Technical Description

English

Release 5.8

MR 5300

3000 151 71921

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1 Introduction

This document is applicable to the following systems:

- MR 5300

All information in this document applies to the above-mentioned systems, unless explicitly stated otherwise.

Philips MR systems comply with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips Healthcare representative.

Philips MR systems comply with relevant international and national law and standards on EMC (electromagnetic compatibility) for this type of equipment when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from equipment, and its required immunity to electromagnetic interference from external sources.

Information in this document is meant for the user of the system and addresses typical system specifications and safety related aspects of the system and installation. Information in this document shall be used for improving safety in relation to the use of the system and environment.

Correctness of the image orientation and location is considered Essential Performance of the MR System, as well as absence of gross technical artifacts. This is part of the (weekly) tests in the Periodic IQ Test (PIQT), see Instructions for Use. These tests are also part of system acceptance criteria in maintenance procedures.

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NOTICE

Users of this Technical Description shall also read Chapter 2 of the Instructions for Use for important safety information, such as warning and safety notices and the explanation of safety signs.

Installation Instructions

The installation instructions for Philips MRI Systems is supplied by Philips Healthcare in separate documentation. This includes Planning Reference Data and Service Manual for Installation, which contain essential information for safe transport, storage, siting and installation.
The installation must be performed by appropriately trained personnel.

Philips Healthcare can only accept responsibility for basic safety, reliability and performance, if:

- qualified personnel carry out assembly operations, extensions, readjustments or repairs,
- the system is installed at a maximum altitude of 3000 meter,
- the electrical installation of the technical room complies with the appropriate requirements, and
- the system is used in accordance with the Instructions for Use.

Philips Service will evaluate the safety provisions of the system and the installation for review with the customer before handover.

The MRI equipment/system must emit electromagnetic energy in order to perform its intended function. When installed according to Philips guidelines, electromagnetic emission will be compliant to IEC60601-1-2. The Responsible Organization is advised to evaluate any nearby electronic equipment for the need of additional shielding or repositioning to ensure proper operation. Guidance for such evaluations may be found in e.g. AAMI TIR18:2010.

WARNING

Do not modify the MRI System without authorization of the manufacturer.

Principle of operation

MRI system operation is based on the principle that certain atomic nuclei present in the human body will emit a weak relaxation signal when placed in a strong magnetic field and excited by an RF signal at the precession frequency. The emitted relaxation signals are analyzed by the system and a computed image reconstruction is displayed on a video screen. Note: during image acquisition, strong electromagnetic fields are emitted by the system in the MHz and kHz range, and loud acoustic signals are generated.

Equipment Classification

EQUIPMENT CLASSIFICATION	
Classification according to IEC-60601-1	
According to the type of protection against electrical shock:	Class I equipment.
According to the degree of protection against electric shock:	Type B and type BF applied parts.
According to the degree of protection against harmful ingress of water:	Ordinary equipment (enclosed equipment without protection against ingress of water, IPX0).
According to the methods of sterilization or disinfection:	Non sterilizable. Use of Liquid surface disinfectants only.
According to the mode of operation:	Continuous operation.

Maintenance and Repair

The operator should always take all practical steps to make sure that the Planned Maintenance Program is fully up to date to ensure Basic Safety and Essential Performance. In addition, all user routine checks must have been satisfactorily completed before using the system to examine a patient.

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Installation, maintenance and repair instructions for the system described are supplied by Philips Healthcare in separate documentation, which includes circuit diagrams, component part lists, descriptions, calibration instructions. Installation, maintenance and repair must be performed by appropriately trained personnel.

Planned maintenance, repairs, or other system modifications, may only be carried out by qualified and authorized Customer Support technicians. Philips provides a full planned maintenance and repair customer support on both a call basis and a contract basis. Full details of maintenance and repair services, and access to relevant technical documentation, are available from your Customer Support Organization.

WARNING

External equipment from other suppliers needs to be MR compatible and shall not impair the MR performance. Compatibility needs to be declared by Philips MR.

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2 Controlled Access Area

Electromagnetic shielding

The Controlled Access Area, also referred to as MR environment, is the area around the MR system to which access is controlled to prevent harm from the main magnetic and RF field. The core of the Controlled Access Area is the B0 hazard area. In this B0 hazard area, the magnetic fringe field exceeds values as defined in IEC60601-2-33. For Ed3.2 and Ed4, the limit value is 0.5 mT (5 gauss) and 0.9 mT (9 gauss), respectively. During site planning of a Philips MR system, the B0 hazard area must be delimited, e.g. by markings on the floor, barriers and/or other means.
All points of entry into the Controlled Access Area must be marked with a Safety Marking Plate.

Emergency Magnet Off buttons
The MRI system is provided with a magnet emergency rundown unit with two or more remote push buttons (Emergency Magnet Off button) to terminate the magnetic field. This shall only be used in case of emergency.

The Planning Reference Data (PRD) gives information where and how to install Emergency Magnet Off buttons. Contact your Philips service engineer for further information.

Contraindications
Persons with fitted pacemakers, neuro stimulators, insulin pumps or similar devices, or with implants of ferromagnetic material, such as surgical clips, artificial cardiac valves, prostheses or metal splinters, must stay outside the controlled access zone.

Magnetic objects
Ferromagnetic objects, such as scissors, tools, gas bottles, vacuum cleaners and stretchers, must not be brought into the neighborhood of the magnet and be kept outside the examination room. Such objects will be pulled to the magnet and may cause injury to the patient or staff or damage to the equipment.

Data Carriers
Information on magnetic data carriers such as tapes and credit cards can be erased by the magnetic field. A safe limit is 1 mT (= 10 Gauss).

Safety procedures
The safety procedures at all entrances of the examination room shall prevent prohibited objects being brought into the examination room. Ferromagnetic Detectors (FMD) can only supplement active screening procedures by trained personnel.

If in a medical emergency instruments must be used, the patient must be removed from the examination room first.

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3 Compatibility technical specification sheet

3.1 Magnet

Magnet Type

Superconductive, actively shielded. Superconducting B_0 compensation function for correcting field variations induced by moving metal objects in the vicinity of the magnet.

Magnet Characteristics

Parameter	Value
Magnet type	Cylindrical bore, superconducting, actively shielded
Field strength	1.5T
Cryogen type	Helium (sealed)
Cryogen consumption	None (sealed)
Bore dimensions	The patient bore diameter is 70 cm and the bore length is 130 cm

Typical spatial distribution of surrounding field

The following figures depict the iso-magnetic contours up to 1T.

The iso-magnetic contours of 2T, 3T, and 4T do not extend beyond the outer system covers. For 1.5T systems this also applies to the 1.0T contour.

The plots show the fringe field of the magnet without any additional passive shielding. Site specific additional passive shielding will significantly reduce the spatial extent of the fringe field.

The front view of the extent of the magnetic field can be derived from these views. The maximum radial distance shall be accounted for in site planning.

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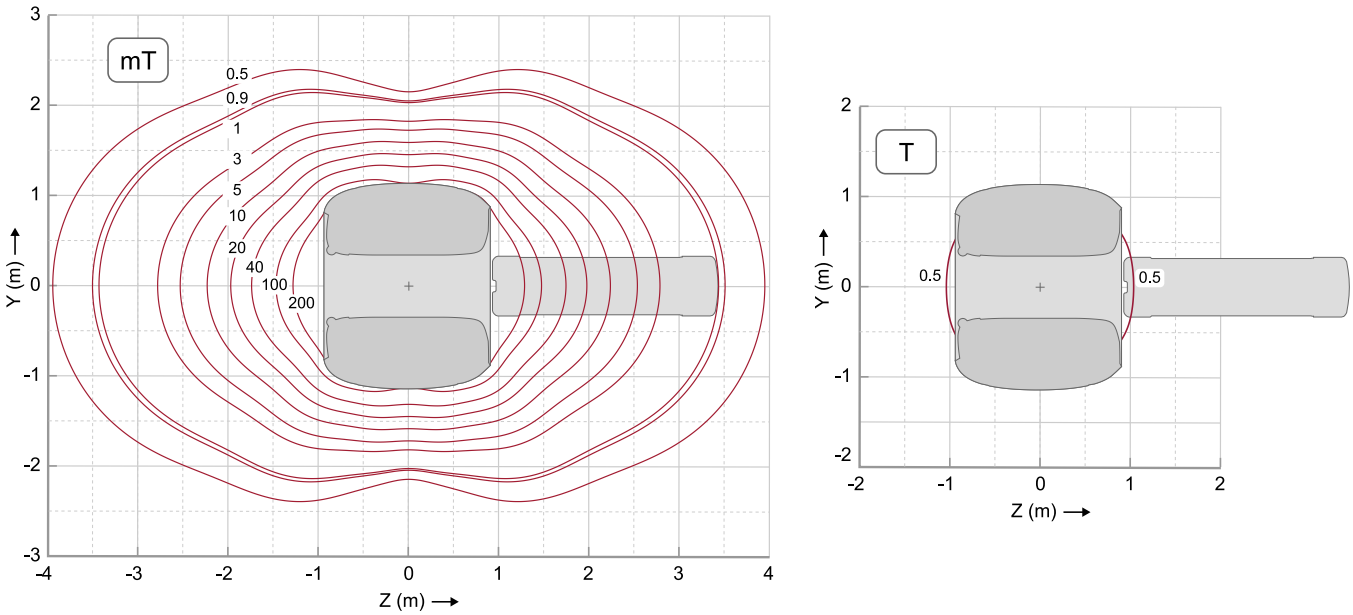

Fig. 1: Plot displaying static magnetic field B0 drop-off which can be useful when interpreting MR Conditional labelling information.

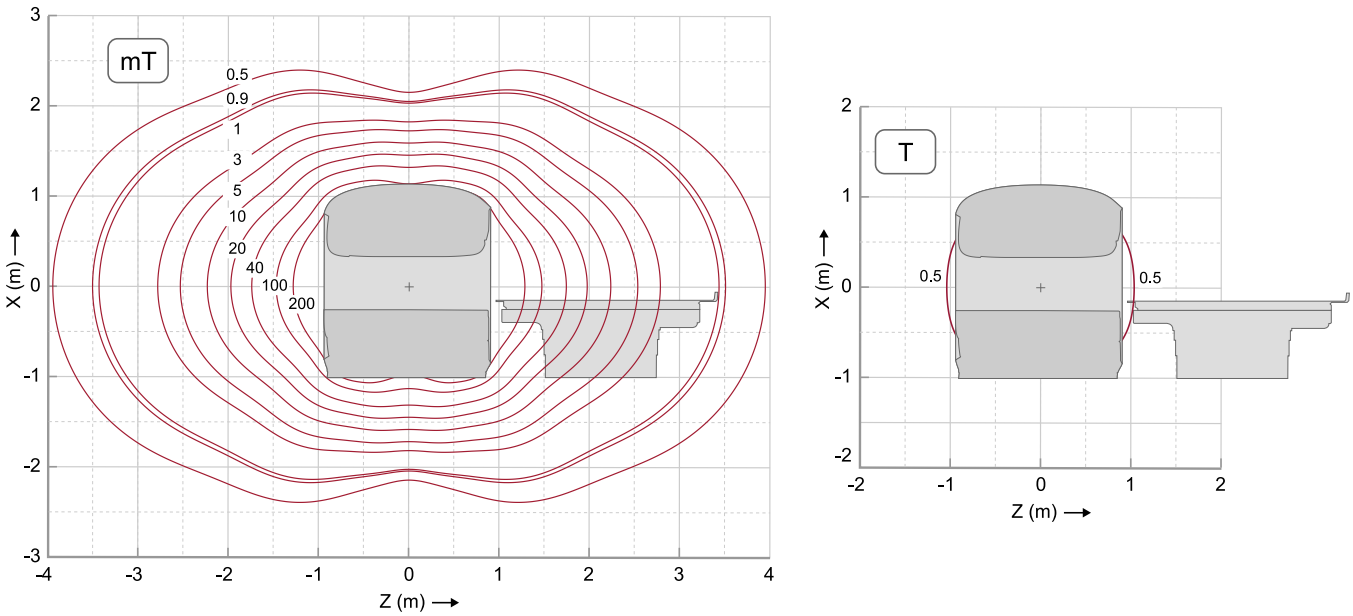

Fig. 2: Plot displaying static magnetic field B0 drop-off which can be useful when interpreting MR Conditional labelling information.

Figures	Unit	Lines
Left	mT	0.5, 0.9, 1, 3, 5, 10, 20, 40, 100, 200
Right	T	0.5

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Decay characteristics of magnetic field

Decay characteristics of the magnet in case of a magnet field loss enables the user to implement adequate life supporting and other safety procedures.
In case of an emergency field shutdown, the time for the field strength in the centre of the magnet to fall to 10 mT is less than 20 seconds.

Note that the fringe field of the magnet decreases in a similar way.

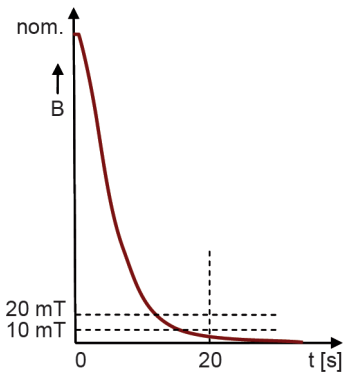

Fig. 3: Schematic magnet field decrease in the center of the magnet as a function of time when initiated by an emergency field shutdown t=0.

The system's installation manual gives information where and how to install the actuator of the emergency field shut-down unit.
Pressing an Emergency Magnet Off button will initiate a magnet field loss within a few seconds.

Spatial Gradient of the static magnetic field B_0

The "spatial gradient of the static magnetic field B_0" is a quantity that expresses how steeply B_0 changes as a function of position. This spatial gradient of B_0 is indicative of the attraction force on magnetic objects.
The spatial gradient values are highest at the entrance of the bore, and near the system covers; see table A1 for actual values at those locations. Spatial gradients can be expressed in T/m or G/cm. In the figures T/m is used, whereby 1 T/m = 100 G/cm.

WARNING

The spatial gradient is always present, even when not scanning, because it is the static gradient of the magnet, not of the gradient coil.

The following figures show cross-sectional views of the system with the spatial gradient distribution.

- The spatial gradient is symmetric around the Z-axis of the scanner, therefore the contour lines in top view and side view are identical.
- The covers of the scanner are not symmetric.

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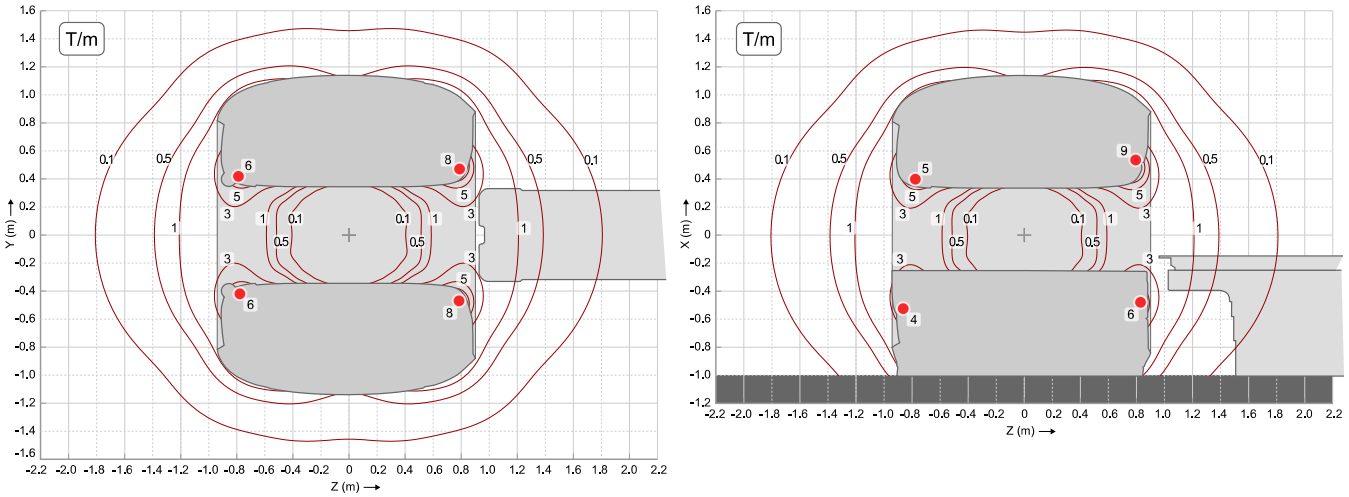

Fig. 4: Top and side view plots displaying SPATIAL FIELD GRADIENT (SFG) drop-off which can be useful when interpreting MR CONDITIONAL labeling information.

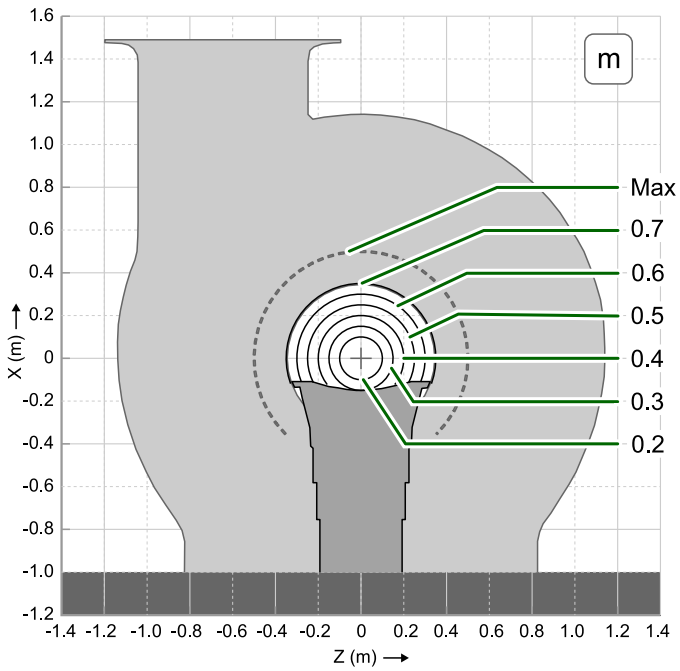

Fig. 5: Front view. Spatial Field Gradient on multiple cylinders and the maximum value on the surface.

The figure shows a front view of the system in which virtual cylinders are drawn on different distances from the center line through the isocenter. The displayed values represent the diameter of these cylinders. It also shows the area of the maximum spatial field gradient on the surface of the system (dashed circle).
The values on the surface of these cylinders and the maximum value are shown in the table.

Cylinder size (m)	Value (mT/m)
0.2	2600
0.3	2800

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Cylinder size (m)	Value (mT/m)
0.4	3100
0.5	3600
0.6	4500
0.7	6400
Maximum	7000

Graphics indicate the location where the product of B0 and the spatial gradient of B0 is maximum. Again, this is very locally on the surface of the front cover, outside the patient area. At this location the force on a diamagnetic or paramagnetic object, or a ferromagnetic material below its magnetic saturation point, is maximum.

Patient positioning

This section specifies the dimensions relevant for patient positioning.

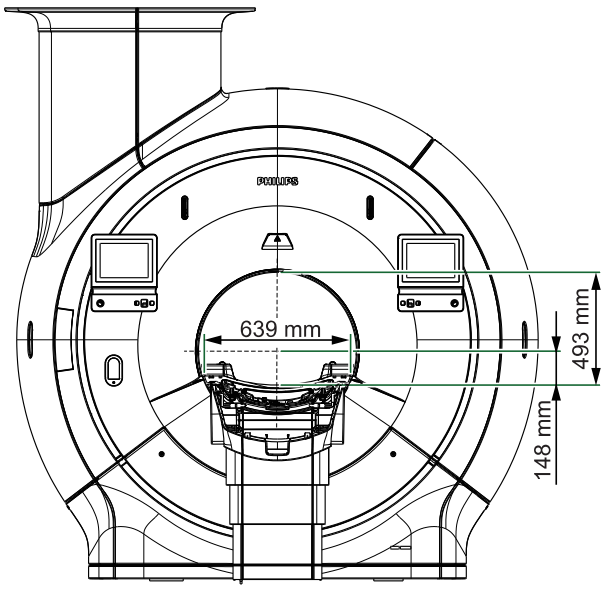

Fig. 6: Cross-sectional overview of the system with dimensions relevant for patient positioning.

Dimensions	Value
MR isocenter to tabletop distance	148 mm
Magnet cover to tabletop distance	493 mm
Width of tabletop	639 mm

Examination Room temperature

Examination Room temperature must be kept to 18 - 22 °C (64 - 72 °F).

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3.2 Gradients

Gradient Type

Non-resonant, actively shielded, 100% duty cycle gradients with three fully independent gradient axes for orthogonal, oblique and double-oblique imaging. The gradient system is a whole body gradient system, following the definition for such a gradient system as given in IEC 60601-2-33.

	MR 5300
Gradient System	Omega
Maximum Amplitude (mT/m)	33
Maximum Slew rate (mT/m/ms)	120
Fastest Rise time (ms)	0.275

Gradient (stray) field distribution

The following information may support assessment of potential Peripheral Nerve Stimulation (PNS) for workers if present at the system during scanning.

Omega

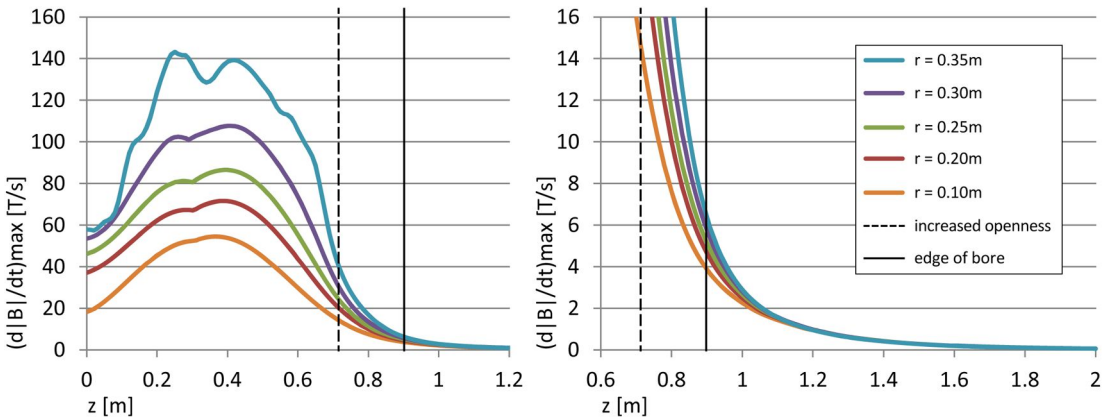

Fig. 7: Omega gradient output: maximum magnetic field rate of change, determined on cylinders with different radii, oriented along the long axis of the magnet. Z = Patient axis.

Colored lines	Omega: d|B|/dt @ SR=120T/m/s - maximum on cylinder r = 10, 20, 25, 30, 35 cm
Dashed black line	Area with improved openness near the magnet end, outside of the RF transmit coil
Black vertical line	Outer edge of system bore

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Omega HP
Mode 1

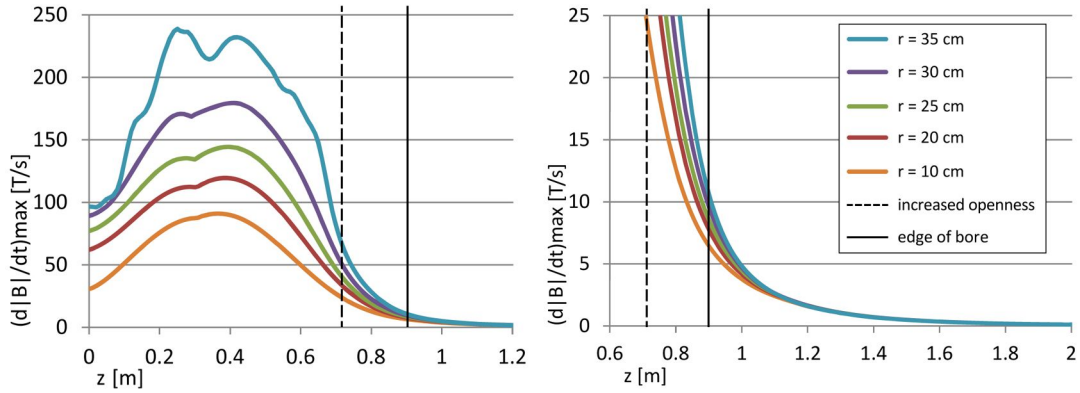

Fig. 8: Omega HP - mode 1 gradient output: maximum magnetic field rate of change, determined on cylinders with different radii, oriented along the long axis of the magnet. Z = Patient axis.

Colored lines	Omega HP mode 1: d|B|/dt @ SR=200T/m/s - maximum on cylinder r = 10, 20, 25, 30, 35 cm
Dashed black line	Area with improved openness near the magnet end, outside of the RF transmit coil
Black vertical line	Outer edge of system bore

Omega HP
Mode 2

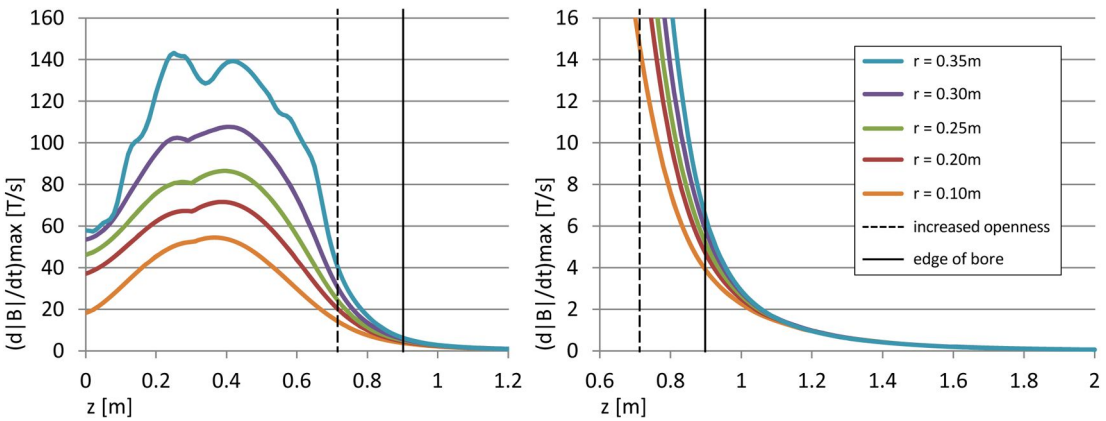

Fig. 9: Omega HP - mode 2 gradient output: maximum magnetic field rate of change, determined on cylinders with different radii, oriented along the long axis of the magnet. Z = Patient axis.

Colored lines	Omega HP mode 2: d|B|/dt @ SR=120T/m/s - maximum on cylinder r = 10, 20, 25, 30, 35 cm
Dashed black line	Area with improved openness near the magnet end, outside of the RF transmit coil
Black vertical line	Outer edge of system bore

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3.2.1 Acoustic energy

The following table indicates the A-weighted RMS sound pressure level (Laeq,8h) at the worker position inside the Examination Room.

Parameter	MR 5300
A-weighted RMS sound pressure level (Laeq)	≤ 99 dB(A)

The measurements may vary depending on site conditions.
The measurement are performed in accordance with NEMA MS 4.

Acoustic noise burden is characterized by the measurement method from NEMA MS 4, to establish A-weighted RMS sound pressure levels, Laeq. Representative measurements for maximum acoustic noise are performed on an MR system installed according to specifications.

3.3 RF system

3.3.1 Body coil

Transmit system characteristics are specified in the table below.

Parameter	1.5T
Nominal center frequency (MHz)	63.87
Bandwidth (kHz)	720
RF Amplifier Peak Power (kW)	18
RF Coil type	Integrated volume RF transmit coil
B1 polarisation capability	CP
Electrical length	50 cm
Max. Transmit Field B1+peak (µT)	23
Max. Transmit Field B1+rms (µT)	3.6

Ratio of the RF power deposition along the long axis of the magnet relative to the value at the isocenter.

The following information may support assessment of SAR exposure of workers if present at the system during scanning.

The pictures show the RF power depositions, magnitude of the RF magnetic field, $| B_1(z) |^2$ / $| B_1(0) |^2$, as a function of position along the z-axis. Numbers 1-2 represent the location along the z-axis where the transmit field is reduced by 3 and 10 dB.
The red vertical lines indicate the outer edge of the system. The orange lines indicate the area with improved openness near the magnet end, outside of the RF transmit coil.

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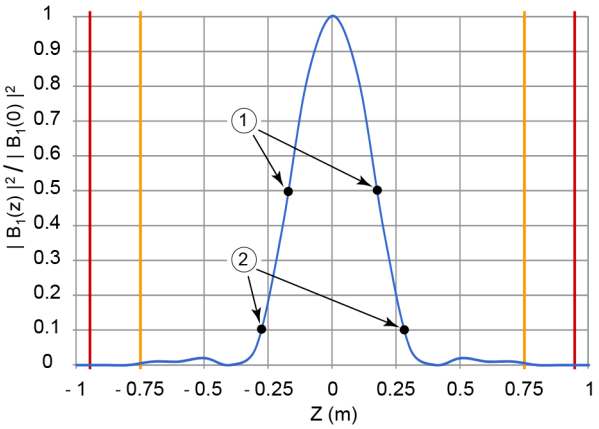

Fig. 10: Plot displaying drop-off of the B1 transmit field along the centerline of the empty RF transmit coil, to support MR WORKER exposure assessment.

Locations along the z-axis where the transmit field is reduced by 3 and 10 dB (also see figure above):

No. in figure	Relative Field Value	z-position (mm)
1	-3 dB	175
2	-10 dB	280

3.3.2 T/R Head coil 1.5T

The field of the T/R head coil is confined inside the coil itself.
In all locations accessible to the MR worker the RF output power is 10 dB or more below the value at the isocenter.

Parameter	1.5T
Nominal center frequency (MHz)	63.87
Bandwidth (kHz)	1000
RF Amplifier Peak Power (kW) [1]	4
RF Coil type	Detachable volume RF transmit coil
B1 polarisation capability	CP
Max. Transmit Field B1+peak (µT)	45
Max. Transmit Field B1+rms (µT)	6.0

[1] *Max RF Peak Power at the Transmit/Receive socket.*

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3.4 Electromagnetic exposure

The graphics in this section show areas where workers may experience MRI-related sensitizations related to movement or active scanning. The red lines represent the threshold values with respect to B_0 and dB/dt. Workers should not enter the identified area unless necessary to perform their duties and should not remain in the area any longer than is necessary. Any staff having to enter the identified area should ensure that they move slowly.

Note that on 1.5T systems the identified area for B_0 does not reach beyond the magnet covers.

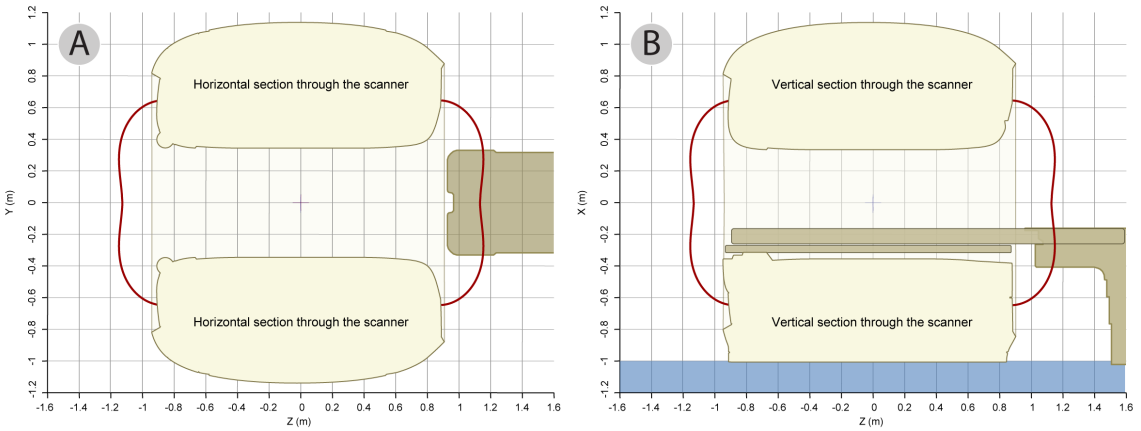

Fig. 11: Area where the dB/dt exposure level value may be exceeded.

No.	View	Lines
A	Top view	dB/dt area
B	Side view	dB/dt area

Note that on Marlin 1.5T the identified area for B_0 does not reach beyond the magnet covers.

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4 Transmit / receive coils

RF information about transmit/receive coils can be found in previous chapter.

Body Coil

The Body coil is a transmit/receive coil for scanning large parts of the body and when large FOV's are required. It is also used for RF excitation in case of imaging with receive-only coils.

Transmit/Receive coils

Philips provides an interface for dedicated T/R coils. Refer to the IFU and the Accompanying Documents of those coils for technical specifications.

Available transmit/receive coils:

- T/R Head coil 1.5T

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5 Patient environment

The design of the scanner allows easy access to the patient and provides optimal patient visibility for the operator.
The bore dimensions are given in Chapter 3 of this Technical Description.

Light and audio

Lights in the magnet bore contribute to patient comfort, as do the in-bore microphone and ceiling-mounted loudspeakers.
The headset, which fully covers the ears, provides music to the patient with minimal disturbance from environmental or MRI system acoustic noise. The connector for the patient headset is located on the patient support unit.

A passive headset is available for personnel or other people in the examination room.

Audio visual contact

When audio and visual contact to the patient is likely to be limited by the design of the examination room, the patient headset and a system microphone allow two-way communication with the operator during the MRI examination.
The responsible organization shall ensure that audio visual contact to the examination room is established so that routine monitoring or medical supervision of the patient can be guaranteed. Visual contact shall be ensured through a window between operating and examination room or via camera monitoring.

Nurse call

A hand-held nurse call button allows the patient to attract the operator's attention at any time and without talking.
The sound pressure of the Nurse call is designed to be at least 80 dB(A).

Ventilation of patient space

Ventilation of the patient space is provided by controllable forced air flow from the rear side of the magnet bore. Sufficient air flow contributes to patient comfort especially in high SAR scans. Air flow through the magnet bore for patient ventilation is maintained up to 135 m^3/h.

Patient positioning

Tabletop positions can be controlled at the front of the magnet or from the operator's console.

A light visor facilitates patient positioning. A laser light reference cross for patient positioning is available. Head or feet-first patient positioning is possible. There is an automatic calculation of tabletop position adjustment to move the planned slice package to the isocenter in feet head direction.

Patient Handling Features

Removable table top with optional patient transportation system FlexTrak and HA FlexTrak (Height Adjustable).

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Patient Space	
Bore Size	70 cm
Lighting	Bore lights
Forced ventilation flow	Adjustable from 0 till maximum
Means of communication	Microphone Ceiling speakers Headset with built-in speaker Visual contact through window* Visual contact through patient observation camera (option) Nurse call to enable the patient to alert the operator

* Responsibility of the responsible organization.

Patient Support / Positioning	
Patient Support working height	89 cm
Patient Support minimum position	59 cm
Patient Positioning	Laser line marker Travel to isocenter
Tabletop Accuracy	± 0.5 mm
Safe working load	250 kg
Safe working load with vertical motion	250 kg
Distance from isocenter to magnet outer cover	90 cm
Lenght of the tabletop available for the patient including head coil	180 cm
Usable length of imaging coverage	160 cm 200 cm (optional)

Optional FlexTrak, fixed height version	
Maximum height	79 cm
Minimum height	79 cm
Width and length	80 x 266 cm
Mass	80 kg
Safe working load	250 kg

Optional FlexTrak, height adjustable version II	
Maximum height	102 cm
Minimum height	70 cm
Width and length	80 x 263 cm

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Optional FlexTrak, height adjustable version II	
Mass	115 kg
Safe working load	250 kg

All values in above table are nominal values.

All values in the table(s) above are nominal values only.

NOTICE

The Safe working Load is the maximum allowable sum of patient weight and accessories and coils.

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6 Compatibility protocols for third party equipment validation

The MRI system contains a set of protocols, which can be run routinely on the MRI equipment, and enable the manufacturer of peripheral equipment to test the functionality of its equipment. The protocols are designed to run the MRI equipment with high transmit RF field or high gradient slew rates and amplitudes so that the manufacturer of peripheral equipment can investigate the influence of the MRI equipment on its peripheral equipment. The tests are not intended for estimation of the possible effect of the peripheral equipment on the resulting image quality of the MRI equipment and are no guarantee that the peripheral equipment will function properly.

Measurement Configuration

During the evaluation of third party equipment, the equipment has to be set up in the same way as during clinical use of the equipment.

The next set of protocols can be used.

Name	Maximum gradient amplitude	Maximum gradient slew rate	Maximum RF amplitude	Maximum SAR	Remark
MaxGrad	Yes	Yes	No	No	Amplitude and slew rate
MaxB1+SAR	No	No	Yes	Yes	B1 and SAR
MaxGrad+RF	Yes	Yes	Yes	Yes	Gradient and RF

Tab. 1: Protocol table

All protocols use the System Body coil.

Scanner info

For each scan the calculated $B_{1\,+rms}$ is displayed on the info page. The $B_{1\,+rms}$ value is defined as the square root of the averaged squared transmit field, whereby the integral over the averaged squared transmit field is taken over an interval equal to the scan repetition time. B1 is expressed in µT (micro Tesla).

Measurement Procedure

Place a 3-liter bottle vertical on the tabletop and bring the bottle in the isocenter using the travel to scanplane function.

In the **new examination** window the option **Gender = Phantom/Other** is available for phantom scanning purposes. After the creation of new examination entry, and selecting the created examination for scanning, protocols can be selected from the folder **Phantom studies, Third Party**.

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7 Electromagnetic compatibility

Philips MR systems are designed in compliance with IEC 60601-1-2:2014 requirements on electromagnetic emissions and immunity requirements for medical electrical equipment. The system is designed to be safe and to perform as intended in the electromagnetic environment as specified on the next pages. The customer or user of the system shall assure that it is used in such an environment.

The system is classified as:

Group 2, Class A Medical Electrical Equipment.

- The system intended to be used in a Professional healthcare facility environment.
- The system is a large permanently installed system.
- The system uses an intentional transmitter of RF electromagnetic energy for the purpose of its operation.
- The system uses an intentional receiver of RF electromagnetic energy for the purpose of its operation.

For the receive frequency the band of reception is applicable. The transmit and the receive frequencies are identical.

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NOTICE

Applicable frequency bands of reception and of transmission are:

System Field Strength	Frequency (MHz) (see note)	Bandwidth (kHz)	Amplifier Peak Power (kW)	Comment
1.5 T	63.87	720	18	1H
Note: The frequency of emission is identical to the frequency of reception				

WARNING

The MRI system is extremely sensitive in the applicable frequencies mentioned in Chapter 3. Any RF disturbance in the band of reception above 60 dBµV/m nearby the system may have influence on the image quality.

WARNING

The RF door shall be closed during scanning. Do not alter or by-pass the RF door switch. This switch is implemented to ensure international and local EM emission regulations.

WARNING

Do not run electrical cables through the exam room wall via ducts, waveguides or venting systems as this will result in increased emissions and decreased immunity of the system.

WARNING

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

WARNING

If systems are used near other MRI systems with the same field strength, verify that the systems do no interfere with each other.

Guidance and manufacturer's declaration - electromagnetic emission

The EMISSIONS characteristics of the MRI system make it suitable for use in industrial areas and hospitals.

Emissions test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR11	Group 2	The system must emit electromagnetic energy in order to perform its intended function
RF emissions CISPR11	Class A	The system is suitable 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	Mains power connection is above 16A
Voltage fluctuation/flicker emissions IEC 61000-3-3	Not applicable	Mains power connection is above 16A

Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and manufacturer's declaration - electromagnetic immunity

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

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Immunity tests	IEC 60601-1-2: Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Relative humidity must be kept to: • 40 - 70% in the examination and operator's room. • 30 - 70% in the technical room
Electrical fast transients/ bursts IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2 kV Line to Ground ±1 kV for I/O lines	Mains power quality shall be that of a typical commercial hospital environment
Surge IEC 61000-4-5	±2 kV Line to Ground; ±1 kV Line to Line	±2 kV and ±1 kV	Mains power shall be that of a typical commercial hospital environment
Power frequency (50/60Hz) magnetic fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields shall be at levels characteristic of a typical location in a typical commercial hospital environment
Short interruption on power supply line IEC 61000-4-11	<5% U for 5 seconds	<5% U for 5 seconds	The system is suitable in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings

Tab. 2: ELECTROMAGNETIC IMMUNITY

Note: ITE equipment complies to CISPR24.

Guidance and manufacturer's declaration - electromagnetic immunity for safety

The MRI system is safe (Basic Safety and Essential Performance) when used in the EM environment as below. The user of the system should assure that it is used in such an environment.

Standard	Phenomenon	Condition	IEC60601-1-2: 2007	IEC60601-1-2: 2014
EN/IEC 61000-4-2	Electro-Static Discharge	Contact discharge	±2, ±4, ±6 kV	±2, ±4, ±6,±8 kV
		Air discharge	±2, ±4, ±8 kV	±2, ±4, ±8 kV, ±15 kV
		Indirect coupling	±2, ±4, ±6 kV	±2, ±4, ±6, ±8 kV
EN/IEC 61000-4-3	Proximity Fields from RF wireless communications equipment	Clause 8.10 of IEC60601-1-2	N/A	See Table 9 of IEC 60601-1-2
EN/IEC 61000-4-3	Radiated RF EM fields	80 MHz–2.7 GHz	3 V/m	3 V/m
EN/IEC 61000-4-4	Electrical fast Transients / Burst	A/C & D/C power supply lines; 100 kHz repetition	± 2 kV	± 2 kV
		Interconnecting lines l > 3 m; 100 kHz repetition	± 1 kV	± 1 kV

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Standard	Phenomenon	Condition	IEC60601-1-2: 2007	IEC60601-1-2: 2014
EN/IEC 61000-4-5	Surge	Line to ground	±0.5; ±1; ±2 kV	±0.5; ±1; ±2 kV
		Line to line	±0.5; ±1 kV	±0.5; ±1 kV
EN/IEC 61000-4-6	Conducted disturbances induced by RF fields	150 kHz-80 MHz	3 V	3 V 6V in ISM band
EN/IEC 61000-4-8	Power Frequency Magnetic Field	50 Hz/60 Hz	3 A/m	30 A/m
EN/IEC 61000-4-11	Voltage Dips	>= 16 A/phase	No requirements	No requirements
EN/IEC 61000-4-11	Voltage Interruption	(%U_T;seconds) = (0 ; 5)	0% UT; 250/300 cycle	0% U_T; 250/300 cycle

Guidance and manufacturer's declaration - electromagnetic immunity for performance

The MRI system performance and intended function is assured when used in the EM environment as below. To maintain normal functionality the user of the system should assure that it is used in such an environment.

Standard	Phenomenon	Condition	IEC TR60601-4-2:2016
EN/IEC 61000-4-2	Electro-Static Discharge	Contact discharge	±4 kV
		Air discharge	±2, ±4, ±8 kV
		Indirect coupling	±4 kV
EN/IEC 61000-4-3	Proximity Fields from RF wireless communications equipment	Clause 8.10 of IEC60601-1-2	See Table 7 of IEC 60601-4-2
EN/IEC 61000-4-3	Radiated RF EM fields	80 MHz–2.7 GHz	3 V/m
EN/IEC 61000-4-4	Electrical fast Transients / Burst	A/C & D/C power supply lines; 100 kHz repetition	± 1 kV
		Interconnecting lines > 3 m; 100 kHz repetition	± 0.5 kV
EN/IEC 61000-4-5	Surge	Line to ground	±0.5; ±1; ±2 kV
		Line to line	±0.5; ±1 kV
EN/IEC 61000-4-6	Conducted disturbances induced by RF fields	150 kHz-80 MHz	3 V
EN/IEC 61000-4-8	Power Frequency Magnetic Field	50 Hz/60 Hz	3 A/m
EN/IEC 61000-4-11	Voltage Dips	>= 16 A/phase	N/A
EN/IEC 61000-4-11	Voltage Interruption	(%U_T;seconds) = (0 ; 5)	N/A

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NOTICE

The MRI system is a device that intentionally receives RF electromagnetic radiation for the purpose of its operation and is exempt from performance requirements in the frequency band of reception. Other MRI systems nearby may emit in the same frequency of reception and may cause interference.

NOTICE

The RF shielding of the examination room needs regular maintenance. Special attention is needed for the examination room door.

NOTICE

3rd party equipment shall be installed only by or under supervision of Philips personnel.

NOTICE

Only MR qualified equipment is allowed inside the Exam Room.

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity tests	IEC 60601-1-2: Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment shall not be used closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance d (m)**
Conducted RF IEC 61000-4-6	3V 150kHz - 80MHz	3V	$d = 1.2\sqrt{P}$

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Immunity tests	IEC 60601-1-2: Test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3V/m 80MHz - 2.5GHz	3V/m	$d = 1.2\sqrt{P}$ 80 MHz-800 MHz $d = 2.3\sqrt{P}$ 800 MHz-2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meter (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [remark a], should be less than the compliance level in each frequency range [remark b&c].

[Remark a] 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 may be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting, shielding or relocating the system.
[Remark b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
[Remark c] The MRI system is a device that intentionally receives RF electromagnetic radiation for the purpose of its operation and is exempt from performance requirements in the exclusion band (frequency of operation) as mentioned in clause 4 of this document. This may include other MRI devices nearby the system using the same frequency of operation.

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meter (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.

NOTICE

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTICE

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTICE

These values are applicable for all frequencies except for the frequencies in the exclusion band as mentioned in the previous table and the Site reference Guide.

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Simplified EU Declaration of Conformity, Radio Equipment Directive 2014/53/EU

Hereby, Philips Medical Systems B.V. declares that the radio equipment is in compliance with Radio Equipment Directive 2014/53/EU.

The following table lists (optional) radio equipment, the frequency band in which the equipment operates and the radio-frequency power that is transmitted.

Equipment	Frequency Band (MHz)	Transmit Power (mW)
wBTU	2402-2482	10
wECG Module (VCG)	2402-2482	2.5
$wSpO_2$	2402-2482	2.5

The full text of the EU declaration of conformity is available at the following internet address: https://www.usa.philips.com/healthcare/about/support/resource-center

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8 Networking and Security

This chapter provides documentary information on the technical security controls embedded in the system. This information may prove beneficial for risk managers tasked with maintaining the organizations risk management file for IT networks incorporating medical devices.

Network Characteristics

Although the system can operate as standalone, it can only aid the clinical workflow when granted access to services on the healthcare facility network. The following is required:

Physical	
Number of wall outlets	1
Connector type	UTP
Network cable	CAT 6A
Logical	
Number of IP addresses	1
IP address sizes (IPv4/IPv6)	Native IPv4 + IPv6
Private IP address range	192.168.70.0 – 192.168.74.255
DHCP support	Client
Clinical accessible ports and interfaces	
Network interfaces wired	Yes DICOM
Network interfaces wireless	None
Infra Red	None
Removable media	Multimedia file export via USB
Performance	
Device class	Network end device (client)
Network bandwidth	1 Gbps
Quality of service	Data only; no audio/video streaming. No need for data coloring or labeling.
IP package frame size	1500 bytes (no jumbo frames)
Network peak load estimation	360 MB in 50 sec, 5 times per hour (using Enhanced-MR)
Network latency requirements	None
Centralized IT management	
Single sign-on (SPNEGO)	LDAP

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Centralized IT management	
Identity life cycle management (LDAP)	Not supported
Policy management (LDAP)	Prohibited for device integrity reasons
Audit trails and alerts (Syslog)	Syslog UDP only
Domain name spaces (DNS/DNSSEC)	DNS supported, but documentation does not highlight the DICOM configuration when using this.
Neighborhood discovery (NDP)	Not supported
Time synchronization (SNTP/NTP)	NTP based

This medical device is multi-homed. Addresses in the private IP range are reserved for internal use only and shouldn't be utilized on the healthcare facility network, for network services internal to this device may interfere with services on the healthcare facility network. An IP address conflict can be resolved within the application; the private range can be altered.

CAUTION

When using addresses in the Private IP address range on the healthcare facility network, the Availability of this medical device is at risk.

Network context

In a typical room setup, the technical equipment is located in a separate room with climate control, and physical access control for authorized service personnel only.

The examination room is reserved for the examination of a patient by supporting staff.

An operator in the Control Room may assist the staff from outside the examination room using some optional user interface modules, as present in the examination room. Shielded glass provides for visual access to the working spot.

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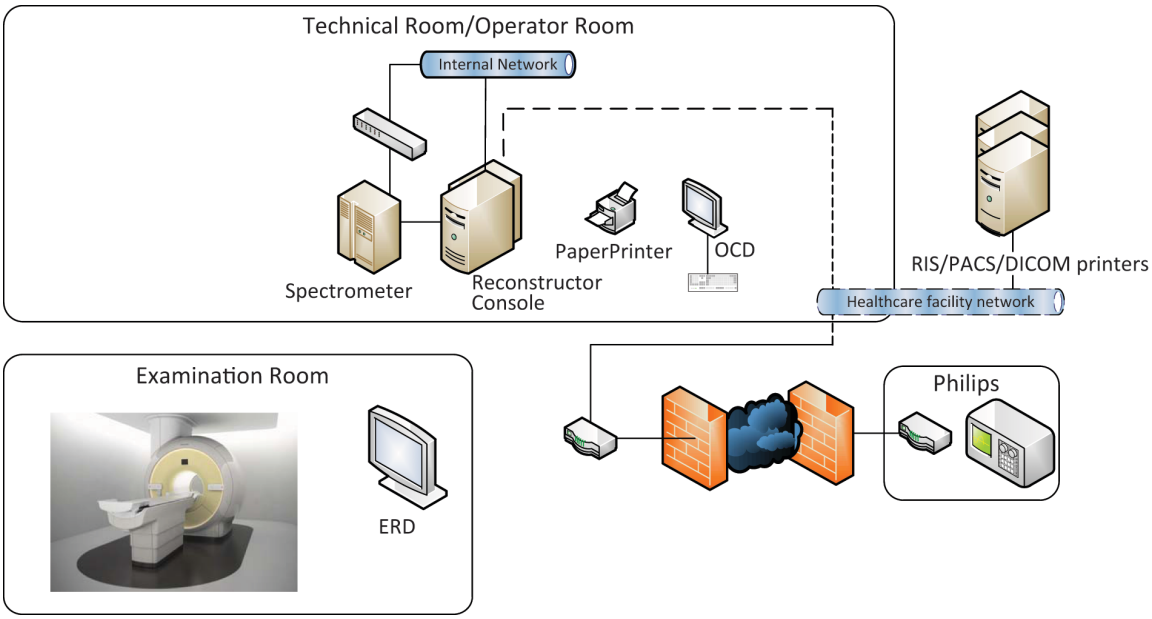

Included are the accessible ports and interfaces, as these can be relevant from a security perspective.

1. The MRI Console is a multi-homed network node connecting to the facility network and two internal networks for control and acquisition of image data. There is no routing between these networks.
2. The clinical application executes on the MRI Console. This console is connected to the ORD (Operating Room Display), a paper printer as well as the optional ERD (Examination Room Display).
3. USB memory sticks can be connected to the MRI Console. Accessibility for these devices is configurable (default disabled).
4. The healthcare facility network allows for access to network services such as DICOM printers, the Radiology Information System (RIS), or the departments Picture Archive Communication System (PACS).
5. The uptime and provisions of services can be enhanced when the equipment status and behavior is monitored at Philips. This also allows for remote application support. Various configurations for Philips Remote Service Network (RSN) access exist. Some require a dedicated router, to setup a Virtual Private Network (VPN). RSN connectivity and service support is optional.

Ports and protocols

The table below provides an overview of the socket ports and protocols utilized, as can be relevant for the proper setup of firewalls and intrusion detection systems. Since the network of the system can be configured in 2 modes (Transparent or iSSLlink), 2 sets of ports are described. In the iSSLlink mode all service traffic is tunneled through an encrypted (SSL) tunnel.

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Customer use	Philips Service use	Usage	Port no.	Inbound	Outbound	Protocol	Optional	Configurable
Transparent								
•		Time synchronization with central server	123:UDP	•	•	NTP	•	
•		Audit trail to central server	514:UDP/TCP		•	Syslog	•	•
•		Image Transfer	104:TCP	•	•	DICOM		•
•		Image Sharing	445,139:TCP	•		SMB	•	
•		Anti-Virus package updates	80:TCP		•	HTTP		
•		Active Directory connections	53:TCP/UDP	•	•	DNS	•	
			389:TCP/UDP	•	•	LDAP		
•	•	Web Browser	80,443:TCP		•	HTTP(S)		
	•	Remote Service and Utilization services	22:TCP	•		SSH		
	•	Remote Desktop	5900:TCP	•		VNC (encrypted)		
	•	Philips Service Connect (Remote Service)	80:TCP	•		HTTP		
	•	Philips Remote Service Agent	443:TCP		•	HTTPS		
iSSL link								
•		Time synchronization with central server	123:UDP	•	•	NTP	•	
•		Audit trail to central server	514:UDP/TCP		•	Syslog	•	•
•		Image Transfer	104:TCP	•	•	DICOM		•
•		Image Sharing	445,139:TCP	•		SMB	•	
•		Anti-Virus package updates	80:TCP		•	HTTP		
•		Active Directory connections	53:TCP/UDP	•	•	DNS	•	
			389:TCP/UDP	•	•	LDAP		
•	•	Web Browser	80,443:TCP		•	HTTP(S)		
	•	Philips Remote Service Agent	443:TCP		•	HTTPS		

Tab. 3: Socket port usage and associated protocols

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Relevant risks

Assumed present in the healthcare facility infrastructure are industry standard practices on network security like intrusion detection and a comprehensive network isolation/segregation architecture with perimeter defenses that limits network exposure of medical devices. In particular towards the Internet and the (non-medical) healthcare facility back office.

The technical security controls embedded in the medical device can be adjusted to local needs. Service level access is required for these modifications. The threat score assumes that these controls are enabled.

Relevant risks – Patient records

This medical device is processing personal data related to the health of patients including personally identifiable information. It is recommended to keep cabinets and the technical room locked and only accessible to authorized personnel to protect this information.

Physical storage is limited to two internal devices:

- The hard disk drive for the main clinical application.
- The hard disk drive(s) for image storage.

Both devices are mounted in the console computer behind metal covers. The computer is installed in the technical room. On Disposal of the system, both hard disk drives must be wiped or disposed in a secure way.

NOTICE

Secure Erasure is supported in the Computer BIOS.

Contact your Philips service engineer to wipe all Drives using Secure Erase before disposal or system hand over.

The patient's personal data resides at this device for a limited time only; once the examination is closed, the patient related information is transferred to the department's medical imaging archive and can be deleted to free-up storage capacity for subsequent use. On customer request, the partitions containing patient data can be encrypted.

This device is not intended for long-term storage of patient records. No particular security controls are implemented with regards to storage confidentiality or integrity; backup/recovery of patient data, and/or integrity checks that may signal tampering of records.

Relevant risks – Account credentials

Four distinct pools of account credentials are recognized:

- Clinical users are forced to authenticate themselves with a user-account/password combination. Their credentials are maintained on the device or on Customer Active Directory and require Service or Hospital Admin level access for administration. Emergency access is not supported.

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- Hospital Admins are users with administrative privileges, and are allowed to manage Clinical user accounts, configuring the Anti-malware solution and installation of Service Packs/Security Fixes provided by Philips. Their credentials are maintained on the device or on Customer Active Directory and require Service or Hospital Admin level access for administration.
- Service users are users with elevated service level privileges. Accounts are managed by Service. Accounts exist for Local and Remote service.
- Machine accounts are non-human accounts reserved for internal usage within the device or communication. These accounts are predefined, fixed, and can't been altered.

Password Complexity rules can be changed by the Service user and by the Hospital Admins.

Centralized Identity life cycle management like LDAP or Active Directory is supported. Group policy management is prohibited for this may interfere with the device integrity.

Automatic log off of medical personnel isn't offered as security control for it interferes with the device's intended use. Only non-password protected screen savers are configurable, since locking the system would interfere with the safe use of the system. Manual Screen Lock is supported.

Software updates and patch management

Philips is systematically analyzing sources of information related to the vulnerability landscape of this medical device. This includes an assessment on the applicability and need for applying security patches, while mitigating circumstances as intended use and design are taken into account.

Philips may recommend specific customer or service actions or issue service recommendations to update, alter, or even replace the security controls embedded in the products design. Recommended customer actions and latest information can be found in the product-specific listing of known vulnerabilities. Be sure to monitor it for updates.

Software updates and security patches alter the design of this medical device and thus require proper validation and approval by Philips. After releasing the updates are distributed via the Philips Field Change Order process.

Operating systems and hardening

The Console PC runs the main clinical application. This PC is the system's User Interface (UI) and the interface for hospital network services. The operating system used is Microsoft ® Windows and patches up-to-date as on date of product design release. Trellix ® Endpoint Security is pre-installed.

When powered-on, the Console will start system application tasks, but the UI is not available until an Operator is logged on. Embedded in the design, but not exposed to UI, are SQL Server databases.

The operating systems used by the internal components are: Windriver ® VxWorks and Microsoft ® Windows. These internal components boot automatically. Auto logon is not provided.

Clinical users are locked into the application and do not have direct access to the underlying operating system.

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Service users can access the equipment configuration including user accounts, and the underlying operating system using the Service password.

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9 Important messages and indications, Symbols

9.1 Important messages and indications

Important messages and indications are displayed in the language of the user interface. The table below displays the English messages and their translation.

Messages	
English	**Translation**
Allow First Level Controlled Operating Mode for SAR?	**Allow First Level Controlled Operating Mode for SAR?**
Medical supervision of the patient is required. Whole Body SAR of scan is between 2 and 4 W/kg.	Medical supervision of the patient is required. Whole Body SAR of scan is between 2 and 4 W/kg.
See Instructions for Use.	See Instructions for Use.
Allow all scans which require Whole Body SAR > 2 W/kg? • Confirm and Start • Cancel	Allow all scans which require Whole Body SAR > 2 W/kg? • Confirm and Start • Cancel
Allow First Level Controlled Operating Mode for PNS?	**Allow First Level Controlled Operating Mode for PNS?**
Medical supervision of the patient is required. Peripheral Nerve Stimulation of scan is between 80 and 100 %. See Instructions for Use.	Medical supervision of the patient is required. Peripheral Nerve Stimulation of scan is between 80 and 100 %. See Instructions for Use.
Allow all scans which require PNS > 80%? • Confirm and Start • Cancel	Allow all scans which require PNS > 80%? • Confirm and Start • Cancel
High total SED	**High total SED**
Total (delivered + scheduled) SED exceeds the recommended maximum of 7.0 kJ/kg.	Total (delivered + scheduled) SED exceeds the recommended maximum of 7.0 kJ/kg.
See Instructions for Use	See Instructions for Use
Lower the scan time or the SAR of the remaining scans to reduce the SED. • **Continue without modification** • **Modify examination**	Lower the scan time or the SAR of the remaining scans to reduce the SED. • **Continue without modification** • **Modify examination**

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Messages	
English	**Translation**
Recommended SED exceeded	**Recommended SED exceeded**
Total (delivered + scheduled) SED exceeds the recommended maximum of 7.0 kJ/kg in the next scan.	Total (delivered + scheduled) SED exceeds the recommended maximum of 7.0 kJ/kg in the next scan.
See Instruction for Use.	See Instruction for Use.
If clinical benefit exceeds the risk of high SED: • Make sure medical supervision is in place. • **Accept high SED, continue scanning** • **Stop scanning**	If clinical benefit exceeds the risk of high SED: • Make sure medical supervision is in place. • **Accept high SED, continue scanning** • **Stop scanning**
Patient Ventilation Warning	**Patient Ventilation Warning**
Sufficient patient ventilation is required.	Sufficient patient ventilation is required.
The patient ventilation is below the recommended level.	The patient ventilation is below the recommended level.
Press <Modify…> to modify the patient ventilation level. Refer to the Instructions for Use for information about patient ventilation.	Press <Modify…> to modify the patient ventilation level. Refer to the Instructions for Use for information about patient ventilation.
Press <Proceed> to proceed with the current patient ventilation level.	Press <Proceed> to proceed with the current patient ventilation level.
Press <Cancel> to cancel the scan. • Modify • Cancel • Proceed	Press <Cancel> to cancel the scan. • Modify • Cancel • Proceed
Moving TableTop	**Moving TableTop**
The tabletop is moving automatically. • Stop	The tabletop is moving automatically. • Stop

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Messages	
English	**Translation**
Enable Remote Desktop Session A Remote Desktop session has been requested. If you accept this Remote Desktop request, you confirm that you know that this is an authorized Remote Desktop session. You further confirm that you are the responsible local operator for the system during this Remote Desktop session and have been fully informed about the possible consequences regarding Safety, Security and Privacy arising from permitting remote operation of the system, including those discussed in the system's "instructions for use". During a single windows Take Over session, you must stay at the system console and monitor the activities performed by the remote user. You can end the Remote Desktop session any time by pressing the "STOP" button on your screen. As the operator of the system, you are responsible for the safe and secure use of the system. Note that certain private information, including electronic Protected Health Information (ePHI) about patients, will become accessible to the remote operator. Be sure to stay within your institution's policy regarding disclosure of confidential information to third parties. • I Agree • Exit Session	**Enable Remote Desktop Session** A Remote Desktop session has been requested. If you accept this Remote Desktop request, you confirm that you know that this is an authorized Remote Desktop session. You further confirm that you are the responsible local operator for the system during this Remote Desktop session and have been fully informed about the possible consequences regarding Safety, Security and Privacy arising from permitting remote operation of the system, including those discussed in the system's "instructions for use". During a single windows Take Over session, you must stay at the system console and monitor the activities performed by the remote user. You can end the Remote Desktop session any time by pressing the "STOP" button on your screen. As the operator of the system, you are responsible for the safe and secure use of the system. Note that certain private information, including electronic Protected Health Information (ePHI) about patients, will become accessible to the remote operator. Be sure to stay within your institution's policy regarding disclosure of confidential information to third parties. • I Agree • Exit Session
Scanner Patient position needs to be defined. Press 'Proceed' to reuse the current position, or use the light visor. • Proceed	**Scanner** Patient position needs to be defined. Press 'Proceed' to reuse the current position, or use the light visor. • Proceed
Planscan Position of the tabletop changed since acquisition of survey. Please select recent survey. • Close	**Planscan** Position of the tabletop changed since acquisition of survey. Please select recent survey. • Close
Warning dS HeadNeck coil is connected. Scanning with a tilted HeadNeck coil is not allowed. Refer to the Instructions for Use for information about the dS HeadNeck coil. Press <Cancel> to stop scanning. Press <Proceed> to start scanning, only if the ds HeadNeck coil is not tilted. • Cancel • Proceed	**Warning** dS HeadNeck coil is connected. Scanning with a tilted HeadNeck coil is not allowed. Refer to the Instructions for Use for information about the dS HeadNeck coil. Press <Cancel> to stop scanning. Press <Proceed> to start scanning, only if the ds HeadNeck coil is not tilted. • Cancel • Proceed

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Messages	
English	**Translation**
Patient Ventilation Control	**Patient Ventilation Control**
Current patient ventilation level	Current patient ventilation level
Level 5 is recommended.	Level 5 is recommended.
Use the <+> and <-> buttons above to modify the patient ventilation level.	Use the <+> and <-> buttons above to modify the patient ventilation level.
Refer to the Instructions for Use for information about patient ventilation.	Refer to the Instructions for Use for information about patient ventilation.
• Proceed	• Proceed
Scanning in First Level Controlled Operating Mode	Scanning in First Level Controlled Operating Mode
Medical Supervision of the patient required.	Medical Supervision of the patient required.
Specific Absorption Rate: <baseline value> W/Kg	Specific Absorption Rate: <baseline value> W/Kg
Scanning in First Level Controlled Operating Mode	Scanning in First Level Controlled Operating Mode
Medical Supervision of the patient required.	Medical Supervision of the patient required.
Peripheral Nerve Stimulation: <baseline value> %	Peripheral Nerve Stimulation: <baseline value> %
Scanning in First Level Controlled Operating Mode	Scanning in First Level Controlled Operating Mode
Medical Supervision of the patient required.	Medical Supervision of the patient required.

Messages related to the Magnet

The following messages may appear when there is an issue with the Magnet.

Messages	
English	**Translation**
Primary cryo compressor reports an issue.	**Primary cryo compressor reports an issue.**
Contact your service provider. Scanning allowed.	Contact your service provider. Scanning allowed.
Secondary cryo compressor reports an issue.	**Secondary cryo compressor reports an issue.**
Contact your service provider. Scanning allowed.	Contact your service provider. Scanning allowed.
Magnet UPS reports an issue.	**Magnet UPS reports an issue.**
Contact your service provider. Scanning allowed.	Contact your service provider. Scanning allowed.
ERROR: Magnetic field is out of specification.	**ERROR: Magnetic field is out of specification.**
Scanning is not possible.	**Scanning is not possible.**
Contact your service provider. Click **OK** to proceed.	Contact your service provider. Click **OK** to proceed.
NOTICE: Magnet internal temperature is high due to cryo-compressor issues.	**NOTICE: Magnet internal temperature is high due to cryo-compressor issues.**
The magnet may discharge in less than 2 hours.	The magnet may discharge in less than 2 hours.
Contact your service provider. Click **OK** to close.	Contact your service provider. Click **OK** to close.

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Messages English	Translation
NOTICE: Magnet internal temperature is high due to cryo-compressor issues. The magnet may discharge in 30 minutes. Contact your service provider. Click **OK** to close.	**NOTICE: Magnet internal temperature is high due to cryo-compressor issues.** The magnet may discharge in 30 minutes. Contact your service provider. Click **OK** to close.

9.2 Symbols on System, Coils and Accessories

The following symbols may be used on your Philips system, on accessories and packaging, as well as at the examination room.

Applied part symbols	Source	Meaning
	IEC 60417-5840	Type B applied part. To identify a type B applied part complying with IEC 60601-1.
	IEC 60417-5333	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417-5336	Defibrillation-proof type CF applied part. To identify a defibrillation-proof type CF applied part complying with IEC 60601-1 .

Mandatory Action symbols	Source	Meaning
	ISO 7010-M002	Refer to instruction manual/booklet. To signify that the instruction manual/booklet must be read.
	ISO 7010-M003	Wear ear protection. To signify that ear protection must be worn.
	n.a.	ONLY screened and approved devices allowed in scanning room.

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Prohibition symbols	Source	Meaning
	ISO 7010-P007	No access for people with active implanted cardiac devices. To prohibit people with active implanted cardiac devices from entering a designated area.
	n.a.	No access for people with metallic implants.
	ISO 7010-P014	No access for people with metallic implants.
	ISO7010-P008	No metallic articles or watches.
	n.a.	Loose ferromagnetic objects and mechanical watches prohibited.
	n.a.	Loose ferromagnetic tools prohibited.
	n.a.	Wheel chairs and equivalent metal objects prohibited.
	n.a.	Magnetic media prohibited (credit cards, diskettes, magnetic tapes).
	ISO 7010-P012	No heavy load. To prohibit the placing of heavy objects on a surface.

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Prohibition symbols	Source	Meaning
	n.a.	Do not scan pediatric patients under 15 kg (33 lbs) with this coil.

Warning symbols	Source	Meaning
	ISO 7010-W001	General warning sign.
	ISO 7010-W006	Warning: Magnetic field.
	ISO 7010-W005	Warning; Non-ionizing radiation.
	ISO 7010-W024	Warning: Crushing of hand.
	n.a.	Danger of clamping.
	ISO 7010-W004	Warning: Laser beam.
	IEC 60825-1	Laser radiation: Do not stare into beam. Class 2 Laser Product .

Alarm symbols	Source	Meaning
	IEC 60417-5307	Low priority alarm.

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Alarm symbols	Source	Meaning
	IEC 60417-5308	Medium priority alarm.

Other symbols	Source	Meaning
	IEC 60417-6193	RF coil, receive only
	IEC 60417-6192	RF coil, transmit and receive
	SJ/T 11364-2014 Figure 2, Mark II	The environment-friendly use period of this product is 50 years. (according to People's Republic of China Electronics Industry Standard SJ/T11364-2014)
	Directive 2012/19/EU WEEE Symbol	Waste electrical and electronic equipment.
	ISO7000-2498	Serial number
	ISO7000-2493	Catalogue number
	ISO7000-3082	Manufacturer

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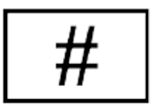
Other symbols	Source	Meaning
	ETL listed	Intertek ETL recognized component
	ISO 7000-1641	Consult Instructions for Use or consult electronic Instructions for Use
	2017/745/EU	Medical Device Indicates the item is a medical device.
	European Commission	CE Marked Device
	ISO7000-0434B	Caution To indicate that caution is necessary when operating the device or control close to where the symbol is placed. To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	2017/745/EU	Unique device identifier.
	ISO 7000-3725	Importer To indicate the entity importing the medical device into the locale.
	IEC60417 - 6049	Country of Manufacture
	IEC60417 - 6050	Model Number
	IEC60417- 5172	Class II equipment

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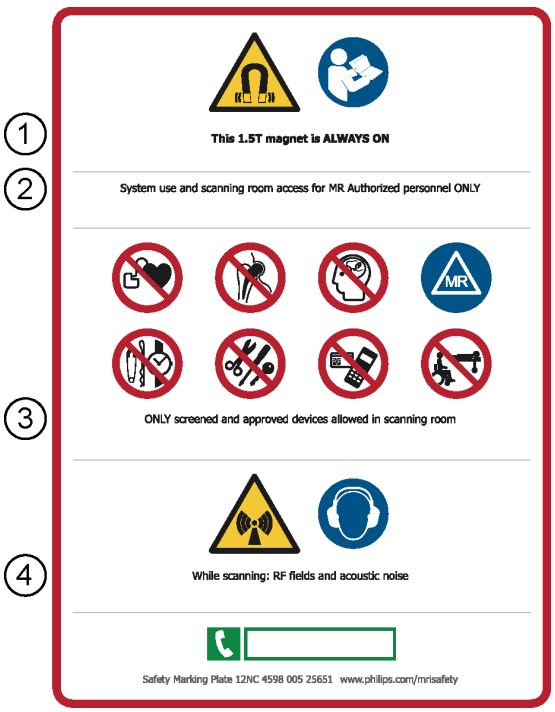
Philips Markings		Meaning
	n.a.	Person trapped by an object that is attracted by the magnet.
	N.A.	FlexTrak Marking
	N.A.	Total Mass and safe working load
	N.A.	Magnetic Field Strength

Safety marking plate	Explanation
	Examination room door safety marking plate. The individual symbols are explained in other parts of this section. Text on the safety marking plate: 1. This 1.5T (3.0T) magnet is ALWAYS ON 2. System use and scanning room access for MR Authorized personnel ONLY 3. ONLY screened and approved devices allowed in scanning room 4. While scanning: RF fields and acoustic noise

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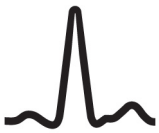
Medical symbols	Meaning
	ECG
	Peripheral pulse/blood pressure

Referenced standards for symbols on the system

- IEC 60417:2002 DB, Graphical symbols for use on equipment.
- ISO 7010:2011, Graphical symbols – Safety colours and safety signs – Registered safety signs.
- ISO 7000:2014 (ed. 5.0), Graphical symbols for use on equipment - Registered symbols.
- EN 50419:2006, Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).
- IEC TR 60878:2015 (ed. 3.0), Graphical symbols for electrical equipment in medical practice.

You can find definitions of used symbols in the symbol glossary on the following website: http://www.symbols.philips.com

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www.philips.com/healthcare

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Veenpluis 6
5684 PC Best
The Netherlands

Printed in The Netherlands
3000 151 71921/ 782/ * 2025-05 - en-US