SIEMENS

System Owner Manual

MAGNETOM
Skyra

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Contents

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Dear customer,

On the occasion of inspections and controls by the authorities you must always have many different documents at hand. The present System Owner Manual is intended to make archiving these documents simpler for you so that you always have them completely at hand if necessary.

We have already filed the most important documents in the System Owner Manual on delivery of your system.

The further updating of the Manual now lies in your hands.

We therefore recommend that you designate an employee right at the start-up of your new system who will be responsible for continuously updating the System Owner Manual and who immediately has it at hand as required.

We wish you much success with your Siemens system.

Siemens AG

Healthcare Sector

Manufacturer	Siemens representative	System Owner
■		
	■	
		■

P.S.: The table on the following page shows which documents are filed in the System Owner Manual and who contributes the documents.

Who supplies what? The documents in the System Owner Manual.

	Manufacturer	Siemens representative	System Owner	Document
1				**Introduction**
	■			Notes on handling the System Owner Manual
			■	Operator and location of the product
2				**Safety information**
	■			Important safety aspects for the owner of a MR system
3				**MR compatibility data sheet**
	■			Information for evaluating the MR compatibility of non-Siemens MR products
4				**Guidance and manufacturer's declaration EMC**
	■			Guidance and manufacturer's declaration regarding electromagnetic compatibility
5				**Technical data**
	■			Technical data
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7				**Preventive maintenance**
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			■	Maintenance contract
			■	Maintenance certificates
8				**Disposal**
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9				**Correspondence with authorities**
			■	Files according to country-specific regulations
10				**Certificates**
		■		Installation certificate
		■		System handover certificate
		■		Customer instruction certificate
			■	Constancy test certificate
11				**Software licenses and warranty**
			■	Software licenses including software warranty conditions

Who supplies what? The documents in the System Owner Manual.

	Manufacturer	Siemens representative	System Owner	Document
12	**Updates**			
			■	Performed updates
13	**Room layout**			
		■		Practice and room drawings
14	**Revision level of components**			
	■			List of the delivered components including hardware and software level
		■		Revision levels after component replacements
15	**Declaration of conformity**			
				Series certification of the entire system with all possible options. Your Siemens service technician will find the appropriate conformity declaration under the following address: https://intranet.medical.siemens.com/Sales+Intranet+International/Divisions/Magnetic+Resonance/CrossProductInformation/?languagecode=de Select the “Certificates & Declarations” link under the “Regulatory” section of “Cross Product Information”.

MAGNETOM Family

System Owner Manual - Safety Information

syngo MR D13

www.siemens.com/healthcare

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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.

Safety instructions

Safety information for the system owner

Preamble

This section of the system owner manual contains the most important safety aspects for which you, as the owner of the MR system, will be responsible.

These include legal requirements, emergency plans, employee information and qualifications, as well as requirements that must be met in the examination room.

Common causes of accidents

Of particular importance is the obligation to inform employees and contractors. Operating personnel as well as personnel who are not regulars in the examination room (e.g. cleaning personnel, rescue personnel) must be informed about the special conditions in the examination room. Magnetizable devices (e.g. floor polishers, vacuum cleaners, wheelchairs, metal gurneys) must not be used in the examination room.

- Please note all safety instructions applicable to all *users* which are described in the operator manual of the MR system. (➡ Operator manual MR system)

Legal regulations

Country-specific regulations

Local and national legal regulations must be observed. It is the operator's responsibility to follow local statutory requirements regarding access to the controlled access area.

The local regulations also define the acceptable exposure limits regarding noise as well as magnetic stray fields for users and patients. (➡System Owner Manual: Technical data)

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)

If required, the RF source must be registered with local authorities in accordance with national EMC guidelines.

Pressure Equipment Directive

The super-conductive magnet is classified as pressure equipment. National guidelines for starting up and operating pressure equipment must be observed.

In Europe, the Pressure Equipment Directive (97/23/EG) regulates the sale of pressure devices.

In Germany, both the Pressure Equipment Directive as well as the relevant Occupational Safety Regulations (BetrSichV) for system start-up and operation apply.

Electromagnetic fields

The 0.5 mT line in the examination room defines the controlled access area of the RF field. For controlling access to this area adequate rules must be established. Therefore, regard the potential risks from the attraction of magnetizable objects or from torque on such materials. Also consider persons inadvertently entering the area who may be affected by the possible dysfunction of their medical implants such as pacemakers.

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

Regarding the static magnetic field, your MR system is continuously operated in the normal mode (means not more than 3.0 T). *For China only*: If the static magnetic field is higher than 2.0 T, the system is operated in the first level mode.

The limits of exposure of MR workers to static and time-varying magnetic fields may be regulated by local laws. Special precautions are necessary for pregnant MR workers, although no epidemiological evidence of any negative health effects currently exists (local laws may apply). It might be that the limits do not apply for pregnant MR workers. Furthermore, it may be required in some countries that the “member of the public” limit is applied to the fetus.

Noise development

The exposure of MR workers to noise may be regulated by local laws. The operator must ensure that the sound level at the operating console is limited in compliance with local rules for the safety of the physician and the MR worker.

For MR equipment that produces noise louder than 99 dB(A), the sound pressure level is measured according to NEMA MS 4.

Laser

The laser of the laser light localizer is classified as Class 2M according to IEC 60825-1 (Class II according to US CDRH).

Video monitoring

Labeling obligation may be regulated by local laws. The operator is responsible to comply with these laws if a video system is installed.

Combination of devices

! Any combination to, or modifications of the system must comply to the requirements of IEC 60601-1:2005 (chapter 16) and must be accepted from Siemens.

Any application of physiological monitoring and sensing devices to the patient is done under the exclusive direction and responsibility of the system owner.

To generally test the proper operation of peripheral equipment, a compatibility protocol is available. Manufacturers of peripheral equipment should use this Siemens compatibility protocol to test the functionality of its equipment. (➡ System Owner Manual: Compatibility data sheet)

Installation

Ensure that the multiple socket of the computers is not placed on the floor.

! WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective ground.

Emergency plans

Specific provisions must be taken for possible emergencies. This includes the generation of emergency plans (instructions on how to proceed/rescue scenarios) to prevent incorrect behavior under special circumstances.

Access to the examination room

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

- Establish measures on how to open the door in case of patient is not accessible (e.g. the handle to the door became defective).
- Ensure that you have tools available to break the door open in case of an emergency.
- Ensure that a window in the examination room can be used as an escape route in the case of an emergency.

⚠ 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.

Emergency procedures

Instructions on how to proceed in emergency situations must be defined to ensure the safety of patients. For this purpose, MR-specific risks must be included (e.g. the presence of a magnetic field).

Among other things, the instructions must establish the fastest possible way for removing patients in emergency cases from the magnet's influence (if necessary by shutting down the magnet). The instructions should also establish measures to ensure medical care as soon as possible.

Especially endangered patients and MR workers

As special precautionary measures, a program for medical supervision as well as a plan for using emergency equipment outside the magnet's influence must be in place for patients with a higher than normal risk factor, such as:

- Patients susceptible to cardiovascular collapse
- Patients who are likely to develop seizures
- Patients who are at an increased risk of heart attacks or other cardiac problems
- Patients with limited thermoregulation
- Claustrophobic patients
- Patients who are unconscious, anesthetized or confused or who are not able to communicate normally for other reasons
- Children

! MR scanning has not been established as safe for imaging fetuses and infants less than two years of age. The responsible physician must evaluate the benefits of the MR examination compared to those of other imaging procedures.

Quench emergency plan

It is strongly recommended that the system owner establishes an emergency plan in case gaseous helium escapes 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)

Quench

During a quench, the super-conductivity of the magnet is suspended. The energy of the magnetic field is converted into heat. The magnet field strength falls off to 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. The escape of gaseous helium via the exhaust line is rather noisy (hissing, gurgling).

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)

Defective vent line

If the vent line fails in part or fully, gaseous helium will enter the examination room. In this case, the air conditioning unit will not be able to ensure sufficient air exchange and the following hazardous situations may arise:

- Poor visibility due to strong fog in the upper area of the room
- Rise in pressure in the examination room
- Hypothermia and risk of suffocation (e.g. in case of large leaks)

!

Due to such hazardous conditions as acute hypothermia and suffocation, rescue attempts must be performed by at least two persons.

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 by helium.

An emergency plan must be established to ensure correct conduct under such hazardous conditions.

Fire fighting

In the event of fire, the fire has to be extinguished with methods appropriate to the surroundings. Respective fire fighting equipment must be available. Fire precautions should be discussed with the local fire department and emergency procedures should be established. It is in the operator's responsibility to take the necessary initiatives.

Mandatory reporting in case of fire

- Prior to initial start-up of the MR system, ensure that the fire department is familiar with MR imaging systems as well as structural on-site conditions.
- Inform the fire department about the contents of the measurement phantoms and the health risks caused by nickelous aerosol formations.

Employee qualifications/ information

MR workers are individuals (e.g. operator, further personnel) who work within the controlled access area or MR environment. The system owner is responsible for ensuring that only trained and qualified MR workers and physicians are working on the MR system, so that they can perform all their tasks safely and efficiently, and in a way that minimizes their exposure to the electromagnetic field. In addition, the MR system may only be used as intended.

The system includes a keyswitch to prevent unauthorized switch on.

Informing MR workers

MR personnel must read and understand the operator manual, paying special attention to the safety chapter, before working with the MR system. The safety hints regarding the magnetic fields must also apply to MR workers. An understanding of MR safety is especially important for those individuals who only work in the MR environment occasionally. For further information, see (➥Operator manual MR system).

The personnel must pay special attention to the following aspects:

- Effects of the magnetic field (➡Operator Manual MR System: Electromagnetic fields)
  - Special effects of 3 T magnetic fields like dizziness, vertigo, and metallic taste, especially when moving the head rapidly inside or close to the MR equipment; these effects can be avoided or minimized by reducing speed of motion (for example, slow movements of the head or table).
  - Effects on electronic and/or electrically conductive implants
  - Possible effects on pregnant MR workers (local laws may apply)
- Safety aspects of the MR-conditional tools and accessories used, with respect to the static magnetic field B_0
- Hearing protection:
  - Wearing hearing protection when working in the controlled access area during scanning if the sound level exceeds 99 dB(A)
  - Required training to correctly apply the hearing protection, especially when the standard headphones cannot be applied (for example, for neonates and infants)

! MR scanning has not been established as safe for imaging fetuses and infants less than two years of age. The responsible physician must evaluate the benefits of the MR examination compared to those of other imaging procedures.

The operator should be particularly aware of:

- Adherence to the positioning information for patients (to avoid current loops and burns)
- Careful input of the patient weight/position and orientation
- Possible peripheral nerve stimulation, as effect of the *First level controlled operating mode* on patients and MR workers

⚠ WARNING

MR workers and all personnel who have access to the MR system are not sufficiently informed!

Personal injury, property damage

- Ensure that all personnel (incl. cleaning crews, rescue personnel, etc.) are regularly informed about the potential risks inherent in MR systems as well as the relevant safety information (for example, regarding magnetic forces).
- The exclusion zone and corresponding safety measures must be observed even when the system is switched off.

Training MR workers and physicians

Personnel and physicians must be trained in the safe and effective use of MR systems. The training must include the following topics:

- Emergency medical care
- Controlled access area
- Emergency switches
- Measures preventing fires
- Quench emergency plan
- Prevention of hazards related to magnet forces
- Combinations with other devices

The physician must complete a special training course on interpreting images.

⚠ 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. 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*".

Pre-screening MR workers and patients

To lower the risks during exposure to the magnetic field, all patients as well as MR workers have to accomplish a pre-screening to avoid accidents and to establish safety measures. Therefore a pre-screening program shall be established by the operator, which helps the user to identify the patients and MR workers at risk. This especially applies to patients and MR workers who are at risk due to their professional activities, medical history and medical state as well as the influence of the MR equipment, such as:

- Patients and MR workers:
  - with implants or with permanent make-up
  - with imbedded metal fragments from military activities
  - who are pregnant
- Patients:
  - with typical contraindications (➡ Operator Manual MR system: Contraindications)
  - with a higher than normal likelihood of needing emergency medical treatment: in general and also in the *First Level Controlled Operating Mode* (➡ Page A.1-6 *Especially endangered patients and MR workers*)

There are no risks regarding materials or ingredients to which the patient or user is exposed. They are all checked for biocompatibility.

Examination room and ambient conditions

Explosion protection

The MR system is not intended for operation in areas prone to explosive anesthetic gases.

Emergency switches

The voltage to the MR system can be turned off via a Power-Off (**System Off** or **Emergency Shut-down**) switch installed on-site. The switch can be used to stop the scan immediately in case of emergency. The room installation must correspond to VDE 0100-710 and/or national laws.

A quench can be released with the **Magnet-Stop** switch. This switch is installed on-site as well.

Air conditioning

An air conditioning system must be used to ensure the required environmental conditions. (➡Technical data)

! The air conditioning is installed on-site by the system owner. 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 are included in the operating instructions of the air conditioning manufacturer.

The functions of the air conditioning or the temperature and relative humidity of the examination room must be checked at regular intervals.

Magnetic fringe field and controlled access area

The fringe field can affect devices in the vicinity of the magnet. For this reason, the required safety distances must be observed. For details, please refer to the MR compatibility datasheet. (➥System Owner Manual: MR compatibility datasheet)

Equipment room (MAGNETOM Verio)

⚠ CAUTION

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

Risk of burns

- Do not position objects behind the amplifier.
- Do not touch the back of the amplifier.

Signs and symbols

The system owner is responsible for properly identifying the accessible areas (e.g. regarding the electromagnetic field), the vicinity of the MR system, as well as adjacent areas by using the appropriate signs.

⚠ 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.

Overview table

The following table of warning and prohibition signs must be installed in a clearly visible location at eye level, preferably at the door to the examination room. Depending on the system, the field strength is also shown (for example, 1.5 T or 3 T).

Protective class symbols

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

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

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 must undergo functionality testing prior to actual use.

RF coils are subject to quality measurements.

Maintenance/repair

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 that 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.

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

Assembling and modifications during the actual service life require evaluation to the requirements of IEC 60601-1.

⚠ 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.

Repairs and modifications

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

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

The person performing the work must provide a certificate describing the nature and extent of work performed. This certificate must 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 (e.g. circuit diagrams, spare parts lists, descriptions, calibration instructions). However, this does not constitute authorization for repairs.

Maintenance at regular intervals

In the interest of the safety of patients, operating personnel, and third parties, it is strongly recommended that only authorized personnel perform the maintenance procedures prescribed by Siemens. System checks should be conducted more frequently if the system is operated under extreme conditions. For further information, see (➡System Owner Manual: Maintenance Plan).

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

Daily checks

In the course of system operation, technical and constructional changes may have been made to the MR system and its environment. It must be ensured that these components function satisfactorily and do not present hazardous conditions.

After system acceptance by the customer, a daily visual inspection should be performed for the MR system with respect to the following constructional changes:

- Changes in the environment at the output of the exhaust line (e.g. window installed retrospectively, inlet and outlet of air-conditioning units, new buildings or 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. prohibited use of the same exhaust line for several MR systems)
- Constructional changes inside and outside the examination room

The examination room must be checked for (newly introduced) magnetic parts.

Annual checks

The annual technical safety inspections are listed in this system owner manual and may only be performed by Siemens Service.

Refilling helium

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 must be refilled by Siemens Service.

When filling the magnet with helium, perform the necessary tasks carefully and accurately, observing all regulations. Wear protective clothing to prevent frostbite.

Helium-related risks

Liquid helium presents the following properties that, among other things, may result in hazardous conditions when not handled professionally:

- Extremely cold: causes frostbites when it comes in touch with skin
- Oxygen in ambient air is displaced during boil-off: risk of asphyxiation

If the helium fill level is too low, the alarm box or the *syngo* Acquisition Workplace will signal this accordingly.

- In case of alarm, notify Siemens Service and/or ensure refilling only through trained and experienced personnel.

Storage

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

- Use non-magnetic coolant containers for the helium.

⚠ WARNING

Improper storing of coolant containers and escaping gaseous helium during refill activities!

Injury to persons, danger of suffocation, frostbite

- Ensure that the rooms are ventilated via an air conditioning system. This includes refilling with helium as well.
- Ensure that escape routes have been determined, are identified as such and are not obstructed (e.g. by coolant containers).
- Ensure that the magnet is only filled by Siemens Service.

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System Owner Manual

MR compatibility data sheet

Skyra

MR compatibility

The data and protocols included in this manual provide the operator with the means for evaluating the MR compatibility of non-Siemens MR products with the MR system described in the System Owner Manual.

The MR compatibility of non-Siemens MR products addresses products of both manufacturers, the company producing the non-Siemens MR product and the company producing the MR system. The operator is ensured the safe operation of the non-Siemens MR product together with the MR system only when both manufacturers provide a test certificate addressing the “testing the effect of non-Siemens MR products on MR systems” as well as “testing the effect of MR systems on non-Siemens MR products”. In all other cases, the operator has to ensure that use of the non-Siemens MR product does not conflict with the functions of the MR system and vice versa.

According to IEC 60601-2-33, the manufacturer of the MR system is obligated to provide a data sheet covering technical information of the MR system to enable items to be assessed for MR compatibility.

A display of the contours of equal field strength of the MR system begins on page 5 of this manual.

Own liability and risk

Based on the information provided, the operator evaluates the non-Siemens MR product at his own risk within the MR environment. Siemens shall not be held liable for any hazards resulting from this evaluation.

MR compatibility test

Manufacturers of a non-Siemens MR product, who would like to obtain a test certificate (“testing the effect of non-Siemens MR products on MR systems”) for their device from Siemens, should get in touch with their Siemens sales engineer.

Parameters

All system-specific parameters are included in the “Technical Data” register of the System Owner Manual.

MR compatibility protocols

According to IEC 60601-2-33, protocols need to be proposed for testing the functionality of non-Siemens MR products. The protocols listed below are routinely used in the system.

! The tests are not used to evaluate the effects of the non-Siemens MR product on the image quality of the MR system.

! Successful tests with the below protocols do not guarantee MR compatibility of non-Siemens MR products.

Directory	Protocol
head/library/T2	t2_tse_tra_320_p2
head/library/SPACE	t2_spc_sag_p2_iso
abdomen/library/T1	t1_fl2d_fs_tra_mbh_320
abdomen/library/T2	t2_tse_tra_fs_p2_mbh_320
abdomen/library/3D	t1_vibe_fs_tra_bh_p2

Magnetic fringe field and control area

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 x, y, and z axes of the magnet.

Magnetic flux density	Minimum distances (x = y = radial, z = axial)	Examples: Devices affected
3 mT	x = 2.1 m z = 3.2 m	Small motors, watches, cameras, credit cards, magnetic media
1 mT	x = 2.3 m z = 4.0 m	Oscilloscopes, computers, disk drives, shielded color monitors
0.5 mT	x = 2.60 m z = 4.60 m	B/W monitors, magnetic media, cardiac pacemakers, insulin pumps
0.2 mT	x = 3.1 m z = 5.7 m	Siemens CT systems
0.1 mT	x = 3.9 m z = 6.8 m	Siemens linear accelerators
0.05 mT	x = 4.9 m z = 8.2 m	X-ray I.I., gamma cameras, third party linear accelerators

Spatial distributions

This section includes the following spatial distributions diagrams:

- Static magnetic field B_0
- Spatial gradient of B_0
- Product of the static magnetic field B_0 and the spatial gradient of B_0

Static magnetic field B_0

The figures show lines of the same magnetic flux density in milliTesla.

The following graphics show the calculated magnetic field in air. Magnetic materials in the vincinity of the magnet (i.e. iron beams or room shielding) may influence the form of the stray field.

The plots represent three orthogonal planes through the isocenter to illustrate maximum spatial extent of iso-magnetic contours.

Each plot contains the iso-magnetic contours with values of 0.5 mT, 1 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT, and 200 mT as well as a distance scale and a superimposed outline of the MR system.

The 0.5 mT line marks the exclusion zone of the static magnetic field (pace maker limit).

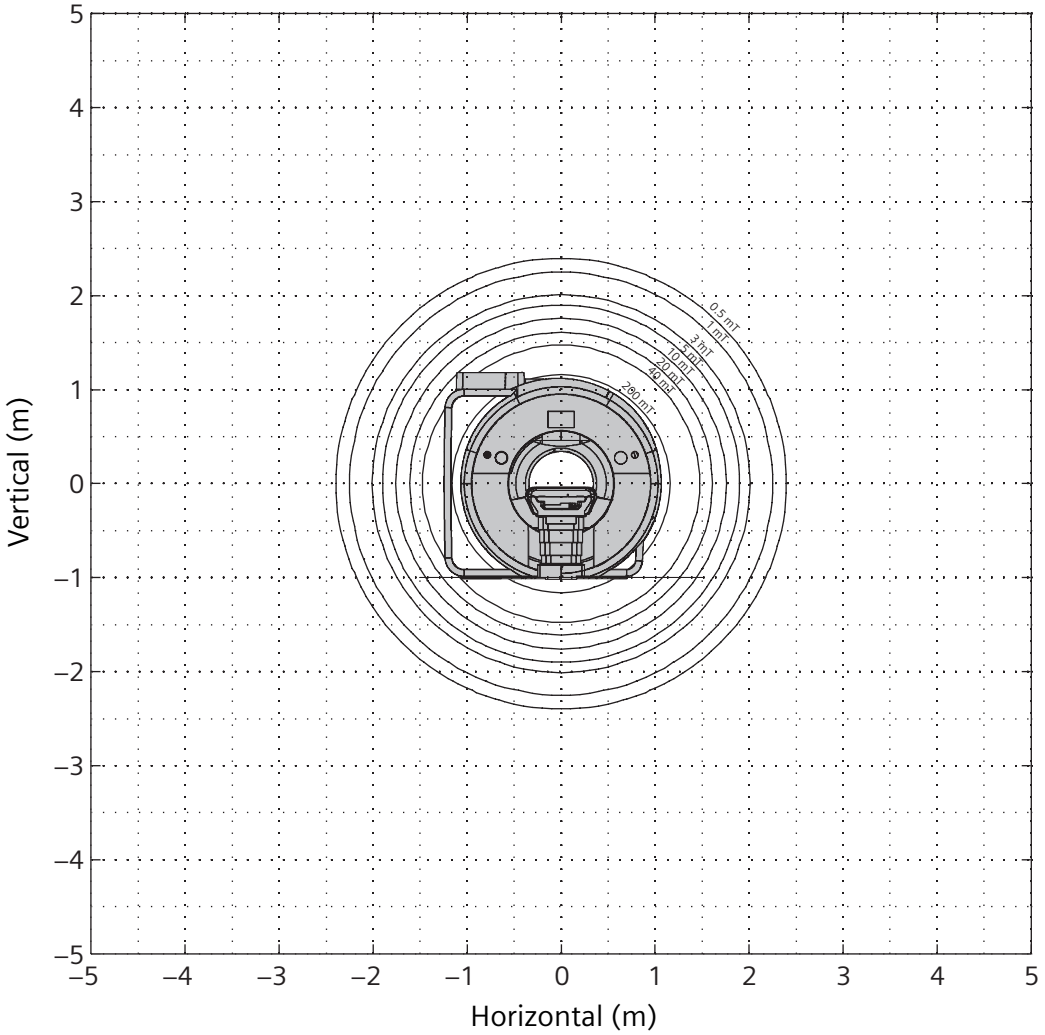
Note: The magnetic field is rotationally symmetric about the z-axis and mirror symmetric about the horizontal axis.

The multiple plots are shown to provide information about the accessible space in different orientations.

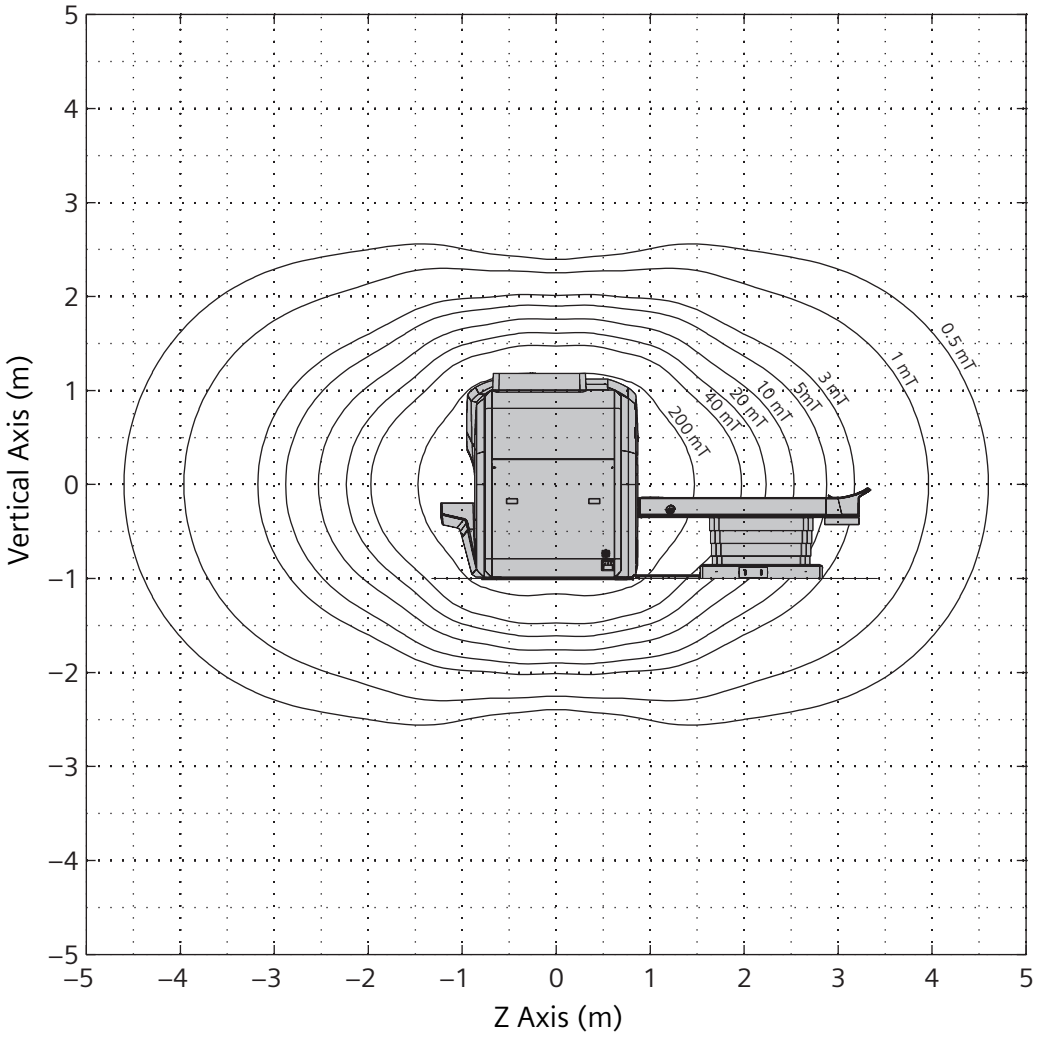
This note also applies to the other magnetic field related plots.

View in the direction of the magnet axis

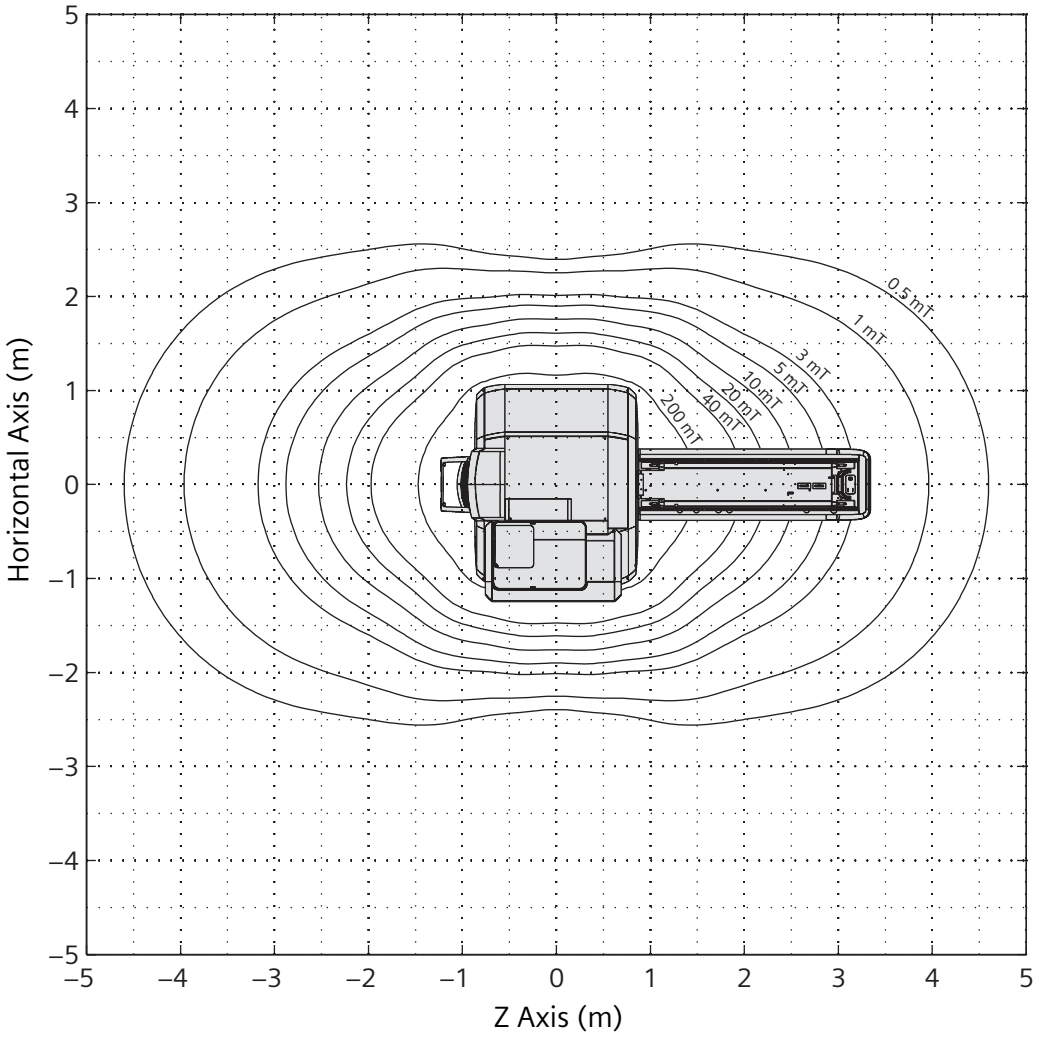
The graphic is referenced to plane z = 0.



Side view of the magnet



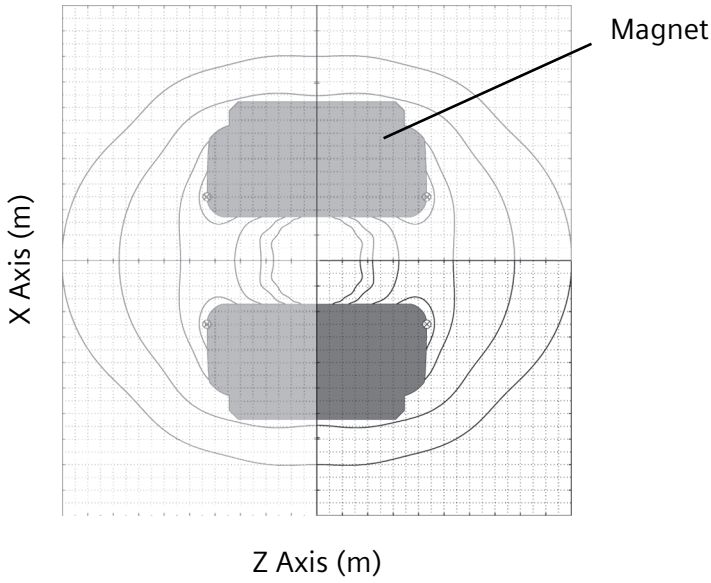
Top view of the magnet



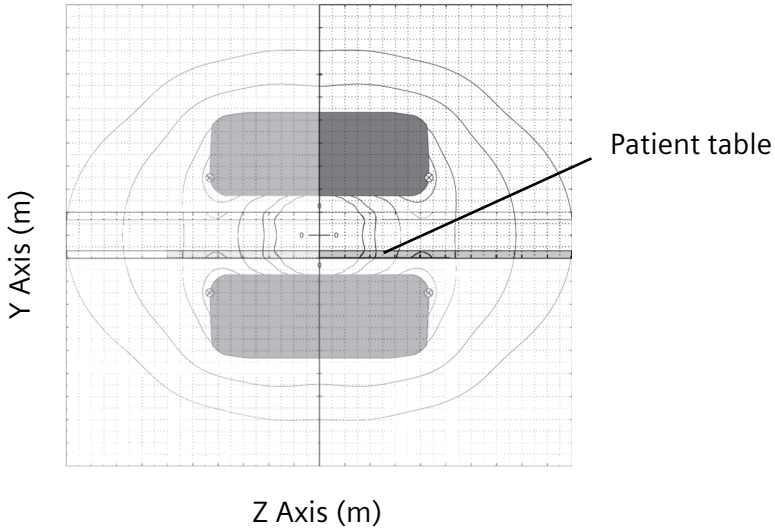
The following graphs all represent one quarter of the magnet as indicated below.

The plot lines each run symmetric to the axis to the isocenter of the magnet. As a result, the graphs can be unfolded.

Top view

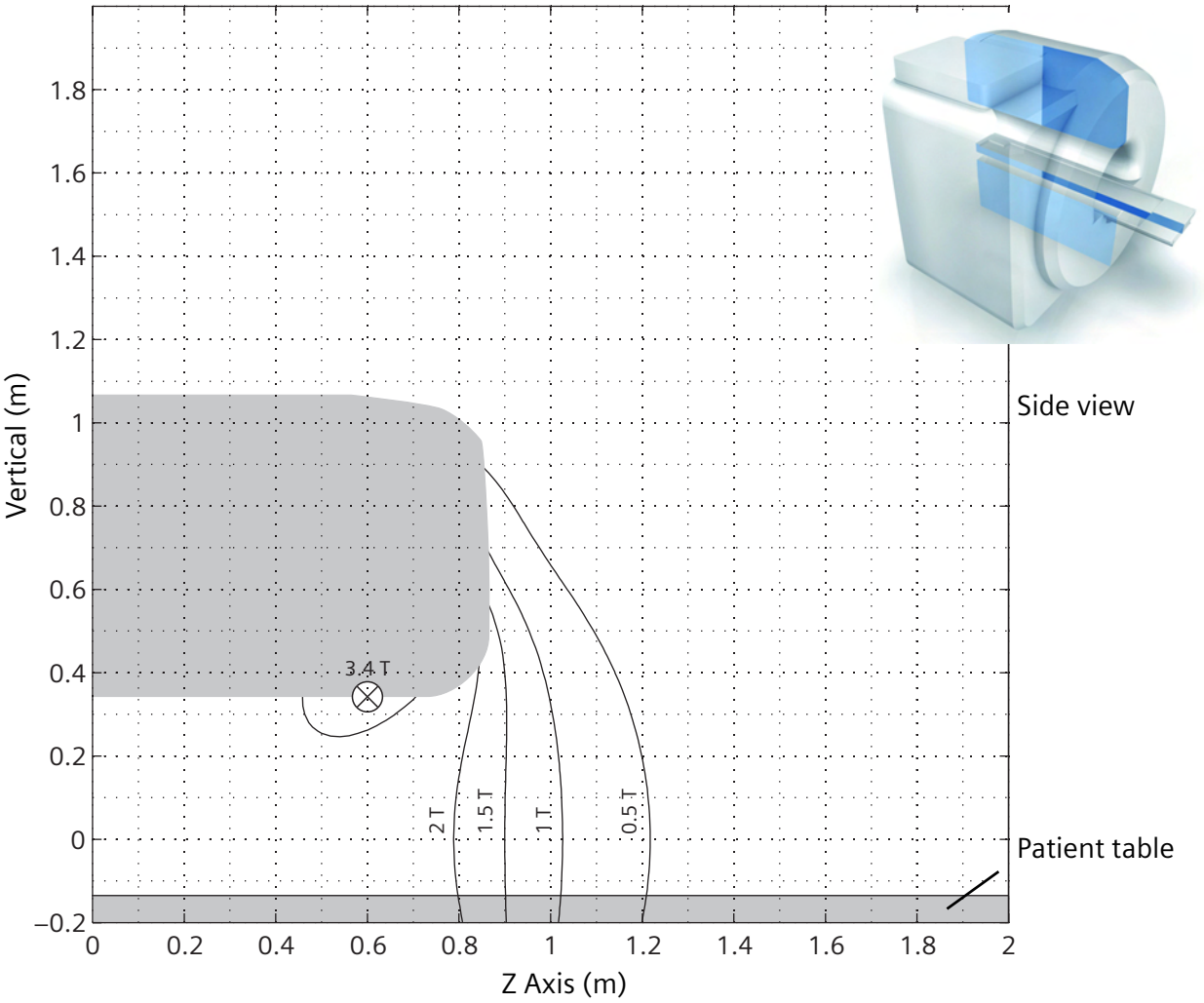


Side view



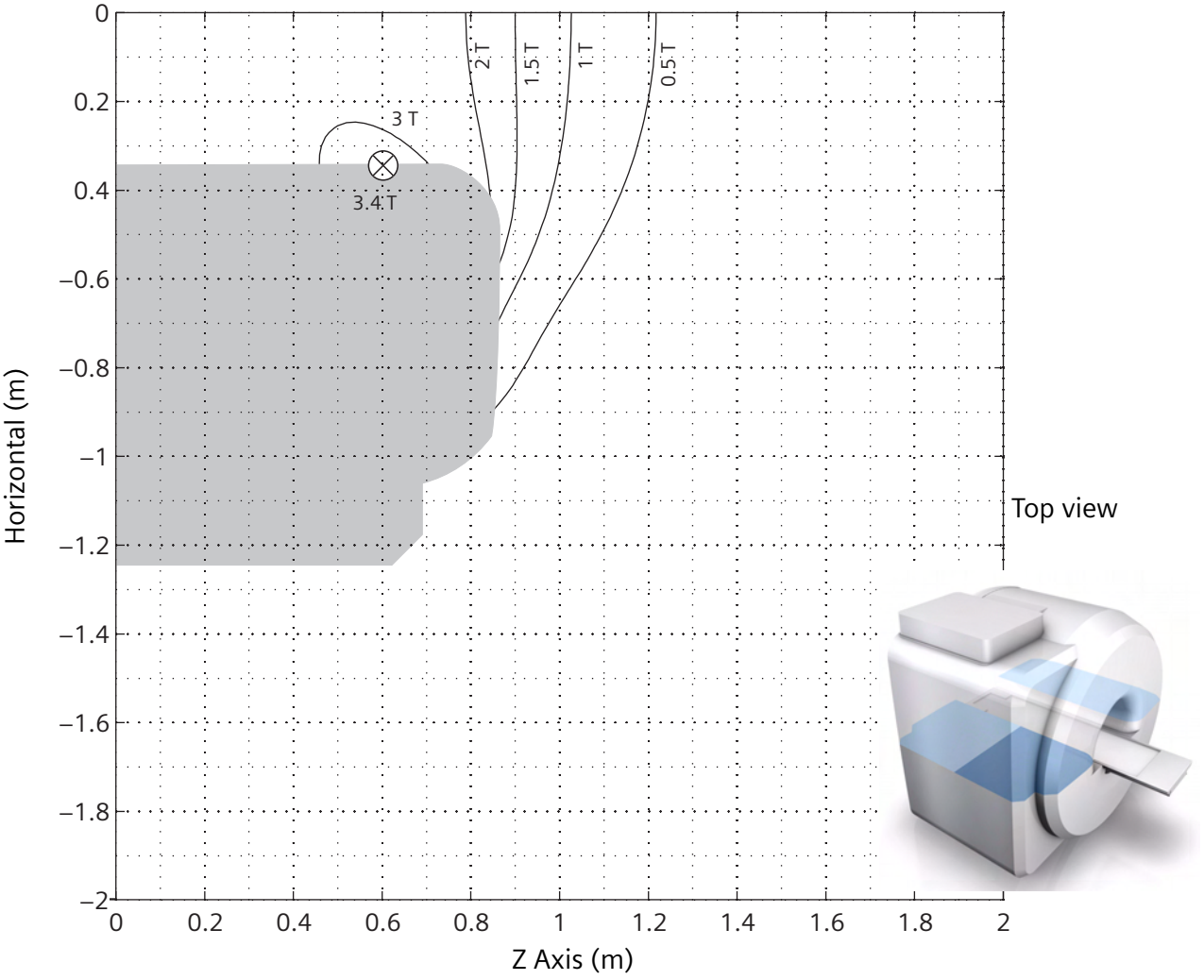
A small overview graphic is displayed on the following pages to indicate the area mapped by the respective graph.

In the following we show a plot representing the 0.5 T, 1 T, 1.5 T, and 2 T iso-magnetic contours at positions accessible to and relevant for the MR worker as far as the static magnetic field in the isocenter exceeds any of these values.



⊗: At this location, the value of the magnetic field B_0 is greatest.

! The iso-magnetic contour lines are accurate to a value better than 1%. There is very little influence from the environment to the scanner. The graphic shows the cover in nominal position. On a variety of scanners, the position can vary ±5 mm in the axial direction. The maximum value therefore has a tolerance of ±10%, as small geometric deviations can cause a significant change in the value.

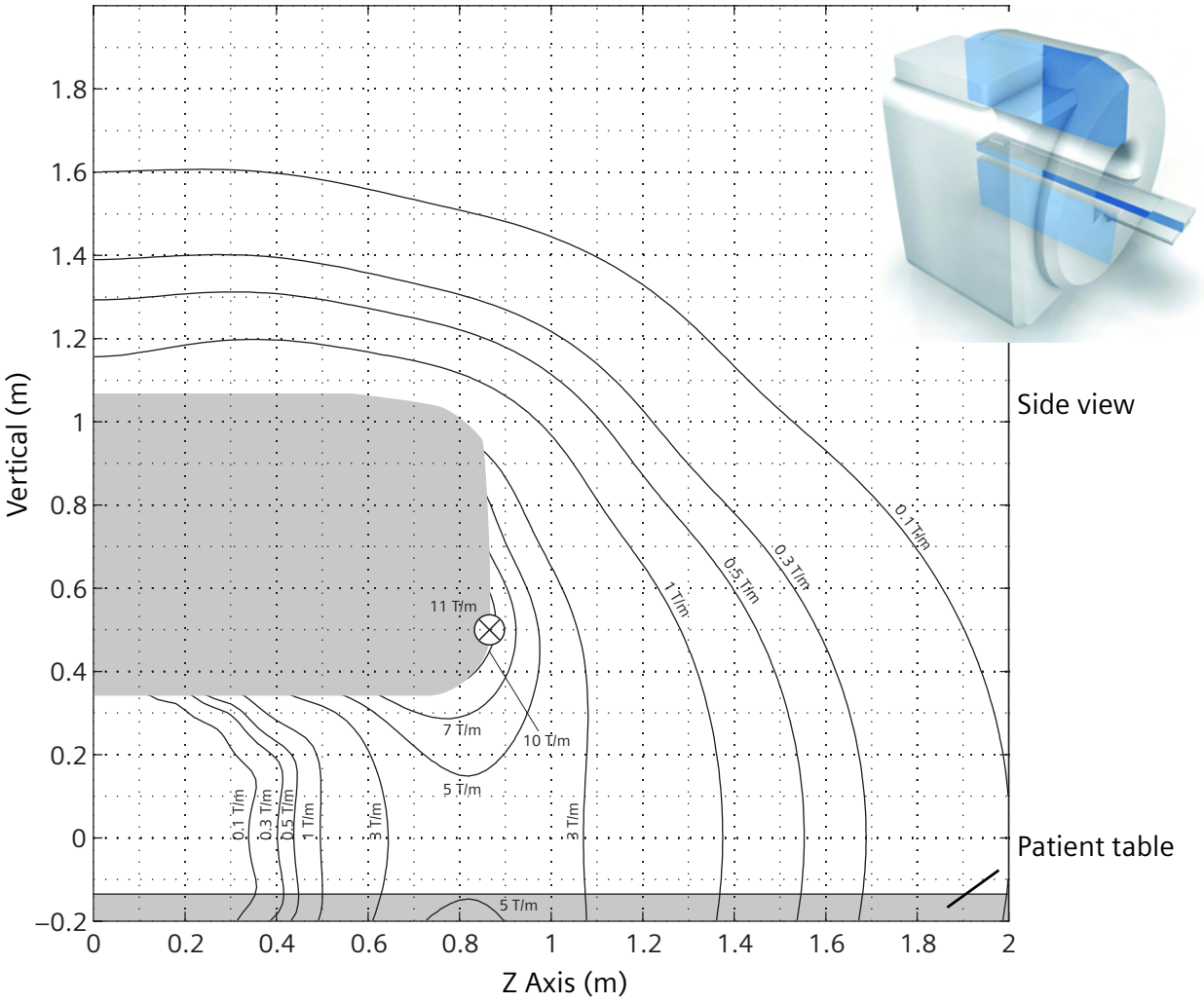


⊗: At this location, the value of the magnetic field B_o is greatest.

Spatial gradient of the static magnetic field B_0

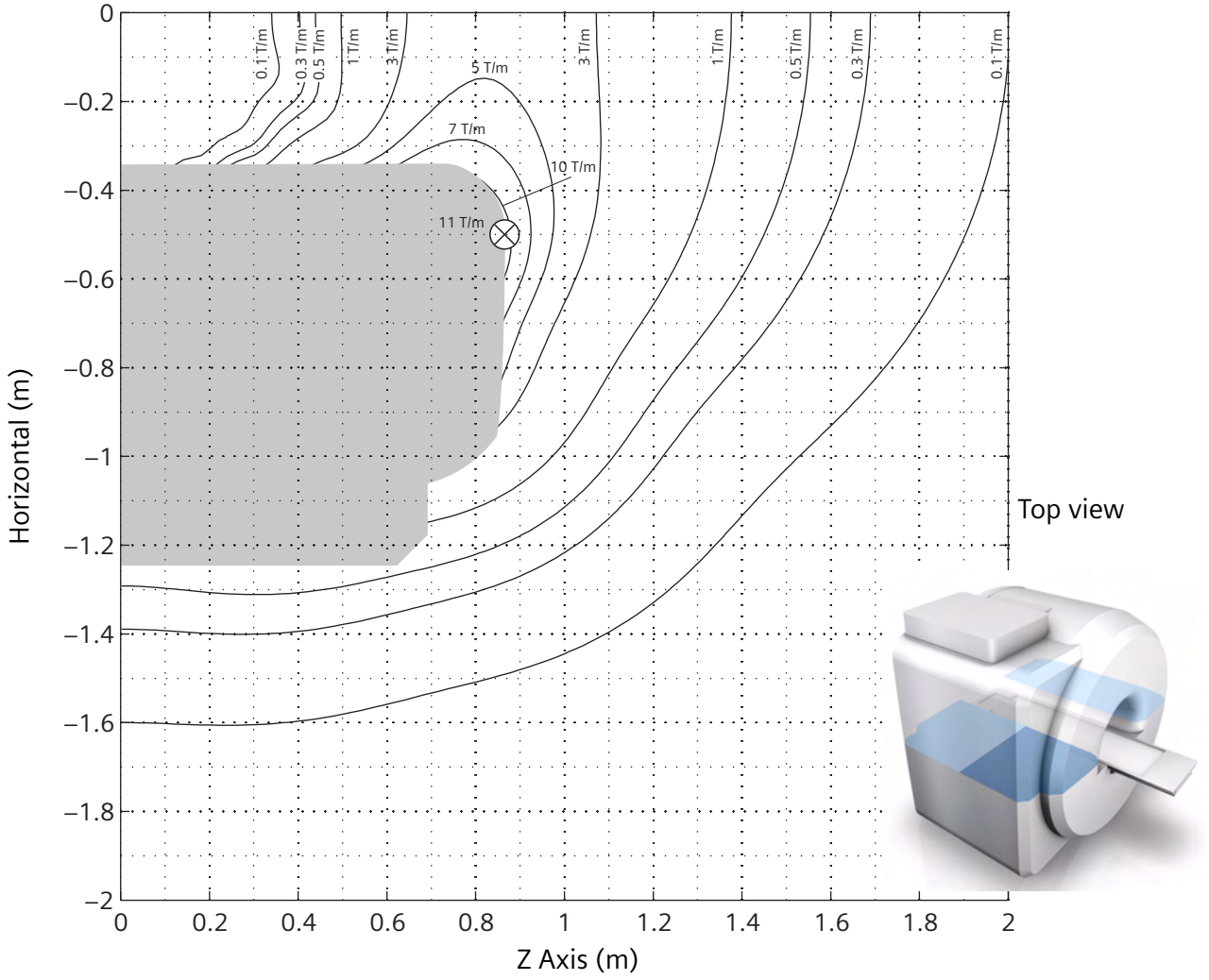
The rise of the magnetic field as a function of the distance to the magnet is expressed by the spatial gradient of B_0. The following figures show lines with the same gradient in T/m. The magnetic attraction force on a magnetically saturated ferromagnetic object is proportional to this quantity.

Please note: Sometimes this quantity is expressed in G/cm (1 T/m = 100 G/cm).



⊗: At this location, the force on a magnetically saturated ferromagnetic object is greatest.

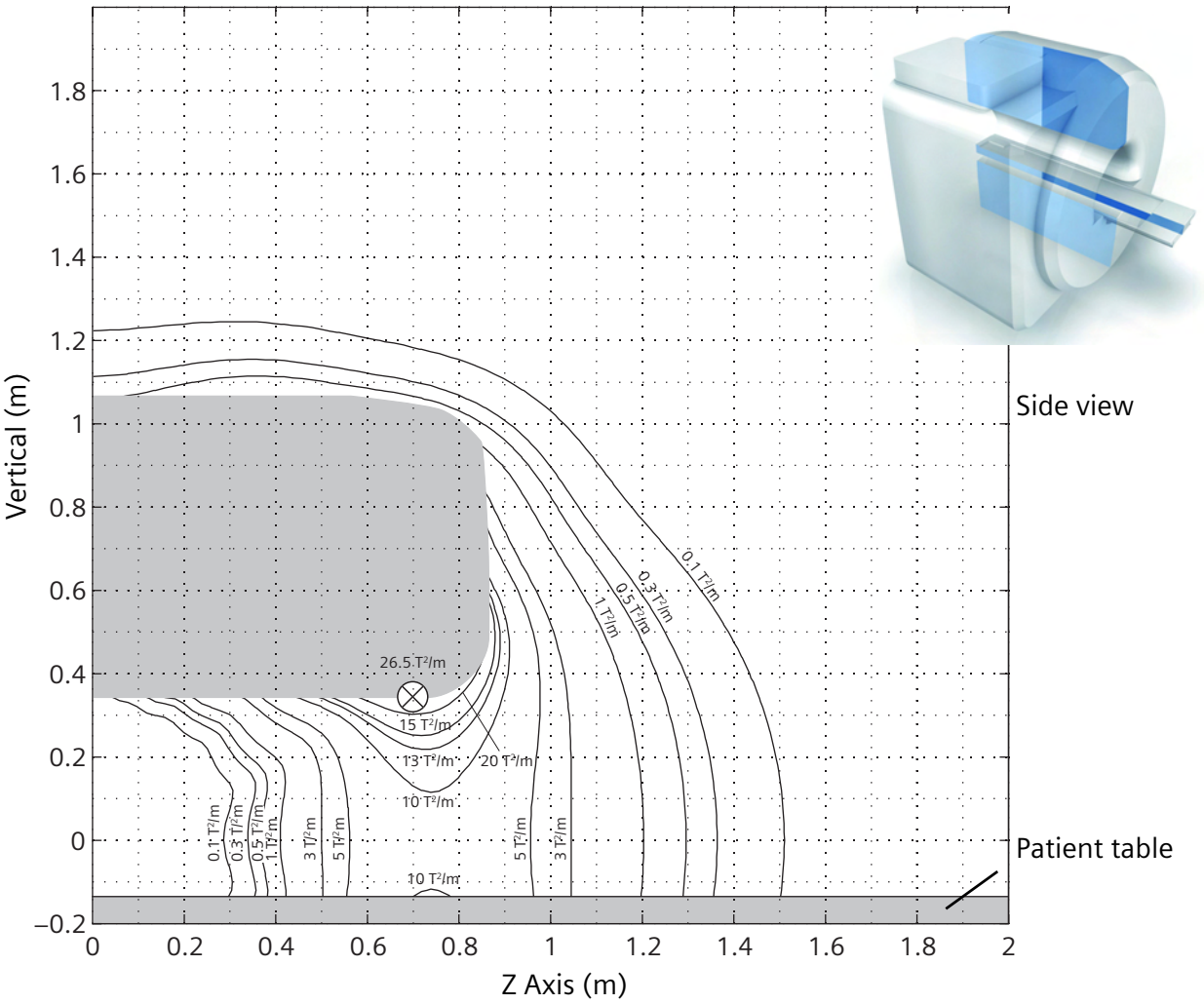
! The iso-magnetic contour lines are accurate to a value better than 1%. There is very little influence from the environment to the scanner. The graphic shows the cover in nominal position. On a variety of scanners, the position can vary ±5 mm in the axial direction. The maximum value therefore has a tolerance of ±10%, as small geometric deviations can cause a significant change in the value.



⊗: At this location, the force on a magnetically saturated ferromagnetic object is greatest.

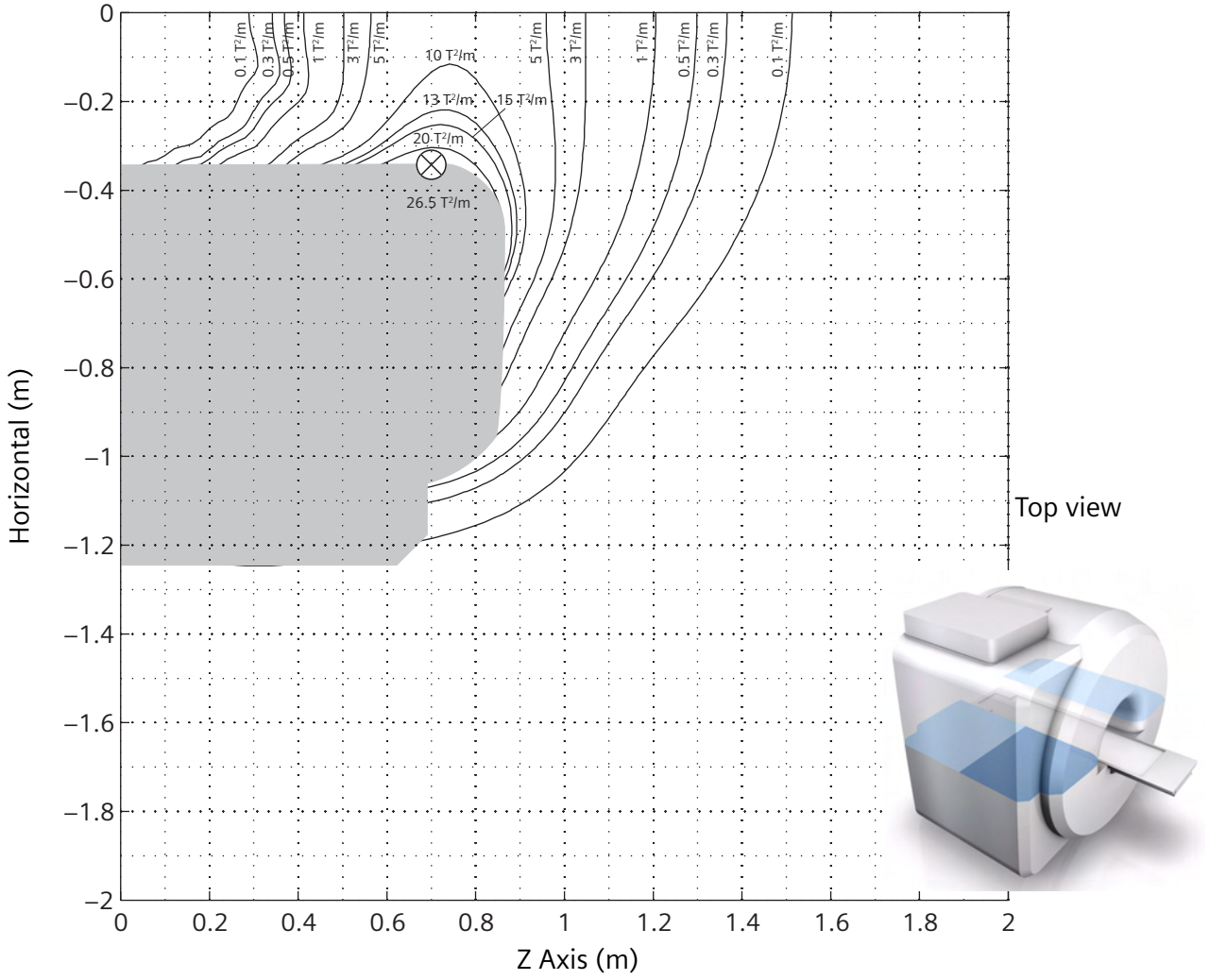
Product of the static magnetic field B_0 and the spatial gradient of B_0

The magnetic attraction force on a diamagnetic/paramagnetic object or on a ferromagnetic material below its magnetic saturation is proportional to this quantity.



⊗: At this location, the force on a diamagnetic/paramagnetic object or on a ferromagnetic material below its magnetic saturation is greatest.

! The iso-magnetic contour lines are accurate to a value better than 1%. There is very little influence from the environment to the scanner. The graphic shows the cover in nominal position. On a variety of scanners, the position can vary ±5 mm in the axial direction. The maximum value therefore has a tolerance of ±10%, as small geometric deviations can cause a significant change in the value.



⊗: At this location, the force on a diamagnetic/paramagnetic object or on a ferromagnetic material below its magnetic saturation is greatest.

Gradient stray field distribution relevant for assessing exposure to MR workers

The diagram shows the magnetic stray field distribution of the gradient system along the patient axis of the MAGNETOM Skyra with the XQ gradient system according to the requirements of the IEC 60601-2-33 standard.

The magnetic fields generated by each of the three orthogonal gradient axis are calculated on a coordinate grid on a virtual cylinder surface. The cylinder encompasses the patient axis and starts in the magnet isocenter.

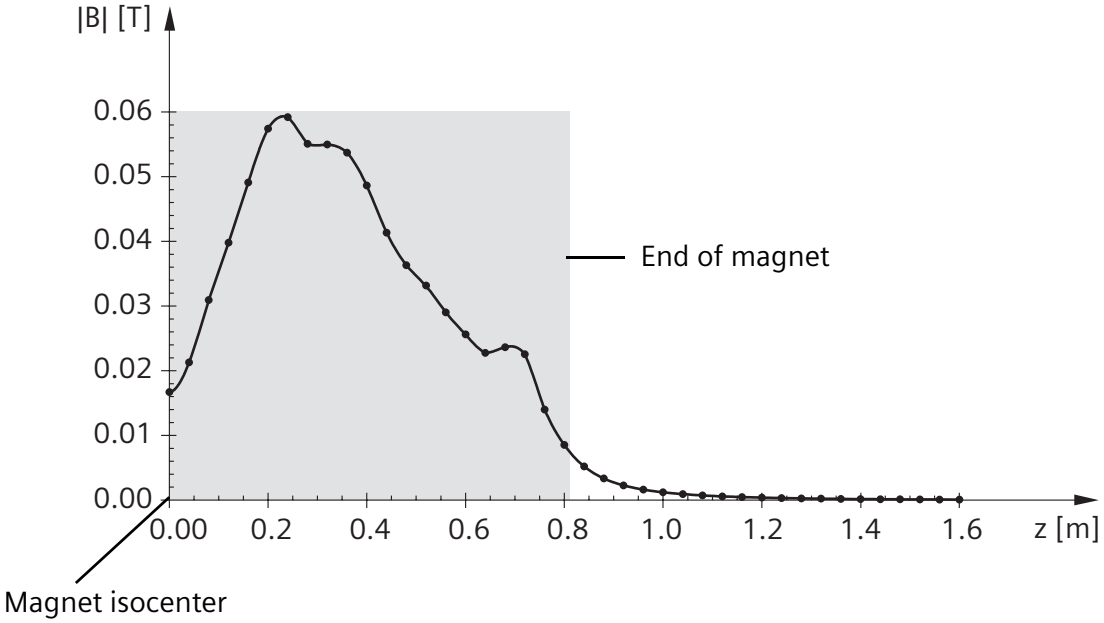
The grid is defined by:

- a point pattern on the surface of a virtual cylinder with a diameter of 70 cm (i.e. max. bore liner);
- points on circles on the cylinder surface perpendicular to the cylinder axis with an azimutal step width of 10 degrees (i.e. 36 points at the circumference) and an axial step width of 4 cm.

The field values are calculated at max. currents that can be handled by the gradient amplifiers. At each space point the field vectors generated by each gradient are calculated, superimposed and then their magnitudes are derived. The max. magnitude field value that can be found on each circle is selected and plotted along the z-axis.

By dividing the maximum field values by the shortest rise time, the dB/dt values can be derived.

	Shortest rise time	**Max dB/dt**
XQ gradient	225 µs	60 mT/225 µs = 267 T/s

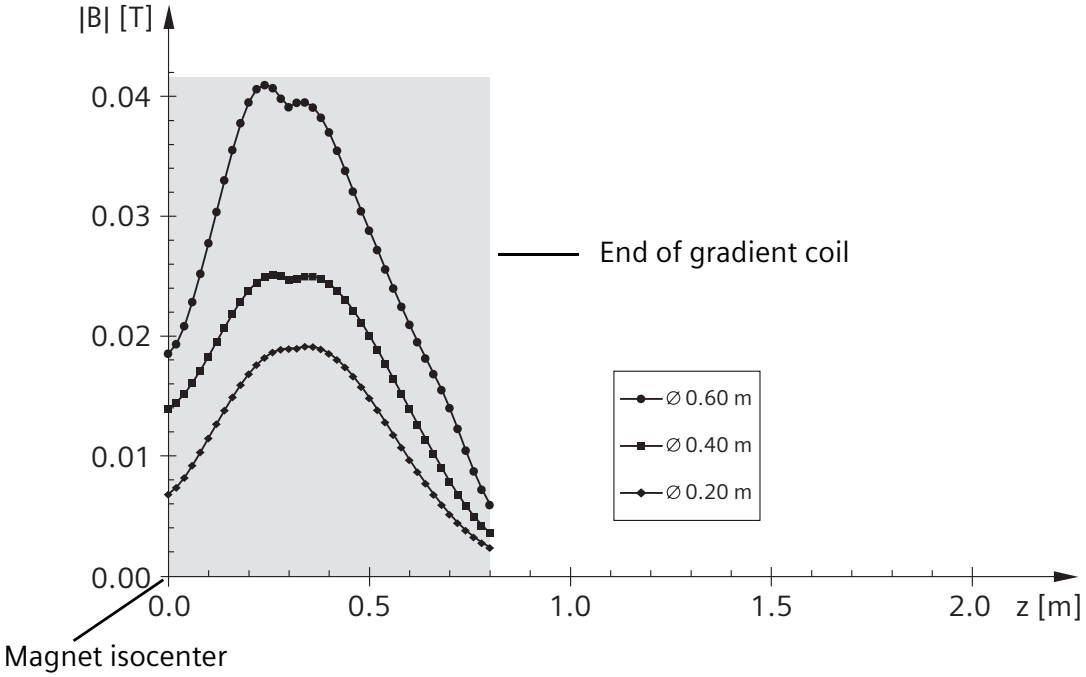


The area shaded in grey indicates the length of the magnet.

Spatial distribution of the gradient field at different positions inside the gradient coil

The diagram shows the spatial distribution of the maximum magnitude values of the vector sum of the field components generated by each of the three gradient units simultaneously at positions on virtual cylinders coaxial with the patient axis with diameters of 0.2 m, 0.4 m, and 0.6 m.

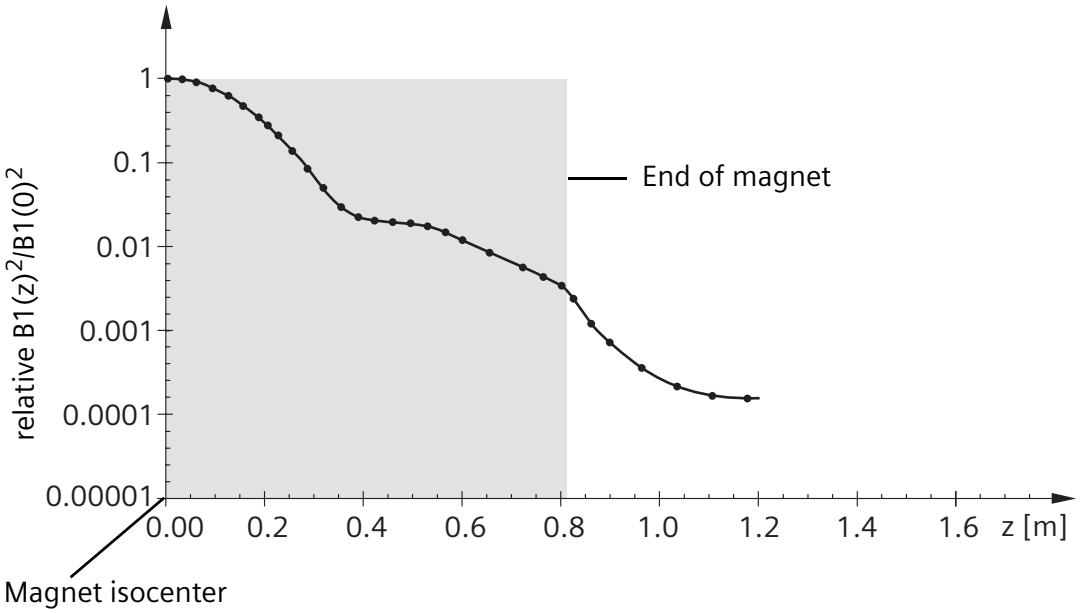
The virtual cylinders have the same length as the gradient coil. In the cylinder axis direction the points have a separation of 0.02 m.



The area shaded in grey indicates the length of the gradient coil.

RF power distribution relevant for assessing exposure to MR workers

The diagram shows the RF power distribution along the patient axis of the MAGNETOM Skyra according to the requirements of the IEC 60601-2-33 standard.



The RF field is calculated along the center line starting in the magnet isocenter. The area shaded in grey indicates the length of the magnet.

The ratio $B1(z)^2/B1(0)^2$ provides a worst case estimation of the SAR contribution to a person who is positioned at a distance z from the isocenter. The SAR contribution is relative to the SAR that is applied to a person in the center of the patient bore.

For example a person standing in front of the system aperture absorbs a maximum of 0.2% of the RF power which is applied to a patient scanned in the center of the bore.

Additional system characteristics

Magnet data	
Operating field strength	3 Tesla
Magnet type	Superconductor
Field stability over time	<0.1 ppm/h
Weight (with cryogens)	5755 kg
Magnet length	163 cm
Open Bore design[1]	70 cm
System length cover to cover	173 cm
Refill interval (typical)[2]	Not applicable
Boil-off rate (typical)[2]	0.0 l/year
Max. helium capacity	approx. 1200 liters
Minimum helium level	35%
Cryostat	Stainless steel

1. incl. shim coils, gradient coil, RF body coil
2. For typical clinical use, depending on sequences and operating time with running helium compressor. The system needs to be serviced at regular interval. Undisturbed magnet cooling for 24 hours and 7 days a week.

RF data		
Peak power of transmitter amplifier Channel 0 Channel 1	40.0 kW ≥16.0 KW ≥24.0 KW	
Transmitter bandwidth	800 kHz	
Receiver bandwidth	500 Hz–1 MHz (for each channel)	
RF transmit coils		
Body coil	Max. applied RF field B1+	24 µT
	Max. specified B1+ rms	3.6 µT
	Distance to isocenter, where RF transmit field is reduced by	
	3 dB	0.15 m
	10 dB	0.27 m
CP Extremity coil	Max. applied RF field B1+	47 µT
	Max. specified B1+ rms	9 µT
Tx/Rx 15-Channel Knee coil	Max. applied RF field B1+	47 µT
	Max. specified B1+ rms	8 µT
Tx/Rx Knee 15 MR coil	Max. applied RF field B1+	47 µT
	Max. specified B1+ rms	8 µT
Tx/Rx CP Head coil	Max. applied RF field B1+	41.1 µT
	Max. specified B1+ rms	6 µT

Tim table		
Max. patient weight for vertical and horizontal table movement		250 kg (550 lbs)
Max. scan range		140 cm; optional 205 cm[1]
Vertical table movement	Range	52–102 cm[2] +13 mm[3]
	Speed	6 cm/s
Horizontal table movement	Max. range	275 cm
	Max. speed	20 cm/s
	Positioning accuracy	±0.5 mm
Continuous table movement during scan capable		

1. With Tim Whole Body Suite option
2. Including Heightening Kit, if necessary
3. Depending on the floor conditions

Tim Dockable Table		
Max. patient weight for vertical and horizontal table movement		250 kg (550 lbs)
Max. scan range		140 cm; optional 205 cm[1]
Vertical table movement	Range	56–106 cm[2] +13 mm[3]
	Speed	6 cm/s
Horizontal table movement	Max. range	275 cm
	Max. speed	20 cm/s
Positioning accuracy		±0.5 mm
Continuous table movement during scan capable		

1. With Tim Whole Body Suite option
2. Including Heightening Kit, if necessary
3. Depending on the floor conditions

Patient comfort	
Open bore design[1]	70 cm
In-bore lighting	can be set at 6 different levels
In-bore ventilation	can be set at 6 different levels
In-bore intercom	including loudspeaker, microphone and earphones

1. incl. shim coils, gradient coil, RF body coil

Gradient data

XQ gradients	
Performance for each axis	
Max. amplitude	45 mT/m
Min. rise time	225 µs
Max. slew rate	200 T/m/s
Vector gradient performance (vector addition of all 3 gradient axes)	
Max. eff. amplitude	78 mT/m
Max. eff. slew rate	346 T/m/s
Gradient duty cycle	100%

SIEMENS

MAGNETOM

[redacted]MR

System Owner Manual

Guidance and manufacturer's declaration EMC

Skyra

Data sheet

The following document applies to all products provided by the Magnetic Resonance (MR) product group of Siemens AG, Siemens Healthcare Sector.

Deviations and additions to this document are provided in accompanying product-specific documents. This information has to be followed respectively applied.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Electromagnetic compatibility is the ability of an equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbance to anything in that environment.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Note

Fixed equipment or system cabeling, which can not be removed by the user, is not listed. This cabeling is part of the system and was regarded at all EMC-considerations. Without this cabeling there is no complete functionality of the system.

! The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the equipment or system.

RF shielding

! The MR system should be used only in the specified type of shielded location.

! The use of other RF-emitting equipment inside the shielded location of the MR system is not allowed.

Guidance and manufacturer's declaration — electromagnetic emissions

The MR system is intended for use in the electromagnetic environment specified below. The customer or the user of the MR system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
Radiated RF emissions CISPR 11	Class A/Group 2	The MR system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted RF emissions CISPR 11	Class A/Group 2	The MR system must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 80 dB from 10 MHz to 20 MHz, 100 dB from 20 MHz to 80 MHz and 80 dB from 80 MHz to 100 MHz. (The minimum at 20 MHz is 100 dB and the minimum at 80 MHz is 80 dB.) The MR system, when installed in such a shielded location, is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	
Note: It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.		

In principle MR systems may be used only together with compatible equipment.
The following definitions apply:

MR-safe	The device or implant is completely non-magnetic, non-electrically conductive, non-RF reactive and indicates no known hazards in all MRI environments.
MR-conditional	The device or implant may contain magnetic, electrically conductive or RF-reactive components. These devices are safe while being used in proximity to the MRI, provided the conditions for safe operation are defined and observed. Similarly, MR-conditional devices (for example, RF communications equipment) may present hazards as well. Please observe the manufacturer's operator manual to avoid potential hazards and injuries.
MR-unsafe	An item that is known to pose hazards in all MR environments.

! The MR system or equipment should not be used adjacent to other equipment, if adjacent or beside use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration — electromagnetic immunity

The MR system is intended for use in the electromagnetic environment specified below. The customer or the user of the MR system should assure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for signal lines	±2 kV for power supply lines ±1 kV for signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment or system requires continued operation during power mains interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply. The MR system has a rated input current of more than 16 A per phase.
	<5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 5 s	—
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to applying the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The MR system is intended for use in the electromagnetic environment specified below. The customer or the user of the MR system should assure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF interference IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	The MR system must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of 80 dB from 10 MHz to 20 MHz, 100 dB from 20 MHz to 80 MHz and 80 dB from 80 MHz to 100 MHz. (The minimum at 20 MHz is 100 dB and the minimum at 80 MHz is 80 dB.) Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m[1]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF interference IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Note 2: It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the MR system is used exceeds 3 V/m, the MR system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the MR system or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

A MR system is classified as a large and permanently-installed equipment. The exemption according to the requirement 36.202.3 b) 9. of IEC 60601-1-2 Edition 2.1 (2004-11) and 6.2.3.2i of IEC 60601-1-2 Edition 3 (2007-03) has been used and the equipment was not tested for radiated RF immunity over the entire frequency range 80 MHz to 2.5 GHz.

! The MR system has been tested for radiated RF immunity only at selected frequencies.

Tested ISM frequencies	80 MHz–2.5 GHz
Modulation characteristic	1 kHz, 80% AM
Test level	3 V/m
Signal generator with amplifier	9 kHz to 3.2 GHz

Recommended safety distances between portable and mobile RF-communication equipment and the MR system

The MR system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MR system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MR system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter in watts (W)	**Separation distance according to the frequency of the transmitter in meters (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

! The MR system may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

Basic safety and essential performance

As a result of the risk management process for the MR systems (according to IEC 60601-1:2005 (3rd Edition)), no essential performance was identified.

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[redacted]MR

System Owner Manual

Technical data

Skyra

Magnet system

- Short-bore, patient-friendly design, high homogeneity
- Easy siting due to AS (Active Shielding) and E.I.S. (External Interference Shielding) magnet technology
- Operating mode: First Level controlled operating mode according to IEC 60601-2-33.

Magnet parameters	
Operating field strength	3 Tesla
Magnet type	Superconductor
Field stability over time	<0.1 ppm/h
Weight (with cryogens)	5755 kg
Magnet length	163 cm
Open Bore design[1]	70 cm
System length cover to cover	173 cm

1. incl. shim coils, gradient coil, RF body coil

Homogeneity (based on highly accurate 24 plane plot)		
	Guaranteed	**Typical**
10 cm DSV	0.01 ppm	0.003 ppm
20 cm DSV	0.05 ppm	0.03 ppm
30 cm DSV	0.3 ppm	0.2 ppm
40 cm DSV	1.4 ppm	1.2 ppm
50×50×45 cm^3 DEV	4.0 ppm	3.6 ppm

In compliance with the German "Qualifikationsvereinbarung".
Standard deviation Vrms (Volume root-mean square) measured with highly accurate 24 plane plot method (20 points per plane).
Standard active shim with 3 linear and 5 non-linear channels (2nd order).
DSV = Diameter spherical volume (x, y and z direction).
DEV = Diameter elliptical volume.

Shimming	
Both: passive and active shimming. Passive shimming during installation.	
Standard active shim with 3 linear channels (1^{st} order) and 5 non linear channels (2^{nd} order).	
3D Shim	Patient-specific automated shim
	Time to shim = approx. 30 s

Shielding		
Active Shielding (AS)	5^{th} generation active shielding (AS) technology with counter coils	
Fringe field (axial×radial)	0.5 mT[1]	4.6 m×2.6 m
	0.1 mT	6.8 m×3.9 m
External Interference Shield (E.I.S.)	Patented shielding system integrated into the magnet	
	Continuous compensation and automatic suppression of external magnetic field interferences during measurement (caused by moving ferromagnetic objects or nearby power lines)	

1. pacemaker safety limit

Magnet cooling system	
Refill interval (typical)[1]	Not applicable
Boil-off rate (typical)[1]	0.0 l/year
Max. helium capacity	approx. 1200 liters
Minimum helium level	35%
Cryostat	Stainless steel

1. For typical clinical use, depending on sequences and operating time with running helium compressor. The system needs to be serviced at regular interval. Undisturbed magnet cooling for 24 hours and 7 days a week.

Patient handling

The patient table is available in two different configurations:

Tim table		
Max. patient weight for vertical and horizontal table movement		250 kg (550 lbs)
Max. scan range		140 cm optional 205 cm[1]
Vertical table movement	Range	52–102 cm[2] +13 mm[3]
	Speed	6 cm/s
Horizontal table movement	Max. range	275 cm
	Max. speed	20 cm/s
	Positioning accuracy	±0.5 mm
Continuous table movement during scan capable		

1. With Tim Whole Body Suite option
2. Including Heightening Kit, if necessary
3. Depending on the floor conditions

Tim Dockable Table		
Max. patient weight for vertical and horizontal table movement		250 kg (550 lbs)
Max. scan range		140 cm optional 205 cm[1]
Vertical table movement	Range	56–106 cm[2] +13 mm[3]
	Speed	6 cm/s
Horizontal table movement	Max. range	275 cm
	Max. speed	20 cm/s
Positioning accuracy		±0.5 mm
Continuous table movement during scan capable		

1. With Tim Whole Body Suite option
2. Including Heightening Kit, if necessary
3. Depending on the floor conditions

Hearing protection data

The A-evaluated, effective sound pressure level was measured according to NEMA MS 4-2006 (National Electrical Manufacturers Association) using the maximum gradient acoustic noise (MGAN) method.

Patient noise	
XQ gradients	Patients require hearing protection with an SNR[1] = 30 dB or more

1. SNR = Single Number Rating

Noise for personnel in the examination room	
XQ gradients	Noise measured: 88.3 dB(A)
	Hearing protection: SNR = 7 dB or more

Gradient system

General features
Actively shielded (AS) whole-body gradient coil system
Extremely low eddy currents
Water-cooled coil and amplifier for maximum performance
All axes force compensated

Gradient amplifier		
• Water-cooled, highly compact, modular design • Ultra-fast solid-state technology with very low switching losses		
XQ gradients	Max. output voltage[1]	2250 V
	Max. output current[1]	750 A

1. Values for each of the 3 gradient axes

XQ gradients	
Performance for each axis	
Max. amplitude	45 mT/m
Min. rise time	225 µs
Max. slew rate	200 T/m/s
Vector gradient performance (vector addition of all 3 gradient axes)	
Max. eff. amplitude	78 mT/m
Max. eff. slew rate	346 T/m/s
Gradient duty cycle	100%

DirectRF™ technology

Direct transmit technology		
Frequency stability (5 min)	$\pm 2 \times 10^{-10}$	
Frequency control	32 bits (0.03 Hz)	
Phase control	16 bits (0.006 degrees)	
Body coil	Integrated whole body no tune transmit/receive coil with 32 rungs	
	Optimized RF efficiency and signal-to-noise ratio (SNR)	
Transmitter path	Real-time feedback loop for excellent RF stabilization	
	Transmit amplitude	16 bit control 25 ns resolution
	Gain stability (after first minute)	<0.05 dB (1 s) <0.2 dB (5 min)
Transmitter amplifier	Extremely compact, water-cooled solid state amplifier, fully integrated at the magnet as part of DirectRF™ technology	
	Transmit amplifier bandwidth	800 kHz
	Peak power	40.0 kW
	Channel 0	≥16.0 KW
	Channel 1	≥24.0 KW

TimTX TrueForm	
• Innovative techniques in the RF excitation hardware • Uniform RF distribution in all body regions	
TrueForm excitation uses amplitude and phase transmission settings optimized for dedicated body regions. Feeding the 2 ports of the integrated body coil with an optimized weighting yields a homogeneous B1 distribution	
a-SPACE	A version of the SPACE sequence. a-SPACE uses composite adiabatic excitation pulses, which are insensitive to B1 spatial variations
B1 Filter	An adaptive inline image filter that reduces any remnant B1 effects without affecting image contrast

RF receiver technology	
Number of coil elements	Up to 204
Number of independent receiver channels	48, 64[1], 128[1]
Quadrature demodulation and filtering	Digital
Receiver bandwidth	500 Hz–1 MHz (for each channel)
Receiver signal resolution	32 bit
ADC sampling rate	80 MHz
Preamplifier noise figure	<0.5 dB
Dynamic range at coil connector (referred to 1 Hz resolution bandwidth)	164 dB instantaneous at receiver 169 dB with automatic gain control at local coil connector

1. Optional

Multi-Nuclear Option[1]				
• Multi-Nuclear Imaging and Spectroscopy for the following nuclei: 3He, 7Li, 13C, 17O, 19F, 23Na, 31P, 129Xe • Decoupling nuclei: 13C, 31P • Hyperpolarization nuclei: 3He, 13C, 129Xe				
Frequency band	**3He**	**7Li**	**13C**	**17O**
Center frequency [MHz]	93.8524	47.8799	30.9806	16.7012
Usable transmitter bandwidth [kHz]	±50	±50	±50	±50
Usable receiver bandwidth [kHz]	±190	±100	±65	±50
	19F	**23Na**	**31P**	**129Xe**
Center frequency [MHz]	115.9040	32.5885	49.8719	34.0816
Usable transmitter bandwidth [kHz]	±50	±50	±50	±50
Usable receiver bandwidth [kHz]	±235	±65	±100	±70

1. Optional

RF coils

Standard coils	Applications
Body 18	• Thorax • Heart • Abdomen • Pelvis • Hip • Vascular
Head/Neck 20	• Head examination • Neck examination • MR Head/Neck Angiography • Combined head/neck examination • TMJ (temporomandibular joints)
Spine 32	• High resolution imaging of the whole spine • Various applications in combination with additional coils
Flex Large 4	• Imaging of large regions such as medium to large shoulder, hip, and knee
Flex Small 4	• Imaging of small regions such as small to medium shoulder, wrist, elbow, and ankle

Optional coils	Applications
Peripheral Angio 36	• High resolution angiography of both legs with high signal-to-noise ratio • Bilateral examinations of long bones of the legs
Loop coil, large	• Examination of upper or lower extremities (e.g. shoulder, axilla)
Loop coil, medium	• Examination of inner ear, structure of wrist and fingers, pediatrics examinations[1]
Loop coil, small	• Examination of small structures near the surface, e.g. joints of fingers and toes, wrist, skin, temporo mandibular joints (TMJ)
Hand/Wrist 16	• High resolution hand and wrist imaging
Foot/Ankle 16	• High resolution foot and ankle imaging
Shoulder Large 16 Shoulder Small 16	• Excellent visualization of small anatomical structures (e.g. labrum) • High SNR and excellent field homogeneity
CP Extremity Coil	• Knee • Ankle • Peripheral MR Angiography • Pediatric imaging[1]
Tx/Rx 15-Channel Knee coil	• Examinations of joints in the area of the lower extremities • High resolution knee imaging

Optional coils	Applications
4-Channel BI Breast coil	• Simultaneous basic imaging of both breasts in all directions • Uni- or bi-lateral basic imaging of the breasts in sagittal direction • Uni-lateral biopsy imaging for lateral, medial and cranio-caudal access
16-Channel AI Breast coil	• Simultaneous imaging of both breasts in all directions • Uni- or bi-lateral imaging of the breasts in sagittal direction • High resolution 2D and 3D breast imaging
Sentinelle Vanguard for Siemens 2-/4-/8-Channel Configuration	• Simultaneous imaging of both breasts in all directions • Uni- or bi-lateral imaging of the breasts in sagittal direction • Uni-lateral biopsy imaging for lateral and medial access • High-resolution 2D and 3D imaging • For quantitative spectroscopy (*syngo* GRACE) a reference bottle can be inserted

Optional coils	Applications
Sentinelle Vanguard for Siemens 8-Channel Configuration/Upgrade to Biopsy Configuration	• Simultaneous imaging of both breasts in all directions • Uni- or bi-lateral imaging of the breasts in sagittal direction • High-resolution 2D and 3D imaging • For quantitative spectroscopy (*syngo* GRACE) a reference bottle can be inserted
Head 32	• High resolution head proton imaging • MR angiography of the head • Functional imaging of the brain
Endorectal	• Visualization of the prostate, colon, rectum, and cervix • Non-invasive preoperative diagnostic evaluation and treatment planning
Tx/Rx CP Head Coil	• Head examinations • High-resolution brain spectroscopy
4-Channel Special Purpose Coil	• Carotids • Examinations with small Field-of-View • Small structures near the surface

1. MR scanning has not been established as safe for imaging fetuses and infants under two years of age. The responsible physician must evaluate the benefit of the MRI examination in comparison to other imaging procedures.

Sequences

Spin Echo family of sequences

- Spin Echo (SE) – Single, Double, and Multi Echo (up to 32 echoes); Inversion Recovery (IR)
- 2D/3D Turbo Spin Echo (TSE) – Restore technique for shorter TR times while maintaining excellent T2 contrast; TurboIR: Inversion Recovery for STIR, DarkFluid T1 and T2, TrueIR; Echo Sharing for dual-contrast TSE
- 2D TSE with multiple average – it is possible to acquire T2-weighted TSE images during shallow breathing, in a time efficient manner
- 2D/3D HASTE (Half-Fourier Acquisition with Single Shot Turbo Spin Echo) – Inversion Recovery for STIR and DarkFluid contrast
- SPACE for 3D imaging with high isotropic resolution with T1, T2, PD, and DarkFluid Contrast

Gradient Echo family of sequences

- 2D/3D FLASH (spoiled GRE) – dual echo for in-/opposed phase imaging
- 3D VIBE (Volume Interpolated Breathhold Examination) – quick fat saturation; double echo for in-phase/opposed phase 3D imaging; DynaVIBE: Inline 3D elastic motion correction for multi phase data sets of the abdomen
- 2D/3D MEDIC (Multi Echo Data Image Combination) for high resolution T2 weighted orthopedic imaging and excellent contrast
- 2D/3D TurboFLASH – 3D MPRAGE; single shot T1 weighted imaging e.g. for abdominal imaging during free breathing
- 3D GRE for field mapping
- 2D/3D FISP (Fast Imaging with Steady State Precession)
- 2D/3D PSIF – PSIF Diffusion
- Echo Planar Imaging (EPI) – diffusion-weighted; single shot SE and FID e.g. for BOLD imaging and Perfusion-weighted imaging; 2D/3D Segmented EPI (SE and FID)
- MRA sequence with Inline subtraction and Inline MIP
- 2D/3D Time-of-Flight (ToF) Angiography – single slab and multi slab; triggered and segmented
- 2D/3D Phase Contrast Angiography
- *syngo* BEAT Tool – TrueFISP segmented; 2D FLASH segmented; Magnetization-prepared TrueFISP (IR, SR, FS); IR TI scout; Retrogating

Computer system

***syngo* Acquisition Workplace**		
Host computer	Processor	Intel Xeon ≥ W3520 Quad-Core
	Clock rate	≥2.66 GHz
	Main memory (RAM)	≥6 GB
	1st hard disk (system SW)	≥146 GB SAS
	2nd hard disk (data base)	≥146 GB SAS
	3rd hard disk (images)	≥146 GB SAS
	CD-R writer	Approx. 4000 images 256^2; DICOM Standard, ISO 9660
	DVD-R writer	Approx. 25000 images 256^2; DICOM Standard, ISO 9660
	Media drives	CD/DVD drive
Color LCD monitor	Screen size (diagonal)	19”
	Horizontal frequency	30–100 kHz
	Vertical frequency	50–75 Hz
	Screen matrix	1280×1024 pixels
Measurement and reconstruction system	Processor	Intel ≥ E5620 2.4 GHz Quad-Core
	Clock rate	2×2.4 GHz, or comparable
	Main memory (RAM)	48 GB
	Hard disk for raw data	≥300 GB
	Hard disk for system software	≥100 GB
	Parallel Scan and Recon	Simultaneous scan and reconstruction of up to 8 data sets
	Reconstruction speed	12195 recons per second (256^2 FFT, full FoV) 37914 recons per second (256^2 FFT, 25% recFoV)

***syngo* Acquisition Workplace**		
Measurement and reconstruction system (optional system configuration with 64 receiver channels)	Processor	Intel ≥ W5580 3.2 GHz Quad-Core
	Clock rate	≥2×3.2 GHz
	Main memory (RAM)	≥64 GB
	Hard disk for raw data	≥400 GB
	Hard disk for system software	≥100 GB
	Reconstruction speed	14800 recons per second (256^2 FFT, full FoV) 56338 recons per second (256^2 FFT, 25% recFoV)
	Parallel Scan and Recon	Simultaneous scan and reconstruction of up to 8 data sets
	GPGPU	1×Tesla C2075
Measurement and reconstruction system (optional system configuration with 128 receiver channels)	Processor	Intel ≥ W5580 3.4 GHz Six-Core
	Clock rate	≥2×3.2 GHz
	Main memory (RAM)	≥128 GB
	Hard disk for raw data	≥750 GB
	Hard disk for system software	≥100 GB
	Reconstruction speed	14800 recons per second (256^2 FFT, full FoV) 56338 recons per second (256^2 FFT, 25% recFoV)
	Parallel Scan and Recon	Simultaneous scan and reconstruction of up to 8 data sets
	GPGPU	2×Tesla C2075

***syngo* MR Workplace (optional)**
Color LCD monitor and host computer as for *syngo* Acquistion Workplace

Euro Connector (System IEC 320)	
Load rating	100–240 Vac
	50–60 Hz
	max. 10 A

Network/data coupling

The MR system provides the level of safety according IEC 60950-1 outside patient environment. All equipment connected to the system's network/data couplings must also provide minimum level of safety according IEC 60950-1.

syngo MR image viewing and filming

Image display

- Various display layouts selectable
- Up to 3 patients can be simultaneously active in the viewer
- Image annotation and labeling
- Non-interpolated display
- Fast paging through up to 500 images with 15 images/s for full screen display

Windowing

- Freely selectable window width and center
- Windowing on succeeding images
- Auto-windowing for optimized contrast
- Saves and sends window values

Interactive movie/Automatic Movie for cine display

Paging by dragging the mouse or Automatic Movie mode by clicking the icon

Evaluation

Parallel evaluation of up to 40 regions of interest

- Circle
- Rectangle
- Freehand ROI
- Pixel lens with position marker
- Statistical evaluation
- Area
- Standard deviation
- Mean value
- Min/max values
- Image scrolling
- Magnification
- Distance
- Angle

2D Post-processing

Image manipulations

- Reversal of gray-scale values
- Image rotation by 90° or by user-defined angle
- Flip horizontally/vertically
- Image zoom and pan
- Shutter
- Annotation

Position display

Displays measured slice positions on localizer image and selected series

Mean Curve

Time-intensity analysis

- Creates and edits DICOM structured reports

Filming

- Connection via DICOM Basic Print
- Interactive filming
- Filming parallel to other activities
- Independent scanning and documentation – no wait time due to camera delays
- Freely selectable positioning of images onto virtual film sheet
- Selectable various film layouts
- Displaying reference images on the film sheet
- Windowing, image zoom and pan on film sheet
- Configurable image text
- Simultaneous handling of multiple film jobs
- Up to 100 virtual film sheets

Argus Viewer

Viewing software for cardiac MR studies and large data sets

- Efficient cine review of cardiac and other dynamic data sets
- Multiple sorting options
- Single movie as well as 2, 4, or 8 simultaneous slices together in movie mode
- Rapid avi creation of 1 to 8 slices simultaneously
- Creates and edits DICOM structured reports

Dynamic Analysis

Arithmetic operations on images and series

- Addition, subtraction, multiplication, division of single images and whole series
- Arithmetic mean and standard deviation across a range of selected images
- Calculation of T1 and T2, and logarithmic images
- Differentiation/integration of selected images
- Calculation of a mean slope image from a range of selected images
- Calculation of z-score (t-test) images for evaluation of BOLD imaging data (Blood Oxygenation Level Dependent)
- Time-to-peak evaluation (TTP)
- ADC maps

Several evaluation functions may be started consecutively in the background

Printing on paper

Interface and software for printing images on paper (laser printer not included)

- Grey levels and color printing supported
- Data format Postscript Level 2

3D Post-processing

MPR – Multi-Planar Reconstruction

Real-time multi-planar reformatting of secondary views

- Viewing perspectives: sagittal; coronal; axial; oblique; double oblique; curved (freehand)
- Reconstruction along polygon and/or curved (freehand) cut lines
- Reconstruction based on reconstructed planes possible
- Reconstruction of user-defined ranges of parallel, radial or freehand cuts
- Selectable slice thickness and slice increment of reconstructed images
- Storing of post-processing protocols
- Annotations and 2D evaluations such as distance and ROI

MIP – Maximum Intensity Projection

3D reconstructions of vessels from a 3D data set, or a 2D sequential slice data set (acquired with dedicated MR Angiography sequences)

- Volume of Interest (VoI) defined to increase reconstruction speed and to improve image quality
- Freehand MIP
- Arbitrary views along any direction can be defined interactively with mouse-driven virtual trackball
- Multiple view angles around any orthogonal axis
- Projections displayed as single images, as interactive movie or by fast paging
- MIP thin/MIP thick

MinIP – Minimum Intensity Projection

Similar to MIP but reconstructs the minimum intensity (e.g. for Dark Blood techniques)

SSD – Shaded Surface Display

Three-dimensional display of surfaces, such as vessels

- Selectable variable threshold values
- Multiple view angles around any orthogonal axis
- Rectangular and irregular Volumes of Interest (VoI) can be defined to improve image quality

Ambient conditions

Control room	
Temperature	15–30 °C (59–86 °F)
Relative air humidity	40 to 60%
Absolute air humidity	<11.0 g/kg

Electronics room	
Temperature	15–30 °C (59–86 °F)
Relative air humidity	40 to 80%
Absolute air humidity	<11.0 g/kg

Examination room	
Temperature	18–22 °C (64–72 °F)
Relative air humidity	40 to 60%
Absolute air humidity	<11.0 g/kg

Specific absorption rates

The specific absorption rate for the RF power and the rate of change of the gradient fields are checked according to the requirements of norm IEC 60601-2-33.

Cooling system

Two different customer specific cooling alternatives (Separator or Eco Chiller) are available.

Separator option (for connection to available cooling system)	Water consumption	90 l/min[1]
	Heat dissipation to water	60 kW
Eco Chiller option with automatic adaptation to the required cooling demands (e.g. different night/day mode) to decrease energy cost	GREEN Cooling Package[2]: • Automatic start if the surrounding temperature is 18 °C (64 °F) or less • If the temperature is less than –10 °C (14 °F) the chiller is switched off[3]	

1. Water temperature: 12 °C (45 °F)
2. Free Cooling Unit, optional
3. In case of clinical routine measurement conditions

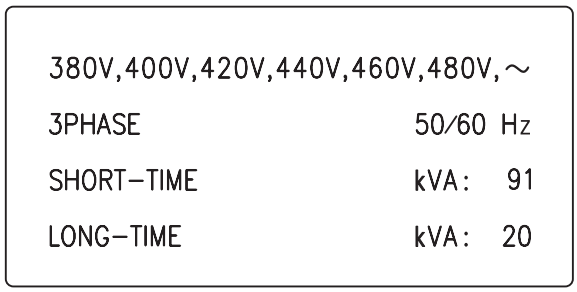
Line power supply

XQ gradients	Values	Tolerance
Voltage	380 V, 400 V, 420 V, 440 V, 460 V, 480 V	±10%
Frequency	50/60 Hz	±1 Hz
Connection value	110 kVA	
On-site protection	160 A	

For all products, line power has to be supplied via an on-site system contact or via another multipole shut-down mechanism. Room installation has to be in compliance with VDE 0100-710[1].

1. In all countries, compliance with local and national legal regulations is required.
   However, we strongly recommend compliance with the regulations described herein – to the extent permitted by relevant local and national laws – in order to ensure the safety of operating personnel, patients, and third parties.

Power rating plate



Power consumption

System off[1]	5.0 kW
Stand-by[1]	5.7 kW
Ready for measurement[1]	13.9 kW
Typical measurement[1]	20.7 kW

1. All data incl. cold head compressor, without cooling

General classifications

Protection class	I
Components used • Patient table • Local coils • Body coil • ECG/Pulse module	 Type B applied part Type B or BF applied part Type B applied part Type BF applied part
IP protection class according to IEC 60529	IP X0
Explosion protection	The MR system is not intended for operation in areas prone to explosion (e.g., highly flammable mixtures of anaesthesia gases with air or oxygen or nitrous oxide)
Operating mode	Continuous operation with short-term load
Disinfection receptors/system components	Disinfectants without alcohol, ether
Degree of safety in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide	No AP or APG category equipment
Mains operated equipment with additional power sources	None

Dimensions

Component	Width [cm]	Depth [cm]	Height [cm]	Weight [kg]	Heat dissipation [kW]
Examination Room					
Magnet 3 Tesla AS (incl. Helium)	205	163	215	5755	
Magnet in operation, incl. gradient coil, body coil, Tim table, and covers	231	433 461[1]	219	7320	
Tim table	76	249	52–102[2] +13 mm[3]		
Required min. room height clearance			240[4]		
Min. transport dimensions	231	182	227		
Control Room					
syngo Acquisition Workplace (table+monitor)	120	80	117 (72+45)		
Host computer	22	46	47		
syngo MR Workplace (optional) (table+monitor)	120	80	117 (72+45)		
Equipment Room					
Electronics cabinet, incl. system control, RF system, gradient power system, image processor	160	65	198[5]	1500	≤5[6]
Cooling system	65	65	189	500	

1. With Tim Whole Body Suite option
2. Including Heightening Kit, if necessary
3. Depending on the floor conditions
4. Finished floor to finished ceiling
5. Without attachments
6. Only ventilation might be required

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[redacted]MR

System Owner Manual

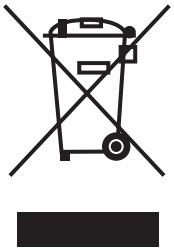
Location of labels

Skyra

At the electronics cabinet

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. Please contact Siemens Service in case of questions about returning and disposing the MR system and/or its components and accessories.

Approval identification for Canada/USA

CSA = Canadian Standards Association

Revision label

Revision:															Model - No.:																	
00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65
66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98

Patent label

This product is covered by one or more of the following US-patents:

4587504	5541514	6073042	6400153
4714887	5545990	6084409	6404195
4743853	5546081	6084410	6411088
4769603	5546299	6100693	6414486
4777807	5550471	6101644	6420870
4825159	5557204	6107799	6430428
4879538	5574372	6111412	6433546
4922204	5581184	6114854	6434412
4945321	5581187	6118337	6462547
4972852	5592091	6118681	6469515
4991586	5614827	6128523	6501273
4992769	5623207	6133737	6515478
	5627470	6145026	6525537
5034692	5633586	6148225	6559641
5111378	5642264	6150880	6570952
5128615	5662112	6154068	6573718
5138259	5663646	6157191	6589431
5144241	5668474	6157193	6591149
5153517	5678549	6160400	6618611
5189370	5680045	6160445	6624631
5200701	5681327	6160453	6640018
5206591	5691678	6169403	6658280
5208537	5692508	6170019	6667617
5210512	5695872	6172558	6689059
5230090	5708361	6188923	6700373
5235283	5712567	6195031	6711434
5245282	5777475	6195578	6711738
5258718	5828215	6198287	6714093
5291741	5850143	6205349	6754545
5294886	5857970	6215911	6762605
5304929	5872500	6218839	6771072
5307014	5879298	6232548	6781378
5309107	5884489	6236204	6795037
5329266	5886524	6236209	6798199
5332990	5901036	6240310	6822445
5345178	5913863	6246239	6825665
5363078	5932936	6253101	6839722
5396174	5944663	6265872	6841998
5442292	5948521	6295465	6841999
5451877	5969568	6297633	6880977
5453866	5973527	6297637	6882151
5459401	5990625	6300761	6882547
5459540	5991179	6307374	6919721
5467017		6335620	6930482
5471142	6009341	6339332	6937016
5474067	6023799	6342785	6943551
5492124	6025716	6342786	6952097
5512828	6025720	6351123	6977430
5515002	6026315	6366090	6982598
5519321	6043651	6369569	
5523689	6064204	6385480	

On the magnet cover

Name plate label

Approval identification for Canada/USA

CSA = Canadian Standards Association

For laser light localizer

Safety certificate label (International)

Safety certificate label (U.S.A. only)

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

SIEMENS

MAGNETOM

MR

Maintenance Plan

System

Operator Responsibilities for Maintenance

Aera
Skyra

Including “Safety-related Tests” according §6 MPBetreibV (Germany)

Print No.: M7-000.664.01.04.02
Replaces: M7-000.664.01.03.02

English
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Disclaimer

Siemens provides this documentation "as is" without the assumption of any liability under any theory of law.

The installation and service of equipment described herein requires superior understanding of our equipment and may only be performed by qualified personnel who are specially trained for such installation and/or service.

Routine checks and periodic maintenance

Routine checks and periodic maintenance are necessary to ensure safe and satisfactory operation of your system.

Proof of these activities is required by authorities in certain countries.

Routine checks include:

Daily, weekly, and monthly inspections as well as legally required checks as described in the "Function and Safety Checks" chapter of the operating instructions. Normally, the system operator entrusts the clinical operating personnel with the task of performing these routine checks.

Periodic maintenance includes:

- Safety check (including safety-related tests)
- Preventive maintenance
- Quality and function tests
- Replacement of safety-relevant parts subject to wear.

This work has to be performed by qualified and authorized service engineers only. In this context, qualified means that the engineers have been trained accordingly or have acquired practical experience through routine service activities. Authorized means that the engineers have been authorized permission by the operator of the system to perform maintenance work.

Upon first start-up of the system, we ask you to designate a staff member responsible for ensuring that routine checks, preventive inspection, and maintenance work are performed. This staff member is responsible for archiving all certificates in the "System Owner Manual" binder.

In addition to our repair service, Siemens also offers you a complete range of services for the preventive inspection and maintenance of your system. These services can be called on as required or agreed upon in a flexibly drafted maintenance contract.

If you have not received a quotation from the Siemens **UPTIME Services** organization, then please contact your Siemens representative.

MAGNETOM maintenance plan

This maintenance plan shows in tabular form the activities that have to be performed by qualified and authorized service engineers in the course of periodic maintenance work. The maintenance work is subdivided into:

- Safety check (including safety-related tests)
- Preventive maintenance
- Quality and function tests

Each table contains an introductory explanation.

Detailed working instructions for all maintenance work are provided in the service documentation for this system. These documents are not included in the shipment of the system.

Safety check (including safety-related tests)

The following checks are intended to ensure the safety of the system. Where appropriate, preventive measures have to be adopted or repairs performed. The points to be checked are generally regulated by laws and standards.

The Safety-related Tests according to §6 MPBetreibV (Germany) are mandatory.

The specified checks and intervals correspond to the minimum requirements. Compliance with stricter national legislation may occasionally be necessary.

Object or function	Reason	What is checked:	Interval
General tests			
System	Safety of patient, personnel, and system	Visual inspection of the system	Annually
Visible cabling, cable routing	Safety of patient, personnel, and system	Visual inspection of cables, cable routing	Annually
Options	Safety of patient, personnel, and system	Visual inspection of options	Annually
Accessories	Safety of patient, personnel, and system	Visual inspection of accessories[1]	Annually
Magnet	Optimum function within specifications Safety of patient, personnel, and system	Check pressure of the magnet Check for ice formation Check for leaks	Annually

Object or function	Reason	What is checked:	Interval
Quench system	Safety of patient, personnel, and system	Visual inspection of the quench tube • Check for water in the quench valve • Check quench tube and isolation • Check quench tube outlet for obstructions • Check outlet rain cover • Check protective mesh • Check quench tube outlet, restricted area and warning signs	Annually
Operating manuals	Safety of patient, personnel, and system	Required operating manuals are available and legible	Annually
User icons, button labeling, warning labels	Safety of patient, personnel, and system	Visual inspection of the user icons, button labeling, and warning labels	Annually
Exclusion zone for magnetic field	Prevent hazards caused by magnetic field	The 0.5 mT zone is marked The examination room is identified with the warning “strong magnetic field”	Annually

Object or function	Reason	What is checked:	Interval
Electrical tests			
Protective conductor MRSC (MRWP)	Protecting personnel from electric shocks. (The protective conductor resistance can change during system operation, i.e. through oxidation, corrosion, and cable breaks.)	Protective conductor resistance of the MRSC (MRWP)	Annually
Protective conductor system	Protecting patients and personnel from electrical shock. (The protective conductor resistance can change during system operation, i.e. through oxidation, corrosion, and cable breaks.)	Protective conductor resistance of the entire system	Every 2 years
Function test			
Emergency power off circuit[2]	Safety of patient, personnel, and system	Checking function of the power circuit	Annually
Fix patient table (option)	Safety of patient, personnel, and system	Inspect table movement and end switches Operation of the emergency stop and safety switches Operation of the emergency release Checking tolerance limits Marking of the hazard area	Annually

Object or function	Reason	What is checked:	Interval
Tim dockable table (option)	Safety of patient and personnel	Inspect table movement and end switches Operation of the emergency stop and safety switches Operation of the emergency release Checking tolerance limits Marking of the hazard area Operation of the locking mechanism Inspect the emergency undocking function Checking the chassis and the wheels	Annually
Intercom, pneumatic bulb	Communication with the patient	Function of intercom Function of pneumatic bulb	Annually
Monitoring the magnet (MSUP) Magnet stop function (ERDU)	Prevent hazards caused by magnet	Operation of the magnet supervision and the magnet stop	Annually
Gradient supervision	Optimum function within specifications Safety of patient, personnel, and system	Function of the gradient supervision	Annually
QA (Quality Assurance) measurements	Optimum function within specifications Patient protection	Interaction of various system components according to the guaranteed system characteristics using the complete QA measurement	Annually

1. According to manufacturer recommendations
2. If installed

Leakage Current Measurements

National regulations have to be observed, e.g. IEC 62353/DIN EN 62353 in Germany.

Instructions for Measuring Equipment Leakage Current

According to IEC 62353, DIN EN 62353, it is not necessary to measure the equipment leakage current.

Reasons:

- the protective conductor is permanently connected
- compliance with the **on-site protective standards**, e.g. DIN VDE 0100-710, are described in the planning documents. The **system owner** has to comply with the **on-site protective standards**.
- The protective conductor is checked at regular intervals and if required after repair and service-related activities.

Instructions for Measuring the Patient Leakage Current at the Patient Table

Patient Table (type B part is applied)

It is not necessary to measure the patient leakage current at the patient table.

Reasons:

- applied part has a non-conducting surface,
- live parts are separated by metallic components with a protective conductor connection, as per IEC 60601-1, section 17.a.2 (2nd edition), and section 8.5.2 (3rd edition).

Instructions for measuring the Patient Leakage Current at the MR Local Coils

Local Coils (type B or BF part is applied)

It is not necessary to measure the patient leakage current at the local coils.

Reasons:

- applied part has a non-conducting surface,
- the live parts are separated from the applied part by a power supply with double insulation (2 MOPP),
- applied part does not have dangerous voltages, as per IEC 60601-1, section 17.a.3 and 17.a.4 (2nd edition), and section 8.5.2 (3rd edition).

Instructions for measuring the Patient Leakage Current at the Body Coil

Body Coil (type B part applied)

It is not necessary to measure the patient leakage current at the body coil.

Reasons:

- applied part has a non-conducting surface,
- the live parts are separated from the applied part by a power supply/transformer with double insulation (2 MOPP) as per IEC 60601-1, section 17.a.3 and 17.a.4 (2nd edition), and section 8.5.2 (3rd edition).

Instructions for measuring the Patient Leakage Current at the ECG/ Pulse Module

ECG/Pulse Module (type BF part applied)

It is not necessary to measure the patient leakage current at the applied part of the ECG/ Pulse module.

Reasons:

- the applied part of the ECG/Pulse module is powered by a battery,
- the applied part of the ECG/Pulse module is completely electrically isolated by a wireless RF operation.

Preventive maintenance

The purpose of preventive maintenance is to keep unforeseen failures to a minimum. This satisfies the prerequisites for system compliance with the guaranteed, long-term characteristics.

The effects of different operating conditions (full or partial load operation, temperature, size of dust particles, humidity, gases, vapors) are checked and the condition of parts subject to wear is determined by recording and analyzing characteristic values. Preventive measures must be adopted or repairs must be undertaken as appropriate.

The specified maintenance intervals correspond to the minimum requirements. Compliance with stricter national legislation may occasionally be necessary.

Object or function	Reason	What is checked:	Interval
Cooling system	Preventive measure to avoid overheating	Check for leaks and condensation Check/replace water filter Check water pressure and add water if necessary	Annually
Air filters, fans	Preventive measure to avoid pollution	Replace air filter Check functionality of fans	Annually
Chiller (option)	Preventive measure to avoid overheating	[1]	[1]

Object or function	Reason	What is checked:	Interval
LCD color display	Optimum function within specifications	Check/adjust according to specifications	Annually
Phantom	Safety of patient, personnel, system, and environment	Phantoms cannot have any defects or air bubbles. Replace or refill as necessary.	Annually
Examination room door	Preventive measure to avoid wear and tear	[2]	[2]
Magnet	Optimum function within specifications Safety of patient, personnel, and system	Check/set pressure on magnet and compressor	Annually
		LHe Refill	n.a.[3]
		Check/Replace[4] the cold head	n.a.
Helium compressor	Optimum function within specifications	Check for leaks	Annually
Adsorber	Optimum function within specifications	Replace adsorber	Every 3 years
Patient table	Preventive measure to avoid wear and tear	Check the hydraulic system Check/refill hydraulic oil	Annually

Object or function	Reason	What is checked:	Interval
Tim dockable table	Preventive measure to avoid wear and tear	Check the docking mechanism Check the hydraulic system Check/refill hydraulic oil Check/clean connectors of the docking station Lubricate RF connectors	Annually
RF connectors	Preventive measure to avoid wear and tear	Check/clean connectors Lubricate RF connectors	Annually
Comfort kit (option)	Preventive measure to avoid overheating	Replace air filter	Every 2 years
Software	Preventive measure against data loss in the case of hard disk failure	Save dynamic data Clean up directories	Every 3 months

1. According to manufacturer recommendations
2. According to manufacturer recommendations
3. Zero helium boil off rate for typical clinical use, depending on sequence and operating time with running helium compressor. The system needs to be serviced at regular intervals. Undisturbed magnet cooling for 24 hours and 7 days a week.
4. If the system is not connected to Siemens Remote Service (SRS) the replacement has to be performed according to manufacturer recommendations. The replacement is performed “on demand” when the system is connected to Siemens Remote Service (SRS).

Quality and function tests

Quality and function tests are used to check whether the system complies with the guaranteed characteristics. Image quality tests determine deviations from the original status. In the case of deviations, preventive measures have to be adopted or repairs performed as appropriate.

The specified maintenance intervals correspond to the minimum requirements. Compliance with stricter national legislation may occasionally be necessary.

Object or function	Reason	What is checked:	Interval
QA measurements	Optimum function within specifications.	Interaction of all system components according to the guaranteed characteristics	Every 3 months

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MAGNETOM

[redacted] MR

System Owner Manual

Disposal

Skyra

Equipment disposal

On disposing of the system or parts thereof, currently valid environmental legislation must be observed.

Examples of environmentally relevant components are:

- Accumulators and batteries
- Transformers
- Capacitors
- Monitor picture tubes
- Phantoms

For details contact your local customer service representative or your Siemens regional office.

NOTICE: System components hazardous to persons or the environment must be disposed of with care and in compliance with legally binding ordinances.