Erwin L. Hahn Institute for MRI

Safety Policy Overview

1. Introduction

This manual outlines the specific safety policies to mitigate the risks and occupational safety hazards unique to the MRI environment and associated laboratories and workshops within the 7T facility at the Erwin L. Hahn Institute for MRI (abbr.: ELH). The 7T facility is installed with an actively shielded 7 Tesla whole-body MRI system from Siemens Healthcare with different radiofrequency (RF) transmission modes and in-house developed RF hardware. Operators need to distinguish between two operation modes, i.e., (1) single channel transmit, which in combination with two vendor-supplied RF coils (head and knee only!) falls under the CE label and medical device directive, and (2) multi-channel transmit without CE label and hence to be considered as a pure investigational device suited for research only. ELH Technical Staff (see 13) is available for advice and training and must be informed prior to any use of new hardware or RF transmission modes.

The safety procedures outlined herein are intended to complement other University safety protocols that apply to the 7T facility (e.g., chemical/laboratory/machine workshop safety, hygiene).

The safety policy also refers to current standards, in particular

- IEC 60601-2-33, Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis, Ed. 3.3, 2015-06
- Directive 2013/35 of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)
- DIN 6876, Operation of Medical MR equipment, May 2014
- BGV B11, Accident Prevention Regulation for Electromagnetic Fields, April 2002

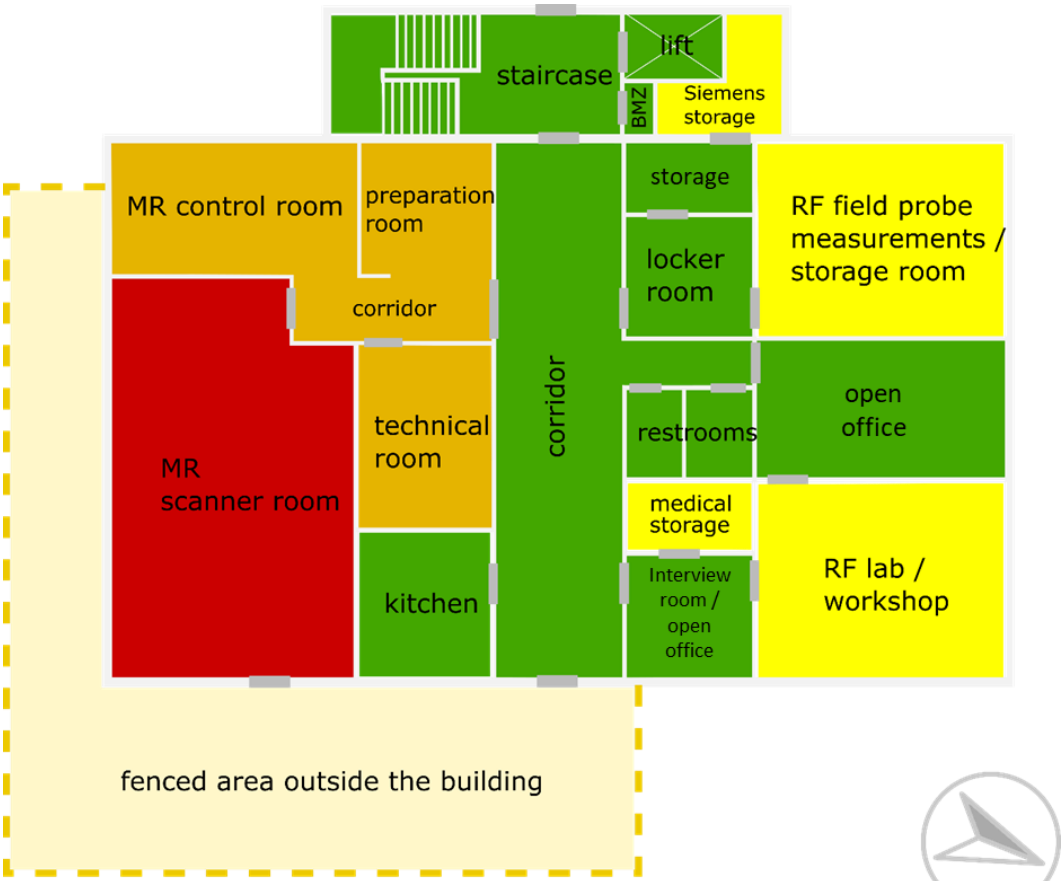
Selected working instructions and MRI emergency procedures are available on the ELH wiki: https://hahn-institute.de/elhwiki

2. Overview of Safety Policy

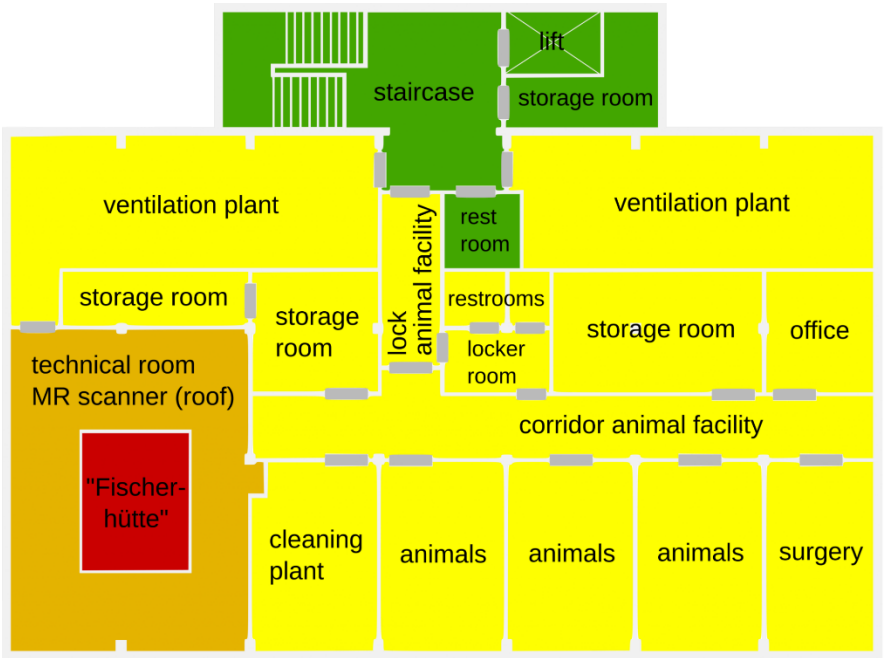
The facility is divided into a number of “Safety Zones”, each with a different degree of stringency in the rules and regulations that apply to that area (summarized in Figures 1-3). Access to these zones is restricted according to a person’s “Safety Level” (summarized in Table 1).

ZONE	ACCESS & ACTIONS
Green	General public access
Yellow	Restricted, obey safety protocols for this zone
Orange	Restricted, individuals must be accompanied by ELH personnel
Red	Restricted, individuals must be screened for MR contraindications and accompanied and supervised by ELH Certified MR Operator (see 4.)

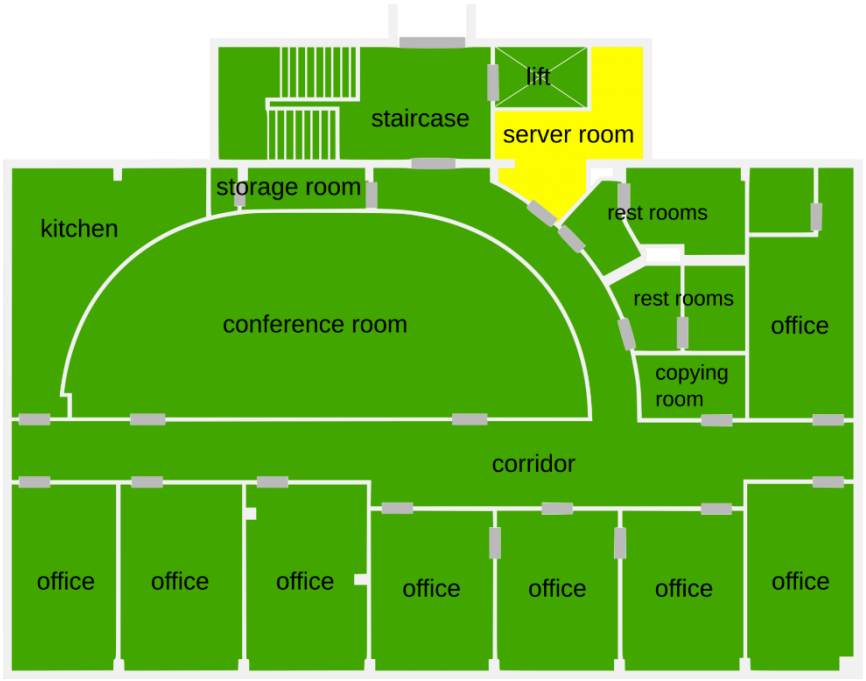
Table 1



Safety zones on the ground floor



Safety zones on the 1st floor



Safety zones on the 2nd floor

3. Screening and Approval

All visitors, personnel or students entering the Yellow Zone must be aware of safety protocols related to the RF lab, storage rooms and workshops. In these rooms, machines may be running, in certain cases even unsupervised, or experiments with RF exposure may be conducted. If it is intended to work in rooms of the Yellow Zone, an introduction to the tools and machines and specific codes of conduct by ELH Technical Staff is mandatory and must be signed by the individual.

All visitors, volunteers, personnel, or students entering the Orange Zone must be accompanied by ELH personnel, whereas for the Red Zone additional and substantial screening for potential contraindications prior to entering the magnet room is mandatory. Individuals will be asked to complete and sign a MRI Screening Form and undergo a screening interview with an ELH Certified MR Operator, after which a decision will be made about the individual's suitability to safely enter a high magnetic field environment. For healthy volunteers, the project owner, or a delegated person (must be a scientist and ELH Certified MR Operator) may conduct the screening interview. Volunteers with known pathologies and diseases, or healthy volunteers scheduled for a contrast-enhanced scan must be screened and accompanied by a physician (must be ELH Certified MR Operator). If some contraindications are revealed during the screening process, the volunteer will be restricted from the Red Zone (magnet room) but may still be allowed access to the Orange Zone as long as supervision is provided.

Although the screening interview and access decisions are the responsibility of the project owner, ELH MR Safety Officer/Expert (see 10/11) must be consulted when there is uncertainty about a person's screening status (i.e., any question on the screening form answered with a "yes"). In addition, obligations from the ethics proposal must be known and followed without exception. Among other obligations, the subject must be informed prior to the examination that the 7T images cannot be used for diagnostics nor may these images be handed out to people other than the project owner or ELH personnel. Exceptions apply to scans that fall under the CE label.

Volunteers are required to fill out the screening form once per study; however, they (or the project owner) must inform the ELH MR Safety Officer/Expert if their screening status changes over time (e.g., possibility of pregnancy, implants, piercings). For every participation in another study a new screening form must be filled out and the subject will be assigned a new Z7T-number. It is the obligation of the project owner to keep track of the Z7T-numbers assigned to the individual study in line with ELH's data protection rules. Registration of the subject at the MR console for imaging must be in the format <Last name = Z7T-number>, <First name = freely selectable>.

In general, metallic objects are not allowed into the magnet room; however, there may be exceptions to this rule when a metallic (non-ferrous) or any MR conditional object is necessary for the successful execution of the experiment. Any apparatus related to the experiment must be approved during protocol review by both the ELH Physicist supporting the project owner and by an ELH MR Safety Expert. In addition, a second review by the ELH Board of Directors and/or ethics committee may be necessary.

4. ELH Certified MR Operator and ELH MR User Safety Training

Short-term visitors and students wishing to enter the Orange or Red Zone will undergo some basic safety training by watching a safety video or through a brief orientation by ELH MR Safety Officer/Expert. This basic safety training must be signed by the individual. However, access to the Red Zone may only be granted if the individual is accompanied by an ELH Certified MR Operator.

A person wishing to conduct MR experiments independently must be approved as an "ELH Certified MR Operator". The individual must demonstrate a solid understanding of scanner operation and safety procedures and must be willing to provide leadership in emergency situations. General MR safety regulations and procedures are presented in the ELH MR User Safety Training. The ELH MR User Safety Training consists either of a presentation given by the ELH MRI Safety Expert or via e-learning tools. In addition, an on-site briefing of site-specific safety and operational aspects is necessary. All personnel involved with the operation of the MR scanner and experimental support must be ELH Certified MR Operators and, according to the accident prevention regulations (BGV B11, Directive 2013/35/EU), are thereby required to renew their ELH MR User Safety Training every year. Personnel with professional experience in MRI of more than 3 years and who have attended at least one ELH MR User Safety Training may decide whether they attend the ELH MR User Safety Training or if they independently study the training material every year. Individuals who were involved in an accident related to a MR scan must attend the ELH MR User Safety Training regardless of their professional experience.

In any case, compliance is documented by signing that the general and site-specific safety requirements are known and will be followed without exception. Access to the magnet room will be denied by deleting the individual's access code in case of failure to comply with this rule.

Please make a reservation for the next ELH MR User Safety Training with Oliver Kraff,
Email: oliver.kraff@uni-due.de, Tel.: +49-(0)201/183-6076.

Safety forms and training material will be available on the ELH wiki:
https://hahn-institute.de/elhwiki

5. MRI Operation – general

Only ELH Certified MR Operators are allowed to independently conduct experiments with phantoms alone. In case of imaging humans, a second person (must be ELH Certified MR Operator) must be present in the ELH building who may be called immediately in an emergency. It is the responsibility of the project owner to define the second person, in particular – but not exclusively – for measurement during off-time hours. In case of imaging volunteers with known diseases or pathologies, a physician must remain within calling distance in the ELH building for the duration of the measurement. Whenever a contrast agent or other medication (e.g., Butylscopolamine) is administered, a physician must be present in the MR operation room for at least 30 minutes after the administration.

In addition to this document the ELH Certified MR Operators are asked to familiarize themselves with the latest version of the International Standard IEC 60601-2-33, regarding "Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis".

As the 7T MR system is already in first level-controlled mode because of its high magnetic field strength, medical supervision is required for in vivo measurements. MR Operators must regularly ask the subjects about their condition during scan. Additional supervision may be necessary depending on the scan situation and nature of the study. This will be defined during the project proposal for each individual study.

In case of a **pregnant** MR Operator her exposure to the electromagnetic fields of the MR system must be limited. According to the guidelines and statements in IEC 60601-2-33, Ed. 3.2, 2015-06, no evidence for long term or dose effects of exposure to static magnetic fields is available, but the body of evidence related to magnetic field effects on fetal development is limited, so that the cautionary principle should be applied. Access to the red zone will be strictly denied, but the ELH will provide assistance to allow continuance of the projects (e.g., ELH staff will prepare measurements within the MR scanner room). Access to the orange zone can be granted as the magnetic field exceeds 0.5 mT only within the direct vicinity of the scanner room door, but not around the MR consoles. For in vivo measurements, a second ELH Certified MR Operator must be present at the MR console for the duration of the measurements. In case the pregnant MR Operator decides to restrict herself from the orange zone further assistance from the ELH for the continuance of the project will be discussed and implemented, as far as possible. These rules may also apply to ELH MR Operators with (selected) **implanted medical devices**.

6. Evaluation of possible MR contraindications

In case there is uncertainty about a person's screening status (i.e., any question on the screening form answered with a "yes") the ELH MR Safety Officer and/or Expert must be consulted. Except for very few and carefully selected implants and tattoos, which have been declared MR conditional at 7 Tesla either through local safety related testing or through publications from external sites which must be approved by the ELH MR Safety Expert, every possible contraindication must be cleared in unison in a case-by-case decision through a ELH MR Safety Panel. The ELH MR Safety Panel consists of the ELH MR Safety Expert, the project-associated ELH-PI, and a third member of ELH Technical Staff with profound knowledge in RF interactions.

A list of carefully selected implants and tattoos declared MR conditional is provided on the ELH wiki: https://hahn-institute.de/elhwiki
It is indispensable to obey the different conditions of use for each individual implant listed on the ELH wiki. In any way, detailed information about the implant, tattoo, or health status must be declared on the screening form by the responsible ELH Certified MR Operator.

7. Different MRI Operation Modes and RF Hardware

The 7T MRI system is capable of different operation modes (standard 1-channel and multi-channel full parallel transmit). ELH Certified MR Operators must obey safety rules relevant for the individual operation modes.
Instructions are available on the ELH wiki: https://hahn-institute.de/elhwiki
Personal instruction regarding the use of any kind of in-house developed RF hardware (e.g., RF coils, power splitters, transmit/receive switches, preamps, …) is mandatory. New RF hardware components need a safety assessment dedicated to the design and purpose of the individual device. The extent of such a safety assessment will be discussed for each component separately. Please consult ELH Technical Staff.

8. Access for Custodial Staff

Custodial staff will be given a brief safety orientation for the Orange and Yellow Zone. Custodial staff never have access to the Red Zone.

9. Access and Training for Emergency Personnel

It may be necessary for police, paramedic, or fire department personnel to enter the facility in response to an emergency. In the case of an emergency, ELH staff should be ready to assist and inform emergency responders, especially regarding potential hazards in responding to situations inside the magnet room and to initiating a magnet quench if required.

The fire department must undergo a safety orientation and consultation with ELH MR Safety Officer and Safety Expert, especially pertaining to emergency procedures within the magnet room. This safety orientation and consultation should be renewed every 5 years in consultation with the fire department.

10. ELH MR Safety Officer

One member of the 7T facility will be appointed as the ELH MR Safety Officer to oversee all elements of the safety policy. The Safety Officer should be competent to assess and manage dangers caused by the MR equipment, be responsible for monitoring the measures taken to protect against such dangers and ensure that appropriate measures for minimizing risks to health that arise from the use of the MR equipment are implemented and monitored. The Safety Officer will liaise with emergency personnel and custodial staff and maintain records of screening activities and safety incidents. The Safety Officer should report periodically to the ELH MR Safety Expert.

11. ELH MR Safety Expert

One member of the 7T facility will be appointed as the ELH MR Safety Expert. The Safety Expert should report periodically to the ELH Board of Directors and should propose any changes to the safety policy as needed.

The Safety Expert should be responsible for the development and continuing evaluation of a safety framework for the MR environment, the development of local rules and procedures to ensure the safe use of MR equipment and provide advice regarding non-routine MR procedures for individual patients and specific patient groups. The Safety Expert should also be involved in purchasing of MRI equipment and in this context provide expertise in acceptance testing prior to the first use of the equipment. The Safety Expert must be consulted when there is uncertainty about a person's screening status (i.e., any question on the screening form answered with a "yes"). The Safety Expert may decline clearance of such a subject.

12. Technical Faults, Accidents, Emergency

In case of technical faults, e.g., a broken component of a RF coil, immediately contact ELH Technical Staff (13) and follow instructions provided in the working instructions of the dedicated device.

In case of accidents or emergency follow instructions provided in the first aid charts and/or MRI Emergency Procedures. All accidents and emergency situations must be reported to the ELH MR Safety Officer/Expert who will inform the Board of Directors and, if necessary, further regulatory authorities or vendors of devices involved in the incidents.

Instructions are available on the ELH wiki: https://hahn-institute.de/elhwiki

13. ELH Technical Staff

Area of expertise	Contact person	Substitute
Animal Facility (to be reactivated)	Dr. Gero Hilken	Dr. Stefan Maderwald, Kim Jotzo
Building Technology	Kim Jotzo	Dr. Stefan Maderwald
ELH Physicists	Dr. Oliver Kraff, Dr. Stefan Maderwald	
ELH MR Safety Experts	Dr. Oliver Kraff	Dr. Stefan Maderwald
ELH MR Safety Officer	Daniel Osenberg	
ELH MTRA	Daniel Osenberg	
Fire wardens	Dr. Oliver Kraff, Dr. Markus May, Stefanie Zurek	
First aiders	Dr. Marcel Gratz, Dr. Franziska Günther, Dr. Oliver Kraff	
First-line MR scanner support	Dr. Oliver Kraff	Dr. Stefan Maderwald
fMRI equipment	Dr. Stefan Maderwald	Dr. Viktor Pfaffenrot, Evgenij Knorr
General Safety Delegate	Kim Jotzo	
Medical equipment	Christiane Seyser	Dr. Stefan Maderwald, Daniel Osenberg
pTx system	Dr. Oliver Kraff	Dr. Viktor Pfaffenrot, Dr. Jenni Schulz
Quality Assurance	Daniel Osenberg	Dr. Oliver Kraff
RF coils in general	Dr. Markus May	Dr. Oliver Kraff
RF experts	Dr. Markus May	Dr. Oliver Kraff
RF lab	Dr. Markus May	
Scanner time bookings	Daniel Osenberg	Dr. Oliver Kraff, Stefanie Zurek
Scientific Integrity	Dr. Franziska Günther	Stefanie Zurek
Server room	Dr. Marcel Gratz	
Special RF coils from Nijmegen	Prof. Tom Scheenen	
Workshop	Dr. Markus May	