

# **GUIDELINES AND PROCEDURES**

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

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# **1** INTRODUCTION

The Scannerlab of Brains Unlimited B.V., brand name Scannexus has been equipped with three wholebody 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; a small chem lab and a dummy scanner.

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 on MR safe practices, updates and critical information 2019;
- Onderzoek naar mogelijke langetermijneffecten van elektromagnetische velden op de gezondheid van werknemers, update 2019;
- Leidraad veilig werken met MRI, NVMBR 2019;
- European guide for minimum of safety requirements to risks regarding workers being exposed to electromagnetic fields
  - http://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=7845&type=2&furt
     herPubs=yes;
  - http://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=7846&type=2&furt
     herPubs=yes;
- GUFI (German Ultrahigh Field Imaging) guidelines:
  - <u>https://mr-</u> gufi.de/images/documents/Approval\_of\_subjects\_for\_measurements\_at\_UHF.pdf

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, Senior Operations and Technical Development Officer, Manager Operations and the Scientific Manager, 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 Team of Scannexus. The following table summarizes responsibilities:

Role	Responsibilities
Senior Operations and Technical Development Officer	<ul> <li>Supervise and approve safety regulations as described in this document</li> <li>Advise CEO</li> <li>Scannexus Senior Operations and Technical Development Officer is the nominated Safety Officer</li> </ul>
Manager Operations	<ul> <li>Work with Senior Operations and Technical Development Officer on safety regulations</li> <li>Advise CEO</li> </ul>
Scientific Manager	<ul> <li>Work with Senior Operations and Technical Development Officer on safety regulations</li> <li>Advise CEO</li> </ul>
Scannexus MRI Research Technicians (MRI Research Technicians under direction of Senior Operations and Technical Development Officer)	<ul> <li>Train and instruct Certified Users</li> <li>Supervise Certified Users in the time assigned by Scannexus Management</li> <li>Suggest changes and improvements to safety regulations as described in this document</li> <li>Conducting MR research in the Scannexus MR facility according to these rules</li> <li>Ensuring safety of his/her subjects, himself/herself and anyone else inside the MR lab at the time of conducting experiments</li> <li>Ensuring care in granting other people access to the Scannexus MR facility</li> </ul>



Certified User	- 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 MRI Research Technicians and Certified Users will have training to meet the requirements of 'Level 2 MR personnel' as defined in the ACR updated guidance document for safe MR Practices: 2019. 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 Management Team 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 within the Management Team 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 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. The Safety Review Board advises the MR Safety Officer. This Safety Review Board consists of members connected to the different faculties of Maastricht University and radiology department of MUMC.

#### 2.2 SAFETY TRAINING

All individuals working within at least Zone 3 (*see Four Zone Concept par.2.4, appendix 1*) 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.
- A liability insurance is obliged when conducting MR scanning of human research participants.

#### 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 Chapter 3; 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 MRI Research Technicians)
- Zone 4: Screened MRI individuals under constant direct supervision of trained MR personnel (Certified Users, Scannexus MRI Research Technicians)
- 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 Research 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 magnet room while the RF and gradients are operating.
- The Senior and Support Staff of Scannexus (CEO, Manager Operations, Scientific Manager, Senior Operations and Technical Development Officer and MRI Research Technicians) have the authority to ask anyone present within the magnet rooms (yellow, orange and red-labeled areas) to immediately leave these areas. Said person must immediately obey such a request.

# 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 research participants out of office hours (before 9:00h and after 17:00h), weekends or national holidays, 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 Par. 3.3; 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

- Researchers are strongly advised to screen the research participants in MRI studies prior to inclusion of the participant into the study. Researchers must use their own screening procedure for this pre-screening.
- 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 contra indicated 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. A personal folder is then created at this server. Users can export the acquired data from the scanner to the personal folder on the BU server. NOTE: This folder is not meant for permanent storage. It is an intermediate step to own backup of data.

This server is backed up by Scannexus. The size limit is 1TB. After 3 months of inactivity, the personal 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 is accessible by all users granted access on the BU server. This folder is emptied automatically on a weekly base.

# 2.8 INCIDENTAL FINDINGS

It is not the investigator's job to check for or to diagnose medical problems in anatomical 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. A Scannexus procedure in case of incidental findings is written in *Appendix 3*.

# 2.9 EMERGENCY OR ILLNESS

- The Certified User (Keyholder) must evacuate an individual or research participant who becomes ill or injured, from the magnetic environment, immediately. Evacuate this person to the safety area. After this, an incident form must be completed.
- If there is an emergency that takes place in or around the magnet, the Senior Operations and Technical Development Officer and Manager Operations 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

#### Attraction

- 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 Safety Review Board and the MRI Safety Officer are allowed to enter the magnetic environment of the magnet 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 MRI Research Technicians 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 SOTDO or Scannexus MRI Research Technicians; they have access to non-magnetic tools for such work.

#### 2.10.2 RADIO FREQUENCY (RF) ELECTROMAGNETIC FIELDS

#### Heating

- Only properly trained individuals should operate devices and monitor equipment in the magnetic environment.
- RF pulse timing sequences that exceed FDA Specific Absorption Rate (SAR) limits must not be used. The scanners limit risk of exceeding SAR.
- 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 MRI 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 Review Board and Safety Officer.

# 2.12 ACOUSTIC NOISE

- Research participants must be supplied with hearing protection to meet the national guidelines: the earplug and if possible, 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

- Do not scan a participant in case of a fever.
- 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 Manager Operations, 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 MRI Research Technician(s) or MR Safety Officer, by the Certified User or researcher involved. Incident form must be completed and handed over to Manager Operations.
- Equipment damage and/or failures must be reported to the Senior Operations and Technical Development Officer or the Scannexus MRI Research Technician(s) and must be documented



via the Service Helpdesk of Scannexus. Incident form must be completed and handed over to Manager Operations, in case scanning had to be stopped of system failure.

Facility safety breaches must be reported by the Certified User to the Scannexus MRI Research Technicians and/or Safety Officer.



# **3** SAFETY ORGANIZATION

Enforcement of safety rules, as well as daily organization and user support, is the task of the Scannexus MRI Research Technicians. 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. The Safety Review Board advises the MR Safety Officer.

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 2019". 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).
- o 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.
- o 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

Within the scanner building different access levels/profiles are present (see table below). Access is granted after completion of specified training levels. The allowed access profile is added to the UM or MUMC ID cards. For external users Scannexus provides a guest card.

Authorization to request UMcard to add access profiles to the ID cards, is given to Scannexus personnel only!

Main access profiles are:

- Access Profile "AA" (Approved Access) allows access to <u>all</u> rooms of the scannerlab, exclusive magnet rooms (Key Cabinet). This is given to employees of Scannexus only!
- Access Profile "MTP" (Magnet Trained Personnel) allows access to all common rooms and the scanner console and technical rooms.
- "CU" profile provides MTP access and access to the scanner room key for the scanner of which the CU is trained for and signed the CU agreement (*Appendix 2*).

To gain access, training within Scannexus is obliged. The present Certified User training is divided into two units: Magnet Safety Training and MR System Operation training. Participating in the Magnet Safety Training will allow you to have MTP Access. Access to the CU profile, is given after completion of the Magnet Safety Training and the MR System Operation Training. The MRI Research Technicians are responsible for training and upgrading of Certified Users.

The requirements for, and the responsibilities connected with the approval of MTP Access and CU profile Access, are:

- $\circ$  MTP has attended the Magnet Safety training as evidenced by signed documentation.
- $\circ$   $\,$  CU is 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
- 3) CU agreement; an authorization form that a Certified User will have to read and sign after the Certified User training.

-

Depending on the Access Profile, the card access will be changed appropriately (see table below). The corresponding room access floorplan is shown in *Appendix 4*.



Authorization Profile	Explanation & Remarks
OXF55 MTP 24/7	Magnet Trained Personnel; Access to the scannerlab, console
	rooms and technical rooms
OXF55 Key Cabinet 24/7	At all times in combination with CU or CU profile
	(MST light for chem. lab key only)
CU profile	Certified Users; Access to the MR key of the magnet room of which the CU has signed the CU agreement + MTP profile
OXF55 MST light	Access during weekdays 08-18 hours. (needed for chem. lab key in Key Cabinet, room 0.03 and room 0.12A)
OXF55 AA 24/7	Approved Access; Access to all rooms, exclusive key cabinet
OXF55 Reception 24/7	Access to room 0.07 (Scannexus personnel only)
OXF55 Basic 24/7	Access to door outside and main entrance scannerlab + MTP profile
OXF55 Lab003 24/7	Access to room 0.03 + MST light profile
OXF55 Lab004 24/7	Access to room 0.04 (for RF lab users only)
OXF55 Lab008 24/7	Access to room 0.08 + MTP profile
OXF55 Lab014 24/7	Access to room 0.14 + MTP profile
OXF55 Lab023 24/7	Access to room 0.23 + MTP profile
OXF55 Lab012A	Access to room 012A and B + MST light profile



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

Scannexus personnel has 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, Scannexus personnel will provide the cleaning service or external technical personnel access to magnet or technical room, perform the mandatory screening and instruct them. The Scannexus MRI Research Technicians will perform checks of scanner function.

#### 3.3 MRI SCANNER OPERATOR - MAGNET ROOM ACCESS AND RESPONSIBILITY

Access to the magnet rooms is given via an electronic Key Cabinet. With UM ID cards access will be given to the Key Cabinet 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.

- 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 the Key Cabinet.
- If two CUs are scanning at the same time, the Keyholder is the CU who picked up the magnet room key.
- The door must not be locked while scanning a research participant. Leave the key in the door lock while scanning.
- The Keyholder's responsibility for safety only ends when the magnet room door is locked and the key is returned to the Key Cabinet.
- 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.
- Failure to ensure that the key is placed in the Key Cabinet will cause problems for following scan slots. Therefore failure to do this will result in a loss of booking privileges for the Keyholder. The Keyholder is responsible for leaving the magnet room in the default condition in which they found it.

Usage of the Key Cabinet 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, MTP, 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 already a screening procedure one week before the scan date, 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 are 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 just 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. For this, the Service Helpdesk of Scannexus must be used.
- Register any problem or discomfort experienced by the subject on the incident form provided by Scannexus.
- Use the Calpendo calendar to register the use of the MR scanner. The CU conducting the measurements must be noted in the booked scan slot.

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 an MRI Research Technician or a member of the Scannexus Team. They ensure 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 in screening research participants). Cleaning personnel is trained in Magnet Safety by participating in a short Magnet Safety Training. Cleaning personnel will only use labeled MR-compatible tools. Detailed modalities regarding these procedures have been defined with the Facility Services, Maastricht University. The communication



of these modalities to the head of the cleaning personnel is the responsibility of the head of the Facility Services, 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 MRI Research Technicians.

#### 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 Safety Review Board and Safety Officer. 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 scannerrelated emergencies (including fire in the magnet room) are described in detail below in this document (see *Procedures for MR- related Emergencies in Chapter 5*).

Additionally, a detailed description is available as a part of the SIEMENS safety instructions/video (part of the Magnet Safety Training) 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. Start CPR immediately if necessary. Individuals in the magnet room are evacuated from the scanner room asap (Zone 4) to a predetermined magnetic safe location (Zone 2).

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

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 must 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 national 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, weekends and national holidays, CUs will need to pick up a Burglar Alarm (BA) key from the Key Cabinet, to unset or set the burglar alarm.

- CUs should pick up the BA key at least 24 hours before their scan slots.
- BA 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 BA key on to another user.

The booking CU is responsible for obtaining and returning the BA key for their scan slot. Usage of the Key Cabinet 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 preces (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 obliged to let every subject undergo a standard screening procedure to determine whether they have any implanted materials that may pose



a risk (see link to screening forms, *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. In 2015, Siemens introduced the first clinical approved 7T scanner, MAGNETOM Terra.

# 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. This means not using the speed button at the 7T and 9.4T scanner bed.** 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:

- Less than 4 W/kg whole body for 15 minutes,
- Less than 3 W/kg averaged over the head for 10 minutes,
- $_{\odot}$   $\,$  Less than 8 W/kg in any gram of tissue in the head or torso for 15 minutes, or
- 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 switching of the gradients is limited. Limitation is 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 scan protocol involves a higher switching rate, the system prompts the operator with the question: "Attention, possible patient nerve stimulation. OK". The subject needs to be warned about the possible nerve stimulation before pressing OK. If the threshold in Normal Mode is exceeded, the system might ask to switch to First Level mode. 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 gradient switching; 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 scan protocol is prescribed that would reach dangerous values, the software will not accept the settings and prompt the user to set a different 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 earplugs we use are rated to reduce acoustic noise by approximately 30 dB if properly inserted.

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



# **5 PROCEDURES 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 Service Helpdesk of Scannexus. And inform MRI Research Technicians, as soon as possible. Next to this, Certified Users are required to fill in an incident form and provide the Manager Operations with this form. This form is available at the reception and in the rack in the safety area.

# 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 handle for manual table removal (disconnecting the motor in case of power failure) is located at the end of the table support.



Intercom 3T

Table stop button

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



Table stop buttons

Handle

# 5.1.2 EMERGENCY ELECTRICAL SHUT-DOWN

In case of an electrical accident or fire, press the SCANNER Power Off button:

#### **3T EMERGENCY SHUTDOWN**





# 7T EMERGENCY SHUTDOWN



# 9.4T EMERGENCY SHUTDOWN





# 5.1.3 MAGNET DISCHARGE (QUENCHING OF THE MAGNET)

To be used **in life threatening situations** in which personal injury has occurred or a person being trapped between the scanner and a metallic object, due to metallic objects attracted by the static field.

#### **3T MAGNET DISCHARGE**

Press the Magnet Discharge Button located inside the magnet room or on the <u>right hand</u> <u>side</u> of the console:



# 7T MAGNET DISCHARGE

Press the Magnet Discharge Button located inside the magnet room or on the <u>left hand side</u> of the console:





# 9.4T MAGNET DISCHARGE

Press the Magnet Discharge Button located inside the magnet room or on the <u>right hand</u> <u>side</u> of the console:



#### IMPORTANT

The switch panels to the right of the 7T and 9.4T consoles do NOT include the Magnet Discharge Button:





# 5.2 PROCEDURE MR-RELATED EMERGENCIES

#### 5.2.1 MEDICAL EMERGENCIES

In the event of small accidents, medical emergencies or inconvenience for the subject and quick evacuation 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.
- Use the gurney or MR compatible wheelchair (situated in the safe area) to evacuate the subject from the patient table to the safe area.

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





**Dial 1333** and describe the location and nature of the emergency. Let them know if an ambulance is needed (e.g. in case of cardiac arrest). The scanners are located at Scannexus Scannerlab, Oxfordlaan 55.

#### Wait for BHV services.

#### **Instructions for BHV-ers:**

**Inside office hours** BHV trained Scannexus staff members will be beeped. At least three persons are needed. Two of them take care of the subject and one waits 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, in weekends or national holidays,** the CU and the accompanying second person take care of the research participant. 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 evacuate the research participant 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:

- 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 research participant. 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 research participant from the magnet;
- In case of an out of control fire, e.g. the fire extinguisher is not enough to fight the fire, the fire is spreading from its origin, press the Magnet Discharge Button.

#### 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 Scannexus 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, in weekends or national holidays.** 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.*)

See floorplan below showing all fire extinguishers and alarms in the scannerlab





The first priority is to **ensure the safety of all personnel and the research participants**. 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 (pressing the Magnet Discharge Button) before the fire has damaged the quench (see 5.2.4 about 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 MRI Research Technician or Safety Officer. **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.

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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

To demagnetize the scanners in case of a life threatening situation or an out of control fire, a **quench** is needed. Quenching (see 3.3.4) means demagnetizing the system by a temperature rise of the liquid helium, which will boil off as a gas. Quenching is done by pressing the Magnet Discharge Button, but can also happen spontaneously, caused by a fault in the magnet itself.

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. Pressure should not be an issue due to there being a knock-out panel and also of the outward-opening magnet room doors. The major **threat in helium gas filling the magnet room is suffocation** of anyone in it, because the helium will push the oxygen away. The oxygen level in the magnet room drops. Therefore, an 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.

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 levels beneath the threshold, the oxygen alarm is activated automatically. It might be an indication of a helium leak.

#### FUNCTIONING AND PROCEDURES OF OXYGEN DETECTION & ALARM SYSTEM

If there are no alarm signs (i.e. if light is not illuminated) it is safe to enter the magnet room. If these **alarm signs are present** then **nobody** may enter the magnet room **except to evacuate a research participant**. People inside the magnet room should leave the room as fast as possible. If a research participant is present in the scanner, **immediately terminate** the scanning and evacuate the research participant as quickly as possible.

During the evacuation of the research participant, leave the magnet room door open to help ensure the oxygen level remains high. Close the door after the evacuation of the research participant. The oxygen alarm is connected to the main UM alarm system. Scannexus team will be beeped when the oxygen alarm is set. Access to the scanner will be blocked and **no further scanning is permitted until** 



**approved by the MRI Research Technicians or Safety Officer**, regardless of whether this is inside or outside office hours.

#### RESET OF THE OXYGEN ALARM

The oxygen alarm will reset itself when oxygen levels return to normal. Thus if the alarm remains present, it is still **not** safe to enter the MRI laboratory. However, after the alarm reset itself, the Safety Officer or MRI Research Technicians only allow access to the scanner after approval.

**Instructions MRI Research Technicians or SOTDO:** 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 until the alarm resets itself and ask facility services for sensor values.

#### 5.2.5 QUENCHING OF THE MAGNET

In **life threatening situations** such as a metal object trapping 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 (see 5.2.4) by pressing the magnet stop. In about 20 seconds the magnetic field will drop to a level where metal objects can be removed.

- After quench 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.

#### Info Location for 1333:

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 Scannexus staff members will be beeped. At least three persons are needed. Two of them take care of the subject and one waits outside for the ambulance. Note that access on the Umcard to the scannerlab is needed to enter the building. The MRI Research Technicians or Safety Officer informs Siemens about the quench.

**Outside office hours, in weekends or national holidays,** 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, e.g. MRI Research Technicians (mobile phone numbers are available in the console room). The CU or the MRI Research Technician dials (0) 070 333 2752 to inform SIEMENS of the emergency <u>immediately</u>. 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 MRI Research Technicians or Safety Officer, 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 MRI Research Technicians or SOTDO:

- 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. For this 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, the RF lab and the Chemical lab. Do not forget to check the kitchen and technical room upstairs (above the kitchen). The other two will walk through the scanner 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. BHV trained people must be made aware of the dangers of a magnetic field. They must not enter the magnet room before screening of themselves and their equipment. Only access magnet room when really needed.

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



# **6 GENERAL GUIDELINES REGARDING SUBJECTS AND VISITORS**

#### 6.1 BEFORE THE MEASUREMENT

It is strongly advised for the Certified User to interview potential participants of the MRI experiments at least one week prior to scanning, using either their own screening procedure, or the Scannexus recommended screening procedure (*see link to screening form, 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 participant.

When the participant arrives for the measurement, the Certified User will make sure that nothing has changed since the screening interview and will, again, carefully screen the subject for any implanted material that could constitute a risk in the scanner using the mandatory Scannexus safety screening form (*see link to screening form, 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 is understood and signed**, the measurement can start.

# <u>Important:</u> No one can be scanned unless he/she has completed the Scannexus safety screening form on the day of the measurement. This screening form needs to be completed <u>each</u> time a subject will be scanned.

- The research participant and Certified User, has to remove all metal from the body, like piercings, metal in clothing etc., before entering the magnet room. It is strongly advised to complete a top down screening procedure, prior to entering the Magnet room.
- Only approved equipment is allowed to be brought into the magnet room. The Safety Review Board and Safety Officer performs approval for the MR compatibility of this equipment.
- The particpant will be given earplugs and if possible, also headphones.
- Position the participant on the scanner bed and position the RF coil needed.
- Provide instructions about the alarm ball and handover the alarm ball to the participant.
- Avoid cable contact to the skin of the participant.
- Avoid looped cables near the participant.
- Any unused cables, transmit or receive coils, or any other unused equipment should be removed from the bore and from the RF coil.
- Instruct the participant not to cross arms and legs.
- Use the laser to position the body part of interest in the iso-center of the bore. The subject must close the eyes while using the laser.



- Move the bed into the magnet bore at a defined rate through a computer-controlled interface.
- Enquire the participant about any discomfort.

# 6.2 DURING THE MEASUREMENT

Participants will be in constant voice contact with the operator via an intercom system. Participants 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 participants comfort and heating. Typically, some verbal contact should be made with the participant prior to each scan. The operator must not leave the console during the measurement. If, at any time, a participant 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 participant about his/her status. Any discomfort and problem reported by the subject must be reported by filling out an incident form.

# 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 Safety Review Board and Safety Officer.



# 6.5 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.

#### 6.5.1 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 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 himself or herself.

#### **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.

#### 6.5.2 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. The parent/guardian must be checked for metals. This will serve as a precaution to avoid risks in case of emergency.



# 6.6 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**. Report to the Senior Operations and Technical Development Officer and Manager Opertions 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.



# APPENDIX 1 FOUR-ZONE CONCEPT OF SCANNEXUS



Floorplan Scannexus Scannerlab showing Four Zone Concept:

Zone 1: green shading	General public
Zone 2: yellow shading	Unscreened MRI individuals
Zone 3: orange shading	Unscreened MRI individuals under constant supervision of trained MR personnel (Certified Users, Scannexus MRI Research Technicians)
Zone 4: red shading	Screened MRI individuals under constant direct supervision of trained MR personnel (Certified Users, Scannexus MRI Research Technicians)



# APPENDIX 2 CERTIFIED USER REQUIREMENTS

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. Both you and the MRI Research Technician performing the supervised sessions must sign the Certified User Agreement.

# 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 MRI Research Technicians until (s)he is satisfied that the system can be used both safely and efficiently (see checklist on the next pages).
- 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-todate 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 MRI Research Technicians for advice and instructions.
- $\circ$   $\,$  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

- $\circ$   $\;$  Know where the find the Key for the magnet room.
- 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.
- $\circ$   $\;$  Never lock the door of the magnet room during scanning of a subject.
- Never leave the console area during scanning of a subject.
- $\circ$   $\,$  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 Tesla. 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.
- 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 MRI Research Technicians can approve scanning the subject!
- Ensure that the subject is wearing appropriate ear protection (headphones or earplugs) 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.
- 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

- $\circ$   $\;$  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, weekends and national holidays.
- Know how to enter the building out of office hours.



Example Certified User Agreement:

Certified User Authori	DEXUS RAUTHORISATION From 1.0 Station – 3T MR System
I hereby declare that I have been instru following:	cted in, and am cognizant of the
<ol> <li>Basic knowledge of MR safety su am responsible for the scanner.</li> </ol>	ch as to avoid damage or injury while I
<ol><li>The rules and regulations of Scar Guidelines.</li></ol>	nnexus as outlined in the Scannexus
3. The items mentioned in the check	klist.
<ol> <li>If I fail to take responsibility for t Scannexus Guidelines my priviles</li> </ol>	the rules and regulations outlined in the ges as a CU will be withdrawn.
	edures at all times.
I commit myself to following these proce	
I commit myself to following these proce Name:	
I commit myself to following these proce Name:	
I commit myself to following these proce Name: Signature:	Date:
I commit myself to following these proce Name: Signature:	Date:
I commit myself to following these proce Name: Signature:	Date: Authorized by:



# APPENDIX 3 INCIDENTAL FINDINGS

It is not the investigator's job to check or to diagnose medical problems in anatomical scans. However, it is possible that you cannot help but notice an anatomical feature that appears out of the normal range.

In case of an incidental finding, you might follow the Scannexus procedure "Incidental Findings".

#### NOTE: FPN users must use the forms and procedures within FPN itself!

#### Scannexus procedure:

- Make sure you have an incidental finding agreement, signed by the participant. Responsibilities for this lies with the researcher (A template incidental finding agreement is available at Scannexus. FPN users must use the FPN form)
- Support team will check if participant has consented to be informed! Without signed consent, this procedure cannot continue.
- Do not inform the participant right away. (If the participant does become aware of the fact that a potentially aberrant anatomical feature was present, then inform the participant that a medical expert will be consulted, and that the participant will be contacted by phone.)
- Inform your supervisor or PI about the incidental finding.
- Scannexus provides contact details of medical expert associated with Scannexus.
- Provide the Scannexus MRI Research Technicians with the relevant data.
- Scannexus MRI Research Technician sends relevant data via secured transfer to medical expert.
- Researcher seeks contact with medical expert, explaining findings.
- Medical expert sends feedback to researcher, notifies researcher about the findings and whether follow up is needed.
- Scannexus will delete provided data to Scannexus and medical expert.

Follow up after feedback medical expert:

- Participants for whom medical follow up is recommended must be invited for a conversation and for pick-up of their referral letter for GP.
- Participants who had become aware of the presence of a potentially aberrant feature, but for whom follow up was not recommended should also be called and informed.
- Participants who had *not* become aware of the presence of a potentially aberrant feature, and for whom follow up was *not* recommended should *not* be called.



# APPENDIX 4 ROOM ACCESS CONTROL

Floorplan of Scannexus Scannerlab and table showing room access control:



Profile			Coror Compilation
OXF55 Lab003 24/7		UM0186, UM0185	00
OXF55 Lab004 24/7		UM0186, UM0184	ŎŎ
OXF55 Lab008 24/7	Combined with MTP	UM0186, UM0180, UM0178	ÖÖO
OXF55 Lab012A 24/7	Combined with Key Cabinet, Chem. Key (MST light)	UM0186, UM0180, UM0181	00
OXF55 Lab014 24/7	Combined with MTP	UM0186, UM0180, UM0176	000
OXF55 Lab023 24/7	Combined with MTP	UM0186, UM0180, UM0171	000
OXF55 Reception 24/7	Scannexus Personnel only	UM0186, UM0180, UM0179	000
OXF55 MTP 24/7	Magnet Trained Personnel	UM0186, UM0180, UM0181, UM0182, UM0170, UM0169, UM0172, UM0173, UM0174, UM0175	000
OXF55 AA 24/7	Approved Access	UM0186, UM0171, UM0176, UM0178, UM0184, UM0185, UM0180, UM0181, UM0182, UM0170, UM0169, UM0172, UM0174, UM0175, UM0179	0000000
OXF55 Basic 24/7		UM0186, UM0180	00
OXF55 Key Cabinet 24/7	Magnet Rooms: At all times in combination with MTP, CU profile For Chem. Key only, always in combination with at least MST light	UM0180	0 0



# APPENDIX 5 IMPORTANT LINKS

SAFETY SCREENING FORM TEMPLATES

http://scannexus.nl/information/documentation

SCANNEXUS SERVICE HELPDESK

https://jira.scannexus.nl/servicedesk/customer/portal/1

CALPENDO

https://scannexus.calpendo.com/

#### BUSERVER NETWORK DRIVE

- (Z:) <u>\\BUsrv0001\backedupdata\*personal-folder*</u>
- (Z:) <u>\\BUsrv0001\backedupdata\~shared</u>
- (Z:) <u>\\BUsrv0001\backedupdata\~documentation</u>



# APPENDIX 6 CALPENDO BOOKING GUIDELINES

(version 2, last update 27 March 2020)

#### **Dedicated time slots / templates**

Scannexus uses the online booking software, named Calpendo, to reserve scanning time: <u>https://scannexus.calpendo.com/</u>. Booking is possible after a signed project scanning agreement of Scannexus. Project scanning agreements are dedicated to different user types. The user type corresponds with a specific faculty or with external users, depending by whom the project is funded. The scanning project agreement is labeled with a project number. The letter at the start of the project number corresponds to the user type:

- F FPN
- M FHML
- A External (Academic)
- S External

Within Calpendo a template is created containing dedicated timeslots to the different user types.

#### **Booking of timeslots/templates**

Users can book themselves, when they are a Certified User or in agreement with Scannexus staff. In all other cases, send your booking request to <a href="mailto:scanlabs@scannexus.nl">scanlabs@scannexus.nl</a>.

Bookings must be made in the dedicated timeslots/templates, belonging to the user type, preferably at full and half hours. Make bookings consecutive to others or leave at least one hour in between.

Within 4 weeks, non external users can book in external timeslots. However, this booking might be canceled when an external user is in need of this timeslot.

In exceptional situations, it is possible to book in the other templates than the one dedicated to your user type. Please contact <a href="mailto:scanlabs@scannexus.nl">scanlabs@scannexus.nl</a> for this request.

Note: Bookings of the user type F must be made by <u>mriplanning-fpn@maastrichtuniversity.nl</u>. Users of FPN are not allowed to book themselves in Calpendo.

#### Booking information/obligated fields

Fill out the following fields while making a booking request:

- Needed resource
- Project number
- Time
- Support (see below)



- Number of subjects (needs to correspond to the number of filled in screening forms within this slot)
- No subjects (only when number of subjects is 0)
- Joystick (only when a joystick is needed, to avoid double bookings using the joystick)
- Certified User
- Contrast Agent
- Other fields may be filled out, but are not obliged.

**Note:** User type F, must hand over all the information needed for booking, including Support and Certified User, to <u>mriplanning-fpn@maastrichtuniversity.nl</u>. Staff of mriplanning-fpn does the booking for you.

#### Support for scanning

In Support, you can select different options. The option you need to select is depending on what is included in the scanning project agreement.

- Yes, operator: Scannexus staff will carry out scanning.
- Yes, supervised session: You are finalizing your CU training by a supervised session.
- Neither: No support is needed
- Yes, laborant: Need of Support of Scannexus staff in using the contrast injector and/or assisting in contrast injections.

When in need of support, your booking is final after approval of your booking by Scannexus staff.

#### Booking Mock scanner/Psychophysics lab/Psychopharma lab

The Mock scanner, Psychophysics lab and Psychopharma lab can be booked to inform, train and test subjects. To use these labs they must be included in the project scanning agreement.

#### **Booking Contrast injector**

In case of contrast agent and/or use of contrast injector, support of Scannexus staff is obliged. Please fill out Yes, laborant in Support. Use of contrast injector must be included in the scanning project agreement. The booking is final after confirmation by Scannexus staff.

#### Cancellation

Canceling of a booked timeslot is allowed at least 7 days in advance. Within these 7 days, canceling is not possible. However, under these circumstances it is allowed to have the slot being taken over by someone else.



# 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 MRI Research Technicians or Scannexus team. Fill out an incident form.
- Report equipment damage or failures in the Scannexus Service Helpdesk and to the Scannexus
   MRI Research Technicians or Scannexus team. Fill out an incident form.
- CU is responsible for leaving the magnet room and console room in the condition which they found it. Report any problems to the Scannexus MRI Research Technicians or Scannexus team.
- Do not bypass the door card readers by leaving the doors unlocked or blocked open in any way.
- Do not bypass the card system by lending out your Umcard; 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 weekdays: before 9:00, after 17:00, and during the weekends and national holidays

#### 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 MRI research technicians/ Senior Operations and Technical Development Officer.

The senior staff and MRI Research Technicians of Scannexus have the authority to ask anyone present within the MR scanner rooms to immediately leave these areas. Said person must obey such a request immediately.



# 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
7T Console	T0.027	85670
9.4T Console	T0.026	85831
RF Laboratory	T0.004	85667



Person	UM Phone	Mobile	E-mail
Support Team	85668	06-xxxxxxx	scanlabs@scannexus.nl
Christopher Wiggins	84802	06-xxxxxxx	c.wiggins@scannexus.nl
Job van den Hurk	85837	06-xxxxxxx	j.vandenhurk@scannexus.nl
Esther Steijvers	85668	06-xxxxxxx	e.steijvers@scannexus.nl
Bianca Linssen	85668	06-xxxxxxx	b.linssen@scannexus.nl
Kim Feron	85817	06-xxxxxxx	k.feron@scannexus.nl

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

INSIDE OFFICE HOURS:	OUTSIDE OFFICE HOURS: Chris Wiggins
Contact Support/ MRI Research Technicians for any problems	Esther Steijvers
Speed Dial Button on the phone!	Job van den Hurk
	Kim Feron