fire**: as long as the fire is small, at user discretion, depending on location
  - If there is fire/smoke in the:
    - Magnet room
    - Operator room
    - Machine room
    - Remove any metallic objects that you may have on you!
    - Equip yourself with MR-compatible extinguishers!

  - If there is fire/smoke in the:
    - Offices
    - Dressing room
    - Kitchenette
    - Use the standard fire extinguisher (powder) until the fire has been neutralised and immediately escape the building

- **Serious fire/smoke in the magnet room only**
  - Press the QUENCH button to the left of the operator window in the operator room – a loud noise will be heard!
  - Pull out and through away the extinguisher’s safety catch outside the magnet/operator/machine room. Go inside only after 20 seconds and extinguish the fire using the special extinguisher and/or evacuate people and immediately escape the building

- **When the fire is only seen and the fire alarm has not activated**, press the alarm activation button in order to inform the university security centre. The buttons (red boxes) are next to the unit entrance and emergency exit.
• When the fire is in the main power cupboard of the unit, the building is to be cleared via the back emergency exit.

Pressing the button cutting the scanner power will cut power supply to the system, but the static magnet is always on!

• At the end of the event the fire detection system must be rebooted, guided by the unit manager.

6.7. Subject medical emergency

• Immediately stop the scan, remove the subject from the bed and the magnet room.

• Outside the magnet room – consider giving first aid or calling for emergency forces (Magen David Adom 101).

• In cases of anxiety attacks – remove the subject from the scanner and the magnet room. If needed, emergency forces must be called (Magen David Adom 101). The event shall be reported to the unit manager and the Medical Director according to medical emergencies procedures (aforementioned).

• Immediately report to security centre 85000.

• Campus security can be summoned by pressing the panic button in the operator desk.

6.8. After any event:

• Inform the Unit Manager and Medical Direction within one day.

• Fill the university’s dangerous situation/accident form and submit it to the Unit Manager.

Appendices

a. Management instructions regarding hazards and accidents on campus grounds

b. Metals questionnaire