PART
A

Safety

CHAPTER A.1

General safety information

Please note the following aspects and topics with respect to the general safety instructions:

- ❏ Structure of the warnings
- ❏ Legal regulations
- ❏ Product safety
- ❏ Regular maintenance

Structure of warning labels

WARNING
Source of danger!

Consequences

- ✧ Countermeasure.

Warning and safety instructions are identified in a special way. The following keywords signal the level of hazard involved:

WARNING	Warning regarding risks that may result in death or serious physical injury.
CAUTION	Warning regarding risks that may result in minor physical injury or material damage.

Legal regulations

Accidents resulting in personal injury

All accidents resulting in personal injury have to be reported immediately to the appropriate authorities or the employer's liability insurance carrier.

Country-specific regulations

In countries outside Germany, local and national legal regulations have to be observed.

National guidelines (for Germany)

The following regulations are in effect in Germany:

- ❏ Medical Devices Act (MPG)
- ❏ Electromagnetic Device Compatibility Act (Gesetz über die elektromagnetische Verträglichkeit von Geräten (EMVG))
- ❏ Medical Device Operator Regulations (MPBetreibV)
- ❏ Accident Prevention Regulations (UVV)

The Accident Prevention Regulations also define the acceptable noise levels to which users and patients may be exposed.

If required, the RF source has to be registered with local authorities (→ Page L.1-14 *Electromagnetic Compatibility (EMC)*).

Medical Devices Book

The MR system may be operated only by qualified, trained personnel who are listed by name in a Medical Devices Book. Maintaining a Medical Devices Book is the responsibility of the customer. Note that Siemens does not provide this book.

Pressure Equipment Directive

The super-conducting magnet is a pressure equipment. National guidelines for starting up and operating pressure equipment have to be observed.

In Europe, the Pressure Equipment Directive (97/23/EG) regulates placing the pressure equipment on the market and putting it into service.

In Germany both the Pressure Equipment Directive as well as the relevant Occupational Safety Regulations (BetrSichV) for system start-up and operation apply. The Occupational Safety Regulations require that the operator performs an acceptance test prior to system start-up. This test includes checking the system functions, the safety equipment as well as the system site. Repeated testing of the cryostat is not required. However, internal as well as stability tests have to be performed repeatedly, when the pressure equipment is no longer in operation due to repairs.

Explosion protection

The MR system is not intended for operation in areas prone to explosion.

Product safety

Combination with other systems, accessories

If the MR system is combined with other systems or components, it has to be ensured that the planned combination and cable routing do not affect the safety of patients, personnel, or the environment.

✧ When using a combination of systems, please contact Siemens Service for MR compatibility and adhere to the instructions provided.

Repairs, changes, use in accordance with operating instructions

Modifications or additions to the product have to comply with legal regulations.

Siemens is not responsible for repairs performed without express written consent.

All work, additions, and modifications to the MR system or to the installation site have to be checked by Siemens in advance to ensure their compatibility with the MR system's functionality.

The person performing the work has to provide a certificate describing the nature and extent of work performed. This certificate has to include information about changes to the nominal data or work area, along with the date, name of company, and signature.

Upon request, Siemens Service will provide technical documents for the MR system. However, this does not constitute authorization for repairs.

Responsibility

As a supplier, Siemens will not be held responsible for the safety, reliability, and performance of the system in the following cases:

- ❏ Installations, additions, adjustments, modifications, and repairs to the MR system, or changes to the software are not performed by Siemens Service.
- ❏ Assemblies are not replaced with original spare parts.
- ❏ The electrical wiring in the room does not meet the requirements of VDE regulation 0107 or applicable national laws.
- ❏ The MR system is not used in accordance with the operating instructions.

Regular maintenance

Maintenance

In the interest of the safety to patients, operating personnel, and third parties, it is strongly recommended that only authorized personnel perform the maintenance procedures provided by Siemens. System checks should be conducted more frequently if the system is operated under extreme conditions.

- ✧ Please inform Siemens Service if a maintenance contract does not exist.

Serious malfunctions

- ✧ In the event of major malfunctions, immediately shut down the MR system.
- ✧ Notify Siemens Service.

WARNING

MR system malfunction!

Hazardous conditions for patients

- ✧ Please note the sounding alarm and signal.
- ✧ Do not perform MR examinations.
- ✧ Notify Siemens Service.

WARNING

High voltage and currents inside the electronics cabinets!

Risk of death by electrocution

✧ Electronics cabinets should be opened by Siemens Service only.

Safety-relevant accessories

The following safety-relevant accessories have to be checked:

❏ All RF coils for the transmitting and receiving system (some are optional)

❏ ECG and respiratory sensor (optional)

❏ Disposable electrodes (optional)

❏ Pulse sensor (optional)

Checks regarding structional or technical changes

Daily checks

During MR system operation, technical or structural changes may be performed as follows: Prior to changes not in the immediate vicinity of the MR system, the user has to ensure satisfactory operation of the exhaust line and the heating/air conditioning unit. Windows, doors, and emergency flaps/valves cannot be blocked.

After having checked the MR system, a visual inspection of the following structural changes needs to performed on a daily basis:

- ❏ Changes in the vicinity of the output of the exhaust line (e.g. retroactively installed windows, inputs/outputs for air conditioning units, new buildings, temporarily installed containers)
- ❏ Changes to the air conditioning unit or venting system (e.g. by adding air inlets and outlets in neighboring rooms)
- ❏ Installation of additional MR systems (e.g. unallowable use of one exhaust line for several MR systems)
- ❏ Constructional changes inside and outside the examination room

Annual checks

The annual technical safety inspections are listed in the operating manual and may be performed by Siemens Service only.

CHAPTER A.2

Personal safety information

Personnel-related safety instructions are divided according to the following topics:

- ❏ Information for all persons
- ❏ Information for operators
- ❏ Contraindications
- ❏ Emergency shut-down switch
- ❏ Patient registration
- ❏ Patient instructions
- ❏ Patient monitoring
- ❏ Artifacts and imaging errors
- ❏ Quality assurance

Information for all persons

According to today's body of knowledge, MR examinations performed as described do not present hazards for patients and operating personnel.

However, certain elements need to be listed to ensure that patients, personnel and devices are not adversely affected.

The following sources for risk may be minimized by adhering to safety-related requirements:

- ❏ Electromagnetic fields
- ❏ Coolant
- ❏ Acoustic noise
- ❏ Laser
- ❏ Mechanical hazards

CAUTION

Insufficient information regarding potential risks when working with MR systems!

Personal injury, property damage

✧ Ensure that all authorized operating personnel are regularly informed about the potential risks inherent in MR systems as well as the relevant safety information.

Electromagnetic fields

During an MR examination, the patient is subject to three different types of electromagnetic fields:

- ❏ Static main magnetic field
- ❏ Gradient fields
- ❏ RF fields

The effects of these fields vary including the immediate vicinity of the MR system. In addition to the patient, accompanying personnel or operating personnel are subject to these fields in the examination room. For this reason, the safety instructions apply without exception to all personnel located in the vicinity of the magnet.

MR system and control areas

The MR system environment includes the MR system as well as the control area of the basic and/or RF field.

The control area of the basic field includes the so-called 0.5 mT exclusion zone (→ Page A.3-6 *Magnetic fringe field and control area*).

The magnetic flux density is less than 0.5 mT outside the control area of the main magnetic field. Magnetic flux densities that exceed 0.5 mT interfer with electronic implants or other devices.

The control area of the basic field is identified on the floor. The magnetic fringe field may extend beyond the examination room (walls, ceilings).

The RF room defines the control area of the RF field.

Outside the control area of the RF field, electromagnetic interferences meet the requirements according to IEC 60601-1-2.

! Exposure of personnel to static and time-varying magnetic fields as well as noise may be regulated by local laws.

Pregnancy

To date, there is no scientific proof that MR examinations are harmless for pregnant women or that RF exposures are harmless for pregnant operating personnel. Qualified physicians (while taking into account alternative methods) have to determine whether the clinical value of the examination outweighs the risks involved.

WARNING

Failure to observe safety measures when the MR system is switched off!

Personal injury

✧ The exclusion zone and corresponding safety measures have to be observed even when the system is switched off.

WARNING

Discharge of 120 °C hot air from the back of the amplifier!

Risk of burns

- ✧ Do not position objects in front of the back of the amplifier.
- ✧ Do not touch the back of the amplifier.

Static magnetic field (basic field)

Generating the basic field

The basic field of MR systems for polarizing atomic nuclei in the body is generated by a super-conducting electromagnet with active fringe field shielding (superposition of an opposing field). The coil of the electromagnet is wound from multifilament wire. The super-conducting wire consists of a niobium-titanium alloy, embedded as fine filaments in a copper matrix.

The static basic field is highly homogeneous in the magnet tunnel and drops considerably outside the tunnel as a function of the distance to the magnet. Especially at the entrance of the magnet bore this leads to large spatial gradients of the magnetic field.

In addition to a high magnetic flux density, the basic field of modern MR systems has to meet such essentials as a highly homogeneous as well as stable magnetic field.

Today these requirements are met exclusively by magnets made from super-conducting material. At very low temperatures, super-conducting materials lose their electrical resistance. Coils made from super-conducting materials generate considerably stronger magnetic fields than e.g. copper coils.

To maintain the super-conductivity of the magnet, liquid helium is used as a coolant. Safety-relevant details for coolants are described in section (→ Page A.2-24 *Coolant*).

Corrections of the basic field

The spatial homogeneity of the area under examination (“Field of View”) is determined by the construction and manufacturing tolerances of the magnet, the ferro-magnetic components in the building as well as by the patient’s effect on the main magnetic field.

Manufacturing-related inhomogeneities as well as interferences caused by ferromagnetic components in the building are compensated for by the individually computed allocation of iron shims (“Passive shim”). To further increase homogeneity, especially in the presence of the patient, active shim methods (shim coils) are implemented.

Force and torque

The main magnetic field poses the hazards of attracting and aligning magnetizable objects in the magnetic field.

In addition to accelerating objects at the speed of projectiles in the examination room, the movements of implants or protheses also present considerable hazards. The main magnetic field applies forces and torques to implants and protheses resulting in serious harm to the patient. The mobility of the implant depends heavily on the type and purpose of use.

As a rule, it is difficult for the user to correctly estimate the material involved, since implants (and other medical devices and tools) may represent a combination of different components and/or alloys.

For this reason, the exacty type of implant has to be known prior to the examination from e.g. operation protocols or other earlier recordings.

In addition to the general warning, specific examples are provided for objects that must not enter the examination room. This list is not exhaustive. It only serves as an illustration of objects that present hazards in the presence of magnetic forces.

WARNING

Magnetizable objects introduced into the magnetic field become projectiles!

Injury to patient and operating personnel

- ✧ Do not use resuscitation devices, for example, defibrillators or oxygen bottles, in the examination room.
- ✧ Do not use transport trolleys, movable beds, stretchers, etc. that consist of magnetizable parts.
- ✧ Do not wear or carry any magnetizable objects on your person, for example, watches, pens, scissors, etc.
- ✧ Only proven MR-compatible accessories, parts subject to wear and tear, and disposable articles should be used with the MR system.
- ✧ Use only MR-compatible tools and devices.
- ✧ Service work on the MR system may be performed by Siemens Service only.
- ✧ Ensure that only authorized personnel, e.g. electricians or cleaning personnel enter the control area (0.5 mT exclusion zone).
- ✧ Keep the door to the examination room closed.

WARNING

Magnetizable objects introduced into the magnetic field become projectiles!

Injury to patient and operating personnel

✧ Inform the operating personnel about the stronger effect of forces on ferromagnetic parts or implants in 3 Tesla systems.

!

Ensure that the devices used in the examination room are compatible with the field strength of the MR system. Devices compatible with 1.5 T systems may be unsuitable for 3 T systems.

Artifacts

Due to their magnetizability, foreign objects in the area of the magnet bore cause strong local distortions of the basic field and lead to considerable image artifacts. Depending on the level of distortion, diagnosis may be difficult, impaired or completely impossible.

Dizziness when exposed to 3 Tesla magnetic fields

The high basic field may cause patients to temporarily experience slight dizziness or sensory irritations.

CAUTION

Dizziness of the patient during table movement inside the magnetic field!

Reaction of fear by the patient

✧ Prior to moving into the magnetic field, inform the patient about temporary feelings of dizziness.

CAUTION

Drowsiness, dizziness or metallic taste during measurements in a 3 Tesla magnetic field!

Reaction of fear by the patient

✧ Prior to the examination inform the patient about the possible occurrence of these symptoms.

Time-dependent magnetic fields (gradient fields)

Generating a gradient field

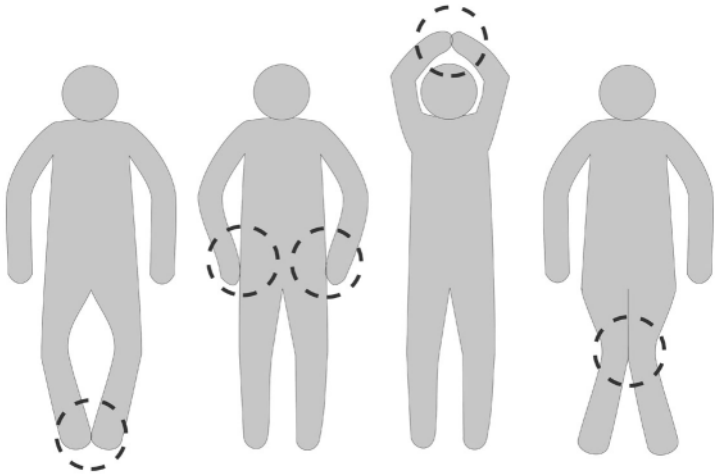
The gradient system (whole-body gradient system) comprises a gradient amplifier and gradient coils. It superimposes three spatially-varying fields over the basic magnetic field, one for each axis. These three fields can be switched on and off, and can have the various amplitudes needed for different types of MR imaging. Gradient fields are characterized by the gradient field strength, the rise time and the spatial linearity of the gradient fields. The Larmor frequency can be locally changed in the object of examination by the gradient field. This allows for spatial encoding of the signals. The gradient fields for the three axes are generated in three separate, actively shielded gradient coils. All gradient coils, including the shielding coils, are wound in layers on a single coil form.

Induction and stimulation

Faraday's Law (law of induction) establishes a relationship between the changes of a magnetic field over time and an electrical rotational field. The low-frequency change of the magnetic flux (switching on and off gradient fields) induces an electrical field in the tissue of the patient that shifts the charge in the nerve fibers of the tissue. This shift in charge dissipates the resting membrane potential of the nerve fibers and may lead to peripheral nerve stimulation depending on the strength, frequency, and duration of the shift in charge.

Current loops

Large current loops, e.g. caused by crossed hands, knee-knee contact may occur if the patient is not positioned correctly. Gradient fields couple very effectively to these loops. This increases the probability of stimulation.



Examples of skin contact that may lead to large-surface current loops

WARNING

Incorrect patient positioning!

Peripheral nerve stimulation through low-frequency magnetic fields

- ✧ Position the arms of the patient along the side of the torso.
- ✧ Ensure that the hands of the patient do not touch.

CAUTION

The patient is wearing electrically-conducting material!

Peripheral nerve stimulation through low-frequency magnetic fields

- ✧ Ensure that the patient is free of metallic rings, chains, or electrically-conducting materials worked into items of clothing (e.g. brassiere support wires).

Acoustic noise

The gradient coils are controlled via gradient amplifiers that rapidly switch high currents with high precision and stability within very short time frames. Time-dependent Lorentzian forces are generated in response to currents being switched quickly in the main magnetic field. The Lorentzian forces affect the gradient coil body. The resulting mechanical stimulations are heard as noise (humming, knocking noises) during the MR examination (→ Page A.2-37 *Acoustic noise*).

Time-dependent electromagnetic fields (RF fields)

Generating an RF field

The nuclear spins of the body tissue are stimulated via pulsed magnetic RF fields. These RF pulses are generated by an RF transmit amplifier in the RF system and transferred via RF coils to the object to be measured. Again RF coils and the so-called RF receive amplifier are used to receive RF signals that are digitized for processing in the image processor.

Inductive warming

The RF fields emitted during MR examinations induce electrical fields analogous to gradient fields. These electrical fields may generate eddy currents. However, due to their high frequency they do not lead to stimulation effects in the electrically-conducting body tissue of the patient. The energy exchange of the RF field leads primarily to warming of the body tissue (→ Page G.1-1 *Physiological effects*). An important value per body weight is the specific absorption rate or SAR. The SAR values are monitored by an integrated SAR monitor.

WARNING

Heat development during the MR examination!

Patient burns

✧ Instruct patients to press the squeeze ball in case of strong heat sensations.

WARNING

Heating up/ignition of synthetic blankets via the RF field during the measurement!

Patient burns

✧ Use only covers made of paper, cotton or linen.

Effect of antenna

Looped cables (e.g. of RF coils, ECG lines, patient monitoring devices) show an exceptionally high capability of receiving RF fields. The loops function as receive antennas and may warm to levels leading to second or third degree skin burns. High current densities caused by damages to the insulation may lead to arcing.

WARNING

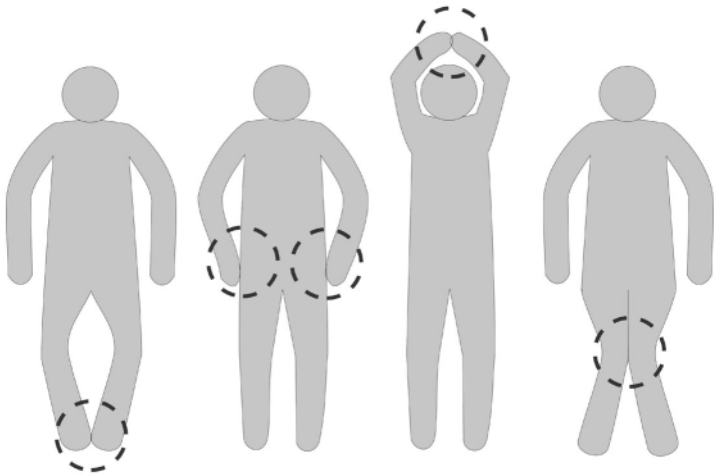
Arcing caused by coil cable loops!

Patient burns

✧ Avoid coil cable loops.

Current loops

If parts of the patient's body touch, hazardous current loops may occur, resulting in burns at the points of contact.



Examples of skin contact that may lead to large-surface current loops

✧ Ensure that patients are not positioned as shown in the illustration.

Current loops are generated when the patient's skin contacts the tunnel lining or RF coil cables. To avoid this source for hazard, special care has to be taken in correctly positioning adipose patients.

WARNING

Incorrect patient positioning in low-frequency and RF-electrical fields! Formation of electric current loops!

Patient burns

Peripheral nerve stimulation of the patient

- ✧ Ensure that the patient does not wear clothing that is wet or dampened by perspiration.
- ✧ Ensure sufficient ventilation.
- ✧ Ensure that hands, arms, and legs do not touch and that arms are aligned with the torso.
- ✧ Maintain a minimum distance of 5 cm between the extremities.
- ✧ Use positioning aids, e.g. blankets made of linen, cotton, or paper, or dry material that is permeable to air and at least 5 mm thick.
- ✧ Keep the patient from contacting the tunnel lining.

RF coils that are not connected

RF coils that are not correctly connected to the coil socket are not detuned with respect to the body coil. They absorb large portions of the body coil's RF power and may warm considerably.

WARNING

Coil cables/plugs not connected!

Patient burns

Irreparable damage to RF coil

- ✧ Ensure that all RF coils used are connected.
- ✧ Remove disconnected RF coils from the patient table.

Coolant

The magnet is filled with liquid helium as a coolant. Following installation, it is adjusted to the desired operating field strength. During normal operation, the magnet does not lose helium. Under special conditions – power failure, malfunctions of the cold head and maintenance activities – liquid helium has to be refilled by Siemens Service.

Properties

Liquid helium has the following characteristics:

- ❏ Extremely cold (causes frostbite upon contact)
- ❏ Oxygen in ambient air is displaced during boil-off (risk of asphyxiation)
- ❏ Odorless
- ❏ Non-flammable
- ❏ Non-toxic

Helium-related risks

WARNING

Unauthorized work on the magnet!

Personal injury, property damage

- ✧ Only authorized personnel (Siemens Magnet Technology or Siemens) may perform work on the magnet.
- ✧ Do not open or remove safety valves and burst disks of the helium container.
- ✧ Do not change the standard configuration.

Risk of fire

Local increases in oxygen may occur due to escaping helium condensing along pipes or the magnet. This increases the possibility of fire in the vicinity of these components.

Risk of asphyxiation

Abruptly escaping helium displaces oxygen in the air. Air has an oxygen concentration of approx. 21 %. The human ability to respond is already limited at an oxygen concentration of below 19 %. Therefore, rooms must be well ventilated; the air conditioning must be switched on and functioning.

! The heating and air conditioning system is installed on-site by the customer. It is not part of the MR system. Information with respect to maintenance (e.g. replacing filters) and monitoring the functions of the air conditioning system are included in the operating instructions of the heating and air conditioning system manufacturer.

Escape routes for the building must be established and well marked. Escape routes must not be obstructed.

A copy of the following first aid measures has to be conspicuously displayed in the examination room.

First aid

First aid in case of breathing difficulty

A person becomes unconscious due to severe shortness of breath:

- ✧ Immediately remove the unconscious person from the room.
- ✧ Start CPR immediately.
- ✧ Call a physician immediately.

First aid in case of frostbite

Direct skin contact with subzero liquids and gases as well as subzero surfaces (e.g. pipes) leads to serious injuries. The eyes and mucous membranes are especially vulnerable.

- ✧ Carefully remove clothing from the affected area.
- ✧ Rinse frozen tissue with cold water.
- ✧ Cover frostbitten skin with sterile dressing.
- ✧ Do not apply powder or creams.
- ✧ Call a physician immediately.

WARNING

Improper handling of liquid helium!

Skin damage caused by frostbite

✧ Do not rub frostbitten skin areas.

Information for developing an emergency plan

It is strongly recommended that the operator establish an emergency plan for gaseous helium escaping into the examination room.

The emergency plan should include the following information:

- ❏ Rescue scenarios that can be practiced with personnel
- ❏ Room-related conditions
- ❏ Rescue personnel (safety personnel, paramedics and firemen)

Quenching the magnet

During a quench, the super-conductivity of the magnet is suspended. The energy of the magnetic field is converted into heat. After releasing a quench, the magnetic field strength drops to approx. 20 mT within approx. 20 seconds. The liquid helium (coolant) boils off during this process and is released to the outside via the exhaust vent line. Depending on the magnet type, approx. up to 1000 m^3 of gaseous helium is released within a short period of time. The escape of large quantities of gaseous helium via the exhaust line is rather noisy (hissing, gurgling).

When the exhaust line is intact, gaseous helium cannot enter the examination room.

A quench may occur as follows:

- ❏ Start-up of the MR system (ramping up or filling the magnet)
- ❏ An accident (earthquake, fire, etc.)
- ❏ Spontaneous without any obvious external reason (highly unusual)

The operator is able to release an intentional quench by activating the **Magnet Stop** switch (→ Page A.2-57 *Magnet Stop switch (magnetic field)*).

As a rule, Siemens Service has to be called following a quench.

The magnet may be put back into operation by Siemens Service only.

Intact exhaust line

The super-conducting magnet and the exhaust line have been designed for the event of a quench. A quench is not critical for patients, personnel and MR system when the magnet functions correctly and the exhaust line is intact.

WARNING

Formation of droplets due to condensation during quenching!

Personal injury

Risk of fire

- ✧ Do not touch the exhaust line.
- ✧ Do not stand under the exhaust line.
- ✧ Avoid open flames.
- ✧ Do not smoke.

Small leaks in the exhaust line

Gaseous helium is released into the examination room through small leaks in the exhaust line. Formation of light fog (condensed) air may impair visibility. When the heating/air conditioning system is intact, the helium is transported to the outside and replaced by fresh air.

There is no risk of suffocation.

Each leakage is indicative of constructional errors that have to be removed.

- ✧ Open the door to the examination room as well as the windows and doors in adjacent rooms.
- ✧ Rescue patients (→ Page D.1-25 *Rescuing the patient in an emergency*).
- ✧ Leave the examination room if it does not involve rescue efforts.
- ✧ Enter the rooms only after the noises (hissing, rushing) have died down and the rooms have been aired.

Partial or complete failure of the exhaust line

When the exhaust venting line fails in part or fully, up to 1000 m^3 of gaseous helium escapes into the examination room (approx. 100 m^3). As a rule, the largest quantity of gaseous helium escapes during the first few minutes of a quench. It is, however, not possible to provide an exact course over time, since the type of defect (large leaks, blocked or torn exhaust line) is not predictable.

In case of partial or full failure of the exhaust line, the air conditioning system is not capable of providing sufficient air exchange.

Heavy fog formation along the upper level of the examination room impairs visibility. The pressure in the examination room will rise.

Depending on the type of defect, e.g. large leakages, acute hypothermia or suffucation exists. The oxygen content of the air can be measured with an oxygen measurement device.

! Due to such hazardous conditions as acute hypothermia and suffucation, rescue attempts cannot be performed by a single person.

Persons not directly involved in the rescue should leave the examination room as well as adjacent rooms.

A filter (gas mask) without its own oxygen supply does not protect against suffocation through helium.

- ❏ If the door opens in the direction of the control room, the door may fly open due to overpressure in the examination room and injure personnel.
- ❏ If the door opens in the direction of the examination room, the overpressure may prevent the door from opening.
- ❏ Portholes or observation windows may fly open uncontrollably and injure personnel.

After opening the door to the examination room, gaseous helium may enter adjacent rooms and endanger personnel. For this reason, all windows and doors in adjacent rooms should be opened before opening the door to the examination room.

- ✧ Open doors and windows in adjacent rooms.
- ✧ Leave the examination room immediately, if personnel do not have to be rescued.

! When pushing in the observation window, avoid injury through glass splinters.

- ✧ If the door to the examination room does not open due to overpressure, open the portholes and the observation window. If this is not possible, shatter the observation window. Push through the wiring for RF shielding.
- ✧ Enter the rooms only after the noises (hissing, rushing) have died down and the rooms have been aired.

Refilling helium

Siemens is not responsible for potential damages in the event non-authorized personnel refill the magnet with helium.

If the helium fill level is too low, a signal will sound at the alarm box (→ Page B.8-1 *Description*) and/or the MR console.

- ✧ Notify Siemens Service in case of alarm and ensure that the helium is refilled.

When filling the magnet with helium, perform the necessary tasks carefully and accurately, observing all regulations.

It is prohibited to store flammable material in the vicinity of containers filled with coolant.

WARNING

Gaseous helium escaping during the fill/refill procedure!

Hazard of suffocation, frostbite

- ✧ Ensure that the rooms are ventilated via an air conditioning system.
- ✧ Ensure that escape routes for the building are established and well marked.
- ✧ Ensure that escape routes are not obstructed.
- ✧ Ensure that the magnet is filled by Siemens Service only.
- ✧ Ensure that patients are outside the room during the filling/refilling procedure.

WARNING

Improper storage of coolant containers!

Personal injury

- ✧ Have experienced personnel regularly check the coolant containers according to manufacturer's specifications.
- ✧ Ensure that coolant containers do not block escape routes.

Acoustic noise

CAUTION

Noise development during the MR examination!

Injury to patient (hearing damage)

- ✧ Provide the patient with hearing protection (headset or ear plugs).
- ✧ Ensure that personnel in the examination room wear hearing protection during the examination.

The hearing protection has to be sufficient to reduce the noise to 99 dB(A).

! The exposition of persons to noise may be regulated through local laws.

- ✧ Do not exceed the max. time allowed in the MR suite.

By responding with increasing anxiety to the permissible sound level, pregnant women and the fetus, newborns, infants and small children as well as seniors may be giving cause for concern.

Patients who are either anesthetized or unconscious have to wear hearing protection.

As protection against noise, all patients have to wear headphones during the MR examination. During the measurement, the headphones are also used to provide the patient with messages from the operating personnel.

! The usual hearing protection (headphones) cannot be used when examining infants or using head coils. The operating personnel require training in providing patients with alternative hearing protection, e.g. ear plugs.

Laser

The laser light localizer on the magnet facilitates correct patient positioning.

The laser light localizer includes two lasers of Class 2M according to IEC 60825-1/01.2001[1] (Class II according to US CDRH).

All laser-relevant locations at the MR system are identified with warning labels directly next to each laser opening (→ Page A.3-13 *Warning signs*).

Increased risk

Anesthetized patients or patients who do not have a blinking reflex for other reasons must be protected from the laser beam.

! The laser light localizer switches off automatically after one minute without patient table movement.

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[1] Class 3A according to DIN EN 60825-1, third edition, 1997.

WARNING

Laser beam of the laser light localizer!

Eye injury caused by laser beam

- ✧ Ensure that the operating and adjustment devices as well as methods given are used as described.
- ✧ Inform the patient about the possible hazards and request that he keep his eyes closed during positioning.
- ✧ Ensure that helpless patients keep their eyes closed during the positioning procedure.
- ✧ Only use the laser light localizer as described.
- ✧ The laser light localizer needs to be checked regularly by Siemens Service.

WARNING

Laser beam exits in dot form at the laser light localizer!

Eye injury caused by laser beam

- ✧ Ensure that the laser light localizer appears in the form of crosshairs on the patient table.
- ✧ Switch off the laser light localizer when it appears in the shape of a dot. Also notify Siemens Service.

Mechanical hazards

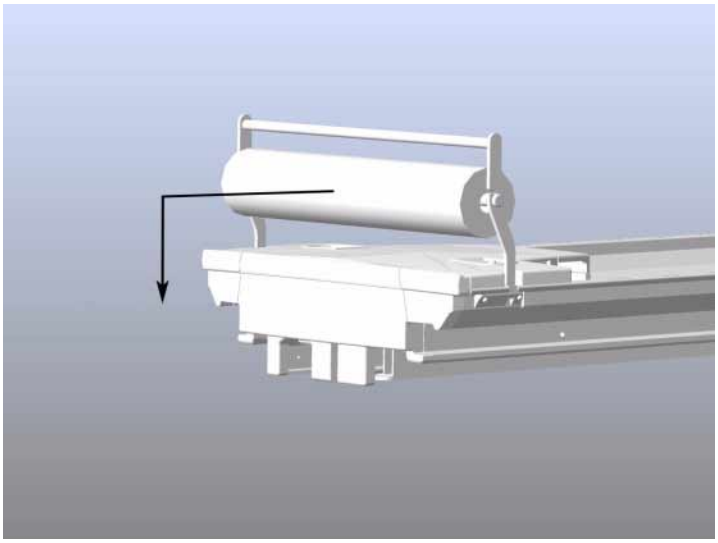
Collision or points of injury

Collisions and injuries are more prevalent when using the patient table or when performing maintenance activities.

✧ Please note the warning and prohibition signs as well as the safety information provided.

Paper roll holder

To minimize the potential for injury in the area of the magnet, the paper roll holder at the patient table can be moved. If the paper roll comes across an obstacle while the patient table is moving into the magnet bore, the roll holder flips behind the foot end of the patient table.



Paper roll holder

✧ Set the paper roll holder upright.

Hazard of falling down

The hazard of falling down is related in particular to the unfavorable routing of cables/hoses of interventional components.

CAUTION

Cable/hoses of interventional components!

Injury to patient and operating personnel

✧ Route cables/hoses of interventional components so that it is not possible to trip over them.

Information for operators

Qualified personnel

The operator has to ensure that all personnel working with the MR system are qualified and have received the appropriate MR system training.

The MR system includes a keyswitch to prevent non-authorized switch on.

Informational signs and identification

The operator has to ensure that informational signs for safety purposes are available in sufficient quantities and are easily visible. At the same time, the operator is also responsible for properly identifying the environment of the MR system as well as adjacent areas by using the necessary signs.

Emergency procedures

The operator of the MR system has to define and provide procedures that ensure the patient's safety in case of emergency. Special consideration has to be given to MR-specific hazards.

For example, the operator of the MR system has to consider the risks associated with the magnetic field and ensure that patients receive immediate treatment in such cases as:

- ❏ In the case of an emergency
- ❏ When the patient suddenly feels ill during an examination
- ❏ When the patient is injured during the examination

Special precautionary measures as well as a plan for using emergency equipment outside the examination room have to be in place for patients with a higher than normal risk factor, such as:

- ❏ Patients susceptible to cardiovascular collapse
- ❏ Patients who are at an increased risk of heart attacks or other cardiac problems
- ❏ Unconscious patients
- ❏ Patients with limited thermoregulation
- ❏ Children
- ❏ Epileptics
- ❏ Claustrophobic patients
- ❏ Patients who are seriously ill, unconscious, anesthetized or confused or who are not able to communicate normally for other reasons (e.g. small children)

The procedures have to define the fastest way possible for removing the patient from the examination room in case of emergency.

- If necessary, the MR system has to be shut down using the **Emergency shut-down** switch (→ Page A.2-62 *Emergency shut-down switch (electrical system without magnet)*). Press the **Magnet Stop** switch in case of fire or accidents where metal parts may be pulled into the magnet and injur personnel (→ Page A.2-57 *Magnet Stop switch (magnetic field)*).

WARNING

Medical emergency during MR measurements!

Risk of death to patients

- Terminate the measurement immediately.
- Remove patients from the examination room for treatment unless it is certain that the medical equipment required is appropriate for use inside an MR room.
- Do not store or operate oxygen tanks, defibrillators or other auxiliary tools for resuscitation in the examination room.

Instructing personnel

The personnel have to read and understand the operating manual and in particular the safety chapter before working with the system. This applies especially to personnel who are only occasionally working in the examination room.

Personnel have to be trained in the safe and effective use of MR systems.

The training has to include the following topics:

- ❏ Emergency medical care
- ❏ Control area
- ❏ Emergency buttons
- ❏ Measures preventing fires
- ❏ Quench emergency plan

Emergency shut-down switch

For the MR system, several **Emergency shut-down** switches have to be installed on site to shut off system voltage. The room installation has to comply with VDE 0107.

Firefighting

General prerequisites for firefighting

In the event of fire, the fire has to be extinguished with methods appropriate to the surroundings. Fire fighters have to be able to take appropriate actions immediately. For this purpose, the fire department has to be familiar with the MR system and its location.

! Prior to initial start-up of the MR system, the operator is responsible for informing the fire department about the MR system and the structural on-site conditions.

Mandatory reporting in case of fire

- ✧ Inform the fire department about the contents of the measurement phantoms.
- ✧ Inform the fire department about the health hazards caused by aerosols containing nickel.

Firefighting

The following devices/materials may be used for firefighting:

- ❏ Non-magnetic CO_2 extinguisher
- ❏ Self-contained, anti-magnetic compressed-air respiratory device (or hose connection)
- ❏ Airtight chemical protective suit

It is the user's responsibility to provide firefighting material.

Contraindications

An MR examination is contraindicated for patients with electronic or electronically-conducting implants or metals, especially those containing ferromagnetic foreign bodies.

The type and material of the implant or type of foreign body have to be known prior to the MR examination and their MR compatibility has been proven.

For each patient – and this applies particularly to patients with implants or other foreign ferromagnetic material – a benefit/risk analysis of the MR examination has to be established and evaluated.

Possible functional interferences in MR-compatible implants have to be clarified prior to the MR examination.

Contraindications for MR examinations are:

- ❏ Electronic implants e.g. pacemakers/insulin pumps
- ❏ Artificial heart valves
- ❏ Aneurysm clips
- ❏ Metal splinters in the eye (danger of retinal detachment)
- ❏ Artificial anus (anus praeter) with magnetic closure
- ❏ Transdermal adhesive dressing
- ❏ Electrically-conducting implants and prostheses

WARNING

Electronic implants in static magnetic fields!

Injury to patient

- ✧ Ask the patient about implants and inclusions.
- ✧ Do not perform MR examinations on patients with electronic implants, e.g. pacemakers, dosing pumps.
- ✧ Ensure that patients wearing implants/inclusions remain outside the exclusion zone (0.5 mT line).

WARNING

Electrically-conducting implants and magnetizable inclusions in static or low-frequency magnetic fields!

Injury to patient

- ✧ Ask the patient about implants and inclusions.
- ✧ Do not perform MR examinations on patients with metallic and electrically-conducting implants or magnetizable inclusions.
- ✧ Ensure that patients with electrically-conducting implants and magnetizable inclusions remain outside the control area (0.5 mT exclusion zone).

WARNING

Eddy currents induced by low-frequency magnetic fields!

Patient burns

- ✧ Do not examine patients with electrically-conducting implants or prostheses.

WARNING

Electrically-conducting implants in RF fields!

Risk of death to patients

- ✧ Do not examine patients with electrically-conducting implants.
- ✧ Ensure that patients wearing implants/inclusions remain outside the exclusion zone (0.5 mT line).

First Level Controlled Operating Mode

WARNING

Exposure to RF electromagnetic fields in *First Level Controlled Operating Mode*!

Patient burns

- ✧ Do not examine patients with restricted thermoregulatory capability (e.g. small children, elderly, sick, or medicated patients).
- ✧ Do not examine patients unable to communicate potential overheating effects (e.g. small children, seriously ill, paralyzed, unconscious, sedated, or handicapped patients).
- ✧ Carefully monitor the patient during the MR examination.
- ✧ Ensure that patients wear light clothing (e.g. light pyjamas or nightgown).
- ✧ Remove all additional insulation, e.g. blankets or covers.

WARNING

Exposure to RF electromagnetic fields in *First Level Controlled Operating Mode*!

Patient burns

- ✧ Monitor the patient with care during the MR examination.
- ✧ Instruct the patient in the use of the squeeze ball.

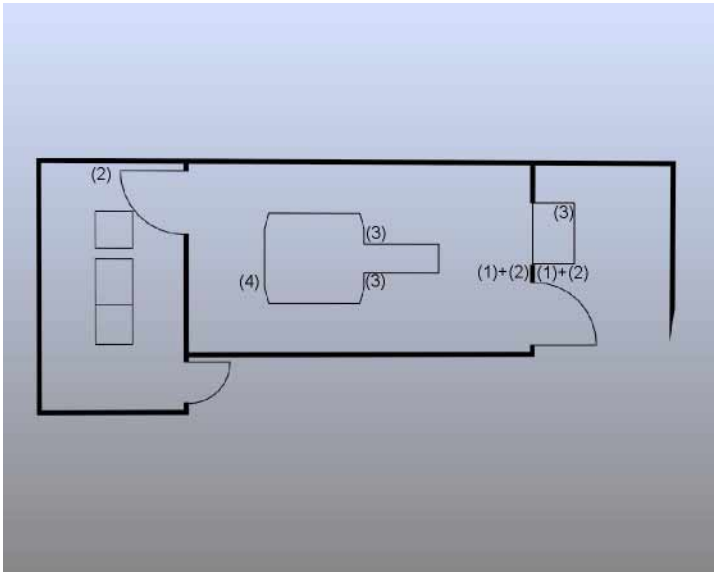
Emergency shut-down switch

✧ Prior to working with the MR system, familiarize personnel with the function and location of the installed emergency switches.

Types of emergency switches

The MR system has three types of emergency shut-down switches:

- ❏ **Magnet Stop** switch
- ❏ **Emergency shut-down** switch
- ❏ **Table Stop** button



Overview showing the location of the emergency shut-down switches (sample installation)

(1) **Magnet Stop** switch
(2) **Emergency shut-down** switch
(3) **Table Stop** buttons
(4) **Table Stop** button (optional)

For the MR system, several **Emergency shut-down** switches have to be installed on site to shut off system voltage. The room installation has to comply with VDE 0107.

Depending on site requirements, the **Emergency shut-down** and **Magnet Stop** switches may also be installed in other places at the MR system.

Magnet Stop switch (magnetic field)

Magnet Stop function

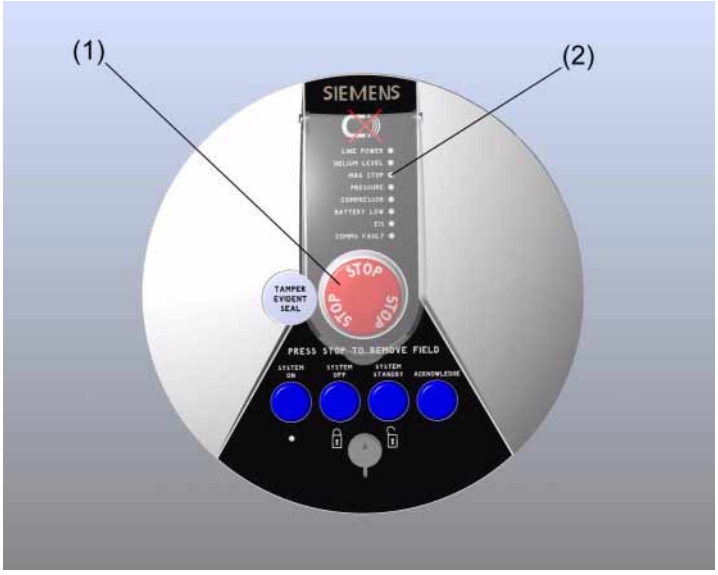
The **Magnet Stop** switch triggers the Magnet Stop function. Examples of situations requiring a **Magnet Stop**:

- ❏ Fire
- ❏ Accidents involving the risk of metallic components being propelled into the magnet and causing personal injury.

Location of the Magnet Stop switches

The **Magnet Stop** switch is available in two different versions: as an individual switch or as an integral part of the alarm box. To prevent accidental switch-on, the key is located under a Plexiglas cover in both cases.

Magnet Stop switch



Alarm box

(1) **Magnet Stop** switch

(2) **MAG STOP** LED

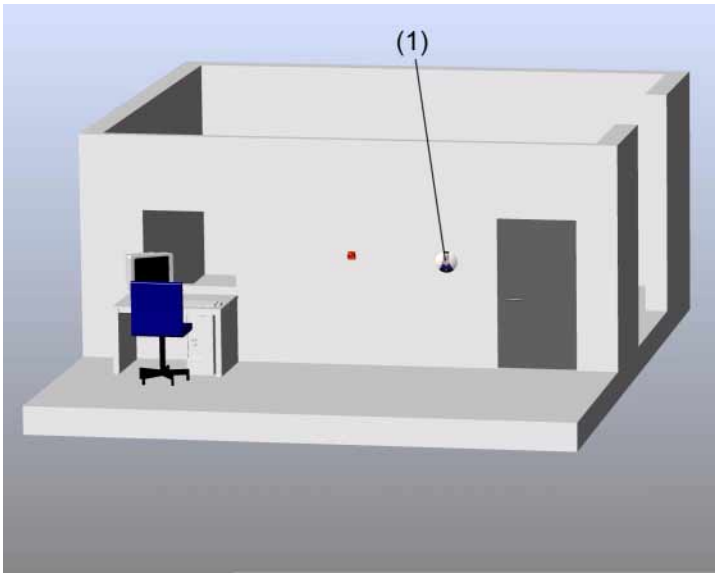
Display and functionality of the alarm box (→ Page B.8-1 *Description*).

Location of the Magnet Stop switches

The **Magnet Stop** switches are located as follows:

- ❏ In the control room at the alarm box near the MR operating console
- ❏ In the examination room next to the door

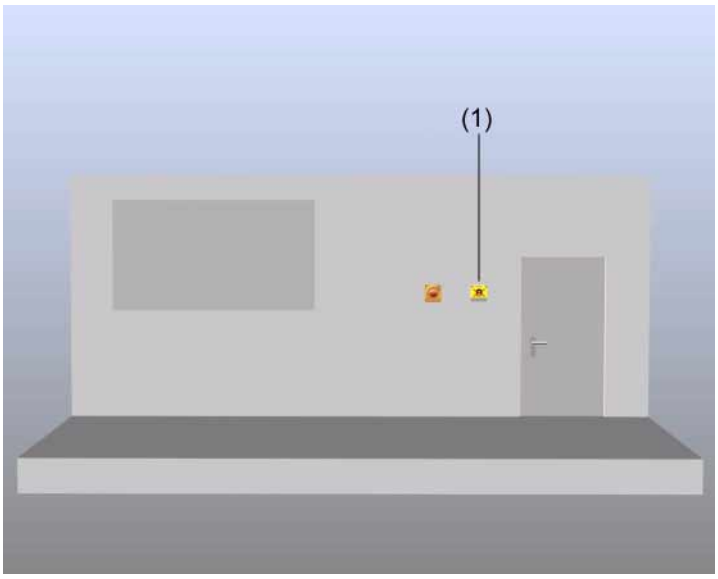
Magnet Stop switch in the control room



Control room

(1) **Magnet Stop** switch

Magnet Stop switch in the examination room



Magnet Stop switch in the examination room

(1) **Magnet Stop** switch

Rescuing patients

✧ In case of emergency, e.g. in case of fire or accidents where metallic parts may be propelled into the magnet causing injury to personnel, open the Plexiglas cover over the **Magnet Stop** and press the **Magnet Stop**.

The alarm is activated at the alarm box. The **MAG STOP** LED will light up, and an alarm signal will sound.

! The MR system is not disconnected from power.

- ✧ Rescue patients immediately (→ Page D.1-25 *Rescuing the patient in an emergency*).
- ✧ Be aware of the dangers involving helium and strong magnetic fields.
- ✧ The magnet may be put back into operation by Siemens Service personnel only.

Emergency shut-down switch (electrical system without magnet)

Emergency shut-down

The **Emergency shut-down** switch shuts down the entire MR system. Examples showing the need for the **Emergency shut-down** switch:

- ❏ Fire
- ❏ Voltage failures

WARNING

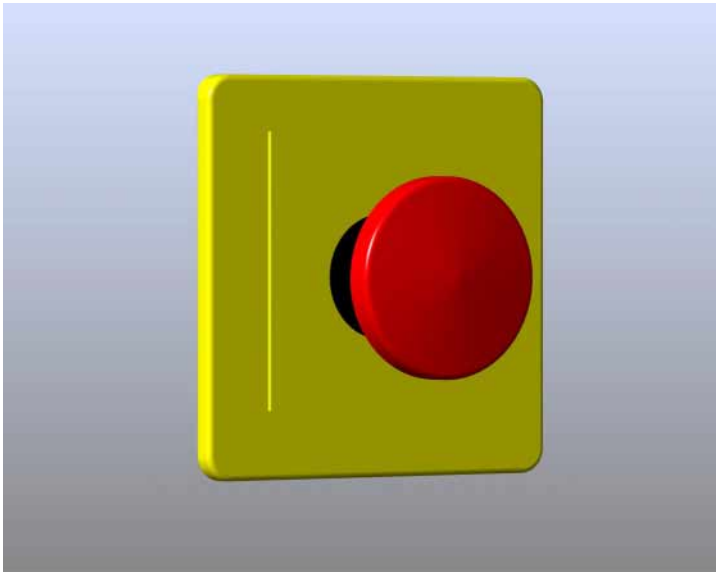
Fire or electrical accidents!

Personal injury

- ✧ Immediately press the **Emergency shut-down** switch.
- ✧ Contact your fire department.

Use of the Emergency shut-down switch

The **Emergency shut-down** switch is installed on-site; it is not a component of the MR system. It is installed on-site by the manufacturer of the RF room or an electrician and may vary in design.



Emergency shut-down switch

Location of the Emergency shut-down switch

At least one **Emergency shut-down** switch is installed in each of the following rooms at eye level next to the entry/exit doors:

- ❏ Control room
- ❏ Examination room
- ❏ Electronics room

✧ Before the MR system is started up, familiarize personnel with the location of the **Emergency shut-down** switches.

In case of emergency

✧ In case of emergency, e.g. in case of fire or electrically-based accidents, press the **Emergency shut-down** switch.

The entire MR system is disabled immediately.

! The magnet remains at field.

Table Stop button

WARNING

Malfunction of the **Table Stop** button!

Injury to patient

Damage to the MR system

- ✧ Immediately press the **Emergency shut-down** switch.
- ✧ Notify Siemens Service.

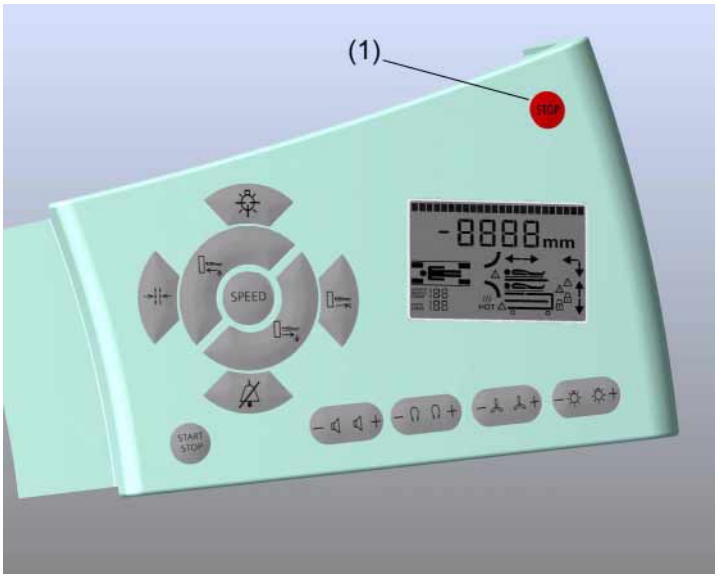
Table Stop function

The **Table Stop** button is used to stop the motorized table movement. Examples of situations requiring use of the **Table Stop** button: Accidents caused by table movement (e.g. injuries due to bruising).

Location of the Table Stop button

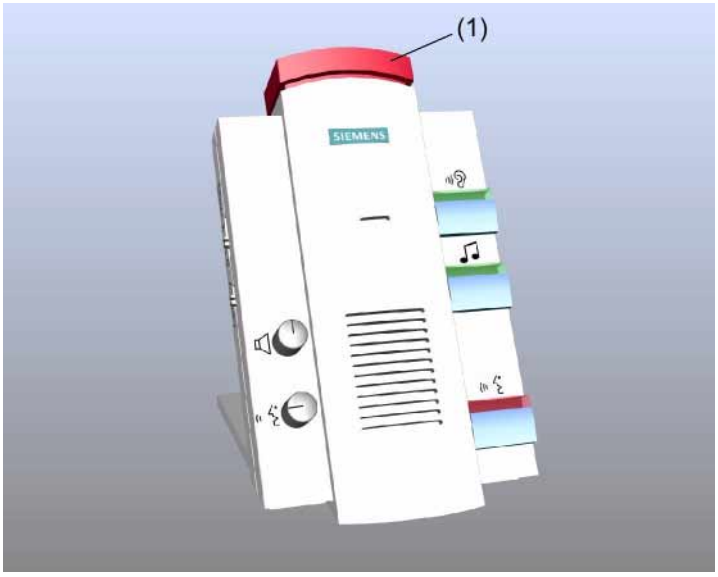
The **Table Stop** button is available in two different versions: as a button on the control unit and the intercom.

Display and functionality of the alarm box (→ Page B.9-1 *Description*).



Control unit with the **Table Stop** button

(1) **Table Stop** button



Control unit of intercom with **Table Stop** button

(1) **Table Stop** button

Location of the Table Stop button

The **Table Stop** button is located as follows:

- ❏ On the control units on the right and left side of the patient table on the front side of the magnet

  As an available option, a secondary control unit with a **Table Stop** button can be installed in back of the magnet.
- ❏ At the control part of the intercom

Control unit

✧ Push the **Table Stop** button in case of accident or risk of injury due to table movements.

The button **Table Stop** lights up red at the control unit. The buttons **Table Movement Up/Inward** and **Table Movement Down/Outward** flash alternately.

The patient table can be moved manually in the horizontal direction.

Intercom

Table movement can be stopped from the control room using the intercom.

✧ Push the **Table Stop** button in case of accident or risk of injury due to table movements.

The patient table can be moved manually in the horizontal direction.

Releasing the Table Stop

After the hazard has been identified and eliminated, patient table operation may be resumed:

✧ Press the **Table Movement Up/Inward** button.

✧ Press the **Table Movement Down/Outward** button.

The Table Stop is released.

Table movement in case of power failure

The electric brakes of the patient table are released in the event of a power failure or following a Table Stop.

The patient table can be moved manually in the horizontal direction.

Patient registration

During patient registration, all patient information required for the subsequent examination is transferred to the system.

CAUTION

Incorrect input of patient name!

Wrong patient identification

✧ Verify that the patient name has been entered correctly.

CAUTION

Incorrect input of patient orientation!

Swapped right-left marking in MR image

✧ Prior to the MR examination, correct the data for patient orientation, especially if the patient is to be repositioned during the examination.

WARNING

Changing safety-relevant data!

Incorrect diagnosis

✧ Safety-relevant data, e.g. weight and patient orientation, should be changed during the MR examination only to correct erroneous inputs.

Patient instructions

Hazards and safety measures

The patient has to be informed with respect to the risks of the basic main field, the gradients and RF fields as well as the safety measures applied during the MR examination:

- ❏ Attraction of magnetizable objects and implants
- ❏ Malfunctions of implants such as pacemakers and insulin pumps
- ❏ Burns from jewelry and other conducting materials
- ❏ Stimulation effects (muscle spasms, tingling)
- ❏ Noise development and hearing protection
- ❏ Function of squeeze bulb as well as additional monitoring and communication devices

- ✧ Inform patients about hazards and safety measures.
- ✧ Confirm that an MR examination is permitted.
- ✧ Check if increased precautions are necessary.

CAUTION

Patient received insufficient clarifaction of facts!

Injury to patient

- ✧ Prior to the MR examination, instruct patients of possible stimulations during the examination, i.e. twitching muscles, tingling sensation.
- ✧ Inform the patient about noise developing during the MR examination.
- ✧ Instruct the patient regarding possible heat development during the MR examination.
- ✧ Inform the patient with respect to the monitoring and communication equipment, e.g. squeeze ball, intercom.
- ✧ Explain to the patient the conduct expected and possible risks involved.

CAUTION

Electrically-conducting objects!

Injury to patient due to warming

Incorrect diagnosis due to artifacts

- ✧ Request that the patient remove all electrically-conducting objects, e.g. necklaces, rings, braces, rubber bands for long hair, piercings as well as jewelry.
- ✧ Request that the patient remove all clothing including electrically-conducting material, e.g. bras.
- ✧ Inform patients that eyeliners and tattoos may contain ingredients causing artifacts or skin irritations during MR examinations. In some cases, patients have been burned.
- ✧ To prevent injuries, instruct patients to remove makeup prior to the examination.
- ✧ Instruct patients to seek medical attention in case of discomfort during or following the MR examination.

Patient monitoring

Patients may be acoustically as well as visually and physiologically monitored in the MR system.

The following aspects and topics regarding patient monitoring need to be observed:

- ❏ Acoustic monitoring
- ❏ Visual monitoring
- ❏ Physiological monitoring

WARNING

MR-incompatible monitoring devices!

Patient burns

- ✧ Use only MR-compatible monitoring devices, e.g. ECG electrodes and pulse sensor.

Acoustic patient monitoring

Operating personnel can monitor patients acoustically, providing instructions via speaker or headphones in the examination room.

Patients, for example, young children or sedated patients, who may not be able to alert the operating personnel in the event of an emergency have to be monitored by a person present in the examination room.

! In order to ensure optimal patient monitoring, keep the Listen mode on in the examination room.

Intercom

An intercom system is available that allows operating personnel to communicate with patients.

CAUTION

Incorrect monitoring due to switched-off intercom!

Risk of injury to patient because emergencies cannot be communicated

✧ Keep the Listen mode continuously enabled at the intercom.

Patient call

Patients may use the squeeze bulb to alert the operating personnel (patient alert):

- ❏ Acoustically:
  - ❏ Continuous tone over the intercom
  - ❏ Brief feedback signal via the patient's headset and wall speaker in the examination room
- ❏ Visually:
  - ❏ LED display on the intercom

CAUTION

Squeeze bulb is defective!

Risk of injury to patient because emergencies cannot be communicated

✧ Check the functionality of the squeeze bulb.

Visual patient monitoring

Video monitoring

An optional video camera may be installed at the back of the magnet bore to monitor patients.

Physiological patient monitoring

Monitoring vital parameters

The vital parameters have to be monitored during MR examinations of seriously ill, unconscious, or physically unstable patients. Also patients who are sedated or under anesthesia have to be monitored with MR-compatible devices.

! The operator is responsible for the use of physiological monitoring and/or measurement devices.

Vital parameters

Vital parameters include:

- ❏ ECG, pulse, and temperature
- ❏ Oxygen saturation of arterial blood
- ❏ Blood pressure
- ❏ Respiratory volume and possibly respiratory pressure
- ❏ Analysis of expiratory gas

Monitoring sedated patients

- ✧ Sedated patients have to be monitored by an anesthesiologist.

Artifacts and display-related errors

Detecting artifacts, avoiding incorrect diagnoses

Artifacts must be detected in order to prevent incorrect diagnoses. The manual *Magnets, Spins, and Resonances, part II* provides detailed instructions with respect to artifacts and display-related errors.

Artifacts and display-related errors are listed according to their source for error:

- ❏ System-related artifacts/imaging-related errors
- ❏ User-related artifacts/imaging-related errors

  These artifacts can be largely avoided through proper system operation.
- ❏ Patient-related artifacts/imaging-related errors

  These artifacts can be largely avoided through patient instructions and proper patient conduct.

System-related artifacts/display-related errors

The MR image may show system-related artifacts despite careful preparation.

System-related artifacts/ display-related errors

If the same artifact appears repeatedly, document and submit it to Siemens Service.

Artifacts caused by the system must be detected to prevent incorrect diagnoses.

CAUTION

Artifacts caused by 3 Tesla magnetic fields!

Incorrect diagnosis

- ✧ MR images should be interpreted by an MR-trained physician only. He must have special training in artifacts that may have been caused by a 3 Tesla magnetic field.

Stripe artifacts

WARNING

RF-signal interference caused by non-MR-compatible accessories, e.g. patient monitoring devices!

Streaks and bright spots in the MR image

- ✧ Use only MR-compatible accessories.
- ✧ Keep the door to the examination room closed.
- ✧ Vary the bandwidth of the MR sequence.
- ✧ Whenever possible, use local coils for the MR examination.

Incorrect slice positioning

CAUTION

Phasing of MR signal is not set correctly!

Structure is shown in the wrong position

- ✧ Repeat the measurement for the structure in question by using a second orthogonal slice and check whether the position of the structure is reproducible nor not.

Variations in brightness

CAUTION

Local variation in the sensitivity of local coils!

Continuous fluctuations in MR image brightness

- ✧ Whenever possible use a local coil with transmit characteristics that are more suitable for the “FoV” desired.
- ✧ Use the normalization filter.

Variations in signal and contrast

CAUTION

Inhomogeneous RF field!

Right-left asymmetry of contrast in the MR image

- ✧ Whenever possible use a local coil with transmit characteristics that are more suitable for the “FoV” desired.

Distortions/signal obliteration along the edges

CAUTION

Spatial non-linearity of the gradient field and inhomogeneity of the static magnetic field!

Pin-cushion and barrel-shaped distortions and/or loss of signal in the margins of the MR-image

- ✧ Go through a distortion correction.
- ✧ Position the region to be examined as close to the magnet isocenter as possible.
- ✧ Use phantoms for the control measurements.

Fat-water offset/flow artifacts

CAUTION

Measurements using a narrow bandwidth!

Image artifacts

- ✧ Use MR images with a narrow bandwidth as a reference only after thoroughly checking them.

Localization errors due to distortion

CAUTION

Incorrect localization data due to spatial non-linearity of the gradient field and inhomogeneity of the static magnetic field!

Incorrect stereotactic planning

✧ Take localization errors into account while planning stereotactic invasions.

Potato chip artifact

CAUTION

Distorted slices edges in the margin due to spatial non-linearity of the gradient field and inhomogeneity of the static magnetic field!

Incorrect stereotactic planning

✧ When planning stereotactic invasions, take into account slice warping at the margins of the MR image. This applies in particular to graphic slice positioning (GSP) as well as other graphic slice displays and slice positioning data independent of the possible use of distortion correction.

User-related artifacts/display-related errors

Spectroscopy

CAUTION

Selection of unsuitable evaluation parameters!

Artifacts in the spectrum (additional or covered lines)

✧ Ensure that interactive evaluations are handled by experts.

Flow Analysis

CAUTION

Incorrect selection of the range of velocity for a specific organ (preset range of velocity is lower than physiological range of velocity)!

Incorrect flow and volume values

✧ Correct the parameter range for the organ to be examined.

Argus

CAUTION

Ambiguous marking of the heart wall contour!

Incorrect ventricular analysis

✧ Correct the markings for the heart wall contour.

Vessel View

WARNING

Ambiguous marking of vessel contour and flag positioning!

Incorrect vascular analysis

✧ Ensure that the contours are correctly drawn in the image prior to confirming a measurement or flag.

✧ Ensure that the flag is positioned correctly in the image prior to confirming a measurement.

✧ Ensure that a stenotic flag is always positioned in the area of maximum vascular stenosis.

Perfusion

CAUTION

Wrong selection of pixels when determining the Arterial Input Function (AIF)!

Incorrect computation of parameter images

✧ Only experienced users should select image pixels for determining the Arterial Input Function.

Composing

WARNING

Distance measurements across image boundaries of combined images are frequently incorrect. This error is additive across the sum of the original images!

Incorrect distance measurement

- ✧ If possible, measure only within the original images.
- ✧ Use only original images for diagnostic purposes.
- ✧ Do not reach a diagnosis on the sole basis of geometrical measurement values. Do not perform measurements across image borders marked **Insufficient match!**

WARNING

Viewing of MR images combined for diagnostic purposes!

Incorrect diagnosis

✧ Use only original images for diagnostic purposes.

WARNING

Dislodging during manual MR-image adjustment!

Incorrect diagnosis

✧ Use only original images for diagnostic purposes.

Pixel lens

WARNING

Incorrect coordinates when using the pixel lens function along image margins!

Incorrect diagnosis

✧ Use the pixel lens function only in the center of MR images.

WARNING

Different coordinate data when using the pixel lens function!

Incorrect diagnosis

✧ Do not use the pixel lens function to compare coordinates between images with distortion correction and those without.

WARNING

Incorrect coordinate data when using the pixel lens function!

Incorrect diagnosis

✧ Reference the coordinates of the pixel lens function only to the table position in the lower right of the image.

Mosaic Images

CAUTION

Use of mosaic images for indicating slice position!

Incorrect diagnosis due to erroneous display of slice position and/or angle

✧ Do not use mosaic images for displaying the slice position.

BOLD

CAUTION

BOLD post-processing with image data generated by Numaris 3 or 3.5!

Incorrect diagnosis through erroneous superposition of anatomical and functional image

✧ Do not use *syngo* MR for BOLD processing with image data generated with Numaris 3 or 3.5.

AutoAlign

WARNING

Use of the AutoAlign function for patients who are not yet 17 years old or for patients with abnormal brain structures, e.g. Alzheimer's, MS or large brain tumors!

Incorrect functioning of AutoAlign

- ✧ Use the AutoAlign function only for patients who are 17 years old and older.
- ✧ Do not use the AutoAlign function for patients with abnormal brain structures.

Functional MR imaging

WARNING

EPI images may show spatial distortion!

Incorrect spatial allocation in certain image areas when superimposing anatomical and functional result data from EPI images.

- ✧ For localizing brain activities, use extreme caution when applying spatial information of superimposed anatomical and functional result data from EPI images.
- ✧ Use other material as well. For example use the evaluation of the field map or use anatomical structures.
- ✧ In addition to EPI images, generate imges with high resolution and high pixel bandwidth (for example TSE).
- ✧ Due not perform stereotactic brain operations on the basis of EPI images alone.

Documentation and evaluation

CAUTION

Unapproved software!

System error

✧ Use only software authorized by Siemens.

CAUTION

MR application does not recognize images from other modalities!

Incorrect diagnosis

✧ Do not load images from other modalities into MR applications. Exceptions: Argus, Vessel View, and Colonography support both MR and CT images.

WARNING

Use of hardcopy documentation for diagnosis!

Incorrect diagnosis

✧ Do not use hardcopy documentation for diagnostic purposes.

CAUTION

When evaluating images, generated or processed on systems of other manufacturers, information regarding distortion correction may be missing!

Distortion-corrected images are not treated as such by the software

Incorrect drawing of cut lines in the image margin

Misdiagnosis

✧ Ensure that you are not loading images as reference images if they have been generated or distortion-corrected on systems by other manufacturers.

Patient-related artifacts/ display-related errors

Spectroscopy

CAUTION

Movement by or repositioning of patient!

Spectrum is not part of the selected “volume of interest”

- ✧ Prior to the examination, inform patients about movements and their negative effects on the measurement.
- ✧ Monitor the patient during the MR examination.

Functional MR imaging

CAUTION

Patient does not follow paradigm (e.g. pattern of motion or movement) or performs it incorrectly during the course of functional MR examinations!

Missing activation of brain areals

Incorrect stereotactic planning

✧ Monitor the patient to ensure that the task is performed correctly.

CAUTION

Noticeable patient movement during the examination!

Statistics may cause ambiguous result images

Incorrect stereotactic planning

✧ Prior to the examination, inform patients about movements and their negative effects on the measurement.

✧ Use Siemens scan protocols with motion correction.

CAUTION

Incorrect MR image due to patient movements!

Incorrect diagnosis

✧ Ensure that the patient does not move between positioning and the actual measurement.

Quality assurance

When measurement phantoms are used as intended within the scope of quality assurance for RF coils, there is no physical contact with measurement phantom fluids. The fluids are sealed in the measurement phantoms.

! Phantoms are filled with water-based nickel sulfate solutions. Other components may include sodium chloride, sodium phosphate buffers, as well as lactates and acetates.

WARNING

Deactivated RF transmitters (SAR) and gradient (dB/dt) monitoring during the quality measurement!

Injury to patient

✧ Ensure that there is no patient located in the magnet.

Risk due to aerosol formation

If phantom fluid has escaped, inhalable droplets (aerosols) containing nickel may form in the event of a fire or atomization caused by strong air currents. Carcinogenic effects cannot be ruled out if these aerosols are absorbed by the body.

CAUTION

Contact with spilled phantom fluid (nickel sulfate)!

Personal injury

- ✧ Wear protective clothing (gloves, work coat, and goggles).
- ✧ Wear a mask with a filter for inorganic vapors if aerosols (inhalable droplets) are formed.
- ✧ Avoid skin contact with phantom fluids.
- ✧ Do not use damaged phantoms.
- ✧ Ensure that fluids from phantoms are disposed of properly.

Handling and storing measurement phantoms

CAUTION

Improper handling of measurement phantoms!

Damage to measurement phantoms

Risk of fire due to lens effect

- ✧ Store the phantoms at 20 °C in a protected location.
- ✧ Do not drop measurement phantoms.
- ✧ Do not change measurement phantoms.
- ✧ Do not store measurement phantoms in a sunny location.

CHAPTER A.3

Device-related safety information

Please note the following aspects and topics with respect to the general safety instructions:

- ❏ MR compatibility
- ❏ Effects of electromagnetic fields on devices
- ❏ Magnetic fringe field and control area
- ❏ Environmental conditions
- ❏ Signs and symbols

MR compatibility

MR-safe

MR-safe products are those that do not present additional risks to the patient or other personnel within the environment of the MR system. They can adversely affect the quality of diagnostic information.

MR-compatible

Devices are considered MR-compatible when:

- ❏ They are MR-safe
- ❏ The image quality is minimally affected by their presence in the MR environment
- ❏ They meet their use with respect to their specifications safely and without interference in the MR environment

! Prior to moving MR-compatible objects/devices into the MR examination room, it has to be clarified for what environmental conditions and/or MR systems their MR compatiblity or safety has been established.

MR compatibility of third-party products

Third-party products have to be released for use in an MR examination room by both manufacturers.

The following hazards or complications may occur through the use of third-party products during MR examinations:

- ❏ Heating of system cables or connection cables
- ❏ Interference with MR image quality
- ❏ Malfunctioning of third-party products

! Similarly, MR-compatible devices may present hazards. The operating instructions of the manufacturer have to be read to avoid potential hazards.

Non-MR-compatible third-party products and additional devices!

Injury to patient and operating personnel

- ✧ Use only MR-compatible third-party products and additional devices. Ensure the MR compatibility of connecting cables.

Effects of electromagnetic fields on devices

! Observe prohibition signs in the area near the entrances to the MR system and the exclusion zone (→ Page A.3-17 *Prohibition and mandatory signs*).

Active/passive devices

Devices are defined as active devices when they fulfill their purpose only after they have been connected to a source of energy. The source of energy is not specified as such. Examples of active devices are pacemakers, medication pumps, patient monitoring systems and pneumatic drills.

Passive devices are devices that fulfill their purpose without a source of energy. Examples are aneurysm clips, scalpels and scissors.

Static main magnetic field

In addition to accelerating and rotating objects, the basic main field may lead to malfunctions or the total failure of active devices. Beginning at a flux density of 0.5 mT, functional interferences may be caused by the interactions of the basic field with the circuitry of electronic implants.

The main magnetic field may either affect or destroy electronic data carriers such as check or credit cards, hard disks, ID cards with magnetic strips and/or magnetic tapes, diskettes or pocket calculators.

Gradients and RF fields

In the presence of gradient and/or RF fields, larger active and passive implants/inclusions may generate conditions leading to considerable electrical eddy currents. Eddy currents may be generated in all electrically-conducting materials and lead to warming. In the case of implants/inclusions dangerous local heating may be generated causing damage to surrounding tissue.

In addition to warming effects, the functionality of electronic components in active implants may be adversely affected through the presence of gradient and RF fields.

In addition, image quality may be compromised.

Magnetic fringe field and control area

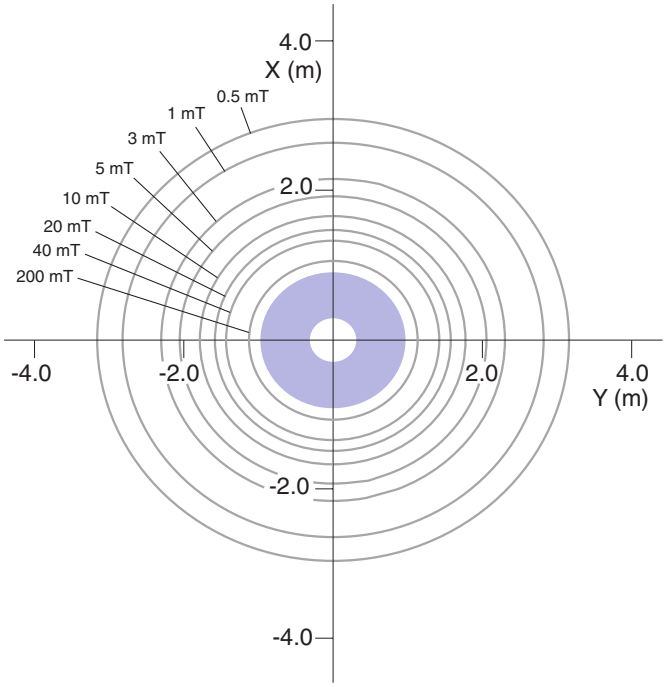
Safety distances

This table shows the effects of the magnetic fringe field on devices located in the vicinity of the magnet and the safety distances required. Observe the minimum distances to be maintained from the center of the magnet's X, Y, and Z axes.

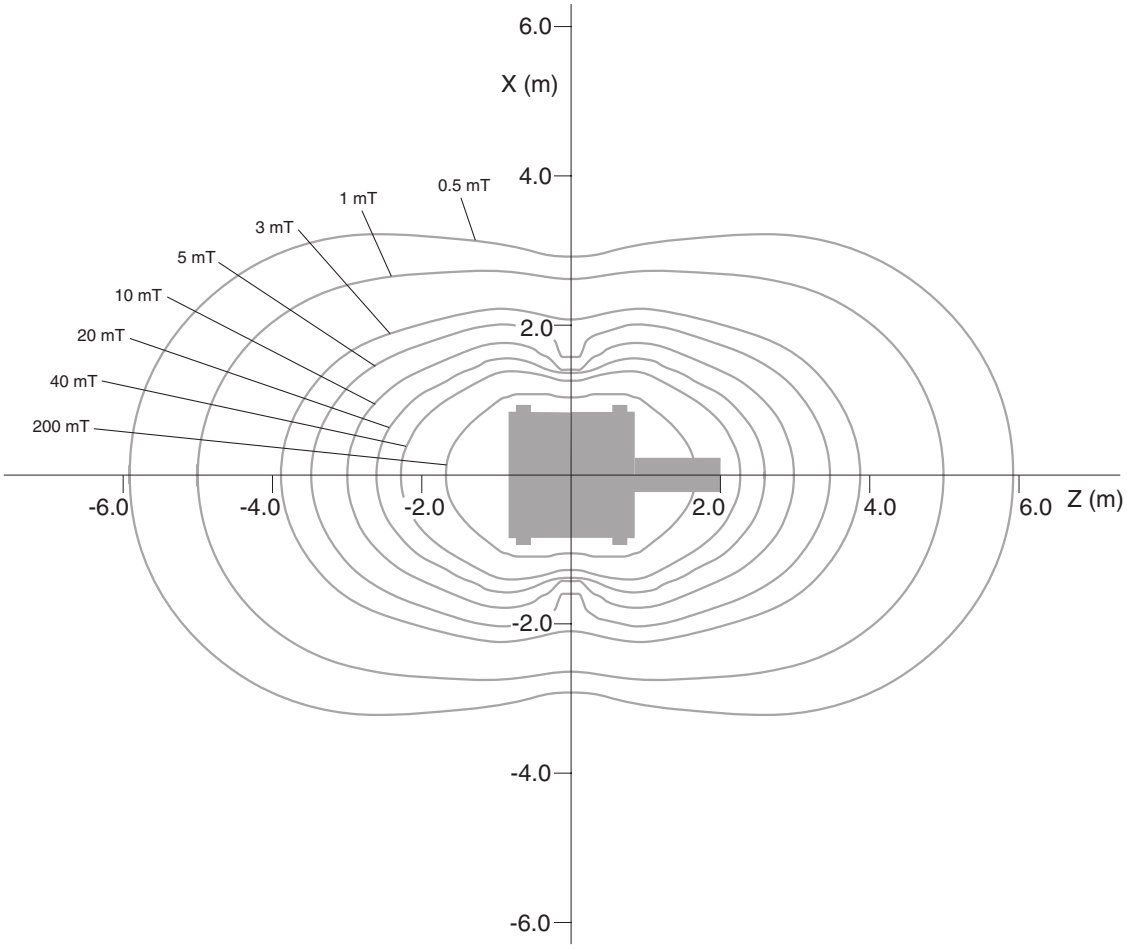
Magnetic flux density	Minimum distances (X = Y = radial, Z = axial)	Devices affected
3 mT	X = 2.2 m Z = 3.9 m	Small motors, watches, cameras, credit cards, magnetic media
1 mT	X = 2.8 m Z = 5.0 m	Oscilloscopes, computers, disk drives, shielded color monitors
0.5 mT	X = 3.1 m Z = 6.0 m	B/W monitors, magnetic media, cardiac pacemakers, insulin pumps
0.2 mT	X = 3.5 m Z = 7.5 m	Siemens CT systems
0.1 mT	X = 3.7 m Z = 9.2 m	Siemens linear accelerators
0.05 mT	X = 7.3 m Z = 11.2 m	X-ray I.I., gamma cameras, third-party linear accelerators

Magnetic flux density

The figure shows lines of the same magnetic flux density outside the MR system for a static basic field of 3.0 T.



Magnetic field lines (viewed in the direction of the magnet axis)



Magnetic field lines (side view of the magnet)

Environmental conditions

Effect on patients

The patient's ability to dissipate surplus heat is increasingly affected as the room temperature and relative humidity increase. As a result, the body temperature increases.

✧ Ensure that the room temperature does not exceed 24 °C and that the relative humidity does not exceed 60 %.

Temperature control inside the examination room

The automatic SAR limit of the MR system is set for a maximum temperature of 24 °C and a maximum relative humidity of 60 % in the examination room.

To ensure these environmental conditions, a heating and air conditioning system has to be used.

If the room temperature and/or relative humidity is higher than the levels specified above, compliance with the SAR limits according to IEC or FDA regulations may no longer be guaranteed.

FDA: Federal Food and Drug Administration (USA)

IEC: International Electrotechnical Commission

A temperature sensor located near the air intake for the patient room monitors the room temperature. If the room temperature exceeds 24 °C, the control mechanism lowers the SAR values accordingly. As a result, certain measurement sequences may no longer be available.

! The operator is responsible for monitoring the functionality of the air conditioning system as well as the temperature and relative humidity inside the examination room.

Signs and symbols

WARNING

Missing hazard labels!

Personal injury, property damage

- ✧ Attach the required warning and prohibition signs and observe national guidelines.
- ✧ Mark critical system areas with warning and prohibition symbols.
- ✧ Ensure that warning and prohibition signs are legible and clearly visible.

Map

Installing the map

The following map of warning and prohibition signs has to be installed in a clearly visible location at eye level in the vicinity of the MR system.

Map

Panel of warning and prohibition signs

Warning signs

Affixing warning signs

The following warning signs have to be affixed at eye level in a clearly visible location in the vicinity of the MR system or potential points of injury.

Warning signs

NMR magnetic field warning sign

RF field warning sign

Observe operator manual warning sign

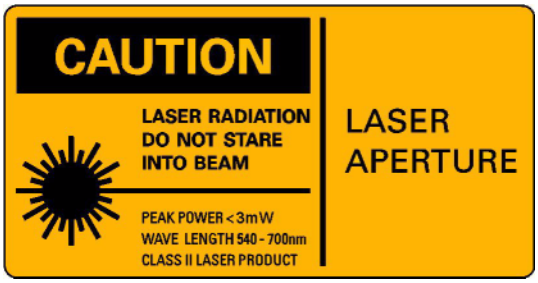
Warning sign for potentional injury to persons

Warning sign for potential point of injury

Warning sign for risk of breakage

Warning sign for laser beam

Warning sign for Laser



Warning sign for Laser (U.S.A. only)

Refilling with liquid nitrogen and helium

Prohibition and mandatory signs

Installing prohibition and mandatory signs

Install prohibition and mandatory signs in a clearly visible location at eye level near the points of access to the MR system and the exclusion zone.

Prohibition signs

Prohibition sign for implants susceptible to electromagnetic effects, e.g. cardiac pacemakers, defibrillators, hearing aids, insulin pumps, medication pumps

Prohibition sign for open flame, no smoking

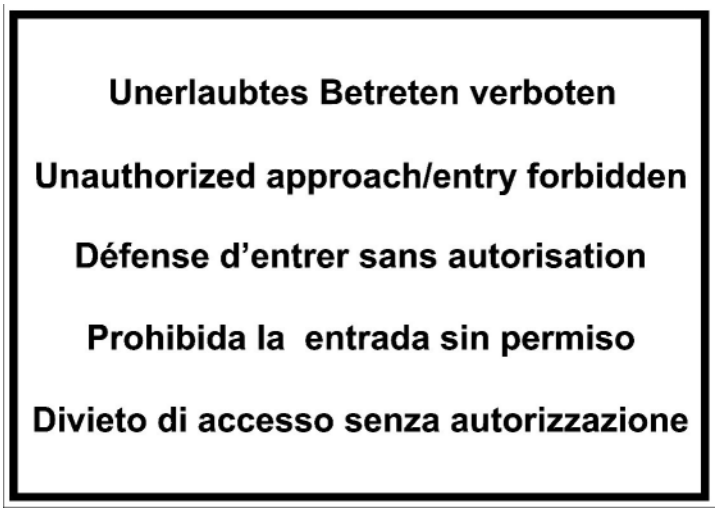
Prohibition sign for metallic implants and other metallic objects inside the body, e.g. splinters

Prohibition sign for mechanical watches and electronic data carriers, e.g. pocket calculator, digital watches

Prohibition sign for fire extinguishers with magnetic metallic housing

Prohibition sign for metal parts, e.g. tools and medical instruments

Prohibition sign for electronic data carriers such as credit cards, debit cards and identification cards with magnetic strips and/or magnetic tapes



Do not enter sign

Descriptive prohibition sign: implants susceptible to electro-magnetic effects

Mandatory signs

Sign requiring mandatory hearing protection

Protection class symbols

Protective class B/BF

Protection class B represents protection against electrical shock with special emphasize on leakage currents.

The protective class symbol Type B/BF for application parts according to IEC 60417-5840 is located, e.g. at the patient table, the components for the physiological measurement unit, and at the RF coils.

Protection class symbol B for application parts

Protection class symbol BF for application parts

Shock indicator

Sensitivity to impacts

The shock indicator contains a precision glass tube filled in part with red liquid. Surface tension keeps the liquid in the shape of drops. Only the pressure created at the time of impact (100 g, 50 ms) destroys the surface tension and the red liquid begins to be distributed in the previously white section of the glass tube. The red coloring cannot be removed retroactively.

Shock indicator

Shock indicators for monitoring the transport are affixed to the packaging and to sensitive components, for example, RF coils.

The red color inside the glass tube (activated shock indicator) signals that the respective component was not handled with the required care.

However, an activated shock indicator does not necessarily indicate damage to the respective component. When the shock indicator has been activated, the respective component has to undergo functionality testing prior to actual use.

RF coils are subject to quality measurements.

System-specific labels

Name plate and safety certificate

The labels are located on the magnet cover.

Name plate label

Labels according to EN 50419:2004

Within the EU, products identified with this symbol are subject to guidelines 2002/96/EG for old electrical or electronics system, modified by guidelines 2003/108/EG.

This product complies with DHHS regulations 21 CFR Subchapter J, applicable at date of manufacture.
Manufactured:
Siemens Aktiengesellschaft
Wittelsbacherplatz 2, D-Muenchen
Germany

Safety certificate label (U.S.A.)