

Safety in the Berlin Ultrahigh Field Facility

MDC Berlin-Buch



This safety instruction is of <u>great importance</u> and a <u>prerequisite</u> for entering and independent work in building 88 (B.U.F.F.). This building is different from other buildings on the campus Berlin-Buch due to its MR scanners. The MR scanners have potential dangers associated with them, which you must be aware of!

This safety instruction is based on reports by the rays Commission (SSC) of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and according to § 22 of the Medical Devices Act.

This safety instruction is available as a PDF for <u>download</u>.

The sections marked with an 'S' and 'P' are only necessary for those who work in the S1 area and the laboratory (S) or for those working in a clinical study with volunteers (P).

Table of Contents

- 1. Specific risk factors at B.U.F.F.
- 2. Danger zone MRI building
- 3. Danger zone MR room
- 4. Danger zone MR scanner (P)
- 5. Dangers of helium filling
- 6. Emergency siruations in the MR room
- 7. The laboratory
- 8. Hazardous substances
- 9. Anesthetics
- 10. Genetically modified organisms (S)
- 11. Waste management (S)
- 12. General Safety
- 13. Fire protection
- 14. Clinical Studies (P)

1. Specific risk factors at B.U.F.F.

- There is an MR scanner on each of the three floors
- There are potential hazards present upon entering the building
- The magnets are always switched on!
- There are three danger zones:
 - o the MRI building
 - $\circ \quad \text{the MR room} \quad$
 - o the MR scanner

2. Danger zone MRI building

• Entering the B.U.F.F. is prohibited for persons with heart pacemakers, insulin pumps or other implants which can be influenced electromagnetically!

The magnetic field is not limited to the MR room, but is present in the entire MRI building. Upon entering the B.U.F.F. you are exposed to the magnetic field. The whole building is thus a danger zone (see yellow line). People with pacemakers, insulin pumps or other implants which can be influenced electromagnetically may not enter the building, as standing within the magnetic field in the building can be life-threatening. Particularly the crossing of the *5 Gauss line* for people affected is dangerous. In the following floor plan the three danger zones are shown.



Due to the hazards of the scanner with it, the MRI building access must be protected. The <u>warning signs</u> at the entrances point to these dangers. The signs should also have to point out that for individuals with metal implants, mechanical watches, keys, credit cards or other metal parts may not be allowed to enter the MR rooms, even though they are allowed to enter the building.



At the entrances, visitors are informed about the risks and dangers of the MR scanner. Visitors must provide written consent and understanding of <u>safety instructions</u> in order for admittance to the B.U.F.F. to be granted.

U.F.F.	MDC	ASSOCIATION	NAMES AND ADDRESS OF
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3. Danger zone MR room

- Very strong magnetic field, which rapidly increases with decreasing distance from the MR scanner. A strong magnetic force can act on metallic objects.
- Entering the MR room is prohibited for pregnant women and people with prosthetics (legs, artificial hip joints)!
- You are not allowed to bring metallic objects (like tools, scalpels, hair clips, and scissors) into the MR room!
- The user of the MR scanner is responsible for volunteers, staff and material!
- Magnetic fields cannot be seen or heard, and if you can "feel it", it is usually too late!

The MR scanner is a high-tech tool and requires intense concentration. You as a potential user bear full responsibility for the volunteer or subject, the staff and the materials. The Magnetic fields cannot be seen, heard, tasted, and if you can feel it, it is (usually) too late! The following pictures show the scanner for human volunteers (on the left side) and the animal scanner (on the right side).



The magnetic field of a scanner is a static magnetic and it is always there although in standby or the console is switched off. The following symbol warns about magnetic fields.



The magnetic attraction to ferromagnetic objects generated by the scanners is very high. These attractive forces are getting stronger with decreasing distance to the magnet. Objects such as scissors or a gas cylinder can turn into projectiles through this magnetic pull of the scanner. Therefore, you may **bring in NO metallic objects into the scanner room**.



Warnings and markings must always be observed! Only objects and devices that are marked with the green MR icon (left) present no danger for staff and equipment when operating in the MR room and are allowed to be brought into the MR room. The yellow MR icon (middle) indicates things that are only MR safe in a limited fashion. There is always specified safety distances must be adhered to from the magnet! The red MR icon (right) marks objects which are strictly prohibited from being in the MR room!





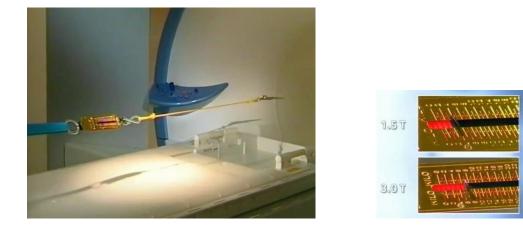
In the following video you can see how a hammer and a pair of scissors in a magnetic field turn into dangerous projectiles. The melon symbolizes the head of a volunteer.

(To start the video, please click the Link)



This video shows the force with which a pair of scissors is attracted to the magnets with different field strengths.

(To start the video, please click the Link)



The static magnetic field involves, as you have seen in the videos, a variety of dangers to which you should always keep in mind when you enter the MR room.

4. Danger zone MR scanner (for clinical studies)

- Volunteers must always wear the dedicated volunteer clothing.
- No one except for the volunteer is allowed to stay in the MR room during measurements.
- People who are in the scanner must wear ear protection!
- The volunteer must be advised to close his / her eyes when the positioning laser is being used.
- Never place ECG and coil cables on bare skin and never cross them!

The gradient fields, which can induce stimulation of peripheral nerves and muscles in the body, are a further source of danger. A particularly high risk exists in patients with implanted wires in anatomically / functionally sensitive regions, and therefore they cannot be admitted as test persons.

During the normal use of an approved device for the investigation no harmful effects on humans are expected.

BUT: Risks for staff, patients or test persons still exist by the static magnetic fields, the gradient fields, the high-frequency pulses, the incorrect positioning of the volunteer and by the laser light localizer.

The acoustic load in the MR scanner is up to 110 dB. Volunteers and persons, who reside in the scanner room during a measurement, therefore should always wear ear protection. **Note:** Typical acoustic MR noise of the scanner is partly to hear outside of the building and should not be confused with alarms!





High-frequency pulses are a source of risk as well. High-frequency electromagnetic waves of the system lead to thermal effects in body tissues. These thermal effects can cause internal burns.



electromagnetic field

When positioning the volunteer you should always keep in mind that direct contact between the volunteer's tissue and inner bore of the magnet is not allowed. Loops of volunteer tissue (left) and the overlapping of the extremities in the scanner are not allowed as well because such positioning can lead to burns. Therefore volunteers always have to wear special clothes.



The coil is positioned in the magnetic center using the laser light localizer. Patients are always asked to close their eyes, because of the risk of suffering retinal damage.



Laser beam warning

5. Dangers of helium

- In the rare event of liquid helium being refilled into an MR scanner be aware that larger amounts of helium may be released by accident.
- Helium bares the risk of suffocation as it displaces the room air and oxygen!
- If you see someone lying on the floor in the MR room be aware and do not enter the room unless you are wearing an oxygen mask!

The magnets are cooled by liquid helium. In case of contact with helium there is a danger to freezer burn. You should always wear protective clothes when working with liquid helium! In high concentrations helium may create a danger of suffocation, since helium displaces oxygen. Therefore you should never bend into a container of helium. Always make sure that the ventilation is working. There is no instrument for the measuring of oxygen content in the scanner room. If you see someone lying next to a helium tank on the ground, then do not enter the room without an oxygen mask.



6. Emergency in the MR room

- The magnet is always switched on and is only allowed to be turned off in lifethreatening situations for humans and during special maintenances!
- First, ALWAYS get people out of the MR room! Starting the emergency measures is ONLY allowed outside the MR room!
- Emergency staff and doctors are generally not allowed to enter the MR room!
- Defibrillators and oxygen bottles are prohibited in the MR room!
- The Siemens ECG unit can be brought into the MR room.
- Emergency situations always have to be reported to the safety officer.

What to do in an emergency?

Only in life-threatening situations caused by the magnet you are allowed to activate the magnet emergency stop and the magnet quench. <u>How to behave in case of a Quench</u> you can find <u>here</u>. Pressing the magnet quench causes costs about more than 100.000€. While special servicing of the magnet you are allowed to switch off the magnet as well. After pressing the magnet quench all people should leave the MR room, because helium escapes (see 5. Dangers of helium)! These emergency facilities are located in the computer rooms of the scanners on each floor.



Additionally, in threatening situations in the scanner room you can activate the electrical emergency stop! But you must be aware that the magnetic field is still present.

Animal scanner	7T MRI / 3T MRI / 3T NaKo MRI	
<text></text>	Elektrischer Notaus Emergency Button Electricity UV KD, BLAUF 22	

How to behave in emergencies in the MR room

First ALWAYS get exposed people out of the MR room! Starting the emergency measures is ONLY allowed outside the MR room!

- Make emergency call (0)112 fire service on call or 3333 security firm
- In an emergency first get exposed people out of the MR room!
- Starting the emergency measures is ONLY allowed outside the MR room! Defibrillators, oxygen bottles or similar you are NEVER allowed to bring into the scanner room!
- In the course of emergencies or hazards the scanner room and the wider area should be evacuated. The doors to the scanner room should be closed.

In this video you can see how an oxygen bottle turns into a dangerous projectile.

(To start the video, please click on the Link)



7. The laboratory









- Access is permitted only for those who hold valid safety instructions for the B.U.F.F. and wear protective clothing consisting of lab coat, gloves, mask and cap!
- Shoes must be cleaned using the shoe cleaning machine located at the two entrances to the lab area. If shoes are very dirty or wet please additionally use overshoes.
- Always observe warning and information signs!

Safe laboratory work can only be ensured by complying with all warnings, the hygiene plan and by wearing protective clothes. If emergencies do occur, you can find first-aid kits, emergency showers and eye showers in the laboratory or in front of it.



Also, the emergency plan with the most important numbers is available in the laboratory.

8. Hazardous substances

- Note GHS pictograms and safety data sheets for hazardous substances!
- The registry of hazardous substances in the laboratory must be updated upon • receipt of new hazardous materials by the person who requested/ordered them!

Hazardous substances pose a hazard in the laboratory. These are substances or mixtures of substances which are classified according to their hazard potential. The danger of these substances is indicated by hazard symbols, as well as H and P phrases

according to the **GHS**. Hazardous substances can cause acute or chronic health effects in humans.

Pregnant women may only work with toxic and very toxic substances after a risk assessment has been carried out. The hazardous substances include not only chemicals but also drugs, anesthetic gases, etc. Further information on the maternity protection law is available <u>here</u>.

The **GHS** (Globally Harmonized System) is a global system to classify chemicals, including labels and safety data sheets. The GHS pictograms look visually different in comparison to the old danger symbols. New icons have been added and some old symbols do not exist anymore in the new system. Within the hazard classes, there are also various categories for classification.

Old danger symbols and new GHS pictograms

	E	Explosive	GHS 01 Explosive
, Ac	F+	Extremelyflammable	GHS 02 Flammable
	F	Highly flammable	GHS 02 Flammable
0	o	Oxidizing	GHS 03 Oxidizing
No symbol		<	GHS 04 pressurized gases
T.	c	Corrosive	GHS 05 Corrosive
	T+	Very toxic	GHS 06 Toxic
X	т	Toxic	GHS 06 Toxic
\checkmark	Xi	Irritant	GHS 07 Irritant
~	Xn	Harmful	GHS 08 Harmful
¥	N	Harmful to the environment	GHS 09 Harmful to the environment

The GHS pictograms 06, 07 and 08 warn of health risks and are used to indicate toxic properties. The GHS symbol 06 warns about acute toxicity. The toxicity of a substance can be classified into three categories with this symbol (1-3), with category 1 being the highest risk. The GHS-07 symbol is used to warn about acutely toxic and skin irritating substances. The toxic effect of substances labeled with this symbol classified in category 4 is less severe. The symbol GHS 08 warns about toxic substances. The toxicity is specific target organ toxicity (**STOT**). Substances that are labeled with this symbol can also be carcinogenic, mutagenic and toxic to reproduction (**CMR**).

For all dangerous substances there are **safety data sheets** available. These data sheets contain information on the composition of hazards and first aid measures, storage and disposal. Location of safety data sheet files: (a) Animal preparation lab: in the cabinet above the sink. (b) RF lab: in the cabinet on the corridor between the two entrance doors.

All hazardous substances are listed in a register of hazardous substances. Upon delivery of a new hazardous substance the person in charge has to ensure that the appropriate <u>safety</u> <u>data sheet</u> (usually included with the delivery of chemicals, www.sigma-aldrich.com) is added to the register.

9. Anesthetics

- Working with isoflurane should always be done under the fume hood and with special attention!
- After inhalation of isoflurane immediately seek fresh air!
- After skin contact: wash with plenty of water!
- After eye contact: rinse immediately with plenty of water and with the eyelid held wide open. Do so for 15 minutes and consult a doctor!
- In the event of an accident (e.g. accidental spill of isoflurane) the room has to be evacuated! The accident service (Eonova) and the S1 range officer must be notified!
- Access to the contaminated room is only allowed when wearing a breathing mask (located on shelf in the corridor; requires attachment of filter!!)
- To absorb and bind liquid isoflurane special granules (Absolyt, located on shelf in corridor) should be used.

ISOFLURANE is an anesthetic gas that is used for anesthetizing mice and rats and is therefore another potential source of danger. As possible vapours should not be inhaled, as they may cause drowsiness and dizziness and can impair the ability to respond. Studies have shown that the uptake of Isofluran can increase cancer risk and fertility may be impaired. Furthermore, isoflurane is suspected of causing a premature Alzheimer's disease. Working with isoflurane should always be done under a fume hood and with SPECIAL CAUTION!



In case of an accident with isoflurane despite warning of hazardous substances you should immediately take first aid action. Immediately after **inhalation of isofluran** fresh air should be supplied, if necessary, artificial respiration or mechanical ventilation. In case of skin contact you should wash with plenty of water. Contaminated clothes should be removed directly. After eye contact rinse immediately with plenty of water with the eyelid held wide open for at least 15 minutes and consult a doctor in all cases. People who have shallow isoflurane should get a gastric lavage as soon as possible. An interim use of PEG as a rinsing agent may be beneficial. The intake of active coal is another first aid action. Poeople in question should not vomit.

ISOFLURANE as a hazardous substance

In **exceptional situations**, such as accidental release of isoflurane, the room should be evacuated immediately. For cleaning up the room you are only allowed to enter this room wearing a **full face mask with filter for organic vapors** (e.g. mask 3M – 4255 FFA2P2, see S1-floor). The Isofluran can be absorbed with absorbent granules (e.g. Absolyt). Than the granules can be collected and placed in a lockable box. Treatment according to toxic organic material.

In any case, the **disaster service EONOVA** and the S1 range officer (see <u>emergency plan</u>) must be contacted.



10. Genetically modified organisms (GMOs) (for laboratory work)

- To protect the animals from infections protective clothes must be worn, consisting of a lab coat, gloves, cap and mask!
- A GMO is an organism whose genetic material has been altered in a way that does not occur under natural conditions. In our lab GMOs are almost exclusively mice.
- GMOs are classified according to their hazard potential in four safety levels (S1 represents the lowest risk).
- Eating and drinking is prohibited in the S1 area!
- For each project using GMOs records must be kept!
- S1-contaminated gloves have to be taken off before using common objects (e.g. phone), and before leaving the S1 area.
- Escaped GMOs (mice) must be captured immediately!
- Contaminated skin and cut or stab wounds and injuries should be thoroughly disinfected and reported to the project leader! A doctor should be consulted!

Everyone should be the aware that it may possibly come to contact with hazardous substances and animals when entering the S1 area. Access to this area is via S1-lock. Here your shoes have to be cleaned and in case of strong dirt you have to wear overshoes. To

protect the animals against infection you also have to wear protective clothes consisting of lab coat, gloves, cap and mask.



The productions of genetically modified organisms (GMO) or usage, storage, destruction or disposal of GMO are genetic engineering operations. A genetically modified organism (GMO) is an organism whose genetic material has been altered in a way that does not occur under natural conditions. Genetic engineering facilities are facilities in which genetic engineering works are carried out in a closed system and where barriers exist to limit the contact of the organisms to people and the environment.

Genetic engineering operations are classified in four levels of security (§7 GenTSV) according to their hazard potential:

S1	Biological agents for which it is unlikely that they cause disease in humans.
S2	Biological agents that can cause disease and pose a hazard to workers. Risk of spread: unlikely! Prevention and treatment: possible!
S 3	Biological agents that can cause severe disease and are a serious hazard to workers. Risk of spread: latent! Prevention and treatment: possible!
S4	Biological agents that can cause severe disease and are a serious hazard to workers. Risk of spread: great! Prevention and treatment: NOT possible!

At security level 1 you must not eat or drink in these rooms. Pipetting by mouth is prohibited. S1 genetic engineering operations must be carried out only in approved laboratories of level 1. Before the start of each new project and during the study records must be kept ("experiment Records" database). When working with genetically modified organisms you should not produce aerosols. Work surfaces must be disinfected after completion of the work. S1-contaminated gloves have to be taken off before using common objects (e.g. phone), and before leaving the S1 area. The windows and doors of the S1 area must be kept closed during the work.

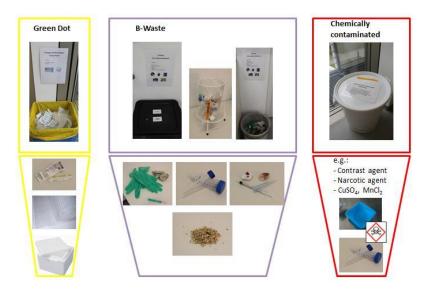
How to behave in case of danger in S1 area

Escaped GMOs must be captured immediately! All contaminated items and surfaces should be disinfected with 2% Kohrsolin (let sink in for at least one hour). In case of spilling contaminated material you have to disinfect the affected area immediately and give the material into a container for autoclaving. Contaminated skin and cut or stab wounds and injuries should be thoroughly disinfected and report to the project leader and a doctor (Durchgangs-Arzt, HELIOS-Klinikum Berlin-Buch, Schwanebecker Chaussee 50, 13125 Berlin) should be consulted.

11. Waste management (for laboratory work)

- Hazardous substances must never reach the sink, they must be disposed separately!
- Chemical solid and liquid wastes have to be separated!
- Materials contaminated with animal waste are collected and disposed in B waste!
- Needles must be disposed of in special boxes!
- S1-waste must be rendered harmless by autoclaving!

S1 waste is separated from household waste and recyclable waste from kitchen and office. The **solid wastes** are classified according to Green Dot (yellow bag), B waste (black bag) and chemical solids (white barrel). Packaging labeled with a **green dot**, Styrofoam and foil are collected in the Green Point container. Gloves, syringes, rags, bedding, blood, feces, and all things that are contaminated with animal material are collected in **B-waste**. With the white ton for **chemical solid wastes** are all solid materials that are contaminated with chemicals disposed of.



Liquid waste in S1 and HF lab are separated into waste containers for **staining solution** and **solvent**. When disposing it always comes with on the concentration of liquids! For example, manganese chloride solution with a concentration of less than 5% is disposed of in a canister for staining solutions, with a concentration of 5%, the solution must be disposed of as heavy metal waste upwards. **Hazardous substances may never reach the sink; they must be disposed of separately!**

Staining



- Copper sulphate solution
- Manganese chloride solution (< 5%)
- Formaldehyde solution (< 25%)
- Buffer solution

Solvents, halogen-free



- Alcohol (> 50%)
- Acetone

Needles must be separated in special boxes (left). Here, too, a distinction is made between the B waste and chemically contaminated waste. Liquid and solid **S1 waste** and contaminated wastewater have to be collected safely and rendered harmless by autoclaving (right).



12. General Safety

- Observe warning signs! Better safe than sorry!
- First-aid kits are located on each floor!

In the laboratory you should always work to the best of your knowledge and belief, therefore, applies in principle: it is better to be safe than sorry!

The most important warnings:

Laser beam





The main prohibition- and mandatory-signs:



The emergency equipment, such as electrical emergency, the magnet quench, the safety shower, eyes shower, and the First Aid Kits are marked as such. The First Aid Kits are located on each floor. On the first floor in the laboratory there is a full body shower and eye bath. Another eye bath is located in the preparation room on the ground floor.





For a full view of steps for First Aid, click on these poster:

13. Fire protection

- Emergency number: (0)112 or 3333
- In the MR room may ONLY be used MR-safe fire extinguisher! Note: There are building both magnetic and non-magnetic fire extinguisher!
- Readily combustible waste must be disposed of shortly!
- Flammable liquids or gases shall be stored in the safety cabinet!
- Emergency exits and escape routes should always be known!
- Director of operations of the fire department must be made aware of the dangers of the MRT!

In case of fire it is always important to ensure that only non-magnetic fire extinguishers are used in the scanner area. Signs bearing the inscriptions "forbidden to use in the magnet room" and "use in the magnet room" give appropriate instructions. ATTENTION: in B.U.F.F: both magnetic and non-magnetic fire extinguishers are distributed!



Fire and accident prevention

Use of open flames, and smoking in the building is strictly prohibited. Welding and brazing operations must be carried out only with a written approval of the conductor. Readily combustible wastes are always ready to dispose of and combustible liquids or gases (from 1L container size) must in safety cabinets (in S1 laboratory) are stored. All electrical appliances must be switched off after use.

When entering an unknown building should always inform about the **escape and rescue routes**. These are always to be found in the <u>escape and rescue plan</u> and are marked by green emergency signs in the building. Corridors, stairs and exits must be kept clear. Emergency exit doors must be closed, but may not be completed. Knowingly misuse of personal protective equipment (eg fire doors) can be prosecuted by imprisonment or a fine.





Detection and extinguishing equipment

In an emergency, the fire protection systems are to be operated and the emergency number (0)**112** or 3333 to dial. Fire extinguishers are located in the corridors and scanner rooms. On each floor fire blankets are provided, which can be used for small fires or for personal protection. For your own safety, you can prepare yourselves by taking part in fire drill by the AG Sicherheit for the worst.



How to behave in case of fire

- Keep calm
- Respond rapidly, but not frantically
- Dail (0)**112** or 3333 information:
- What happened?
- Where is it happening (Bldg., room no.)
- Name of Reporter
- Press emergency stop
- If possible, close window in the fire room
- All employees are required to leave the building (staging area = rear exit)
- Do not use elevators in case of fire
- All employees have to participate in the rescue
- Upon arrival of the fire brigade its team leader is to point out the dangers of MRI, his instructions are to be followed

Important Contacts in B.U.F.F. are <u>here</u> to find again.

14. Clinical Studies (for clinical studies)

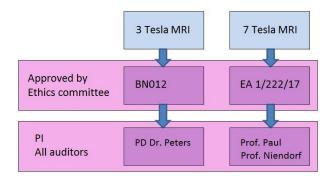
- Clinical studies must be approved by the ethics committee!
- Each volunteer is informed by an investigator and asked about possible contraindications.
- Each volunteer must sign a consent form.

• The communication between volunteers and researchers investigator is always running on the study nurse.

What is a clinical study on B.U.F.F.?

A clinical study involves volunteers. Initiation takes place in most cases by an investigator. In a study the feasibility of new technologies is demonstrated. Each study requires approval by the ethic committee.

Exemplary Approval overview



Role of the study nurse

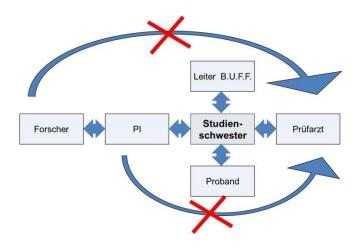
The study nurse communicates with the Principal Investigator (**PI**) and the researchers and prepares all the needed study documents. They recruited patients and controls and checks them for MRI compatibility. The communication between the volunteer and the investigator (Dr. Mehling) also runs over the study nurse. Furthermore, she reserves the slots on the device and prepares the volunteers on the MRI before. Each volunteer who participates in a study, a consent form must be signed by an informed consent discussion. Only after complete documentation (More information) a volunteer may be put into the MRI.



Required information three weeks prior to study entry

Before the study is a brief summary of the objectives, a study plan or protocol and a schedule must exist. There must be information about possible doses of contrast agents.

Communication chain – and the course of action by leading researchers course of action



SOP summary

- Make sure that you adhere to the work instruction
- Make sure that you include the study nurse
- Each volunteer is to introduce the investigator
- Each volunteer requires its own patient clothing
- Food and drinks are not allowed in the scanner area
- After completion of work, the scanner area is restore to its original state so that the next user finds a clean workplace
- It is imperative that the PI / researcher collects its data and secures
- Failure to follow these instructions will result in the loss of the scan permission!

Correct behavior for dealing with volunteers during normal operation:

- Volunteer must wear patient clothing
- Volunteer instruction
- Control of all parties **before** they enter the scanner room (volunteers, doctors, MTAs, nurses, partners, guests, etc.)
- All metal parts have to be stored, otherwise wearing of metal parts can lead to combustion!
- Hearing protection for those who remain in the room during the scanning
- Emergency bell for the volunteer
- No companion / caregivers in the scanner room
- Close the door!

Volunteer instruction and contraindications

Volunteers are informed prior to any investigation about the risks of MRI and asked about contraindications. People with implants, metal fragments, body piercings or other metal parts in the body, as well as pregnant women and people with tattoos are not allowed in MRI machine for security reasons.

People with claustrophobia, ICU volunteers, children and people with insufficient thermoregulation represent a risk group and may be examined only after examination of the investigator.

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