MAGNETOM Trio a Tim System

Operator Manual - MR System

syngo MR B15

www.siemens.com/medical
Manufacturer’s notes:

This product bears a CE marking in accordance with the provisions of regulation 93/42/EEC of June 14, 1993 for medical products.

The CE marking applies only to medico-technical products/medical products introduced in connection with the above-mentioned comprehensive EC regulation.
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Overview

Purpose of the MR system

MAGNETOM Trio a Tim System is a diagnostic imaging device. It generates cross-sectional images in any orientation (tomograms), representing the internal structure of the patient’s body/head. MR images indicate the spatial distribution of hydrogen nuclei (protons) in tissue. When interpreted by a physician with MR training, these MR images provide diagnostic information.

The MR system is not a device with measuring functions. Measured values obtained are for informational purposes and cannot be used as the basis for diagnosis.

For the USA only: The device is limited by Federal Law to investigational use for indications not in the Indications Statement.

For the USA only: Federal law restricts this device to sale, distribution and use by or on the order of a physician.
Using this manual

Correct and safe operation of the MR system requires technical knowledge on the part of the operating personnel and a high degree of familiarity with the operating instructions. Read these operating instructions carefully prior to the start-up of the MR system.

This operator manual includes a description of the hardware component which are part of the standard delivery volume. In addition, there also descriptions included for optional hardware component that can be obtained.

The graphics, figures, and medical images used in this operator manual are examples only. The actual display and design of these may be slightly different on your system.

Male and female patients are referred to as “the patient” for the sake of simplicity. References to “Siemens Service” include service personnel authorized by Siemens.
Structure of this operator manual

This manual consists of multiple parts (Part A, Part B, etc.). A comprehensive table of contents can be found at the beginning of each part.

Part A “Safety” needs to be closely observed during your daily routine.

The other parts contain descriptive and instructive chapters.

The descriptive chapters explain the design, application, and function of the individual MR system components. The instructive chapters explain the operation of the individual components.
Overview

**Important symbols**

- ! Information regarding the optimal use of the MR system.
- i Information provided to facilitate tasks for the user.
- ❔ Problem
  - ✦ Description of possible sources for error
    - ✦ Request for action to solve the problem
  - ✓ Prerequisites for subsequent operating steps
  - ❖ Request for Action
  - ❑ List item
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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 (EMVG)
- Medical Device Operator Regulations (MPBetreibV)
- Accident Prevention Regulations (UVV)

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

Based on national EMC guidelines, the RF source may have to be registered with local authorities (→ System Owner Manual).
### 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

Combinations 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.

✧ Contact Siemens Service prior to combining the MR system with other devices.

✧ Ensure MR compatibility and adhere to the instructions provided by Siemens Service.

Repairs and modifications

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.

Responsibilities, use according to operating instructions

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 0100-710 or applicable national laws.
- The MR system is not used in accordance with the operating instructions.
**Maintenance at regular intervals**

**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 case of serious malfunctions, switch off the MR system immediately.

✧ Notify Siemens Service.

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**WARNING**

MR system malfunction!

**Hazardous conditions for patients**

✧ Please note the sounding alarm and signal.

✧ Do not perform MR examinations.

✧ Notify Siemens Service.
Safety-relevant accessories

The following safety-relevant accessories have to be checked:

- All coils for the transmitting and receiving system (some are optional)
- ECG and respiratory sensor (optional)
- Disposable electrodes (optional)
- Pulse sensor (optional)

**Checks regarding structural 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.

**WARNING**
High voltage and currents inside the electronics cabinets!

**Risk of death by electrocution**

✧ Electronics cabinets should be opened by Siemens Service only.
After having checked the MR system, a visual inspection of the following structural changes needs to be 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 instruction and may be performed by Siemens Service only.
Personal safety information

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

- Information for all persons
- Information for operators
- Contraindications
- Emergency switches
- 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
Personal safety information

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

The controlled area of the basic field includes the so-called 0.5 mT exclusion zone (→ Page A.3-5 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 interfere with electronic implants or other devices.

The controlled 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-conductive 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 bore and drops considerably outside the magnet as a function of the distance to the magnet. This leads especially at the entrance of the magnet bore to large spatial gradients of the magnetic field.

In addition to a high magnetic flux density, the basic field of a modern MR system 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-conductive material. At very low temperatures, super-conductive materials lose their electrical resistance. Coils made from super-conductive 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.2-18 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 exact 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.

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 main magnetic 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. Linearly rising additional fields of variable strength - gradient fields - are superimposed on the static main magnetic field in three different orientations. Gradient fields are characterized by gradient field strength, their rise time, and the spatial linearity of the gradient fields. The gradient field alters the main magnetic field throughout the object to be examined (changing the Larmor frequency), resulting in the spatial encoding of signals. The gradient fields for the three Cartesian coordinates are generated in three separate, actively-shielded gradient coils. All gradient coils (inclusive shielding) are wound layer-by-layer on the gradient coil body.

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

Ensure that patients are not positioned as shown in the illustration.
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. The fast switching of currents in the presence of the main magnetic field leads to time-dependent Lorentzian forces that affect the gradient coil structures. The resulting mechanical stimulations are (→ Page A.2-30 Noise development) heard as noise (humming, knocking noises) during the MR examination.

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 D.5-1 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.

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 incorrect patient positioning are shown in the “Current Loop” section in the Page A.2-11 Time-dependent magnetic fields (gradient fields) chapter.

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**

Arcing caused by coil cable loops!

**Patient burns**

✧ Avoid coil cable loops.

**WARNING**

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

**Burns and 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 the patient's hands, arms and legs do not touch (minimum distance is 5 mm).

✧ Ensure that the minimum distance of 5 mm is maintained between patient and tunnel covering.

✧ To ensure this distance, use positioning aids, e.g. blankets made of linen, cotton, or paper, or dry material that is permeable to air.
**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.

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**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.

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**Coolant**

The magnet is filled with liquid helium as a coolant. Following installation, it is adjusted to the desired operating field strength. Liquid helium has to be refilled at regular intervals 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.

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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.

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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 measures

First aid in case of breathing difficulty
A person becomes unconscious due to severe shortness of breath:
- Remove unconscious persons immediately from the room.
- Start artificial respiration immediately.
- Contact 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.
- Remove clothing carefully from the locations involved.
- Rinse frostbitten skin with lukewarm water.
- Cover frostbitten skin with sterile bandages.
- Do not apply powder or creams.
- Contact a physician immediately.
**WARNING**

Improper handling of liquid helium!

*Skin damage caused by frostbite*

✧ Do not rub frostbitten skin areas.

---

*Information for establishing 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 firefighters)
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 m³ 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.)
- Spontaneously without any obvious external reason (highly unusual)

The operator is able to release an intentional quench by activating the Magnet Stop (→ Page A.2-49 Magnet Stop switch (magnetic field)) switch.
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 doors and windows of adjacent rooms.

✧ Rescue the patient (→ Page B.10-22 Rescuing the patient in an emergency).

✧ Leave the examination room, if no persons need to be rescued.

✧ Enter the rooms only after the noises (hissing, gurgling) 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 m³ of gaseous helium escapes into the examination room (approx. 100 m³). 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 and suffocation exists. The oxygen content of the air can be measured with an oxygen measurement device.

Due to such hazardous conditions as acute hypothermia and suffocation, 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, if no persons need to be rescued.

When breaking the observation window, avoid injuries through glass splinters.

✧ Open the ports and the observation window if you cannot open the door to the examination room due to overpressure.
✧ Break the observation window if it cannot be opened. Push through the wire braiding for the RF-shielding.
✧ Enter the rooms only after the noises (hissing, gurgling) 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, the alarm box ( → Page B.8-1 Description) or the syngo Acquisition Workplace will signal this accordingly.

✧ In case of alarm, notify Siemens Service and/or ensure refilling.

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.
Noise development

CAUTION
Noise development during the MR examination!

Injury to patient (hearing loss)

- Provide the patient with appropriate hearing protection that lowers noise to 99 dB(A) (→ System Owner Manual).
- Ensure that personnel in the examination room wear hearing protection during the examination.

- Due to an increase in tension, the permissible sound pressure level may be reason for concern for pregnant women and their unborn, for newborns, infants and small children as well as older persons.
- Anesthesized or unconcious patients have to be provided with mandatory hearing protection.

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

- Adhere to local laws when selecting suitable hearing protection.
For each MR examination, use suitably dimensioned hearing protection to protect the patient from noise.

For MR examinations on infants or MR examinations with head coils, use an alternative hearing protection, e.g. ear plugs.

Ensure that the operating personnel are informed about the correct application of hearing protection.

Observe the acceptable length of stay.

**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 (Class II according to US CDRH).

All laser-relevant locations at the MR system are identified by warning labels affixed directly next to the laser opening (→ Page A.3-11 **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.

---

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.
Safety

Personal safety information

Mechanical hazards

Collision or points of injury
Collisions and injuries are more prevalent when using the exchangeable tabletop, the patient table or when performing maintenance activities.

✧ Observe the warning and prohibition signs as well as the safety information.

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. To minimize points of injury in the area of the magnet bore, the paper roll holder on the patient table can be folded 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 key switch 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 case of 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
Safety

Personal safety information

- Claustrophobic patients
- Patients who are seriously ill, unconscious, anesthetized or confused or who are not able to communicate normally for other reasons.

The instructions have to establish the fastest possible way for removing patients in emergency cases from the examination room.

- If necessary, shut down the MR-system using the EMERGENCY SHUT-DOWN (→ Page A.2-54 EMERGENCY SHUT-DOWN switch (electrical system without magnet)) switch.

- 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, press the Magnet Stop switch to trigger a quench (→ Page A.2-49 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**

Personnel have to read and understand the operating instruction 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

CAUTION
Untrained or uninformed personnel!

Injury of persons

Damage to measurement phantoms

Fire hazard due to lens effect

- Train all personnel who have access to the MR system (incl. e.g. cleaning crews, rescue personnel, etc.).
- Inform these people with respect to the hazards and protective measures to be used when handling measurement phantoms.
- Ensure that the training includes the topic on “Handling leaks occurring with measurement phantoms” as well as “Handling and storing measurement phantoms”.
**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 correspond to VDE 0100-710 and/or national laws.

**Fire fighting**

**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 CO₂ extinguisher
- Self-contained, anti-magnetic compressed air breathing apparatus (without hose connection)
- Airtight chemical protective suit

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

Access to the examination room

Free access and exit to and from the examination room has to be ensured at all times.

WARNING

RF door does not function as required!

It is not possible to freely access or leave the examination room in case of an emergency

✧ Ensure that the RF door is checked and maintained regularly.
✧ Regularly check the correct functioning of the door to the examination room.
✧ Ensure that the door to the examination room opens and closes correctly.
✧ Establish measures on how to open the door in case of emergency (e.g. the handle to the door became defective).
✧ Ensure that you have tools available to break the door open in case of emergency.
✧ Ensure that a window in the examination room can be used as an escape route in the case of emergency.

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: 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-conductive implants and prostheses
WARNING
Electronic implants in static magnetic fields!

**Patient injury**
- 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 the *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.
Emergency switches

Before working with the system, familiarize yourself with the location and functionality of the emergency switches installed.

- Magnet Stop switch
- EMERGENCY SHUT-DOWN switch
- Table Stop button

Types of emergency switches

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.
Overview showing the location of the emergency 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 correspond to VDE 0100-710 and/or national laws.

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)

<table>
<thead>
<tr>
<th>Magnet Stop function</th>
<th>The <strong>Magnet Stop</strong> switch triggers a magnet quench. Examples of situations requiring a <strong>Magnet Stop</strong>:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Accidents involving the risk of metallic components being propelled into the magnet and causing personal injury.</td>
</tr>
<tr>
<td></td>
<td>- Fire</td>
</tr>
</tbody>
</table>

| Design 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 operator room, in the alarm box close to the *syngo* Acquisition Workplace
- In the examination room next to the door
Magnet Stop switch in the control room

Magnet Stop switch in the 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.
After the **Magnet Stop** switch has been pressed, a magnet quench is triggered.

The MR system is not disconnected from power.

✧ Rescue the patient immediately (→ Page B.10-22 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. However, the magnet continues to operate. 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.

Design 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.
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

- Familiarize yourself with the location of the **EMERGENCY SHUT-DOWN** switches prior to putting the MR system into operation.

In case of emergency

- In case of emergency, e.g. fire or voltage-related accidents, immediately 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).

The Table Stop button is located as follows:

❖ On the control units to 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.

❖ On the intercom
If you plan a patient intervention outside the magnet, activate the Table Stop button as a precautionary measure to avoid accidental patient table movement. After completion of the intervention, the control unit at the magnet is enabled again.

The Table Stop button on the control unit

Control unit with **Table Stop** button

(1) **Table Stop** button
The Table Stop button on the intercom

Intercom with the **Table Stop** button

(1) **Table Stop** button

Display and functionality of the intercom: (→ Page B.9-1 Description).

**Control unit**

◇ Push the **Table Stop** button immediately in case of accidents or risk of injury due to table movements (points of injury through crushing/bruising).

The **Table Stop** button 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 immediately in case of accidents 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 information

Risks 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 conductive materials
- Stimulation effects (muscle spasms, tingling)
- Noise development and hearing protection
- Function of squeeze bulb as well as additional monitoring and communication devices

✧ Inform the patient with respect to risks and safety measures taken.
✧ Prior to the examination, check whether an MR examination is permitted.
✧ Prior to the examination, check whether safety measures and cautions have to be increased.
CAUTION

Patient received insufficient clarification 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 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.
**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**

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.
**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.
Patient alert

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

The operator is responsible for using 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
✧ Have an anesthetist plan the monitoring of sedated patients.

NO monitoring via the PMU display
✧ Monitoring the vital parameters via the PMU display is prohibited.
**WARNING**
Monitoring vital parameters via the PMU display!

*
Anomalies of the vital parameters are not recognized or, if then too late

✧ Never use the display for physiological data to monitor the vital parameters of a patient.
✧ Use only suitable MR-compatible devices for monitoring vital parameters.

---

**Artifacts and imaging errors**

**Detecting artifacts, avoiding incorrect diagnoses**

Artifacts must be detected in order to prevent incorrect diagnoses.

Artifacts and imaging-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/imaging-related errors**

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

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

**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.
Safety Personal safety information

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.

**CAUTION**
Static and/or stationary brightness errors on the LCD monitor!

**Incorrect diagnosis**
- Change the image to ensure that the MR image does not show differences in brightness, spots, or cloudiness.
- Check bright objects for afterglow.
- View the LCD monitor only when it is centered and in vertical position.
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.
Personal safety information

Safety

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 slice 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/imaging-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 drawn correctly 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.
CAUTION
Missing identification of critical areas (e.g. seams) in composed images (composer)!

Incorrect diagnosis

✧ When storing composed images ensure that critical areas (seams) in manually corrected images or in those with Q numbers that are too small, are blanked out.

✧ To blank out critical areas, confirm while you store the image in the pop-up window that the composed image does not correspond with the anatomy of the patient.

✧ When you go to the pop-up window and confirm that the composed image corresponds with the anatomy of the patient, the critical areas are not blanked out.

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 displaying the 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.

Motion correction

WARNING
Missing or incorrect display of small anatomical structures as a result of motion correction!

Incorrect diagnosis and omitted treatment due to false negative diagnosis.

Incorrect diagnosis and unnecessary biopsies due to false positive diagnosis.
✧ For diagnosis, always use the original image in addition to the corrected image.
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 images with high resolution and high pixel bandwidth (for example TSE).

✧ Due not perform stereotactic brain operations on the basis of EPI images alone.
Software

**CAUTION**
Unapproved software

**System error**
✧ Use only software authorized by Siemens.

Documentation and evaluation

**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.
Patient-related artifacts/imaging-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 areas

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 measurement protocols with motion correction.

CAUTION
Incorrect MR image due to patient movements!

Incorrect diagnosis
✧ Ensure that the patient does not move during the measurement.

Quality assurance

Safety instructions covering the use of measurement phantoms are included under (→ Coil operator manual).
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:

- These devices are considered safe for MR use
- 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 compatibility 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 as well. The operating instructions of the manufacturer have to be read to avoid potential hazards.

- Use only MR-compatible non-Siemens products and additional devices to avoid injury to the patient or the operating personnel.
- 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.3-14 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.
Safety device-related safety information

### 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.

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

The figure shows lines of the same magnetic flux density outside the MR system at a static basic field of 3.0 T. The 0.5 mT line marks the exclusion zone of the basic main magnetic field.

Magnetic field lines (viewed in the direction of the magnet axis)
Magnetic field lines (side view)
**Ambient 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 is at max. 22 °C and the relative humidity does not exceed 60%.

**Temperature control inside the examination room**

The automatic SAR limit of the MR system is configured for maximum temperature of 22 °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 tunnel ventilation, monitors the room temperature. If the room temperature exceeds 22 °C, the SAR values are lowered 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 of warning and prohibition signs
Safety

Device-related safety information

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
0.0

Warning sign for potential injury to persons

Warning sign for potential point of injury

Warning sign for risk of breakage

Warning sign for laser beam
Laser warning sign

Laser warning sign (for the US 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

Unerlaubtes Betreten verboten
Unauthorized approach/entry forbidden
Défense d’entrer sans autorisation
Prohibida la entrada sin permiso
Divieto di accesso senza autorizzazione

Unauthorized access prohibition sign
Device-related safety information

Descriptive prohibition sign: Implants susceptible to electromagnetic effects

Mandatory signs

Sign requiring mandatory hearing protection
Protective class symbols

Protection classes B and 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.
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 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 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.