



scannexus

GUIDELINES AND PROCEDURES **for conducting Magnetic Resonance Imaging** **(MRI) experiments involving human subjects at** **Scannexus Scanning Facility (Oxfordlaan 55)**

Last updates:

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1 INTRODUCTION

The Scannerlab of Scannexus B.V. (Scannexus) has been equipped with three whole-body clinical MR scanners of 3 Tesla, 7 Tesla and 9.4 Tesla (all Siemens). The MR scanners are located in a dedicated facility, located at Oxfordlaan 55, Maastricht. In addition to the MR scanners, the research facilities also include data processing facilities; a small electronic engineering workshop and a dummy scanner (see *Appendix 1*).

The purpose of the MRI Safety Policies and Procedures is to maintain a safe environment, during scanning procedures, in the magnetic resonance (MR) imaging area of the Scannexus Research Facility. There are potential risks in the MR environment, not only for patients or research participants, but also for accompanying aides, visitors, firefighters, facility staff such as security or who find themselves only occasionally or in case of an incident in the magnetic fields of the MR scanners.

For the purpose of maintaining safe MRI practices, the following recommendations are used:

- ACR Guidance Document for Safe MR Practices: 2007;
- Veilig omgaan met MRI voor werknemer – praktijkregels RIVM 2008;
- Arbocatalogus UMC's: veilig werken met MRI 2010;

Because MRI technology continues to progress, this is a dynamic document that will be updated as needed.

The various sections of the present document describe:

- The safety policies that are applied by Scannexus;
- The organization of the safety system and the standard safety procedures for conducting MRI experiments at Scannexus;
- The potential risks associated with MRI research and guidelines for risk management;
- The procedures for the management of emergencies;
- General guidelines regarding (f)MRI research with healthy adult human subjects.

All researchers that conduct MRI research using the SCANNEXUS MR facilities must adhere to the standards and the procedures defined in this document.

Supervision of MR-related research activity:

The Scannexus CEO, Operations Manager and Senior Operations and Technical Development Officer will ensure that the research activity related to the MR-scanners is conducted according to the organizational and safety system defined in this document. The final responsibility lies with the Management Board of Scannexus B.V. The following table summarizes responsibilities:

Role	Responsibilities
Senior Operations and Technical Development Officer	<ul style="list-style-type: none">- Supervise and approve safety regulations as described in this document- Advise CEO- Scannexus Senior Operations and Technical Development Officer is the nominated Safety Officer
Operations Manager	<ul style="list-style-type: none">- Work with Senior Operations and Technical Development Officer on safety regulations- Advise CEO
Scannexus Support Team (experienced MRI Operators/ Technologists under direction of Senior Operations and Technical Development Officer)	<ul style="list-style-type: none">- Train and instruct Certified Users- Supervise Certified Users in the time assigned by Scannexus Management- Suggest changes and improvements to safety regulations as described in this document
Certified User	<ul style="list-style-type: none">- Knowing all regulations and safety issues described in this document- Conducting MR research in the Scannexus MR facility according to these rules- Ensuring safety of his/her subjects, himself/herself and anyone else inside the MR lab at the time of conducting experiments- Ensuring care in granting other people access to the Scannexus MR facility

The Scannexus Support Team and Certified Users will have training to meet the requirements of 'Level 2 MR personnel' as defined in the ACR guidance document for safe MR Practices: 2007. This training is documented in the Certified Users Training documentation.

An annual report of the functioning of the system (including safety) will be prepared and communicated to the Supervisory Board of Scannexus and, as an additional measure, the Faculty Board of the Faculty of Psychology and Neuroscience (FPN), Maastricht University. In case of serious malfunctioning, research activity will be immediately suspended and required changes will be discussed with the Supervisory Board of Scannexus and the Faculty Board of FPN, and, in case of safety incidents and/or accidents with the Occupational Health and Safety executive MUO-HRM, Maastricht University.

2 SAFETY POLICIES

This section describes the safety policies that are applied by Scannexus.

2.1 MR SAFETY OFFICER

Scannexus appoints a MR Safety Officer with responsibility and authority for implementing and enforcing MR safety procedures.

2.2 SAFETY TRAINING

- All individuals working within at least Zone 3 (*see Four zone concept*) of the MR environment are documented as having successfully completed the MRI Safety Training approved by Scannexus prior to conducting or participating in studies.
- The Safety Training should be repeated at least annually and appropriate documentation should be provided to confirm these ongoing educational efforts (*see MRI scanner operator- certified user*). Other personnel such as e.g. facility staff, security staff, BHV (ERO) or fire fighters who are not familiar with the MRI environment will be given a minimal safety education to ensure their own safety as they work –enter Zone 3 and Zone 4.

2.3 MRI SAFETY APPROVAL

- Only researchers with a valid Scanning Project Agreement are allowed to schedule MRI scanner time for research studies.
- Researchers of FPN must have approved protocols by the Project Proposal Meeting (PPM). This is not mandatory for other than FPN projects.
- Researchers using the MRI system for human studies must have an approval from the relevant ethical committee for their protocol prior to scanning human research participants. This approval should be obtained by the researchers. Scannexus is not responsible for obtaining approval of the ethical committee.

2.4 FOUR ZONE CONCEPT

- Scannexus ensures restricted access to MRI sites by implementing a four zone concept based on the ACR Guidance Document for Safe MR Practices: 2007. The four zone concept (*Appendix 1 and Safety Organization*) provides for progressive restrictions in access to the MRI scanner:
 - Zone 1: General public
 - Zone 2: Unscreened MRI individuals
 - Zone 3: Unscreened MRI individuals under constant supervision of trained MR personnel (Certified Users, Scannexus Support Team)
 - Zone 4: Screened MRI individuals under constant direct supervision of trained MR personnel (Certified Users, Scannexus Support Team)

- Individuals - access Zone 4
 - All individuals who enter Zone 4 i.e. the magnetic environment must first undergo a mandatory screening interview
 - by the MRI technician for personnel.
 - by the Certified User (Keyholder) for research participants, patients. This includes individuals who may be accompanying a research participant.
 - By the special Keyholder in case of cleaning, repairs or maintenance, for the cleaning service or external technical personnel.

THERE ARE NO EXCEPTIONS TO THIS POLICY.

- Individuals who are or may be pregnant are requested not to remain in the MR scanner room while the RF and gradients are operating.
- The Senior and Support Staff of Scannexus (CEO, Operations Manager, Senior Operations and Technical Development Officer and Support Team) have the authority to ask anyone present within the MR scanner rooms (yellow, orange and red-labeled areas) to immediately leave these areas. Such a request must be immediately obeyed by said person.

2.5 MRI SCANNER OPERATOR – CERTIFIED USER

- Certified Users must attend the Certified Users training, specified for the specified system as evidenced by signed documentation (*Appendix 2*). This training is divided into two units, Magnet Safety Training and MR System Operation Training.
- When scanning subjects out of office hours (before 9:00h and after 17:00h), one Certified User must be present, and one person that is at least magnet safety trained. At least one of these must have current BHV training.
- When scanning out of office hours, the Certified User who booked the time must be certified for the system being used. S/He is the Keyholder (*see MRI Scanner Operator-Magnet room access and responsibility*).
- The Certified User must personally complete a detailed MRI safety screening of all participants prior to the MRI scan.
- The Certified User must personally take precautions to prevent RF burns to the research participant during scanning.
- The Certified User must personally verify proper fit of the hearing protection before initiation of the MRI scan.
- The Certified User must assess that the individual in the scanner is safe to be scanned prior to continuation of scanning.
- The Certified User must also verbally monitor the research participant throughout the procedure.
- The Certified User has the authority to stop MRI procedures that are deemed by them to be unsafe.

2.6 RESEARCH PARTICIPANTS

- Research participants in MRI studies are strongly advised to fill in the online screening forms or undergo an own screening procedure set by the researcher. Research participants undergo a screening interview by the Certified User (Keyholder) for safety risks prior to entering the magnetic field. It is mandatory for research participants to fill in the safety screening form every time they enter the magnet room. **THERE ARE NO EXCEPTIONS TO THIS POLICY!** Scannexus has a zero tolerance policy regarding breaches of safety protocols. All safety guidelines must be followed by all personnel.
- The Certified User (Keyholder) must interview research participants identified in the screening as having tattoos and proceed accordingly.
- Research participants in MRI studies must be treated within institutional and national guidelines and regulations.
- Research participants or other individuals with implants, devices, piercings and other possible ferromagnetic objects are not allowed to enter the magnetic environment.
- Research participants must be evaluated for medical status that would indicate a safety risk and/or prevent a successful MRI study.
- Research participants cannot exceed the relevant weight limits for the individual scanners.
- Research participant's age must conform to those allowed by the relevant authorization / ethics approval.
- Research participants must be given an operator call alarm squeeze ball with instructions for use by the scanner operator.

2.7 BU DATA SERVER

Users can access this server from their UM PCs. Access is granted after completion of the contract with Scannexus and completion of the CU Training.

Export your data to your personal folder on the BU server. It is a read only folder, only the scanner can write the data into this folder. This folder is not meant for permanent storage.

This server is backed-up by Scannexus. The size limit is 1TB. After 3 months of inactivity your folder will be emptied. You will get a warning e-mail in advance. In case of space limits this period may be shorter.

The ~Shared folder on the BU server is cleaned weekly. Every Monday morning this folder will be emptied.

2.8 INCIDENTAL FINDINGS

It is not the investigator's job to check for or to diagnose medical problems in anatomical brain scans. However, it is possible that you cannot help but notice ('incidental observation') an anatomical feature that appears out of the normal range (e.g. a space-occupying tumor). If students or student assistants are involved in the

measurements, CUs should monitor that the students they supervise do not give out (or show) the images to the subject. How to act on incidental findings is written in Appendix 3.

2.9 EMERGENCY OR ILLNESS

- An individual or research participant who becomes ill or injured must be removed, from the magnetic environment, immediately by the researcher or Certified User (Keyholder). After this, a report form for accidents should be completed.
- If there is a Magnet Emergency, the Senior Operations and Technical Development Officer and CEO must be notified.
- The Senior Operations and Technical Development Officer must report any emergency incident to Siemens and if applicable the Researcher/Certified User must report to the Faculty Board.

2.10 MAGNETIC FIELDS

2.10.1 STATIC MAGNETIC FIELD

- Only properly safety screened individuals are allowed in the magnetic environment of the MR scanner room. **THERE ARE NO EXCEPTIONS TO THIS POLICY.**
- Only equipment and accessories approved by the MRI Safety Officer are allowed to enter the magnetic environment of the MR scanner room. Such equipment will have a label issued by Scannexus.
- Any incident or near incident of a projectile accident must be reported to the Scannexus Support Team and a report form for accidents must be filled in.
- For any repairs or adjustments within the magnet room, help must be requested of the Scannexus Support Team, who has access to non-magnetic tools for such work.

2.10.2 RADIO FREQUENCY (RF) ELECTROMAGNETIC FIELDS

- Only properly trained individuals should operate devices and monitoring equipment in the magnetic environment.
- RF pulse timing sequences that exceed FDA Specific Absorption Rate (SAR) limits must not be used.
- Only equipment, accessories and materials that have been thoroughly tested and determined to be safe for MR procedures are allowed. Such equipment will have a label issued by Scannexus under guidance of the Safety Officer.
- Siemens recommendations for safe use of all devices must be followed.
- All non-essential electrically conductive materials must be removed from the MR system bore, including unused RF coils, cables and wires prior to scanning.
- Research participants must be instructed to not clasp their hands or in any other way form a closed loop with their extremities to avoid tissue heating.
- Loops in cables and wires must be avoided.
- Skin contact of cables and wires must be avoided.

2.10.3 TIME VARYING MAGNETIC FIELDS: GRADIENTS

Peripheral Nerve Stimulation

- Phase and Frequency encoding directions must be selected carefully by the scanner operator (Certified User) to avoid peripheral nerve stimulation.
- Researchers and Certified Users must continuously monitor research participants being scanned in a study and stop scanning immediately if any pain or uncomfortable peripheral nerve stimulation is reported or suspected and correct the situation before proceeding.

2.11 EQUIPMENT

- Any equipment to be used within the magnet room must be approved by the MRI Safety Officer.

2.12 ACOUSTIC NOISE

- Research participants must be supplied with hearing protection to meet the national guidelines: the ear-plug and if possible also a head set system. Any researcher or individual who remains in the scanner room during data acquisition must wear hearing protection.
- The intercom and stimulus equipment must be adjusted to comfortable levels for the research participant (sound level for auditory stimulus, brightness for visual stimulus).

2.13 INFECTION CONTROL

- The scanning head coil and any other surfaces that have been in contact with the research participant must be cleaned.
- Hygienic gloves (if used) must be removed and disposed of properly BEFORE touching common areas such as scanner keyboard, documentation, light switches, counter surfaces and other objects.
- Surfaces touched with gloves must be cleaned properly with the wipes present in the console area before leaving the area.

2.14 REPORTING

- All reporting must be carried out as soon as it is safe to do so.
- Injuries to personnel or a research participant must be reported to the MR Safety Officer. The MR Safety Officer will then inform the CEO, Principal Investigator (PI) and the Occupational Health and Safety Executive MUO-HR.
- Any incident or near incident of a projectile accident must be reported to the Scannexus Support Team by the Certified User or researcher involved.
- Equipment damage and/or failures must be reported to the Senior Operations and Technical Development Officer or member of the Scannexus Support Team and must be documented in the digital logbook on the Wiki.
- Facility safety breaches must be reported by the Certified User to the Scannexus Support Team.

3 SAFETY ORGANIZATION

Enforcement of safety rules, as well as daily organization and user support, is the task of the Scannexus Support Team. The MR Safety Officer (Senior Operations and Technical Development Officer) is appointed by the CEO Scannexus with responsibility and authority for implementing and enforcing MR safety procedures.

This section defines the safety system at the Scannexus scanning facility.

3.1 MR SUITE SAFETY BOUNDARIES

The American College of Radiology (ACR) developed the "ACR Guidance Document for Safe MR Practices 2007". Scannexus uses a four-zone model of integrated screening and access controls in the MR suite based on the ACR guidance (*Appendix 1*). Each zone represents a different safety level of static magnetic field exposure for the general public. Scannexus defined the four zones as follows.

- Zone 1:
 - All of the areas, outside of the MR environment, that are freely accessible to the general public (e.g., corridors and entrances just outside the MR environment).

- Zone 2:
 - The area between the public accessible Zone 1 and the more strictly controlled MR environments (Zones 3 and 4). Zone 2 areas typically include reception, waiting and patient dressing and holding rooms. The general public is generally not free to move throughout Zone 2 without the supervision of MR personnel.

- Zone 3:
 - The area in which access of unscreened non-MRI personnel is only permitted under supervision of the appropriate MR personnel. Access to Zone 3 is physically restricted from the general public through the use of a locking system (e.g., key lock, electronic access control).

- Zone 4:
 - The area containing the MRI scanner (magnet) and is associated with the strongest magnetic fields. Only access for screened MRI individuals and personnel. Zone 4 should be clearly marked as being potentially hazardous due to the strong magnetic fields.

3.2 MRI SCANNER OPERATOR – ACCESS LEVELS

Access to the scannerlab is via UM ID cards. There are two Access Profiles:

- Access Profile "AA" (Approved Access) allows access to all rooms of the scannerlab. This will only be given to people who have due reason to enter the scannerlab, i.e. are either involved in research within the scannerlab or are support/BHV trained personnel.
- Access Profile "MTP" (Magnet Trained Personnel) allows access to all common rooms and the scanner console and electronic rooms.

The present Certified User training will be divided into two units: Magnet Safety Training and MR System Operation training. MTP Access will be given to Certified Users who attended the Magnet Safety Training and the MR System Operation Training. BHV certified personnel will be given MTP Access after attending the Magnet Safety Training.

One or more of the lab spaces might be converted to activities that are not necessarily connected with MRI scanning (e.g., EEG or TMS). For these activities it is not considered necessary to have safety training related to MRI.

Depending on the Access Profile, the card access will be changed appropriately. The corresponding room access map can be found in Appendix 4.

Authorization Profile	Explanation & Remarks
OXF55 Lab003 24/7	Access to room 0.03
OXF55 Lab004 24/7	Access to room 0.04
OXF55 Lab008 24/7	Access to room 0.08
OXF55 Lab014 24/7	Access to room 0.14
OXF55 Lab023 24/7	Access to room 0.23
OXF55 Reception 24/7	Access to room 0.07
OXF55 MTP 24/7	Magnet Trained Personnel; Access to scanner console and electronic rooms
OXF55 Key Cabinet 24/7	<i>At all times in combination with MTP or AA profile</i>
OXF55 AA 24/7	Approved Access; Access to all rooms
OXF55 Basic 24/7	Access to door outside and main entrance scannerlab

The requirements for, and the responsibilities connected with the approval of MTP Access and access to the specified scanner room, are:

- CU must be trained for the specified system as evidenced by signed documentation.
- This CU must adhere to the policies of the MRI scanner Operator as described before in this document.

Appendix 2 specifies:

- 1) the training procedure to become Certified User and
- 2) the set of rules/items a Certified User must be cognizant of.

Appendix 2 also includes an authorization form that a Certified User will have to read and sign after the training information. The MR Support Team is responsible for training and upgrading of Certified Users.

In the console and common areas there are a number of small lockers within which users and guests are obliged to place their valuables, ferromagnetic objects, and magnetically encoded cards.

Certain personnel (members of the Scannexus Support Team) have access to all areas. They all have detailed knowledge of the scanner and of the potential hazards associated with MR systems and related equipment. In the case of cleaning, repairs or maintenance, these people will provide the cleaning service or external technical personnel access to magnet or technical room, perform the mandatory screening and instruct them. The Scannexus Support Team will perform checks of scanner function.

3.3 MRI SCANNER OPERATOR – MAGNET ROOM ACCESS AND RESPONSIBILITY

Access to the scanner rooms is via a Key box. With UM ID cards access will be given to the Key box and the Key for the specified system, depending on the level of training of the Certified User (*Appendix 4*).

Use of this key also involves the CU (Keyholder) taking responsibility for safety around the magnet. This key is thus referred to as the Keyholder key.

- By picking up the key and unlocking the magnet room door, the CU becomes the Keyholder and takes responsibility for safety until the door is locked and the key returned to its storage location.
- If two CUs are working at the same time (e.g. evenings or weekends), the Keyholder should be the CU who picked up the magnet room key.
- The door must not be locked when a subject is being scanned.
- If the Keyholder fails to lock the door at the end of their scan slot, they remain responsible for safety even if the next scan slot is empty.
- The Keyholder's responsibility for safety only ends when the magnet room door is locked and the key is returned to its storage location.
- Failure to ensure that the key is placed in its storage location will cause problems for following scan slots. Therefore failure to do this will result in a loss of booking privileges for the Keyholder.

- The Certified User is responsible for leaving the magnet room in the condition which they found it.

Usage of the Key box is registered. This activity log is used as a checkup for usage and scan times. Any misuse will result in a loss of booking privileges for the Keyholder.

The Keyholder is responsible for ensuring that the magnet room is only entered by Certified Users or by volunteers or guests who have filled out the safety screening in order to enter the magnet room in accordance with the rules defined in this document. S/He is strongly advised to perform a screening procedure beforehand, either their own procedure, or the Scannexus screening procedure. S/He is particularly responsible for ensuring that no ferromagnetic objects are brought into the magnet room. S/He supervises access to the console and magnet area for outside persons (volunteers, patients, visitors).

If studies on humans are being performed then the Keyholder is responsible for ensuring that the protocols used conform to the current standards of Scannexus and the appropriate regulatory framework, that the subjects of the experiments are adequately monitored and cared for and that the rules of Scannexus regarding duration of experiments are adhered to. The Keyholder has the responsibility to screen the subjects and to ensure that subjects undergo the final safety screening before participating in the measurements. To reduce risks related to the static magnetic field, gradients, electromagnetic RF fields, and acoustic noise, the Keyholder must follow the requirements outlined in this document (*see below*).

- Never bypass the door card readers and their locks either by blocking the doors open or otherwise stopping the lock from latching shut.
- Never bypass the card system by lending out your UMcard, this card is strictly personal!

The Keyholder is also responsible for ensuring that the use of the system is documented according to the procedures of Scannexus and that any incidents or malfunctions are reported (*see below*).

The Keyholder must:

- Register any accident or malfunctions with scanner or stimulus equipment. This registration will be in the digital logbook (Wiki) provided by Scannexus.
- Register any problem or discomfort experienced by the subject. This registration will be on the report form for accidents provided by Scannexus.

The use of the MR scanner must be documented in Calpendo.

If the Certified User fails to take responsibility for the rules and regulations outlined in this document his/her privileges as a CU will be withdrawn.

3.3.1 CLEANING OF THE MAGNET ROOMS

Cleaning of the scanner console room and of the magnet room is regulated in the following way: Cleaning personnel does not have a key for accessing the scanner rooms; thus cleaning in the magnet room is possible only during the presence of a member of the Scannexus Support Team. The Scannexus Support Team ensures that cleaning personnel have had the mandatory screening, do not carry any metal object in the magnet room (by using the same screening procedure that is used with the subjects). Cleaning personnel will use only MR-compatible tools. Detailed modalities regarding these procedures have been defined with the Facilitaire Dienst, Maastricht University. The communication of these modalities to the head of the cleaning personnel is the responsibility of the head of the Facilitaire Dienst, Maastricht University.

In the event of an incident requiring cleaning (spillage of liquids, subject vomiting, etc.) use the absorbent powder provided in the spill kit that is kept in the console room and alert the Scannexus Support Team.

3.3.2 MAINTENANCE

Maintenance service on the systems will follow Siemens guidelines.

3.3.3 USE OF ADDITIONAL INSTRUMENTS FOR MRI EXPERIMENTS

It is prohibited to introduce and use in the magnet room any device or instrument that has not been tested and approved by the Scannexus Support Team – who may consult additional groups for advice. It is the responsibility of the researcher to arrange for such testing to be performed prior to their scheduled scanner time. If the equipment has not been tested prior to the scheduled slot, the scanner time will be cancelled but still charged.

3.3.4 MANAGEMENT OF EMERGENCIES

MR is extremely safe and no adverse event is anticipated. It may be possible, however, that under exceptional circumstances a specific (i.e. related to the nature of the equipment used) emergency situation may arise. One of these may lead to a so-called *magnet quench situation*. To reduce electrical resistance, superconductive magnets use cryogens to super-cool the electrical conductor that generates the static magnetic field. Temperatures of the cryogens used are as low as -269°C . It is possible (although very rare) that a sudden boil-off of all of the cryogen or a quench occurs. A quench is accompanied by a loud noise and causes the rapid loss of the magnetic field. It is also possible that steam may be released into the magnet room. An induced quenching of the magnet may become necessary if a metal object traps a subject in the magnet bore so that removal is not possible without 'turning off' the magnet. On rare occasions, a spontaneous quench of the magnet may occur.

Scanner-related emergencies:

The procedures that are to be followed in case of magnet quench or other specific scanner-related emergencies (including fire in the magnet room)

are described in detail below in this document (see ***Procedures for MR-related Emergencies***). Additionally, a detailed description is available as a part of the SIEMENS safety instructions/video (part of the safety training for certified users) and in the SIEMENS System Manual (Part A pp. 2-1 to 2-72) available in the MR-scanner console room. A printed copy of the Guidelines with the specific emergency procedures will always be present at the scanner console.

Other emergencies:

Other emergencies at the MR scanner should be treated as they would at any other facility on the UM campus. The standard procedure consists in dialing the **Emergency Number 1333** and describing the location and nature of the emergency situation. Start CPR immediately if necessary. Individuals in the scanner room are removed from the scanner room (Zone 4) to a predetermined magnetic safe location (Zone 2).

Then, the Certified User has to wait for the BHV and/or Emergency services.

A folder of the 'UM Facilitaire Dienst' describing how to behave in the emergency circumstances is present near the scanner console.

Personnel involved in the management of emergencies have been informed of the special requirements needed for operating in the magnet room by the CEO of Scannexus and the Safety & Security Consultant of Maastricht University. If possible all personnel involved will be screened for their own safety accordingly to the mandatory MRI safety screening. Additionally, the Keyholder should ensure that no-one of the emergency personnel will introduce metallic objects in MR-scanner room.

IMPORTANT NOTES:

Out office hours (before 9:00h-after 17:00h) in the Scannexus scanning facility (Oxfordlaan 55) and during the weekends and holidays, MRI measurements involving scanning of subjects must be conducted **under the supervision of one Certified User and one Magnet Safety trained person.** At least one of the users must have had BHV (ERO) training.

To work during out of office hours, CUs will need to pick up a smart key from a member of the Scannexus Support Team:

- CUs should pick up the smart key at least 24 hours before their scan slots.
- Smart keys must be returned within 48 hours of the finish of the scan slot (Tuesday 5pm in the case of weekend work).
- It is not permitted for one CU to pass the key on to another user. A Scannexus Support Team member must be involved in the transfer.

The booking CU is responsible for obtaining and returning the smart key for their scan slot. Usage of the Key box is registered. This activity log is used as a checkup for usage and scan times. Any misuse will result in a loss of booking privileges for the Keyholder.

4 POTENTIAL RISKS ASSOCIATED WITH MRI RESEARCH AND RISK MANAGEMENT

In the subsequent sections we describe:

- 1) The *typical steps* that are followed for conducting magnetic resonance imaging (MRI) experiments involving **healthy adult human subjects** at the Scannexus scanner facility;
- 2) The *potential risks* of conducting MRI experiments and 3) how these risks will be *managed*. A brief description of the principles of MR imaging is provided as background to the risks associated with MR experiments.

4.1 PRINCIPLES OF MR IMAGING

Magnetic resonance imaging (MRI) is a highly flexible technique for making images of the human body. Hydrogen nuclei (protons) behave like small magnets, so that when a subject lies in a magnet the protons tend to align with the magnetic field. When properly excited the protons precess (rotate), producing a measurable signal in a nearby detector coil. The frequency of precession is proportional to the local magnetic field, so by making the field vary across the body the signals arising from different locations can be distinguished based on their frequency.

There are three basic components to an MRI system:

- 1) **a large, static magnetic field**
- 2) **radio frequency (RF) coils**
 - used as a transmitter to excite the MR signal, and as a receiver to detect the MR signal;
- 3) **gradient coils**
 - pulse on and off to produce linear gradients of the magnetic field for imaging.

The main magnetic field (e.g. 3 Tesla) is provided by a large magnet with a cylindrical bore. Fixed within the bore is the gradient coil. A computer controlled bed moves in and out of the magnet bore to position the body part of interest (e.g. the head) at the midpoint of the gradient coil. For brain imaging, the subject's head rests inside the head RF coil. Every body part needs its own RF coil.

MRI techniques involve pulsing currents through the RF and gradient coils, so a particular technique is often referred to as a pulse sequence. By varying the pulse sequence, one can produce an enormous range of images with different spatial and temporal resolutions, and with substantially different contrast between tissues in the image.

4.2 POTENTIAL RISKS AND RISK MANAGEMENT

The main established hazard associated with MR imaging is that the magnet exerts a strong force on ferromagnetic objects. For this reason, ferromagnetic objects are excluded from the vicinity of the magnet so that they will not become projectiles. In addition, it is strongly advised to let every subject undergo a standard screening procedure to determine whether they have any implanted materials that may pose a

risk (see screening forms at the end of this document, Appendix 5). If there is any doubt about the nature of any implanted material, the subject will not be scanned. **No ionizing radiation is used with MRI.**

Although no other risks have been established for MRI, there are four areas of potential concern for which the FDA and IEC recommend prudent limits:

4.2.1 EXPOSURE TO A STATIC MAGNETIC FIELD

In the United States, the Food and Drug Administration (FDA) guideline is that magnetic fields up to and including 8 Tesla pose no significant risk. The limit of 8 Tesla is based not on known risks at higher field, but rather simply a lack of long-term data at those fields. This guidance is described in the FDA document: "Guidance for Industry and FDA Staff: Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices", July 14 2003.

In Europe, actual limits for the parameters for patient scanning are given in the document from the International Electro technical Commission, IEC 60601-2-33 (standard for the safety of MR scanners). The static magnetic field ceiling value is 4T for patients for whole body scanning, a number which is based on the clinical experience with 4T MR Scanners at a limited number of hospital sites since 1987.

The magnetic field of the SCANNEXUS 3T scanners are within the guidelines provided by the IEC and FDA for clinical imaging and fall within the category of no significant risk.

In high magnetic fields, rapid motion of the head can cause dizziness, vertigo, nausea or a metallic taste. For this reason, the scanner bed moves slowly into the magnet bore and the subject is encouraged to remain still while in the region of the static magnetic field. **The Operator will insure that rapid movements on the subject's part are minimized as the subject enters and exits the vicinity of the magnet.** During scanning of the subject, motion is restrained by padding inserted between the subject's body part of interest and the RF coil or other similar support. In the event that such dizziness or other effects are experienced by the operator or subject, the first reaction of the individual should be to slow their movements.

No pacemakers, metallic implants, neurostimulators, or loose metal objects are permitted inside the magnet room. Metal objects (e.g. limb braces, traction mechanisms, or stereotaxic devices, etc.) should not be placed within the MR magnet.

4.2.2 EXPOSURE TO THE RF FIELD

The RF fields used in MRI are non-ionizing electromagnetic radiation, and so do not pose the same type of risks as x-rays and radioactive tracer techniques. However, the RF fields may cause tissue heating.

The FDA guideline is that there is no significant risk if the specific absorption rate (SAR) is:

- a. Less than 4 W/kg whole body for 15 minutes,
- b. Less than 3 W/kg averaged over the head for 10 minutes,
- c. Less than 8 W/kg in any gram of tissue in the head or torso for 15 minutes, or
- d. Less than 12 W/kg in any gram of tissue in the extremities for 15 minutes.

Before starting each scan, the scanner software calculates the amount of heating expected during the scan and compares the estimate against predetermined safe levels. **If the estimate exceeds the limits, the system stops and suggests scan parameters.** The complete estimate of excessive heat exposure is based on the subject's weight. **Consequently each subject's weight must be accurately entered into the system before scanning.**

Finally, subjects with reduced circulatory function (e.g. those with hypertension or impaired cardiac output), diabetes, obesity, fever, or impaired ability to perspire may have a reduced capacity to disperse heat and must be closely assessed during screening and during the study.

4.2.3 EXPOSURE TO RAPIDLY SWITCHED MAGNETIC FIELDS

The gradient coils used for imaging produce time-varying magnetic fields (slew rate in dB/dt). Such fields, if sufficiently strong, can produce peripheral nerve stimulation. Stimulation can occur in peripheral nerves, muscle, and blood vessels.

The FDA guideline is that switched gradient fields pose a significant risk if dB/dt is sufficient to produce severe discomfort or painful stimulation. The mean pain nerve stimulation threshold - the level at which half of subjects are likely to report painful stimulation - is 90 Tesla/Second. The mean peripheral nerve stimulation threshold - the level at which 50% of subjects might report a tactile sensation or metallic taste - is 60 Tesla/Second.

By default, the scanner operates in the **Normal Operating Mode**. In this mode, the power limits are based on stimulation limits including a statistically determined standard deviation. The ratio of subjects that may be affected by a light peripheral stimulation is less than 1% when fully utilizing the power limit.

If the pulse sequence involves a higher switching rate, the system prompts the operator with the question: "Attention, possible patient nerve stimulation. OK". If the operator presses OK the system switches to a **First Level Controlled Operating Mode**. Theoretically, in this mode up to 50% of the subjects may experience mostly mild stimulations when fully utilizing the power limit; a smaller portion may experience significant stimulation. When operating in this mode, the operator should frequently inquire about the subject comfort and if the subject

reports significant stimulation and discomfort, the measurement should be immediately terminated.

If a pulse sequence is prescribed that would reach dangerous values the software will not accept the value and prompt the user to set a lower value.

4.2.4 ACOUSTIC NOISE

When current is pulsed through a gradient coil sitting in a magnetic field it acts somewhat like a loudspeaker, creating a sharp tapping sound at the characteristic frequency of gradient pulsing (around 1 kHz). The sound levels are most intense during dynamic imaging that requires rapid gradient switching. Sound pressure levels at the center of a head gradient coil were measured to be in the range from 122-131 dB SPL for a 3T scanner during echo planar imaging (Foster, et al 2000). The FDA guideline is that the acoustic noise poses a significant risk if peak acoustic noise is over 140 dB. For the pulse sequences used on our scanners the acoustic levels are below this limit. In addition, **all individuals entering the magnet bore must be provided with adequate sound protection.** The ear-plugs we use are rated to reduce acoustic noise by approximately 30 dB.

The subject always has the right to end the study at any time if the acoustic noise is not tolerable.

5 PROCEDURES FOR MR-RELATED EMERGENCIES

In normal conditions, MR is extremely safe and no adverse event is anticipated. It is however important that users of the MR scanner are prepared to manage emergency situations that may potentially arise during the measurements.

The basic requirements for emergency management are provided during the Magnet Safety training and are based on the knowledge of the location and functioning of the MR scanner **emergency switches** and of the **procedures for MR-related emergencies**, which are described below.

Certified Users should report all accidents and situations of emergency in the digital logbook on the Wiki and, as soon as possible, to the Scannexus Support Team. Next to this Certified Users are required to fill in an incident form and give this to the Office Manager or Support Staff. This form can be obtained at the reception.

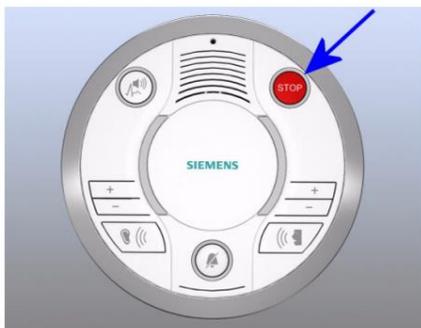
5.1 EMERGENCY SWITCHES

5.1.1 TABLE STOP

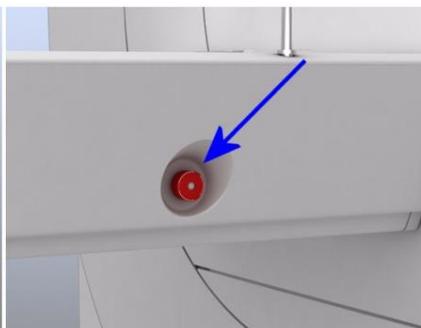
The table stop buttons stops the electrical movement of the table in case of small accidents.

3T TABLE STOP BUTTONS

The table stop buttons are located on the side of the table and on the intercom system. The pull for manual table removal (disconnecting the motor) is located at the end of the table support.



Intercom



Table



Manual table removal

7T & 9.4T TABLE STOP BUTTONS

The table stop buttons are located on the side of the bed control panel at the sides of the bed.

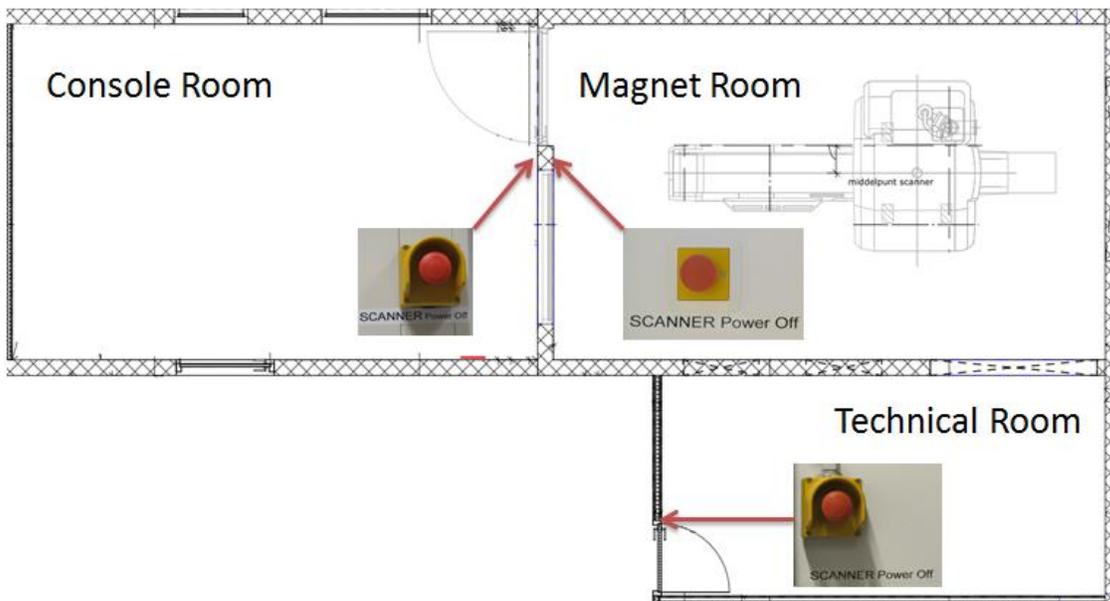
The pull for manual table removal (disconnecting the motor) is located at the end of the table support.



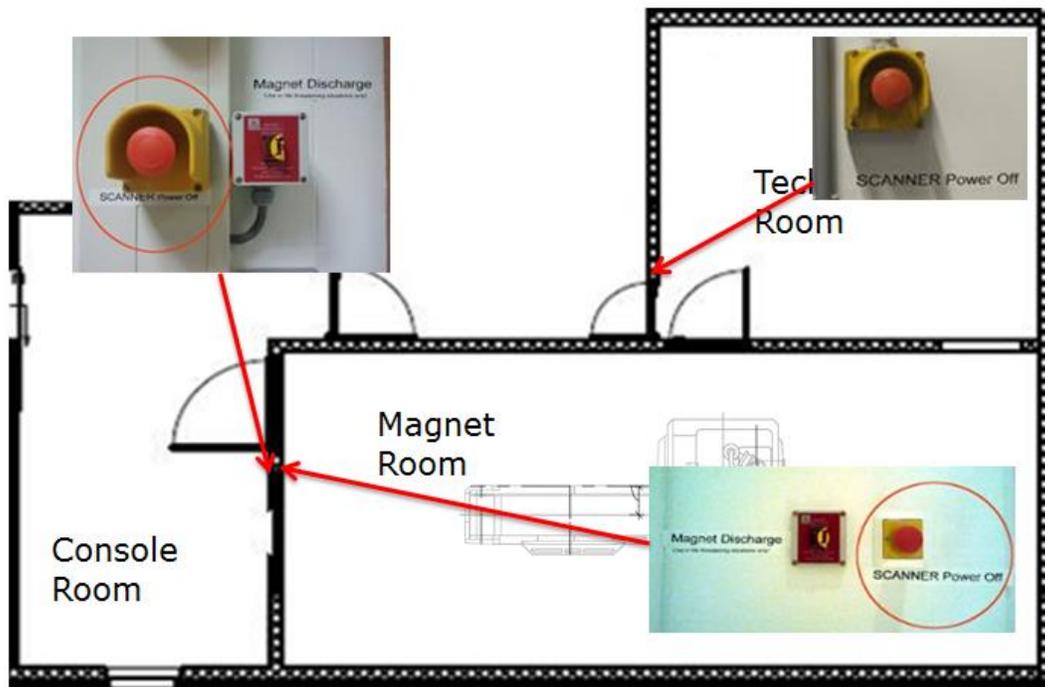
5.1.2 EMERGENCY ELECTRICAL SHUT-DOWN

In case of an electrical accident or fire.

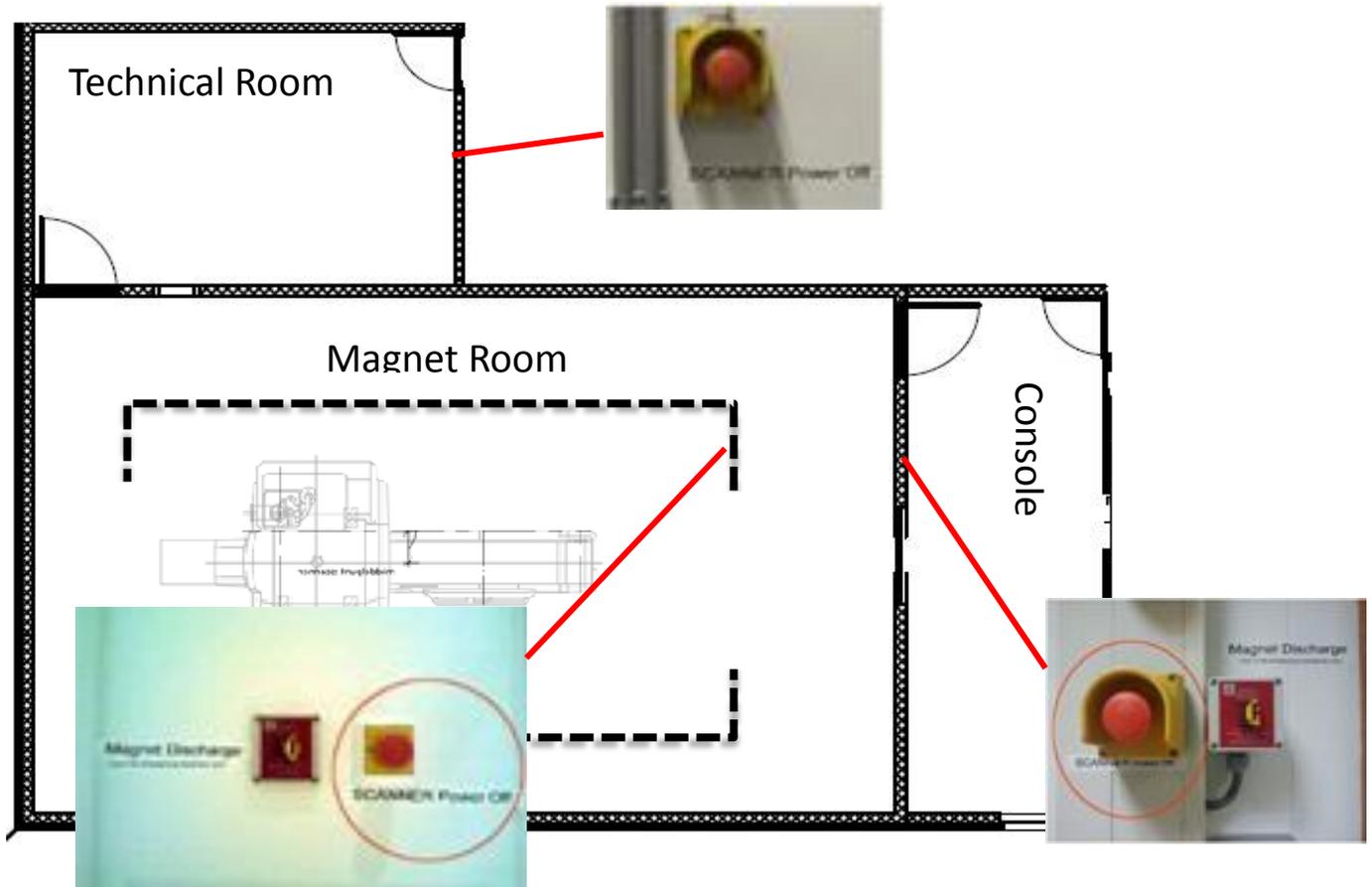
3T EMERGENCY SHUTDOWN



7T EMERGENCY SHUTDOWN



9.4T EMERGENCY SHUTDOWN

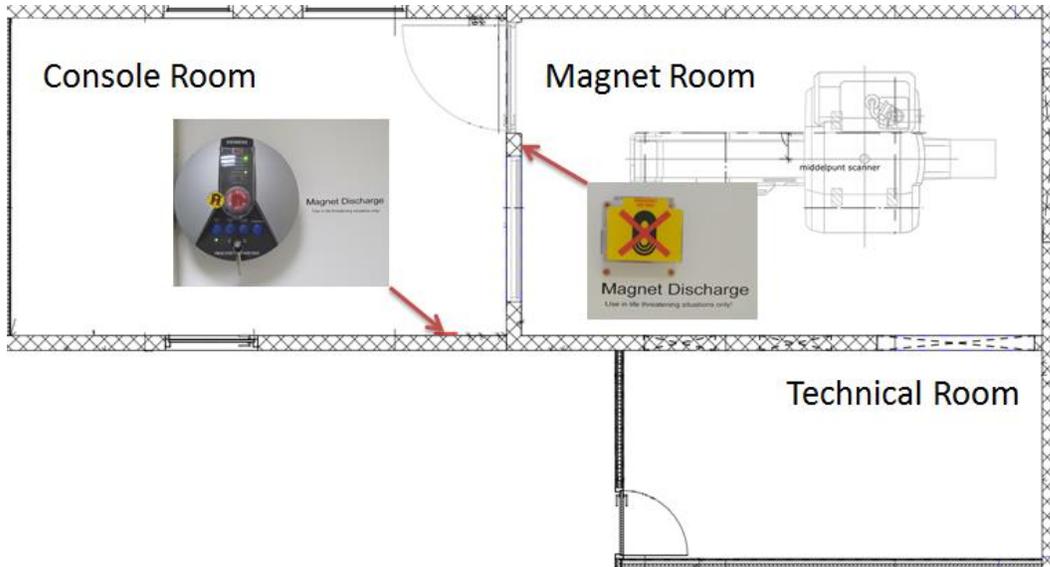


5.1.3 MAGNET STOP (QUENCHING OF THE MAGNET)

To be used in accidents in which personal injury has occurred or is in immediate danger of occurring due to metallic objects attracted by the static field.

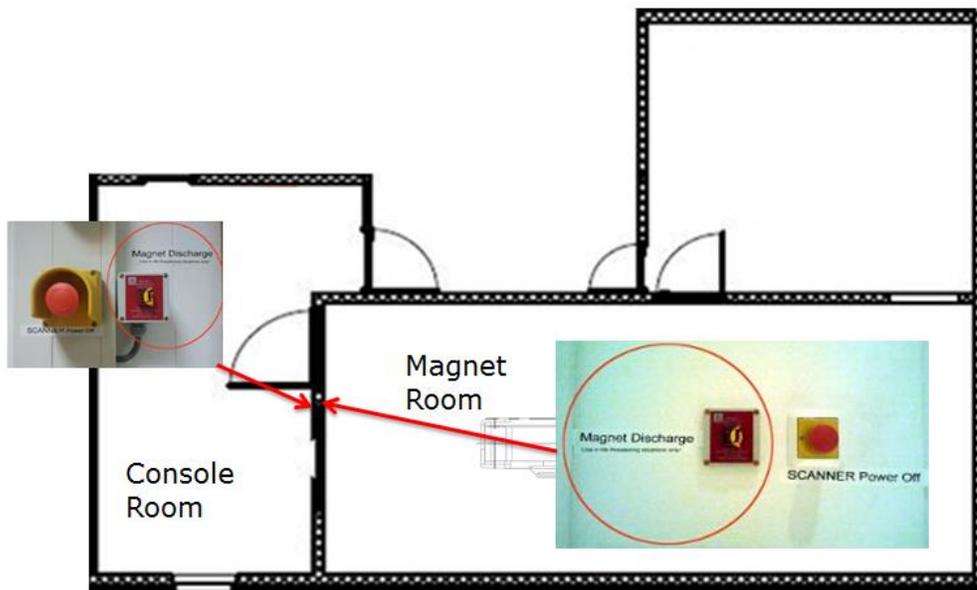
3T MAGNET STOP

Press the Magnet Stop button located inside the magnet room or on the right hand side of the console:



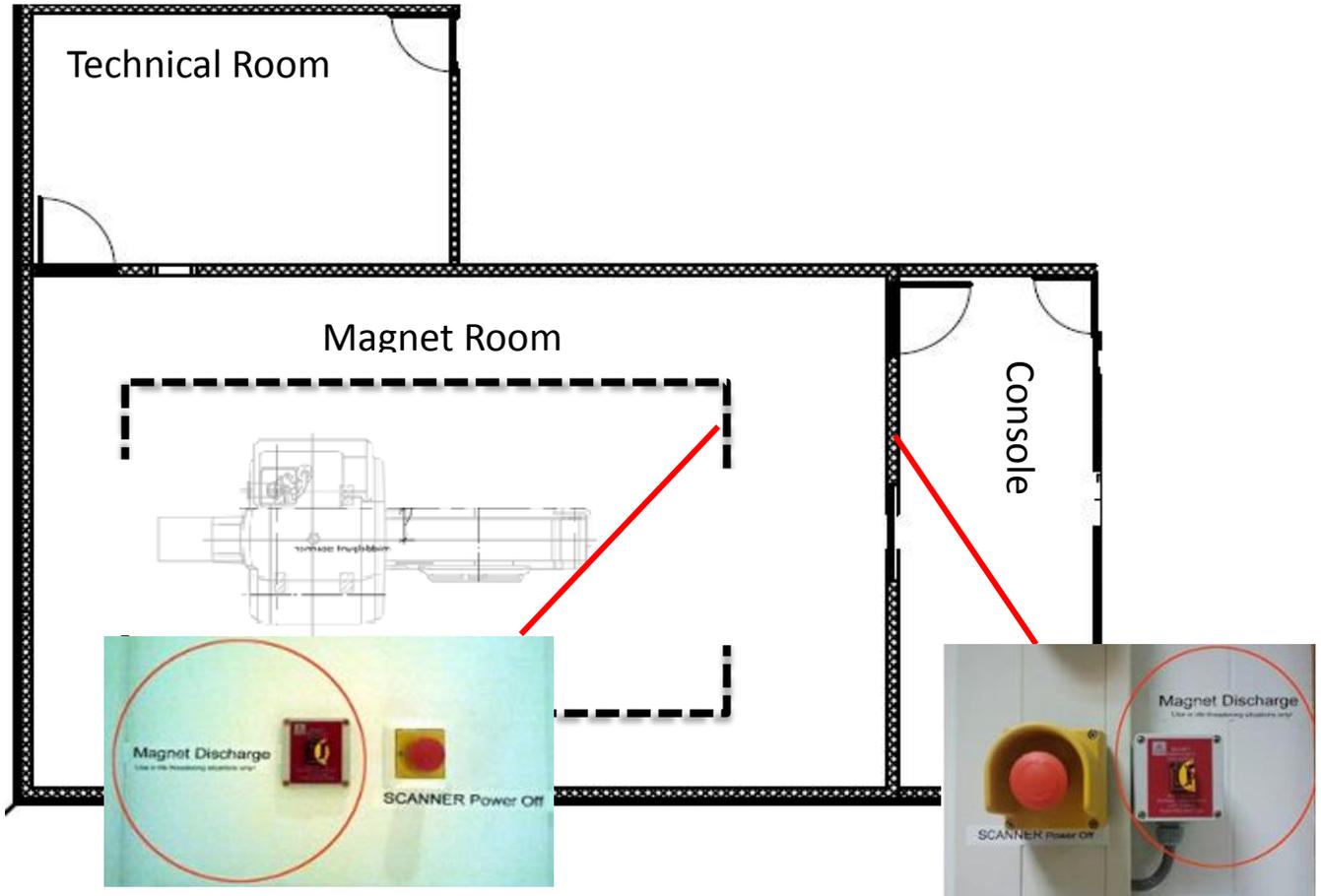
7T MAGNET STOP

Press the Magnet Stop button located inside the magnet room or on the left hand side of the console:



9.4T MAGNET STOP

Press the Magnet Stop button located inside the magnet room or on the right hand side of the console:



IMPORTANT

The switch panels to the right of the 7T and 9.4T consoles do **NOT** include the magnet stop button:



5.2 PROCEDURE MR-RELATED EMERGENCIES

5.2.1 MEDICAL EMERGENCIES

In the event of small accidents, medical emergencies or inconvenience for the patient and quick removal of the table is needed;

The Certified User will take the subject out of the magnet bore:

- The fastest method for moving the tabletop out of the magnet bore is to press the '**Home Position**' button. Use this method whenever the power supply and/or motorized drive are intact.
- In case of power failure and/or defective motorized drive, pull the tabletop manually out of the magnet bore. To disconnect the tabletop from the motor an additional handle needs to be pulled, which is underneath the end of the table support.
- The gurney can be used to move the subject from the patient table to the safe area.

The predetermined, magnetically safe location is the common area after the changing rooms (T0.021).



Dial 1333 and describe the location and nature of the emergency situation. The scanners are located at Scannexus Scannerlab, Oxfordlaan 55.

Wait for BHV services.

Instructions for BHV-ers:

Inside office hours BHV trained support staff members will be beeped. At least three persons are needed. Two of them take care of the subject and one wait outside for the ambulance. Note that access on the Umcard to the scannerlab is needed to enter the building. Ensure that no-one of the emergency personnel will introduce metallic objects in MR-scanner room.

Outside office hours the CU and the accompanying second person take of the subject. BHV trained security people will come from the UM alarm center. One of those two has to wait outside for the ambulance. Make sure this person can enter the building. Ensure that no-one of the security people and emergency personnel will introduce metallic objects in MR-scanner room.

In case of cardiac or respiratory arrest or other medical emergency within Zone 4 for which emergency medical intervention or resuscitation is required, appropriately trained personnel should immediately remove the subject from Zone 4 to the safe area and initiate basic life support or CPR as required by the situation as soon as possible. All priorities should be focused on stabilizing (e.g. basic life support with cardiac compressions and manual ventilation) and then evacuating the patient as rapidly and safely as possible from the magnetic environment that might restrict safe resuscitative efforts. A defibrillator can be found in the safe area.

5.2.2 ELECTRICAL EMERGENCIES

In the case of an electrical accident (e.g. serious malfunction of the MR system) the Certified User will:

- o Press the Emergency Shutdown Button
 - Pressing this button cuts the power to the magnet room and removes electrical power of all components of the system other than the static magnetic field.

Dial 1333 and describe the accident.

Wait for BHV services.

Instructions for BHV-ers: Do not turn on the scanner yourself call Siemens Service for further instructions.

5.2.3 FIRE

The first priority if a fire occurs is to ensure the safety of all personnel and the subject. In the case of a fire the Certified User will:

- Press the Emergency Shutdown Button;
 - Pressing this button cuts the power to the magnet room and removes electrical power of all components of the system other than the static magnetic field.
- Pull handle that disconnects the bed from the motor;
- Remove the subject from the magnet;

Activate the fire alarm;

The slow whoop signal will be audible.

- Leave the building

Wait for BHV services outside.

Instructions for BHV-ers:

Inside office hours. BHV trained support staff members will be beeped. At least six persons are needed. Two of them take care of the fire and quench the magnet if needed (see below), two take care of the evacuation of the building (see chapter 5.2.6), one makes sure no one is entering the front door, one waits outside for the fire department. BHV-ers from the other building will work together with a BHV-er from the support team. Monitor that personnel from the fire department only uses MR-compatible objects (*MR-compatible fire extinguishers are located throughout the building; Those fire extinguishers are labeled as MR-compatible and can be used inside the magnet room. The fire hose cannot be used in the magnet rooms.*)

Outside office hours. The first priority is to **ensure the safety of the subject and yourself**. One person will evacuate the subject and waits outside for the fire department. The other (the BHV-er) will evacuate the building and can try to fight the fire with the help of the security personnel of the UM alarm center (see below for general instructions) The BHV-er will quench the magnet closest to the fire if necessary (see below). Monitor that personnel from the fire department only uses MR-compatible objects (*MR-compatible fire extinguishers are located throughout the building; Those fire extinguishers are labeled as MR-compatible and can be used inside the magnet room. The fire hose cannot be used in the magnet rooms.*)



The first priority is to **ensure the safety of all personnel and the subject**. Only if the BHV-er can judge it as safe to fight the fire should they attempt to extinguish it themselves. A rough rule can be to say that if the fire has just started (i.e. confined to the point of origin, such as a trashcan or computer monitor) and all personnel are in safety, an attempt could be made if the individual judges the circumstances to be sufficiently safe to try. If, however, the fire has spread from its origins (e.g. to adjacent curtains), this probably indicates a situation too dangerous for an individual to attempt to extinguish the fire.

If the fire spreads it is necessary **to quench** the magnet before the fire has damaged the quench circuit and it has become impossible to quench the magnet. The decision if and when to quench the magnet is made **-inside office hours-** by the head of BHV advised by a member of the support team. **Outside office hours** the decision is made by the Certified User (advised by member of the support by phone) Quench the magnet closest to and threatened by the fire. If the fire spreads it is not safe to stay inside and therefore not safe to go to all systems to quench it. The other systems will be quenched by the fire department if necessary.

The head of the BHV team decides if it is necessary to evacuate the whole building, see chapter 5.2.6 about evacuation.

Smoke detectors are present in all magnet rooms. If smoke is detected it will set off the slow whoop. Fire indicators above the doors will indicate in which the room the fire is located. The scanners themselves have fire detectors as well. The scanner will give a warning and shut down automatically. Only after a reset in the technical room the scanners can be powered on again. Call Siemens for information before resetting the scanner.

5.2.4 OXYGEN ALARM SYSTEM

An oxygen alarm system is installed in each MRI magnet room. The system is linked to the central alarm system of the University of Maastricht. In each console room is a yellow light that indicates that the oxygen alarm has been activated. When the oxygen reaches a level under the oxygen alarm automatically will be activated. It indicates that there might be a helium leak.

MAGNET QUENCH

When the superconducting magnet quenches, the helium undergoes a dramatic thermal expansion and will be vented through the quench pipe. If the quench pipe fails - very rare cases - the expanding helium can fill and pressurize the magnet room. This can be a major threat to the safety of anyone in it. It can lead to suffocation because the helium will push the oxygen away. The knockout panel will automatically open if the magnet room is pressurized. The oxygen sensor is located in the technical room inside the exhaust pipe of the ventilation system of the magnet room. When the oxygen reaches a level under 17% the oxygen alarm will be activated.

FUNCTIONING AND PROCEDURES OF OXYGEN DETECTION & ALARM SYSTEM

If there are no alarm signs (i.e. if light is not illuminated) it's safe to enter the magnet room. If these alarm signs are present then **nobody** may enter the magnet room **except to evacuate a subject**. People inside the magnet room should leave the room as fast as possible. If a subject is present in the scanner the study **must be immediately terminated** and the subject removed as rapidly as possible. During the evacuation of the subject the magnet room door should be left open to help ensure the oxygen level remains high. Close the door after the evacuation of the subject. The oxygen alarm is linked to the main UM alarm system. Following an oxygen alarm, access to the scanner will be blocked and no further scanning is permitted until approved by the Scannexus Support Team as well as inside as outside office hours.

RESET OF THE OXYGEN ALARM

At the Scannexus scanner lab, the alarm will reset itself when oxygen levels return to normal. Thus if the alarm remains present, it's still **not** safe to enter the MRI laboratory. If, however, the alarm has reset itself, it is still the case that access to the scanner will be blocked and no further scanning is permitted until approved by the Scannexus Support Team

Instructions for support team: Contact Siemens for information about helium loss or potential quench. If there is no indication of helium loss, check with facility services if sensor in the technical room is faulty. This might have resulted in a false alarm. Facility services are able to read the sensor values from distance. If there is an indication for helium loss, wait till the alarm resets itself and ask facility services for sensor values.

5.2.5 QUENCHING OF THE MAGNET

If a metal object traps a subject in the magnet bore so that removal is not possible without "switching off" the static magnetic field, the Certified User will quench the magnet by pressing the magnet stop. In about 20 seconds the magnetic field will drop to a level where metal objects can be removed.

- Enter the Magnet room and remove the metal object.
- If possible, immediately evacuate the scanner area together with the subject and collaborators. The gurney can be used to move the subject from the patient table to the safe area.
- **Dial 1333** to inform the emergency service of the situation. If required, ask medical help for assisting the subject.

The scanners are located at Scannexus Scannerlab, Oxfordlaan 55.

- 3T: Room T0.009, Tel. 38 - 85669
- 7T: Room T0.027, Tel. 38 - 85670
- 9.4T: Room T0.026, Tel. 38 - 85831

- **Wait for BHV services.**

Instructions for BHV-ers:

Inside office hours BHV trained support staff members will be beeped. At least three persons are needed. Two of them take care of the subject and one wait outside for the ambulance. Note that access on the Uocard to the scannerlab is needed to enter the building. The support team informs Siemens about the quench.

Outside office hours the CU and the accompanying second person take of the subject. BHV trained security people will come from the UM alarm center. One of those two has to wait outside for the ambulance. Make sure this person can enter the building. Call a member of the support team (mobile phone numbers are available in the console room). The CU or member of the support team dials **(0) 070 333 2752** to inform SIEMENS of the emergency immediately. Siemens has to start refilling the magnet on the same day to keep damage to the system as small as possible. Regardless of the use of the Magnet Stop button, **always** assume the magnet is **on**.

However, if no subject is trapped or in imminent danger of being trapped or injured by a metal object, do **not** quench the magnet and do **not** attempt to remove the object! Contact Scannexus personnel who will arrange the safe removal of the object.

5.2.6 EVACUATION

An evacuation of the building will be announced by the sloop whoop signal. Stop scanning immediately, take your subject out of the scanner, shut the door to the magnet room, but do not lock. Leave the key in the door and leave the building.

Instructions for the support team: 1) Warn all CU's who are scanning at the moment. 2. Go to the main reception 3. Wait for instruction from the BHV head.

Instructions for BHV:

Inside office hours: The head of the BHV decides if the building needs to be evacuated. At least five persons are needed. One should stay in front of the door to prevent people from walking in. Two will check the TMS lab and the RF lab. The other two will walk through the building starting with 3T console room and to make sure it is empty. Close all doors if empty, but do not lock. If the door in middle of the 9.4T magnet room to the upper floor is locked one might assume that nobody is upstairs. Do not forget to check the kitchen and technical room upstairs (above the kitchen)

Outside office hours: The first priority is to **ensure the safety of the subject and yourself**. BHV trained security people will come from the UM alarm center and they will take care of the evacuation if necessary.

6 GENERAL GUIDELINES REGARDING SUBJECTS

6.1 BEFORE THE MEASUREMENT

It is strongly advised for the Certified User to interview potential participants of the MRI experiments using either their own screening procedure, or the Scannexus recommended online screening procedure (*see Appendix 5*). If there are no counter-indications for MRI, a measurement can be scheduled. In the case of any doubt, do **not** scan the subject.

When the subject arrives for the measurement, the Certified User will make sure that nothing has changed since the filling of the screening form and will, again, carefully screen the subject for any implanted material that could constitute a risk in the scanner using the safety screening form (*see Appendix 5*). **If the subject is not sure about the answer to any of the safety screening questions, he/she will not be scanned.**

If there are **no counter-indications for MRI** and the **safety screening form** (*see Appendix 5*) **has been understood and signed**, the measurement can start.

Important: No one may be scanned unless he/she has completed the **Scannexus safety screening form**. It is also strongly advised to complete a **screening procedure** (for the first measurement and/or in the case something changes).

The subject has to remove all metal from the body, like piercings, metal in clothing etc., before entering the magnet room. The subject will lie on the bed outside the magnet and be positioned in the coil. The subject will be given ear-plugs and if possible, the subject should also wear headphones.

The subject must be given the alarm ball. No cables should touch the subject's skin. Looped cables should not be placed near the subject. Any unused cables transmit or receive coils, or any other unused equipment should be removed from the bore and from the RF coil. The subject must be instructed not to cross arms and legs. Any equipment to be brought into the magnet room must be approved for MR compatibility by the Scannexus Support team. MR compatibility must be documented. The laser is used to position the part of the body that needs to be scanned in the isocenter of the bore. The bed is then advanced into the magnet at a defined rate through a computer-controlled interface.

6.2 DURING THE MEASUREMENT

Subjects will be in constant voice contact with the operator via an intercom system. Subjects who cannot communicate reliably with the console operator should not be studied except in specially defined protocols (e.g. deaf subjects). Given the potential risks of peripheral nerve stimulation and overheating associated with rapid dynamic imaging, the Certified User should frequently inquire about the subjects comfort and

room temperature. Typically some verbal contact should be made with the subject prior to each scan. The operator must not leave the console during the measurement. If, at any time, a subject becomes unable to tolerate the procedure, the study must be terminated. Each examination will last approximately 0.5 - 1.5 hours.

6.3 AFTER THE MEASUREMENT

Following each scan session, the operator should enquire the subject about his/her status. Any discomfort and problem reported by the subject should be documented in the digital logbook on the Wiki.

6.4 SUBJECTS SAFETY

As described above, the primary risk for subjects is from metallic objects brought into the scanner room that could become projectiles. To minimize this risk, nonessential personnel are excluded from the scanner room to insure that no ferromagnetic objects are brought near the magnet. No one may enter the magnet room unless they have been screened and checked for metal objects by the Certified User running the console.

Reviews of the few cases where metal objects caused death or injury during a scan have found confusion about who had the authority and responsibility to prevent metal objects from entering the scanning room. The Certified User has the ultimate authority to enforce safety standards. In addition, before any behavioral or physiological device is brought into the magnet room, it must be reviewed by the technical team.

6.5 VISITORS

Visitors are not permitted in the console room without prior approval of a Certified User. Visitors or assistants to an experiment are not allowed in the magnet room without screening for safety (including safety screening form) as described in this document and will be under the responsibility of the Keyholder (the CU who has ownership of the Keyholder key, see above).

When a visitor or visiting group, such as a visiting scientist, television or radio crew, or a student group wants to visit the lab this has to be reported at least 24 hours in advance, to the Senior Operations and Technical Development Officer and CEO of Scannexus, mentioning the number of people, the reason for visit and the responsible CU. The responsible Certified User has to be an experienced user. In case of a scanning session during the visit, the Certified User warns the members of the group of the MRI-related safety issues (e.g. using the demo video) before scanning. None of the group is allowed to enter the magnet room. The Certified User is responsible for the privacy of subject and the secrecy of his/her MRI data and the ethical issues surrounding media coverage of his/her scanning session, including obtaining full written permission from the subject and consulting the appropriate ethical committee to clear the planned media activities. The group has to leave the lab immediately after the booked timeslot is past. The header of the reservation

should mention not only the acronym but also the name of the responsible Certified User, as is required for any scanner agenda booking.

6.6 GENERAL GUIDELINES CHILDREN

Generally, all normal safety procedures as stated in the guidelines of Scannexus apply.

As an extra guideline for research projects which involve children, two CUs have to be present during the scanning session. One CU will be taking care of the child and is responsible for safety. The other CU will take care of the parent/guardian, prepares the experiment, etc.

As usual, ethical approval is required for any scanning.

6.6.1 PREPARATION OF CHILDREN

It is recommended to use the online screening forms and inform the parent/guardian and child before inviting them for a scan session to make sure the child is eligible for the study.

In the first visit, the study will be again explained when the parent/guardian and the child arrive. As a preparation it is recommended to show an instructive video to the child. It is highly recommended to do a training session in the Mock scanner and a head motion training before scanning the child for your study.

The following forms have to be filled in:

- The parent/guardian who is present is **responsible** for filling in the forms (online screening and safety screening) in the name of the child.
- **ONLY** if the child is between 12 and 18 years old, the child has to sign a safety screening form as well.
- The parent/guardian fills in a separate safety screening form for themselves.

IMPORTANT:

Make sure that the parent/guardian as well as the child understands the importance of the check for metal objects. Also reassure them about the safety of MRI, since there is plenty misconception.

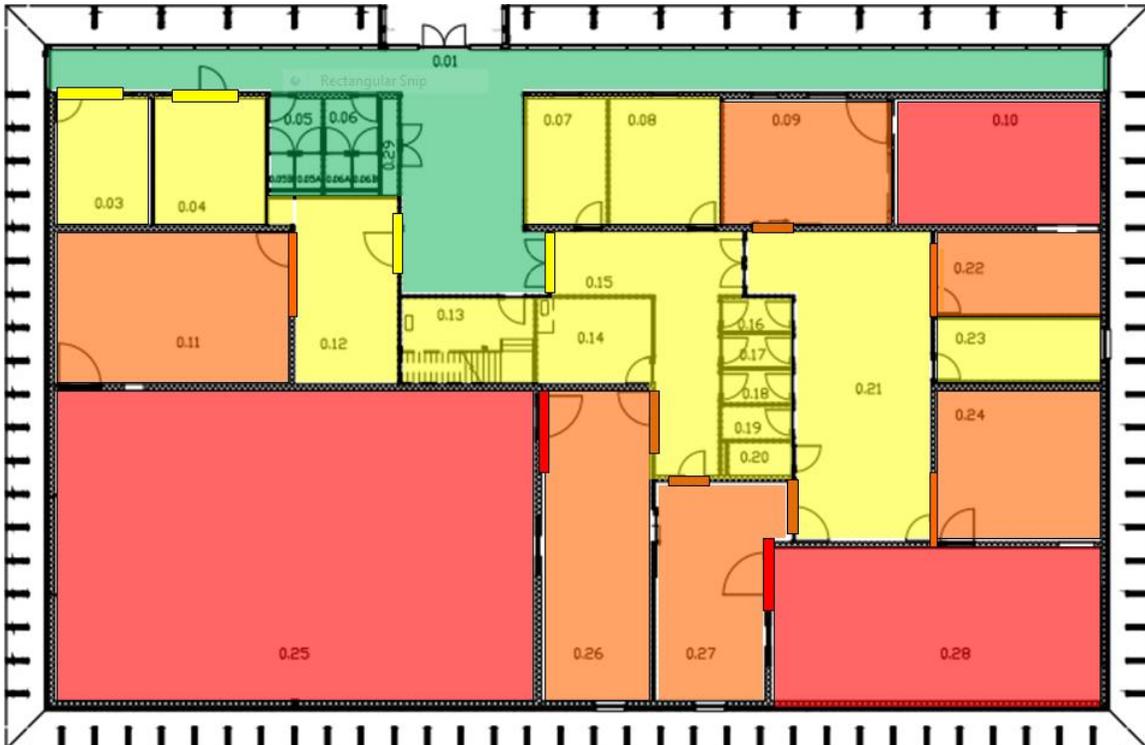
6.6.2 CHECKS

The parent/guardian and child can be brought into the control room after all necessary precautions are taken.

ALL persons present in the control room must remove every metal object: parents/guardians, child and researchers. It is recommended to check the parent/guardian for metals. This will serve as a precaution to avoid risks in case of emergency.

APPENDIX 1 FOUR-ZONE CONCEPT OF SCANNEXUS

Map of the Scannexus Scannerlab, Oxfordlaan 55.



- Zone 1: green shading
- Zone 2: yellow shading
- Zone 3: orange shading
- Zone 4: red shading

APPENDIX 2 DOCUMENTATION ON CERTIFIED USERS

After the Certified User training you have to confirm that you know how to operate the scanner and that you are aware of the risks and safety issues related to MRI and Scannexus-specific procedures, by signing the Certified User Agreement. This will be also signed by a member of the Scannexus Support Staff.

BASIC REQUIREMENTS

- Attendance to all the Certified User Training sessions.
- Knowledge of Scannexus procedures for handling volunteers and scanning (see checklist)
- Hands-on training with the MR Support Team until (s)he is satisfied that the system can be used both safely and efficiently (see checklist).
- Signature on a document stating that Certified User has read and understood all items and will comply with regulations.

To become a Certified User he/she must be cognizant of the following rules / items.

RESPONSIBILITIES OF CERTIFIED USERS

- To ensure that they are responsible for the safe usage of the scanner from the moment that they open the scanner room door till the moment that they lock it again.
- To ensure controlled access to the magnet room for volunteers and visitors.
- To ensure that objects brought into the magnet room have been certified as safe.
- To ensure that their knowledge of MRI safety regulation and access procedures is always up-to-date when they perform MRI research.
- Not to start scanning if there are aspects of safety, operation or regulation that they are unsure of. They are in case of doubts about their own knowledge or otherwise required to ask the Scannexus Support Team for advice and instructions.
- To ensure that the system and rooms are left in an orderly and clean state.
- Ensure to keep to the scheduled system times.
- It is the responsibility of the Certified User to conduct proper screening for contra indications.

KEY SYSTEM

- Know where the Key for the magnet room can be found.
- Know the responsibilities by picking up the Key.
- To keep the Key in the key-lock of the MR scanner at all times when the magnet room is open.
- Never lock the door of the magnet room during scanning of a subject.
- Never leave the console area during scanning of a subject.
- The door to the scanner room must remain locked at all times when the room is not in use.
- Unauthorized persons may enter the magnet room only when accompanied by a Certified User. Before entering, the Certified User must check if it is safe for the persons to enter the scanner room. All people should sign the safety screening form onsite and are strongly advised to have completed a screening procedure beforehand (either own procedure or the Scannexus online screening forms).

RULES CONCERNING SUBJECTS

- Be sure that the subject has read all the information (latest version). It is also strongly advised that they have completed a screening procedure beforehand (either own procedure or the Scannexus online screening forms).
- Be sure that the volunteer fills in the safety screening and check if all questions are answered and the papers are signed.
- Know what the exclusion criteria are.
- Able to inform the subjects about the possible effects of an MR session (peripheral nerve stimulation, heating, noise).

- Able to position a subject correctly.
- ⊖ A metal wire behind teeth is allowed **ONLY** at 3 Tesla and 7 Tesla and is an exclusion criterion at 9.4 T. In this case that the subject has a metal wire and is being scanned at 3 T or 7 T, the Certified User must inform the subject about the risks. He/she must answer the question regarding metal parts in the body (safety screening form) with Yes.
There are some details we need to know for a review reference of the ECP: after the scan, the participants with wire behind the teeth will receive some general questions with regard to potentially negative experiences. We have created a document for this located in the console room. Please let your subject note down their experiences!
- ⊖ A small tattoo is allowed at 3, 7 and 9.4T. The Certified User must inform the subject about the risks. He/she must answer the question regarding tattoos and permanent makeup (safety screening form) with Yes.
- In questionable cases **ONLY** a member of the MR Support Team can approve scanning the subject!
- Ensure that the subject is wearing appropriate ear protection (headphones or ear plugs) during the course of the experiment.
- Ensure that subject received alarm squeeze ball and verified its function.
- Use a clean table paper every time, also on the head-cushion and replace covers for the ear foam.
- The use of EMG/EEG co-recording equipment requires an additional certification by The Scannexus Support Team. Investigators must obtain this certification before their scanning session.
- Ensure that the maximum time for subjects to stay in scanner is not exceeded, as well as all other requirements of the relevant Ethics Board approval.
- While there is no known effect of exposure to strong magnetic fields, even over long durations, users should be aware that the generally accepted limit has until recently been a time-averaged exposure of 0.2T. If this limit is used as a guideline, based on an exam time of 1.5 hours, a subject could be scanned at 3T every 1.5 weeks, at 7T every 3.5 weeks, and at 9.4T every 4.7 weeks.

LOGBOOK

- Write down in the digital logbook any incident or malfunctions with scanner or stimulus equipment.

INTERCOM AND MICROPHONE

- How to use the Siemens intercom
- How to use the microphone in case of auditory stimuli
- How to reset the alarm

OPERATION OF MR-SCANNER

- How to place, position and remove the coils
- How to move table in/out of magnet
- How to stop movement

- How to register subject
- How to use Exam explorer
- How to start examination
- How to use Patient Browser
- How to export the data to the servers
- How to export PDF
- How to reboot the MR-scanner
- Where to find the manuals (quick guide) of scanner
- How to adjust the light (both in the room and bore)

OPERATION OF STIMULUS EQUIPMENT

- How to use the projector
- How to use the button box
- How to use the in-ear system
- How to use the mixer

SAFETY

- Places of emergency buttons
- When to use Magnet Stop button (Quench)
- When to use Electrical shutdown
- When to use Table stop button
- How to get subject out of magnet in case of emergency or power breakdown
- Emergency procedures
- Place of list with emergency phone numbers
- Knowledge of the closest "MR safe" area for each scanner

INCIDENTAL FINDINGS

- Follow procedures in Guidelines/Summary

ENTRANCE TO THE SCANNEXUS BUILDING

- Know what the rules are out of office hours.
- Know how to enter the building out of office hours.



scannexus

CERTIFIED USER AUTHORISATION

version 1.0

Certified User Authorisation – 3T MR System

I hereby declare that I have been instructed in, and am cognizant of the following:

1. Basic knowledge of MR safety such as to avoid damage or injury while I am responsible for the scanner.
2. The rules and regulations of Scannexus as outlined in the Scannexus Guidelines.
3. The items mentioned in the checklist.
4. If I fail to take responsibility for the rules and regulations outlined in the Scannexus Guidelines my privileges as a CU will be withdrawn.

I commit myself to following these procedures at all times.

Name:

Signature:

Date:

Authorized by:

APPENDIX 3 INCIDENTAL FINDINGS

It is not the investigator's job to check for or to diagnose medical problems in anatomical brain scans. However, it is possible that you cannot help but notice ('incidental observation') an anatomical feature that appears out of the normal range (e.g. a space-occupying tumor). If students or student assistants are involved in the measurements, CUs should monitor that the students they supervise do not give out (or show) the images to the subject (unless previous approval of the CU).

Scannexus offers the following procedure for users to follow in case of incidental findings. Users are free to use other means of checking incidental findings. If users choose to use the Scannexus procedure, they must follow the steps hereunder.

A. Steps to take after incidental observation

1. In principle, if you (the investigator) notice something that appears out of the ordinary on an anatomical scan, you must do everything you can to NOT immediately inform the subject.
2. If the subject does become aware of the fact that a potentially aberrant anatomical feature was present, then inform the subject that a medical expert will be consulted, and that the subject will be contacted by phone.
3. When the subject leaves the room, you must immediately seek contact with the qualified medical expert associated with the Maastricht Brain Imaging Center (dr P. Hofman, Department of Radiology azM, telephone xx31-43-387 4910) and ask whether the anatomical observation requires medical follow-up.
4. In order to provide Dr Hofman with the relevant data, you also contact the SCANNEXUS Support Team via scanlabs@scannexus.nl. See paragraph D hereunder.
5. For non-staff members: If you are not a staff member of our faculty (e.g. student, PhD student, external user / visitor), you must immediately inform the senior staff member who is your supervisor (contact person) about the situation.
6. After receiving feedback from the medical expert, the subject must be contacted as soon as possible by phone.
 - a) Subjects for whom medical follow-up is recommended must be invited for a conversation, and for pick-up of their referral letter.
 - b) Subjects who had become aware of the presence of a potentially aberrant feature (A.2), but for whom follow-up was not recommended should also be called and informed.
 - c) Subjects who had not become aware of the presence of a potentially aberrant feature (A.2), and for whom follow-up was not recommended should not be called.

B. Supporting conversation with a subject after incidental observation

1. The aim of the conversation is to help subjects with the uncertainty that is created because of the observation of a potentially abnormal anatomical feature in the brain.

- i. The conversation immediately after an incidental observation of which the subject has become aware (see A.2) should explain the procedure that will be followed, and reassure the subject.
 - ii. The conversation after handing over of the referral letter (see A.4) should inform subjects that follow-up has been recommended, and help subjects to deal with the uncertainty that has been created.
 - iii. It is not the aim of this conversation to comment on medical risks, prognosis, diagnosis, etc., simply because the medical follow-up still has to take place.
 - iv. Before engaging in this conversation, contact the Ombuds-person (see C).
2. Contacting the subjects to invite for a conversation (see A.4), or to inform them that follow-up is necessary or not (after A.2) should take place by phone rather than by mail or email. This allows for at least some intervention in case the news relayed in the phone conversation elicits emotional reactions in the subject.

C. The role of the Ombuds-person

1. All investigators exposed to an incidental observation must contact the Ombuds-person (R. Hoekstra MSc, Secretary to the Ethics Committee Psychology, Faculty Office FPN) before this information is discussed with the subject and a referral letter is handed over.
2. In consultation with the Ombuds-person, it is decided whether the referral conversation is held by the Ombuds-person, the investigator, or by both. In case you are not a senior staff member: the conversation must be held together with either the Ombuds-person or with your supervisor.
3. After the referral conversation, subjects should be made aware of the possibility to contact the Ombudsperson for further help.

D. Storage and use of anatomical data associated with recommendation for medical follow-up

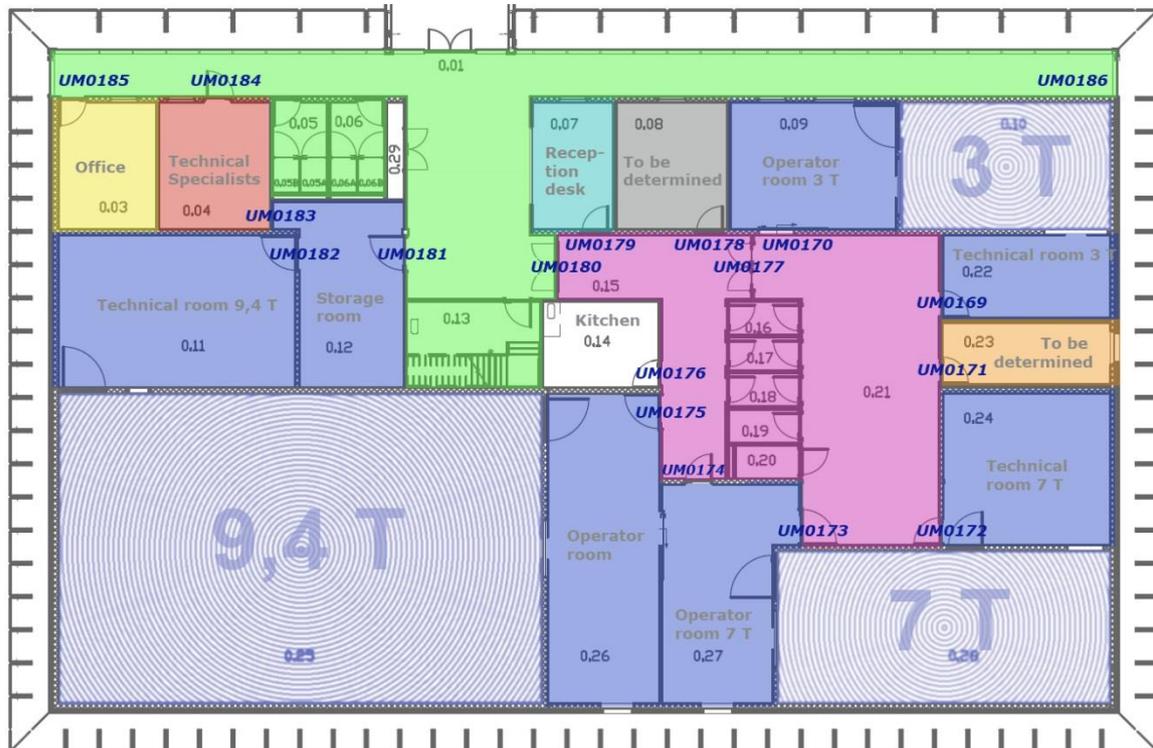
1. Data will be stored by the Scannexus Support Team in a password-protected, read-only directory.
2. Access will be restricted to the researchers involved in the project, and the medical advisor.
3. Storage will be confidential, but not anonymous.
4. Use of the anatomical data for the original scientific purpose of the project (and which handles the data in an anonymous way) remains permitted if the anatomical abnormality itself is not visualized in the resulting publication, or in any other media (e.g. a poster).
5. For any other use of the data (e.g., analysis of image material related to the anatomical abnormality), explicit written consent of the subject must be obtained.

E. Subjects who do not have a (local) GP

In the event that the subject with an incidental observation does not have a local GP, and the referral to a medical specialist would take some complicated routes, the chair of the Department of General Practice, professor Job Metsemakers MD, is available to see the subject and refer this subject to a specialist if expected necessary. In such cases, the contact with professor Metsemakers will be made by the Ombuds-person.

APPENDIX 4 ROOM ACCESS CONTROL

Access Control to Scannexus Scannerlab, Oxfordlaan 55.



Authorization Profile	Explanation & Remarks	Card Readers	Colour Combination
OXF55 Lab003 24/7		UM0186, UM0185	
OXF55 Lab004 24/7		UM0186, UM0184	
OXF55 Lab008 24/7		UM0186, UM0180, UM0178	
OXF55 Lab014 24/7		UM0186, UM0180, UM0176	
OXF55 Lab023 24/7		UM0186, UM0180, UM0171	
OXF55 Reception 24/7		UM0186, UM0180, UM0179	
OXF55 MTP 24/7	Magnet Trained Personnel	UM0186, UM0180, UM0181, UM0182, UM0170, UM0169, UM0172, UM0173, UM0174, UM0175	
OXF55 Key Cabinet 24/7	At all times in combination with another profile	UM0177?	
OXF55 AA 24/7	Approved Acces	UM0186, UM0171, UM0176, UM0178, UM0184, UM0185, UM0180, UM0181, UM0182, UM0170, UM0169, UM0172, UM0173, UM0174, UM0175, UM0179	
OXF55 Basic 24/7		UM0186, UM0180	

APPENDIX 5 FORMS AND IMPORTANT LINKS

SCREENING AND SAFETY SCREENING FORM TEMPLATES

<http://scannexus.nl/information/documentation>

WIKI

<http://137.120.141.83:8090/>

CALPENDO

<https://scannexus.calpendo.com/>

FTP SERVER

<ftp://ftp.scannexus.nl/>

DATABASE (ONLINE SCREENING AND RECRUITEMENT)

<http://db.scannexus.nl/>

APPENDIX 6 CALPENDO

- Rules in Calpendo
 - No double bookings are possible.
 - CUs can only book resources connected to their own project.
 - Only members of the 3T group can create 3T bookings requests.
 - Only members of the 7T group can create 7T bookings requests.
 - Only members of the 9.4T group can create 9.4T bookings requests.

- Bookings
 - Projects associated with the two UM faculties (FPN or FHML) have to book in designated time blocks.
 - Allocation of time/slots within these blocks is decided by the appropriate faculty.
 - With permission of the appropriate faculty, projects may book outside their designated blocks -in slots not already occupied by another project- but not in the block of another faculty.
 - These out-of-block bookings can only be made within four weeks of the date of scanning.
 - Projects that are not associated with the two UM faculties, can be booked freely in the out-of-block slots. The four weeks booking window does not apply for these projects.
 - Bookings in out-of-block slots must apply to the following Scannexus rules:
 - Bookings must be consecutive. If not possible: the gap between bookings has to be at least 60 minutes.
 - Booked timeslots can only be cancelled a week in advance.
 - Timeslots may be lengthened if the measurement exceeds the booked time (if possible) but not shortened if the measurement ends early. This has to be communicated with Support staff.
 - If a booked time slot will not be used by the original booker, they may contact other researchers to take over the time slot. This has to be communicated with Support staff.

- Users
 - Users will not be approved until there is a project available in Calpendo for them to book on (thus a signed project agreement). Users of the mock scanner form an exception to this.
 - Support Staff must be present during the first scan of a CU.

- Tours
 - Request for tours at shorter notice than 24 hours will be refused regardless of availability of staff or resources.
 - No tours can be made in areas where scanning is happening for reasons of safety, patient privacy and researcher concentration.
 - A member of the Scannexus Staff must be present for every tour.

APPENDIX 7 OVERVIEW OF THE RULES

- Scanning rules:
 - By picking up the key and unlocking the magnet room door, the CU becomes the Keyholder and takes responsibility for safety until the door is locked again and the key returned.
 - Any incident or near incident of a projectile accident must be reported to the Scannexus Support Team.
 - Equipment damage or failures must be reported in the logbook and to a member of the Scannexus Support Team.
 - CU is responsible for leaving the magnet room and console room in the condition which they found it. Any problems should be reported to a member of the Scannexus Support Team.
 - Do not bypass the door card readers by leaving the doors unlocked.
 - Do not bypass the card system by lending out your Umcad, this card is strictly personal!
- Scanning during out of office hours:
 - One CU and one person with at least Magnet Safety training have to be present.
 - One of the users has to be an ERO (BHV).
 - Out of office hours are: **before 9:00, after 17:00**, and during the weekends and national holidays. Additional out of office hours will be identified in Calpendo.
- Taking others with you to your scan sessions:
 - Do not leave uncertified people (for example interns/ students) without you in the rooms (including the room with the mock scanner!).
 - Uncertified people cannot be given responsibilities around the scanners.
 - Do not take uncertified people with you into the magnet room if it is not absolutely necessary.
 - Anyone who enters the magnet room has to complete the safety screening form.
 - Do not bring visitors to your scan session.
- Visitors:
 - A tour is not allowed during a scan session or maintenance: a timeslot must be booked. Submit the request for the visit at least 24 hours in advance. Approval of the CEO and Senior Operations and Technical Development Officer is required.
 - A tour must be accompanied by a member of the Scannexus staff.
 - Do not enter the magnet rooms.
- Magnet room objects clearance:
 - It is prohibited to introduce and use in the magnet rooms any device or instrument that has not been tested and approved by the Scannexus support team/ Senior Operations and Technical Development Officer.

The senior and support staff of Scannexus have the authority to ask anyone present within the MR scanner rooms to immediately leave these areas. Such a request must be immediately obeyed by said person.

APPENDIX 8 LIST OF IMPORTANT TELEPHONE NUMBERS
**Contact numbers for MRI Scanning Facility -
Oxfordlaan 55**

Room	Room #	UM phone
Reception	T0.007	85668
3T Console	T0.009	85669
7 T Console	T0.027	85670
9.4T Console	T0.026	85831
RF Laboratory	T0.004	85667



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Person	UM Phone	Mobile	E-mail
Support Team	85668	06-38764939	scanlabs@scannexus.nl
Christopher Wiggins	84802		c.wiggins@scannexus.nl
Esther Steijvers	85668		scanlabs@scannexus.nl

Service	UM Phone	Full number
Servicedesk Facilitaire Dienst	82002	043-3882002
Security/Burglar Alarm	75566	043-3875566
UM Emergency	1333	043-3882452 / 112
Siemens Hotline	070-3332752	070-3332752

INSIDE OFFICE HOURS: Contact the Support Staff for any problems (speed dial button on the phone!)	OUTSIDE OFFICE HOURS: Chris Wiggins, Esther Steijvers
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