

English

Release 12.1



MR 7700

3000 113 87602

PHILIPS

Table of contents

1	Introduction.....	5
2	Controlled Access Area.....	9
2.1	2013/35/EU Workers Electromagnetic Safety Directive	10
3	Compatibility technical specification sheet.....	13
3.1	Magnet.....	13
3.2	Gradients	19
3.3	RF system	21
3.3.1	Body coil	21
3.3.2	dS T/R Knee 16ch coil 3.0T.....	21
3.3.3	T/R Head coil 3.0T.....	22
3.3.4	MultiNuclei (MN) coils.....	23
4	Transmit / receive coils.....	25
5	Liquid cryogen and cryogenic gases	27
6	Patient environment.....	31
7	Compatibility protocols for third party equipment validation	33
8	Electromagnetic compatibility	35
9	Networking and Security	43
10	Important messages and indications, Symbols	51
10.1	Important messages and indications.....	51
10.2	Symbols on System, Coils and Accessories.....	75

Table of contents

3000 113 87602/782 * 2024-10

Philips

1 Introduction

This document is applicable to the following systems:

- MR 7700
- MR 7700 with upgrade package **Upgrades dStream to R12**
- Ingenia 3.0T with upgrade package **Smartpath to MR 7700**
- Ingenia Elition S with upgrade package **Upgrade to MR 7700**
- Ingenia Elition X with upgrade package **Upgrade to MR 7700**

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.

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.

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.

The following Accessories are provided with the system to enable specific procedures or to ensure safety:

- All RF coils.
- PPU Sensor for wireless physiology.
- Pediatric PPU Sensor.
- Acoustic Hood.
- FlexTrak.
- MR Elastography.



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.

Introduction

Philips

3000 113 87602/782 * 2024-10

2 Controlled Access Area

It is the responsibility of the user and operator that the following safety requirements are met.

5 gauss line

During the site planning, a controlled access area around the MRI system must be defined where the field strength will exceed 0.5 mT (= 5 Gauss). Warning signs "CAUTION Magnetic field permanently switched on" shall be used to indicate this area.

Electromagnetic shielding

Electromagnetic shielding of the Controlled Access Area shall be designed to ensure compliance with IEC 60601-1-2:2014. This includes the implementation of an RF Door Switch and interlock. Refer to Philips Site Planning information for more details.

Controlled access area

All entries to the controlled access area shall be labeled by appropriate warning signs, including an indication of the presence of magnetic fields and their attractive force or torque on ferromagnetic materials. Refer to Philips Site Planning Information for a suitable set of symbols.

Floor markings

The controlled access area must be clearly visible, e.g. by markings on the floor, barriers or other means to control access to this area by unauthorized persons.

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.

No liquid helium container may be brought into the magnet area unless it has been ascertained that the container is made of non-ferromagnetic material.

Special non-ferromagnetic containers are available from liquid gas suppliers and must be appropriately labeled as non-ferromagnetic containers.

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.

2.1 2013/35/EU Workers Electromagnetic Safety Directive

The graphics in this section show areas where workers may experience MRI-related sensitizations related to movement or active scanning. These graphics are required by the 2013/35/EU Workers Electromagnetic Safety Directive and can be printed to be displayed in or at the examination room.

Workers should not enter the identified area unless necessary to discharge 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.

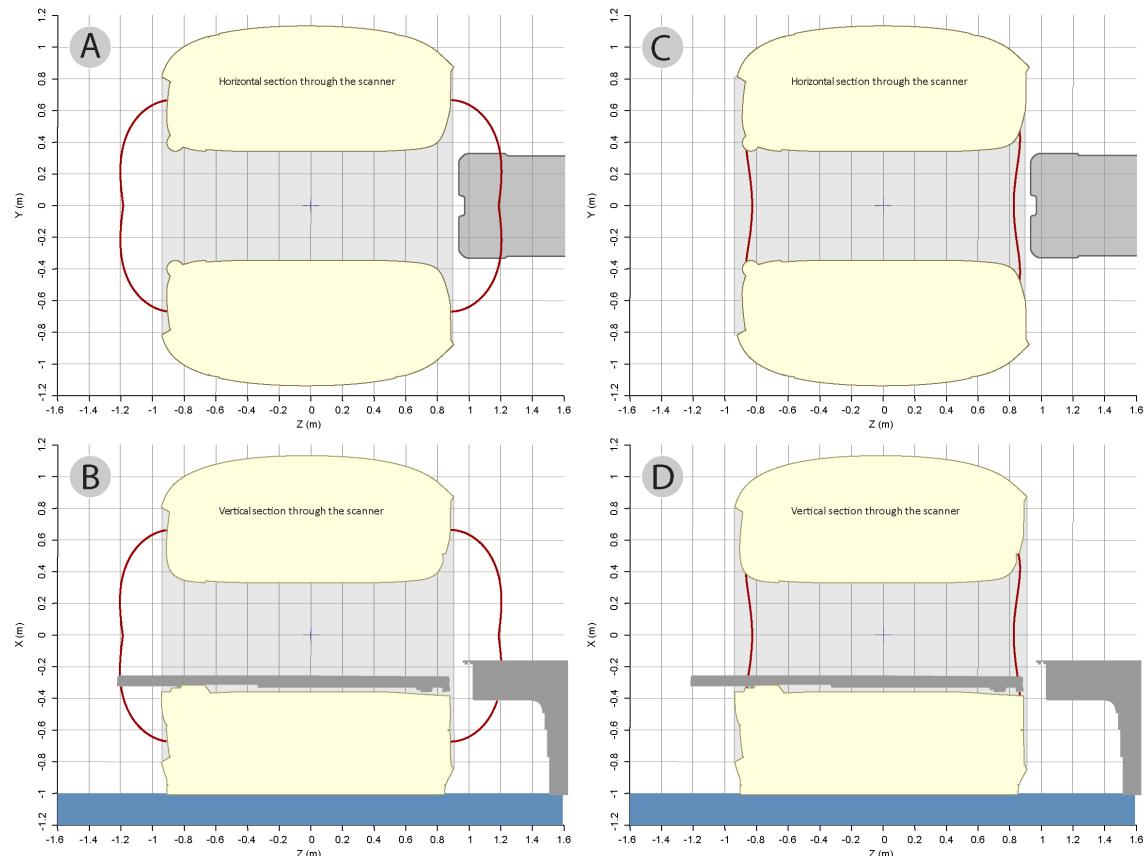


Fig. 1: 3.0T systems - Area where exposure limit values from 2013/35/EU may be exceeded.

No.	View	Lines
A	Top view	dB/dt area

No.	View	Lines
B	Side view	dB/dt area
C	Top view	B_0 area
D	Side view	B_0 area

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.

Field Strengths and Cryogen Consumption

Field Strength	Cryogen consumption (typical)
3.0T	0.00 l/h

Bore dimensions

The patient bore diameter is 70 cm and the bore length is 130 cm.

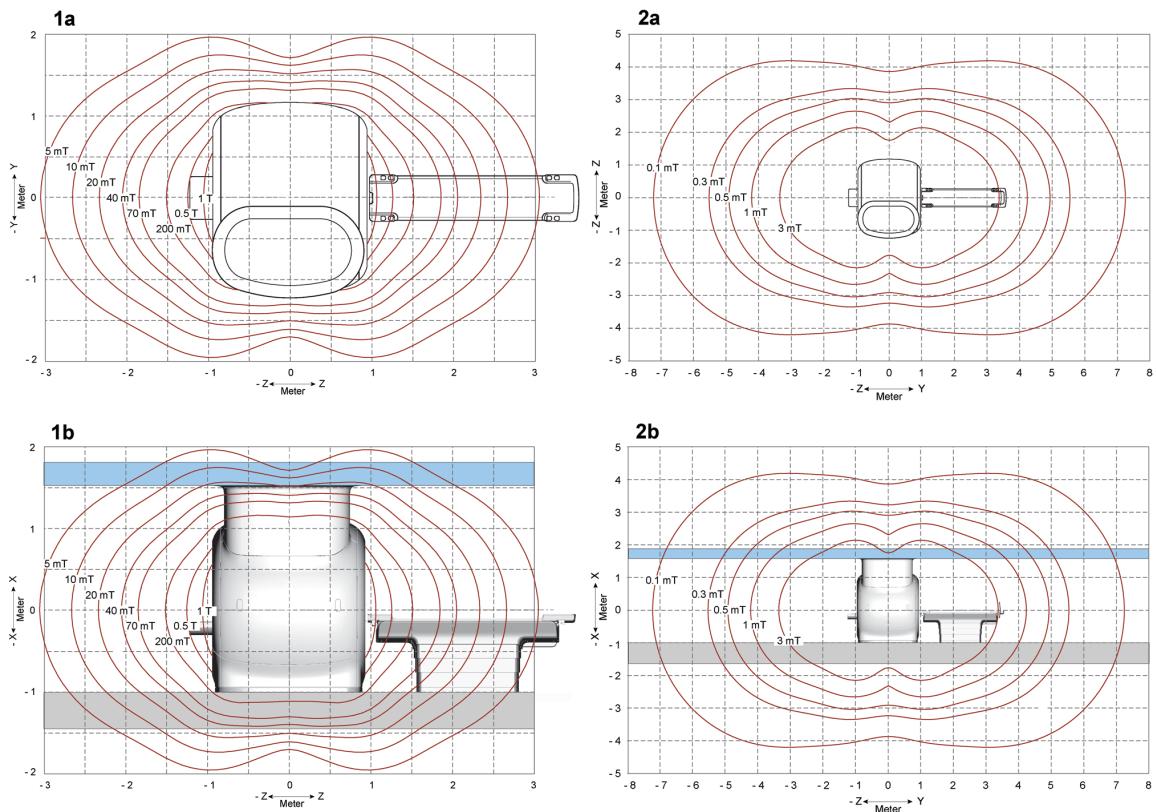
Typical spatial distribution of surrounding field

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

The iso-magnetic contours of 1.5T, 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.

**Fig. 2:** Typical spatial distribution of surrounding field

No.	View	Lines
1a	Top view	5, 10, 20, 40, 70, 200 mT, 0.5, 1 T
1b	Side view	5, 10, 20, 40, 70, 200 mT, 0.5, 1 T
2a	Top view	0.1, 0.3, 0.5, 1, 3 mT
2b	Side view	0.1, 0.3, 0.5, 1, 3 mT

3000 113 87602/782 * 2024-10

Philips

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.

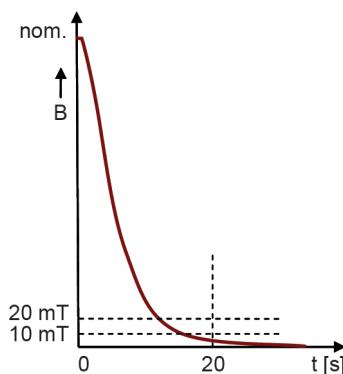


Fig. 3: Schematic magnet field decrease in the center of the magnet as a function of time when initiated by an emergency field shutdown $t=0$.

On Ingenia Elition systems, pressing an Emergency Magnet Off button will initiate a quench within a few seconds.

During a quench on Ingenia Elition systems, the magnet will make a loud noise caused by the rapid relief of helium gas through the helium venting system. This loud noise is proof that the magnet has actually quenched and that the magnet central field has decreased from nominal field to less than 10 mT.

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.

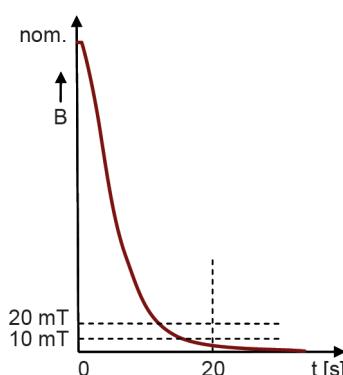


Fig. 4: Schematic magnet field decrease in the center of the magnet as a function of time when initiated by an emergency field shutdown $t=0$.

The system's installation manual gives information where and how to install the actuator of the emergency field shut-down unit.

Pressing an Emergency Stop button will initiate a quench of the magnet within a few seconds. The magnet will then make a loud noise caused by the rapid relief of helium gas through the helium venting system.

This loud noise is proof that the magnet has actually quenched and that the magnet central field has decreased from nominal field to less than 10 mT.

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.

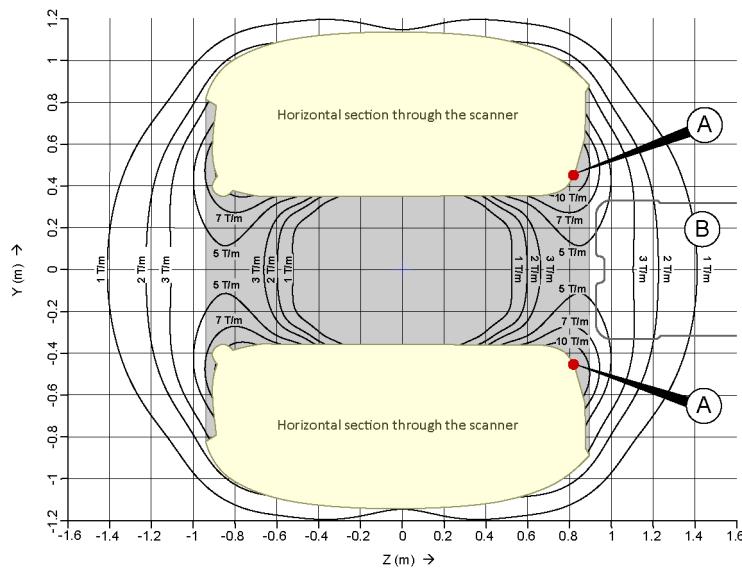


WARNING

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

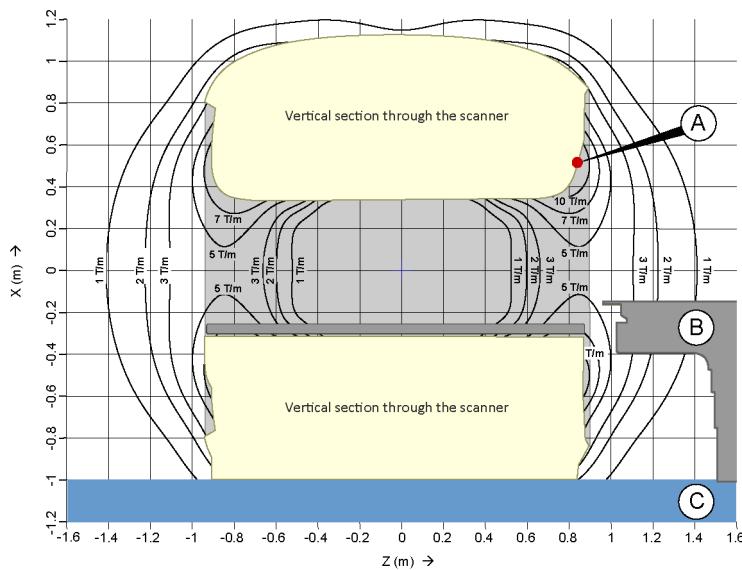
The following figures show the spatial gradient distribution in a top view and a side view of the scanner.

- 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.
- The yellow colored parts represent the inaccessible space behind the covers.

Top View**Fig. 5:** Top View, horizontal section: Spatial gradient of static magnet field B_0

A Highest gradient locally on cover surface: 16 T/m

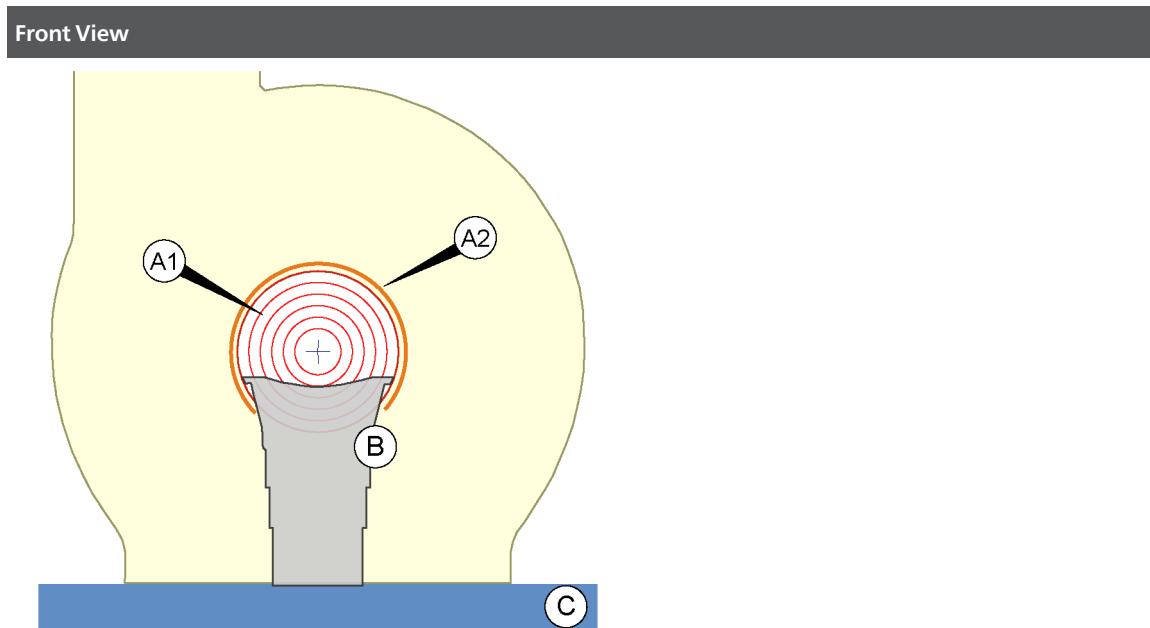
B Patient table

Side View**Fig. 6:** Side View, vertical section: Spatial gradient of static magnet field B_0

A Highest gradient locally on cover surface: 20 T/m

B Patient table

C Floor level

**Fig. 7: Front cover View**

A1 See table A1 for maximum values along the length of the cylindrical tubes

A2 See table A2 for local maximum values on the front cover surface

B Patient table

C Floor level

The orange ring shown in the front view figure is the location where:

- The spatial gradient of B_0 is the highest.

This is very locally on the surface of the front cover, outside the patient area at a radius of 0.35 - 0.37 m. At this location the force on a saturated ferromagnetic object resulting from the spatial gradient of the static magnetic field B_0 is maximum.

- The product of B_0 and the spatial gradient of B_0 is maximum.

This is very locally on the surface of the front cover, outside the patient area at a radius of 0.45 - 0.51 m. At this location the force on a diamagnetic or paramagnetic object, or a ferromagnetic material below its magnetic saturation point, is maximum.

A1: Maximum spatial gradient of B_0 occurring along the length of a cylindrical tube around the Z-axis (see figure above).

Diameter	Value
On the z-axis	4.7 T/m 470 G/cm
Tube of 20 cm diameter	5.0 T/m 500 G/cm

A1: Maximum spatial gradient of B_0 occurring along the length of a cylindrical tube around the Z-axis (see figure above).

Diameter	Value
Tube of 30 cm diameter	5.3 T/m 530 G/cm
Tube of 40 cm diameter	5.8 T/m 580 G/cm
Tube of 50 cm diameter	6.6 T/m 660 G/cm
Tube of 60 cm diameter	7.9 T/m 790 G/cm
Tube of 70 cm diameter	10.2 T/m 1020 G/cm

A2: Maximum spatial gradient of B_0 occurring on the surface of the (front) cover

Static magnetic field B_0	3.7 T
Spatial gradient of the static field B_0	20 T/m (or 2000 G/cm)

Maximum product of B_0 and the spatial gradient of B_0 occurring on the surface of the (front) cover at a radius of 0.37 - 0.45 m

Product of B_0 and spatial gradient of B_0	46.0 T ² /m
--	------------------------

Graphics indicate the location where the product of B_0 and the spatial gradient of B_0 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.

3.2 Gradients

Gradient Type

For all systems: 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 defined in IEC 60601-2-33.

Gradient Performance

Gradient System	Maximum Amplitude (mT/m)	Maximum Slew rate (mT/m/ms)	Fastest Rise time (ms)
XP	65	220	0.295

Gradient (stray) field distribution

For evaluating the risk of scanning persons fitted with MR Conditional implants the following information applies.

Pre-scans dB/dt value:

If a maximum dB/dt has been specified in ScanWise Implant, all scans, including prescans, will be restricted to the dB/dt value specified.

PNS for workers:

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

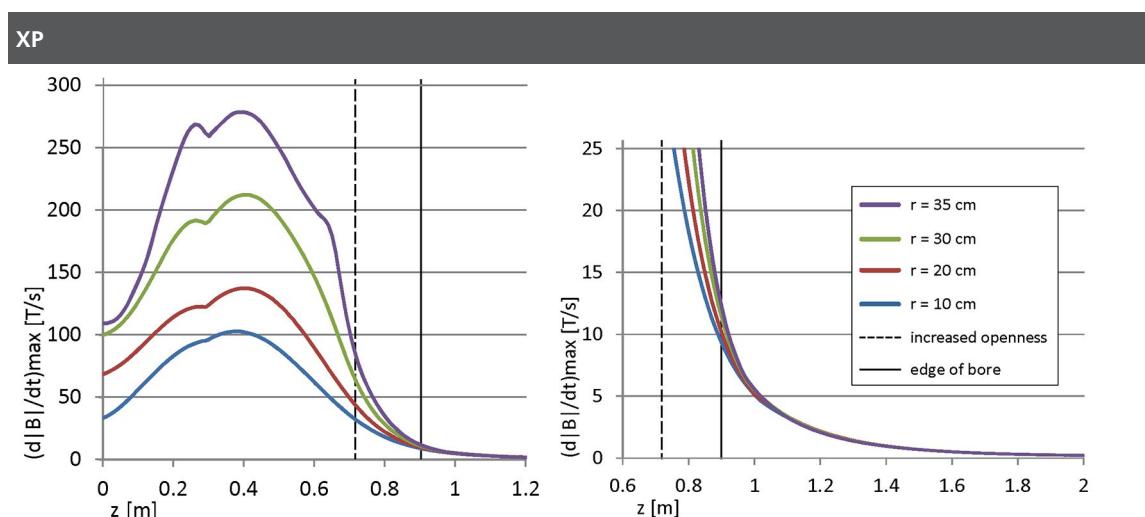


Fig. 8: XP gradient output: maximum magnetic field rate of change, determined on cylinders with different radii for all three gradient axes simultaneous @ SR=220T/m.s. Cylinders oriented along the long axis of the magnet. Z = Patient axis.

Colored lines

XP: $d|B|/dt$ - maximum on cylinder $r = 10, 20, 30, 35$ 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

3.3 RF system

MultiTransmit

3.0T systems use two transmit channels for the Body transmit coil and are Multichannel-2 (MC-2) systems with respect to RF excitation types. Restriction to Circular Polarization (CP) can be selected at the sequence definition user interface.

3.3.1 Body coil

Transmit system characteristics are specified in the table below.

Nominal freq. (MHz)	Max freq. offset (kHz)	Amplifier Peak Power (kW)	RF coil type	Max. Transmit Field $B_{1\text{peak}}$ (μT)	Max. Transmit Field $B_{1\text{rms}}$ (μT)
127.73	± 550	2x18	Integrated volume coil	22	2.3

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.

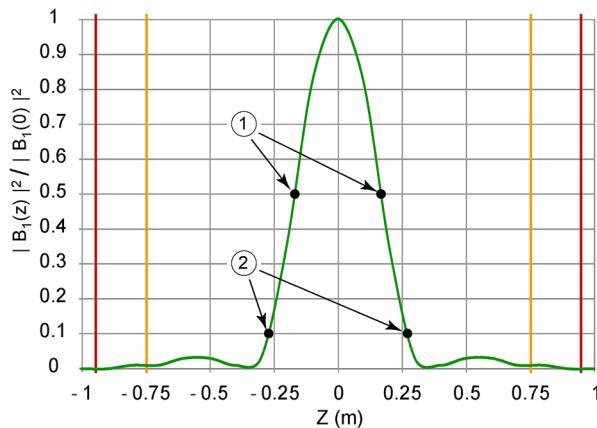


Fig. 9: Normalized RF power depositions along the axis of the system.

3.3.2 dS T/R Knee 16ch coil 3.0T

Transmit system characteristics are specified in the table below.

Coil	Nominal freq. (MHz)	Amplifier Peak Power (kW) ¹⁾	RF coil type	Max. Transmit Field $B_{1\text{peak}}$ (μT)	Max. Transmit Field $B_{1\text{rms}}$ (μT)
3.0T	127.73	4	Detachable volume coil	27	5.0

¹⁾ Max RF peak power at the Transmit/Receive socket.

Ratio of RF power deposition along the long axis of the coil 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.

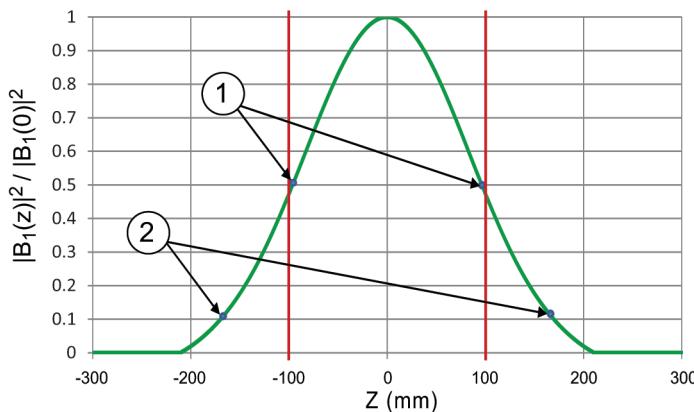


Fig. 10: Normalized RF power deposition along the axis of the dS T/R Knee 16ch coil 3.0T.

The picture shows the RF power deposition for the dS T/R Knee 16ch coil, 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 and 2 represent the location along the z-axis where the transmit field is reduced by 3 dB and 10 dB respectively. Note that the points at distance $\pm 200\text{mm}$ from the coil isocenter, where the power deposition is already negligible, are still within the system bore (assuming the coil is placed at magnet isocenter).

The red vertical lines indicate the outer edges of the coil.

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	±100
2	-10 dB	±170

3.3.3 T/R Head coil 3.0T

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.

Nominal freq. (MHz)	Amplifier Peak Power (kW) ¹⁾	RF coil type	Max. Transmit Field $B_{1\text{peak}} (\mu\text{T})$	Max. Transmit Field $B_{1\text{rms}} (\mu\text{T})$
127.73	4	Detachable volume coil	20	2.65

¹⁾ Max RF peak power at the Transmit/Receive socket.

3.3.4 MultiNuclei (MN) coils

Transmit system characteristics of the MultiNuclei coils are specified in the table below.

Coil	Nominal freq. (MHz)	Max freq. offset (kHz)	Amplifier Peak Power (kW) ¹⁾	RF coil type	Max. Transmit Field $B_{1\text{peak}} (\mu\text{T})$	Max. Transmit Field $B_{1\text{rms}} (\mu\text{T})$
P-140-Flex	51.7	± 215	4	Detachable local coil	60	2.41
C-140-Flex 3.0T	32.1	± 140	4	Detachable local coil	75	2.52
Na-140-Flex 3.0T	33.8	± 140	4	Detachable local coil	75	2.52

¹⁾ Max RF peak power at the Transmit/Receive socket at the RF amplifier output.

Ratio of RF power deposition along the long axis of the coil 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.

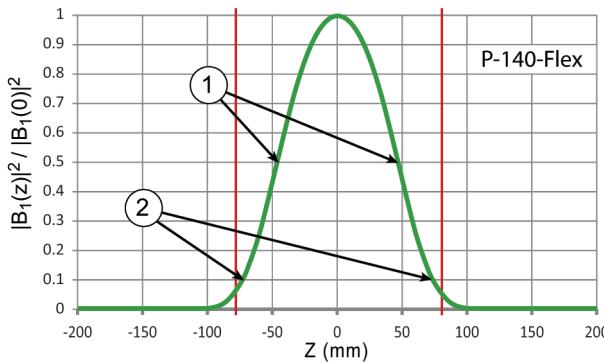


Fig. 11: P-140-Flex: Normalized RF power deposition along the axis of the coil. The coil is positioned 7 cm underneath the isocenter.

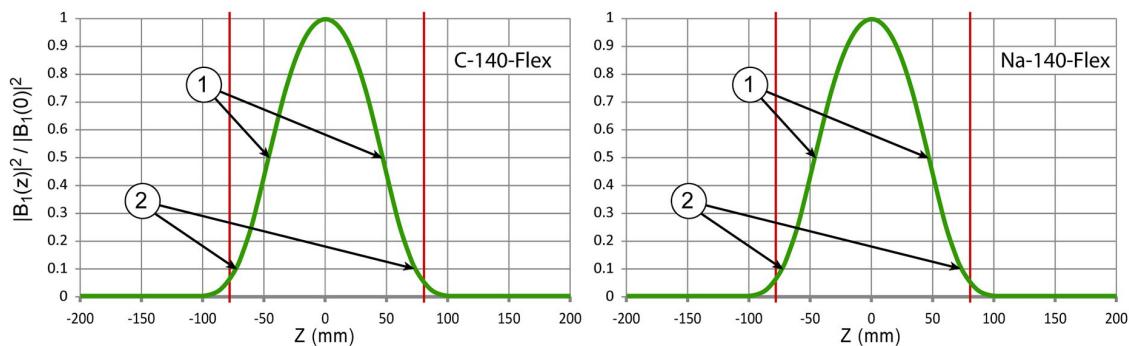


Fig. 12: Left C-140-Flex, right Na-140-Flex: Normalized RF power deposition along the axis of the coil. The coil is positioned 7 cm underneath the isocenter.

The graphs show the RF power deposition for coils, 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 and 2 represent the location along the z-axis where the transmit field is reduced by 3 dB and 10 dB respectively. Note that the points at distance $\pm 200\text{mm}$ from the coil isocenter, where the power deposition is already negligible, are still within the system bore (assuming the coil is placed at magnet isocenter).

The red vertical lines indicate the outer edges of the coil.

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	P-140-Flex z-position (mm)	C-140-Flex 3.0T z-position (mm)	Na-140-Flex 3.0T z-position (mm)
1	-3 dB	± 47	± 48	± 48
2	-10 dB	± 75	± 78	± 78

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:

- dS T/R Knee 16ch coil 3.0T
- T/R Head coil 3.0T
- Phosphorous coil P-140-Flex 3.0T
- Carbon coil C-140-Flex 3.0T
- Sodium coil Na-140-Flex 3.0T

Transmit / receive coils

Philips

3000 113 87602/782 * 2024-10

5 Liquid cryogen and cryogenic gases

A venting system for cryogen gasses is connected to the outside of the examination room and is designed to withstand a quench and to protect near-by persons in the case of a quench. This provision assures that the oxygen concentration in the accessible area remains at acceptable levels during a quench.

Safety with liquid helium and helium gas

Helium gas has the following properties:

- odorless
- nonflammable
- non-poisonous
- on evaporation a cold mist is formed
- lighter than air

A high concentration of helium gas in the examination room can lead to suffocation, as it will dilute the oxygen in the air.

Under normal operating conditions a small amount of helium may evaporate caused by boil-off of the liquid helium in the magnet. It will escape via the helium gas exhaust pipe.

A large amount of helium gas may escape when the Emergency Magnet Off button is used for immediate shutdown of the magnetic field, or during a spontaneous magnetic field shutdown.

Philips MRI systems are equipped with a helium venting system, which ensures that under normal operation and emergency switch-off conditions the escaping helium gas from the magnet is vented outside of the building.

NOTICE

Guidelines for the construction (dimension, position, assembly and material to be applied) of the venting system for the superconducting magnet inside and outside the examination room are available from your customer support organization.

NOTICE

It is recommended to install a preventive maintenance program, which states that regular checks of the adequate function of the venting system for the superconducting magnet are to be made. Full details are available from your customer support organization.

The design of the examination room must guarantee safety of the patient and other persons inside and outside the examination room in the event of failure of the venting system during a quench.

The design shall address the issues of reducing pressure build-up, temperature decrease and oxygen depletion during a quench.

Acceptable solutions of such provisions are:

- Configurations in which the RF door opens outwards or is a sliding RF door. This will enable the door to be opened easily in case of pressure build-up in the examination room.
- Configurations where the RF door opens inwards, if these include extra precautions to prevent pressure build up. This can be realized by one of the following:
 - an extra examination room ventilator system, which can be switched on (possibly automatically via an oxygen monitor in the ceiling of the examination room to detect the escape of helium gas) in case of a quench, or
 - an opening in the wall or ceiling or RF door of the examination room, venting towards an open area, or
 - a possibility of opening the observation window in the examination room outward or by sliding, or
 - a second independent venting system for the superconducting magnet that remains operational in case the regular venting system for the superconductive magnet is obstructed.



WARNING

In the very unlikely event of a failure of the venting system (e.g. venting system is blocked), AND shutdown of the magnetic field, a high concentration of helium gas may penetrate quickly into the examination room, which will be visible as clouds of cold mist.

If this situation occurs, the patient and personnel must immediately be evacuated from the examination room.

The system owner shall develop and rehearse an evacuation plan.

NOTICE

DO NOT switch off the air conditioning or air circulation in the room (normal procedure in the event of fire), but maintain circulation and replenishment of air to allow the helium gas to dissipate.

Additional controls may be required to bypass a smoke-detector initiated stop of air circulation. Install extra control measures for the patient ventilation system to prevent that the patient is exposed to helium transported by the ventilation system.

Liquid helium is extremely cold and will cause frostbite when in contact with the human body. Use protective gloves, goggles and clothing when handling liquid helium.

Only properly trained staff shall handle cryogenic liquids such as helium.

Under normal circumstances, always keep the ventilation of the examination room running. The magnet system has a dedicated venting system, which is to be connected to a helium gas exhaust pipe, leading outside the building. This system prevents escape of helium into the examination room. The helium gas exhaust pipe outside opening shall be located at a non-accessible area. It must be periodically checked that the exhaust pipe is not blocked, dislocated or damaged.

Under no circumstances should the magnet be energized prior to the installation of the helium gas exhaust pipe and the emergency run-down unit.

Monitoring of the oxygen content of the ambient air, may be obligatory under local regulations.

During refill of liquid helium an amount of helium gas will evaporate in the examination room and will dilute the oxygen in the air. For sites with small examination rooms or low ceilings, it is highly recommended to install an oxygen detector with audible alarm, and a remote sensor on top of the magnet. In case of low oxygen level the engineer will be warned. An oxygen detector with audible alarm will be useful as an additional warning instrument in case of an immediate magnetic field shutdown (quench) or failure of the venting system.

NOTICE

Install extra control measures for the patient ventilation system to prevent that the patient is exposed to helium transported by the ventilation system.

The patient ventilation system shall have its inlet opening at a safe place (i.e. at low level in the examination room or directly connected to the air conditioning of the examination room) or be connected to a quench detector, so that the patient ventilation system can be automatically controlled when a quench occurs preventing helium to be transported to the patient inside the scanner.

Liquid cryogen and cryogenic gases

Philips

6 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 m³/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).

System	
Patient Support Safe working Load	250 kg
Patient Support Safe working Load with Vertical Motion	250 kg
Controls on Gantry	Located left and right at the front of the magnet.
Coil Connections	Integrated in the patient table.
Horizontal Drive	Gantry control or console operation. Automatic movement of slices to isocentre. MobiTrak/MobiFlex option provides automated multi-station imaging.
Tabletop Travel	275 cm
Tabletop Acceleration	316 mm/s ²
Tabletop Speed	325 mm/sec Maximum
Tabletop Accuracy	±0.50 mm
Patient Positioning	Laser line marker. Table travel to isocenter.
Vertical Drive	Electrically powered.
Patient Support Height, working position	89 cm
Patient Support Height, minimum position	59 cm
Docking Patient Trolley	Optional fixed height and variable height versions.

Optional FlexTrak, fixed height version

Safe working Load	250 kg
Height, trolley with tabletop	79 cm

Optional HA FlexTrak, height adjustable

Safe working Load	250 kg
With Vertical Motion	250 kg
Vertical movement	Manual, foot operated lever.
Height, trolley with tabletop, working position	79 cm
Height, trolley with tabletop, minimum position	56 cm

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.

7 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. B_1 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**.

Compatibility protocols for third party equipment
validation

3000 113 87602/782 * 2024-10

Philips

8 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.

NOTICE

Applicable frequency bands of reception and of transmission are:

System Field Strength	Frequency (MHz) (see note)	Bandwidth (kHz)	Amplifier Peak Power (kW)	Comment
3.0T MR 7700	127.73	1100	2*18	1H
3.0T	32.12	280	4	Multi Nuclei option (13C)
3.0T	33.79	280	4	Multi Nuclei option (23Na)
3.0T	35.3	290	4	Multi Nuclei option (129Xe)
3.0T	51.7	430	4	Multi Nuclei option (31P)
3.0T	120.2	1050	4	Multi Nuclei option (19F)

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 dB μ V/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

Emissions test	Compliance	Electromagnetic environment -guidance
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.

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: <ul style="list-style-type: none">• 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	$\pm 2, \pm 4, \pm 6$ kV	$\pm 2, \pm 4, \pm 6, \pm 8$ kV
		Air discharge	$\pm 2, \pm 4, \pm 8$ kV	$\pm 2, \pm 4, \pm 8$ kV, ± 15 kV
		Indirect coupling	$\pm 2, \pm 4, \pm 6$ kV	$\pm 2, \pm 4, \pm 6, \pm 8$ 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 $I > 3$ m; 100 kHz repetition	± 1 kV	± 1 kV
EN/IEC 61000-4-5	Surge	Line to ground	$\pm 0.5; \pm 1; \pm 2$ kV	$\pm 0.5; \pm 1; \pm 2$ kV
		Line to line	$\pm 0.5; \pm 1$ kV	$\pm 0.5; \pm 1$ 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	$(\%U_T; \text{seconds}) = (0; 5)$	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	$\pm 2, \pm 4, \pm 8$ 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

Standard	Phenomenon	Condition	IEC TR60601-4-2:2016
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 _r ;seconds) = (0 ; 5)	N/A

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	$d = 1.2\sqrt{P}$
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].			
<p>[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.</p> <p>[Remark b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> <p>[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.</p>			
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		
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz

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.

	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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

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.

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>

9 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

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

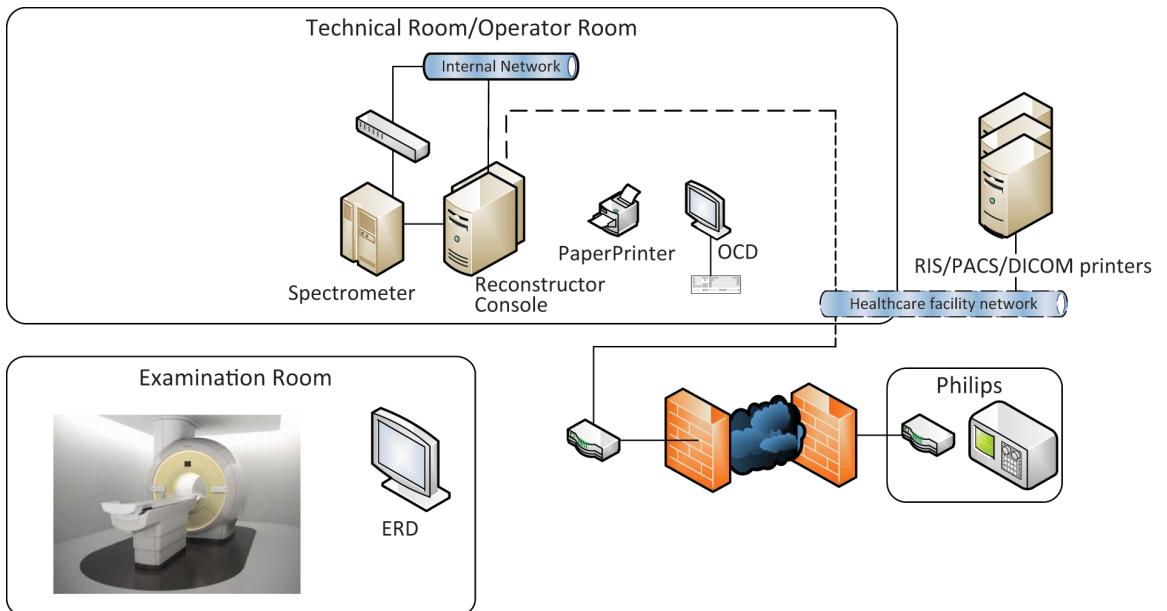
When using addresses in the Private IP address range on the healthcare facility network, the Availability of this medical device is at risk.

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.



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.

Customer use	Philips Service use	Usage	Port no.	Inbound	Outbound	Protocol	Optional use	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 389:TCP/UDP	•	•	DNS	•	
•	•	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 389:TCP/UDP	•	•	DNS	•	
•	•	Web Browser	80,443:TCP		•	HTTP(S)		
•	•	Philips Remote Service Agent	443:TCP		•	HTTPS		

Tab. 3: Socket port usage and associated protocols

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.

- 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 be 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.

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

10 Important messages and indications, Symbols

10.1 Important messages and indications

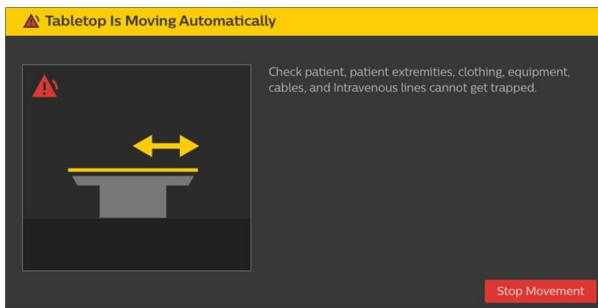
Important messages and indications are displayed in the language of the user interface. The table below displays the English messages and their translation.

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

Nurse Call Check	
English	Your language
 Nurse Call Check	 Nurse Call Check
The system detected that the Nurse Call was not tested in this examination.	The system detected that the Nurse Call was not tested in this examination.
I acknowledge that I am responsible for patient observation.	I acknowledge that I am responsible for patient observation.
This message pops up when the first scan of an examination is started and the Nurse Call was not tested during the examination.	
<ul style="list-style-type: none"> To acknowledge your responsibility for patient observation, click Confirm and Start. To close the pop-window without confirmation, click Cancel. 	
There is no default value. You are requested to test the nurse call to prevent the pop-up message, or to acknowledge the responsibility for patient observation without Nurse Call check.	

Tabletop is Moving Automatically

English	Your language
 Tabletop is Moving Automatically	 Tabletop is Moving Automatically
Check patient, patient extremities, clothing, equipment, cables and Intravenous lines cannot get trapped.	Check patient, patient extremities, clothing, equipment, cables and Intravenous lines cannot get trapped.
The message pops up when tabletop movement is requested.	
<ul style="list-style-type: none"> Stop movement immediately stops the tabletop movement. Stop movement is the default value. 	



Enable Remote Desktop Session

English

⚠️ 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.

This message pops up when a Remote Desktop session is requested.

- To enable the Remote Desktop session, click **I Agree**.
- To not allow the Remote Desktop session, click **Exit Session**.

Exit Session is the default value.

Your language

⚠️ 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.

Remote Desktop session enabled

This button pops up when a Remote Desktop session is enabled.

- To terminate the Remote Desktop session, click the red button.

Helium overpressure too low**English****Scanner**

Helium overpressure too low. Please contact Philips service immediately!

If this condition is not solved within x days from now scanning will be disabled. Press **Proceed anyway** to continue the examination.

This message pops up when an insufficient helium overpressure is detected. This error must be resolved within two days. From the third day onwards, the scanner is disabled.

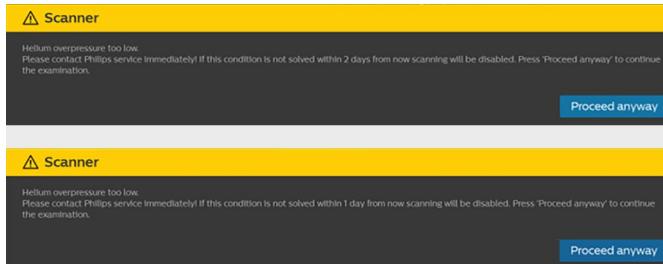
- To continue the examination, click **Proceed anyway**.

Proceed anyway is the default value.

Your language**Scanner**

Helium overpressure too low. Please contact Philips service immediately!

If this condition is not solved within x days from now scanning will be disabled. Press **Proceed anyway** to continue the examination.

**Planscan: Position of the tabletop changed****English****Planscan**

Position of the tabletop changed since acquisition of survey. Please select recent survey.

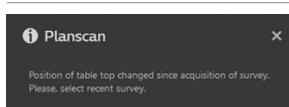
Your language**Planscan**

Position of the tabletop changed since acquisition of survey. Please select recent survey.

This message pops up when the movement of the tabletop invalidates the current survey.

- To set the scan back to **Ready to run**, click **Close**. This action allows you to adjust parameters.

Close is the default value.



Unsupported configuration**English****Configuration Check Failed**

This computer may be running an unsupported configuration! Either there is PMS approved patch software installed, or there is non PMS approved software installed.

If there is PMS approved patch software installed press **CANCEL** to dismiss this popup.

Else press **OK** to display the version discrepancy report and contact your local Philips Medical Systems service center.

This message pops up when unsupported software is detected.

- To display the version discrepancy report, click **OK**.
- To dismiss the pop-up, click **Cancel**.

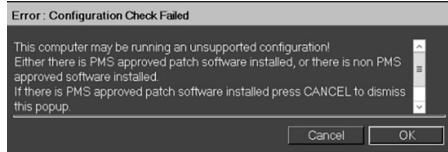
Cancel is the default value.

Your language**Configuration Check Failed**

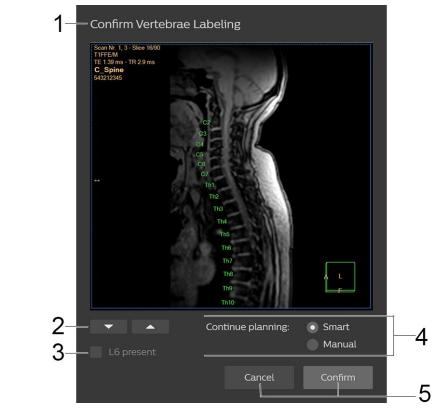
This computer may be running an unsupported configuration! Either there is PMS approved patch software installed, or there is non PMS approved software installed.

If there is PMS approved patch software installed press **CANCEL** to dismiss this popup.

Else press **OK** to display the version discrepancy report and contact your local Philips Medical Systems service center.

**SmartExam Spine**

An explicit confirmation of the planning results by the operator is required.

**1. Window Confirm Vertebrae Labeling****2. Arrows to fine-tune the vertebrae labeling****– Smart**

To enable Smart planning.

– Manual

To enable Manual planning.

3. Cancel to quit without changes, or Confirm to confirm the current vertebrae labeling.**Remote Control Permission****English****Your language**

Remote Control Permission**Remote control permission**

You are giving remote control permission to a remote user.

Sharing control allows the remote user to initiate a scan and table movement.

Risk of injury

I confirm that:

- I will stay at the MRI console to monitor the patient.
- I am aware that remote users have access to patient private data.

**Remote control permission**

You are giving remote control permission to a remote user.

Sharing control allows the remote user to initiate a scan and table movement.

Risk of injury

I confirm that:

- I will stay at the MRI console to monitor the patient.
- I am aware that remote users have access to patient private data.

This message pops up when you activate Collaboration Live, and then initiate Remote Desktop Sharing.

- To share the desktop, click **Give Control**. Then click **Agree**.
- To exit without sharing the desktop, click **Deny Control**.

Give Control is the default value.

⚠️ Remote control permission

You are giving remote control permission to a remote user.
Sharing control allows the remote user to initiate scan and table movement.
Risk of Injury
I confirm that
- I will stay at the MRI console to monitor the patient.
- I am aware that the remote users have access to patient private data

Give Control

Deny Control

⚠️ Remote desktop sharing

Screen sharing allows the remote user to view private patient (ePHI) data.

Agree

Cancel

Implants

English

Your language

Implants

Magnetic and electromagnetic fields exert strong forces on implants.



Risk of serious patient injury or death

Do not allow persons fitted with implants to enter the Controlled Access Area unless they have specific approval to do so.

MR scanning or the MRI system itself can:

- Cause the dislodgement of metallic implants through strong attraction or torque.
- Interfere with the operation of electronically, magnetically or mechanically activated implants.
- Cause excessive (local) heating of implants.

These effects can cause tissue damage, loss of physiologic function, serious injury or death. Presence of implants may also cause significant MR image artifacts due to magnetic field distortion. All these effects may also apply to patients and personnel who rely on electrically, magnetically or mechanically activated external life support systems.

It is the responsibility of the implant manufacturer to declare an implant MR Safe, MR Conditional or MR Unsafe. For MR Conditional devices, the general contraindications regarding implants, may not be applicable in their entirety.

[More about MR Safe and MR Conditional Implants.](#)

Magnetic and electromagnetic fields exert strong forces on implants.



Risk of serious patient injury or death

Do not allow persons fitted with implants to enter the Controlled Access Area unless they have specific approval to do so.

MR scanning or the MRI system itself can:

- Cause the dislodgement of metallic implants through strong attraction or torque.
- Interfere with the operation of electronically, magnetically or mechanically activated implants.
- Cause excessive (local) heating of implants.

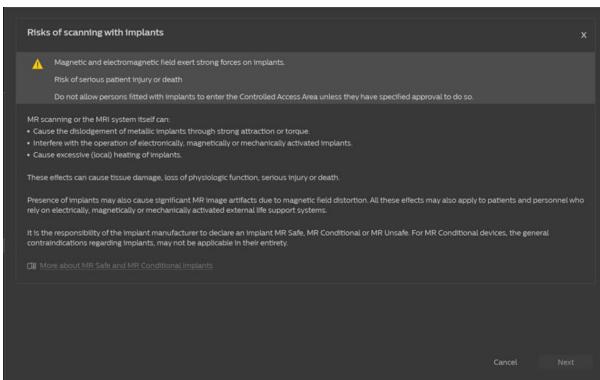
These effects can cause tissue damage, loss of physiologic function, serious injury or death. Presence of implants may also cause significant MR image artifacts due to magnetic field distortion. All these effects may also apply to patients and personnel who rely on electrically, magnetically or mechanically activated external life support systems.

It is the responsibility of the implant manufacturer to declare an implant MR Safe, MR Conditional or MR Unsafe. For MR Conditional devices, the general contraindications regarding implants, may not be applicable in their entirety.

[More about MR Safe and MR Conditional Implants.](#)

This message pops up when you select **What are the risks of scanning patients with implants?** in the MR Label screen of the implant guidance.

- To display more information about implants, click **More about MR Safe and MR Conditional Implants.**



More about MR Safe and MR Conditional Implants

English

More about MR Safe and MR Conditional Implants

Implantable medical devices labeled MR Safe or MR Conditional have been cleared, approved and/or licensed by the Competent Governmental Authorities and/or labeled by the manufacturer. For such devices, the general contraindications may not be applicable in its entirety.

It is the responsibility of the implant manufacturer to declare an implant MR Safe or MR Conditional and to define the conditions (restrictions) that allow for safe MR scanning.

It is the obligation of the MR operator to be aware of these conditions and to assure that they are strictly adhered to.

Refer to the user documentation of the implant or contact the implant manufacturer to obtain these specific conditions. The system provides options to restrict whole body and head SAR and dB/dt, and to review other system characteristics, as specified in the Technical Description.

Philips does not assume responsibility or liability for the operation of their MRI system with any implantable medical device.

This message pops up when you select **What are the risks of scanning patients with implants?** in the MR Label screen of the implant guidance, and then **More about MR Safe and MR Conditional Implants**.

More about MR Safe and MR Conditional Implants

Implantable medical devices labeled MR Safe or MR Conditional have been cleared, approved and/or licensed by the Competent Governmental Authorities and/or labeled by the manufacturer. For such devices, the general contraindications may not be applicable in its entirety.

It is the responsibility of the implant manufacturer to declare an implant MR Safe or MR Conditional and to define the conditions (restrictions) that allow for safe MR scanning. It is the obligation of the MR operator to be aware of these conditions and to assure that they are strictly adhered to.

Refer to the user documentation of the implant or contact the implant manufacturer to obtain these specific conditions. The system provides options to restrict whole body and head SAR and dB/dt, and to review other system characteristics, as specified in the Technical Description. Philips does not assume responsibility or liability for the operation of their MRI system with any implantable medical device.

Your language

More about MR Safe and MR Conditional Implants

Implantable medical devices labeled MR Safe or MR Conditional have been cleared, approved and/or licensed by the Competent Governmental Authorities and/or labeled by the manufacturer. For such devices, the general contraindications may not be applicable in its entirety.

It is the responsibility of the implant manufacturer to declare an implant MR Safe or MR Conditional and to define the conditions (restrictions) that allow for safe MR scanning.

It is the obligation of the MR operator to be aware of these conditions and to assure that they are strictly adhered to.

Refer to the user documentation of the implant or contact the implant manufacturer to obtain these specific conditions. The system provides options to restrict whole body and head SAR and dB/dt, and to review other system characteristics, as specified in the Technical Description.

Philips does not assume responsibility or liability for the operation of their MRI system with any implantable medical device.

Maximum dB/dt

English

Your language

Maximum dB/dt

The maximum dB/dt on the info page does not take the maximum dB/dt for automatically inserted prescans into account. However, if a maximum dB/dt has been specified in the Implant Conditions menu, all scans, including prescans, will be restricted to the dB/dt value specified.

For more information, refer to the paragraph Gradients in the Technical Description.

This message pops up when you click the **Which conditions are typically provided by the manufacturer of the implant?** link in the **Which MR label does the implant have?** screen in the Implant Conditions menu.

It is the obligation of the MRI operator to be aware of these conditions and to ensure that these conditions are strictly adhered to.

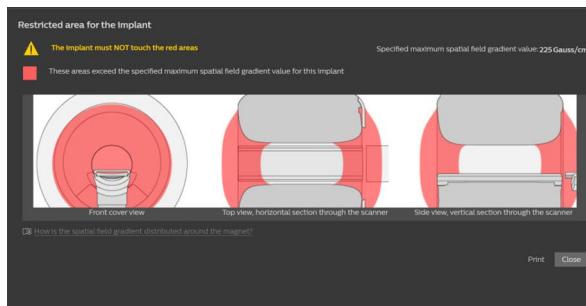
The maximum dB/dt on the info page does not take the maximum dB/dt for automatically inserted prescans into account. However, if a maximum dB/dt has been specified in the Implant Conditions menu, all scans, including prescans, will be restricted to the dB/dt value specified.

For more information, refer to the paragraph 'Gradients' in the Technical Description.

Implant and spatial field gradient**English**

 The implant must NOT touch the red areas These areas exceed the specified maximum spatial field gradient value for this implant.

This message pops up in the Spatial Field Gradient screen of the implant guidance when you enter a maximum spatial field gradient value. It also pops up when you click the **Details...** button.

**Your language**

 The implant must NOT touch the red areas These areas exceed the specified maximum spatial field gradient value for this implant.

Maximum SAR for scanning Pregnant Patients**English****Your language**

Maximum SAR for scanning Pregnant Patients**Maximum SAR for scanning Pregnant Patients**

It is advised to scan in normal operating mode (maximum SAR < 2W/kg).

In first level controlled operating mode, high SAR may cause heating of the fetus. Only enter first level controlled operating mode if the clinical benefit exceeds the potential risks.



Limit to normal operating mode. Maximum SAR 2W/kg (advised).



Allow first level controlled operating mode.

Maximum SAR 4 W/kg.

Medical supervision must be provided while scanning.

**Maximum SAR for scanning Pregnant Patients**

It is advised to scan in normal operating mode (maximum SAR < 2W/kg).

In first level controlled operating mode, high SAR may cause heating of the fetus. Only enter first level controlled operating mode if the clinical benefit exceeds the potential risks.



Limit to normal operating mode. Maximum SAR 2W/kg (advised).



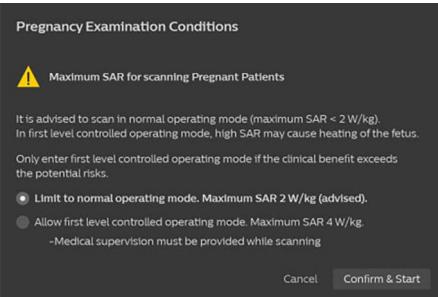
Allow first level controlled operating mode.

Maximum SAR 4 W/kg.

Medical supervision must be provided while scanning.

This message pops up in the New Exam window when you set **Patient gender to female, Pregnancy to Yes, SAR mode to 1st level**.

- To select normal operating mode or first level controlled operating mode, click the corresponding button.

**Inconsistent magnet sensors****English**

Unclear if the magnet is on or off field, because the magnetic field sensor and the magnet discharge status are inconsistent. The system should be considered on field, until proven that it is off field.

Your language

Unclear if the magnet is on or off field, because the magnetic field sensor and the magnet discharge status are inconsistent. The system should be considered on field, until proven that it is off field.

This message pops up at the end of the procedure Corrective Maintenance-Magnet-Magnet Discharge if the magnetic field sensor and the magnet discharge status are inconsistent.

- To remove the message, close the pop-up window.

ERRORS:

- MAGNET WARNING: Unclear if the magnet is on or off field, because the magnetic field sensor and the magnet discharge status are inconsistent. The system should be considered on field, until proven that it is off field.

Patient Position Undefined**English****Your language****Patient Position Undefined****Patient Position Undefined**

Patient position needs to be defined. Reuse the current position, or use the light visor.

Patient position needs to be defined. Reuse the current position, or use the light visor.

This message pops up when the patient position is unknown to the system.

- To continue the examination, select **Reuse Current Position**.

Reuse Current Position is the default value.

**Helium overpressure is too low for 3 days or more****English****Your language****Scanner****Scanner**

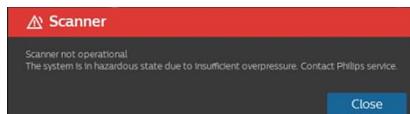
Scanner not operational. The system is in hazardous state due to insufficient overpressure. Contact Philips service.

Scanner not operational. The system is in hazardous state due to insufficient overpressure. Contact Philips service.

This message pops up when the Helium overpressure is too low for 3 days or more.

- To close the pop-up, click **Close** .

Close is the default value.

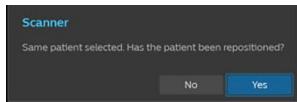
**English****Your language****Scanner****Scanner**

Same patient selected. Has the patient been repositioned?

Same patient selected. Has the patient been repositioned?

This message pops up when you create a new examination selecting the same patient.

- To reset the patient reference point, click **Yes**. Then use the light visor to reposition the patient. Re-plan of the patient examination is required.
- Yes** is the default value.
- To continue the examination, click **No**.



Implant responsibility

English

I confirm that:

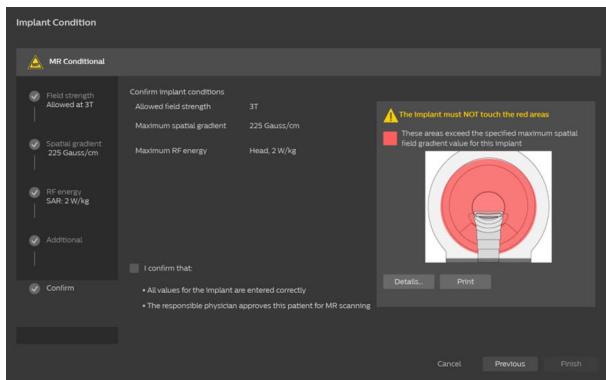
- All values for the implant are entered correctly.
- The responsible physician approves this patient for MR scanning.

Your language

I confirm that:

- All values for the implant are entered correctly.
- The responsible physician approves this patient for MR scanning.

This message pops up in the **Confirm** screen of the implant guidance.



Direct link to the Help page for SAR

English

Help menu page for Specific Absorption Rate (SAR).

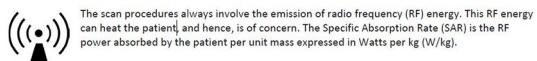
Your language

Help menu page for Specific Absorption Rate (SAR).

This message pops up in the SAR screen of the implant guidance when you select the link **What should I know about SAR, B1rms and patient heating?**

Safety during scanning Safety

Specific Absorption Rate (SAR)



NOTICE

Personnel working inside or very close to the magnet during scanning may experience heating due to RF exposure. Relative SAR levels for occupational exposure can be derived from the spatial distribution provided in the Technical Description. Exposure can be reduced by keeping distance from the magnet or by selecting Normal Operating Mode.

There are different SAR types each with its own limit:

Whole body SAR	the SAR averaged over the total mass of the patient.
Head SAR	the SAR averaged over the mass of the patient's head.
Local torso SAR	the SAR averaged over any 10g of tissue of the patient.
Local extremities SAR	the SAR averaged over any 10g of extremity tissue of the patient.

The system determines the limiting SAR type of a scan (whole body, head, local torso, or local extremity) based on the applied coil, table position, and patient orientation. This SAR type is the first to reach its maximum allowed value and thus poses the strongest restriction on the scan.

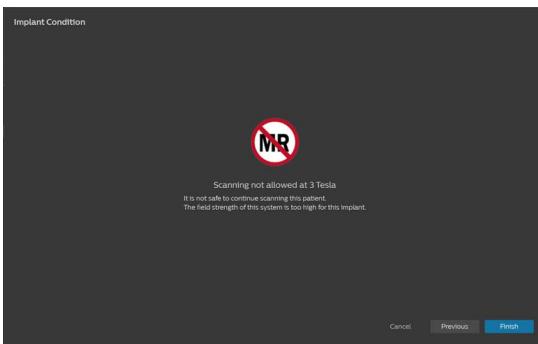
Scanning of implants depending on the field strength

English

Scanning not allowed at XX Tesla.

It is not safe to continue scanning this patient. The field strength of this system is too high for the implant.

This message pops up in the Field Strength screen of the implant guidance. XX indicates the magnetic field strength of the system.



Your language

Scanning not allowed at XX Tesla.

It is not safe to continue scanning this patient. The field strength of this system is too high for the implant.

MR Safe implant

English

MR MR Safe implant.

No examination conditions will be set.

I confirm that:

- The implant is MR Safe.
- The responsible physician approves this patient for MR scanning.

Your language

MR MR Safe implant.

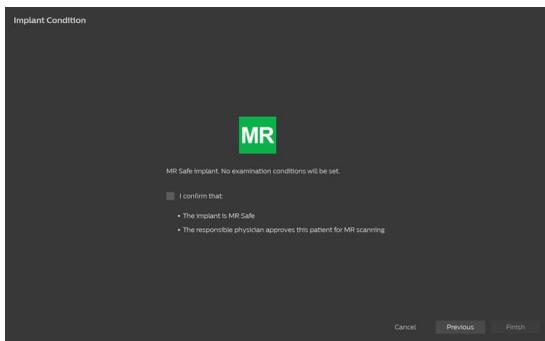
No examination conditions will be set.

I confirm that:

- The implant is MR Safe.
- The responsible physician approves this patient for MR scanning.

MR Safe implant

This message pops up in the screen of the implant guidance when you selected MR Safe.

**Multiple VCG modules****English****Wireless Physiology**

Multiple VCG modules detected. Only one must be powered on.

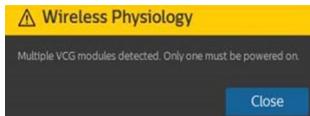
Your language**Wireless Physiology**

Multiple VCG modules detected. Only one must be powered on.

This message pops up when multiple VCG modules are detected.

- To close the pop-up window, click **Close**.

Close is the default value.

**Multiple VCG modules****English****Wireless Physiology**

Multiple PPU modules detected. Only one must be powered on.

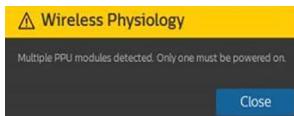
Your language**Wireless Physiology**

Multiple PPU modules detected. Only one must be powered on.

This message pops up when multiple PPU modules are detected.

- To close the pop-up window, click **Close**.

Close is the default value.



High Whole Body SAR**English****High Whole Body SAR**

The next scan requires 1st level controlled operating mode for whole body SAR. In this mode, the SAR value is between 2 and 4 W/kg. Medical supervision is required to monitor body temperature rise.

If you observe that the patient is feeling warm, lower the SAR mode to Normal. Do you allow high whole body SAR for the current patient?



Read about 1st level controlled operating mode for SAR.

Your language**High Whole Body SAR**

The next scan requires 1st level controlled operating mode for whole body SAR. In this mode, the SAR value is between 2 and 4 W/kg. Medical supervision is required to monitor body temperature rise.

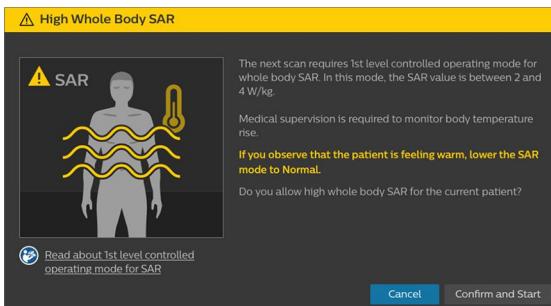
If you observe that the patient is feeling warm, lower the SAR mode to Normal. Do you allow high whole body SAR for the current patient?



Read about 1st level controlled operating mode for SAR.

This message pops up upon **Start Scan** when 1st level controlled operating mode for SAR and high SAR are not confirmed for the current examination.

- **Confirm and Start** immediately starts the scan.
All scans for the current patient which require medical supervision due to high SAR are allowed.
- **Cancel** sets the scan back to **ready to run** and allows you to adjust parameters.
Cancel is the default value.

**High Whole Body SAR (applies for Italy)****English****Your language**

High Whole Body SAR (applies for Italy)**High Whole Body SAR**

The next scan requires 1st level controlled operating mode for whole body SAR. In this mode, the SAR value is between 2 and 4 W/kg. The SAR level exceeds the limits set by Italian regulation (D.M 3-8-93).

Medical supervision is required to monitor body temperature rise.

If you observe that the patient is feeling warm, lower the SAR mode to Normal. Do you allow high whole body SAR for the current patient?



[Read about 1st level controlled operating mode for SAR.](#)

**High Whole Body SAR**

The next scan requires 1st level controlled operating mode for whole body SAR. In this mode, the SAR value is between 2 and 4 W/kg. The SAR level exceeds the limits set by Italian regulation (D.M 3-8-93).

Medical supervision is required to monitor body temperature rise.

If you observe that the patient is feeling warm, lower the SAR mode to Normal. Do you allow high whole body SAR for the current patient?



[Read about 1st level controlled operating mode for SAR.](#)

This message pops up upon **Start Scan** when 1st level controlled operating mode for SAR and high SAR are not confirmed for the current examination.

- **Confirm and Start** immediately starts the scan.

All scans for the current patient which require medical supervision due to high SAR are allowed.

- **Cancel** sets the scan back to **ready to run** and allows you to adjust parameters.

Cancel is the default value.

⚠ High Whole Body SAR

The next scan requires 1st level controlled operating mode for whole body SAR. In this mode, the SAR value is between 2 and 4 W/kg. The SAR level exceeds the limits set by Italian regulation (D.M 3-8-93).

Medical supervision is required to monitor body temperature rise.

If you observe that the patient is feeling warm, lower the SAR mode to Normal.

Do you allow high whole body SAR for the current patient?

[Read about 1st level controlled operating mode for SAR](#)

Cancel

Confirm and Start

High Local SAR

English

Your language

High Local SAR**High Local SAR**

The next scan requires 1st level controlled operating mode for local SAR. In this mode, the SAR value is between 10 and 20 W/kg. Medical supervision is required to monitor local body temperature rise.

If you observe that the patient experiences local warming, lower the SAR mode to Normal. Do you allow high local SAR for the current patient?



Read about 1st level controlled operating mode for SAR.

**High Local SAR**

The next scan requires 1st level controlled operating mode for local SAR. In this mode, the SAR value is between 10 and 20 W/kg. Medical supervision is required to monitor local body temperature rise.

If you observe that the patient experiences local warming, lower the SAR mode to Normal. Do you allow high local SAR for the current patient?



Read about 1st level controlled operating mode for SAR.

This message pops up upon **Start Scan** when 1st level controlled operating mode for SAR and local high SAR are not confirmed for the current examination.

- **Confirm and Start** immediately starts the scan.
All scans for the current patient which require medical supervision due to high SAR are allowed.
- **Cancel** sets the scan back to **ready to run** and allows you to adjust parameters.
Cancel is the default value.

**High Local SAR (applies for Italy)****English****Your language**

High Local SAR (applies for Italy)**High Local SAR**

The next scan requires 1st level controlled operating mode for local SAR. In this mode, the SAR value is between 10 and 20 W/kg. The SAR level exceeds the limits set by Italian regulation (D.M 3-8-93).

Medical supervision is required to monitor local body temperature rise.

If you observe that the patient experiences local warming, lower the SAR mode to Normal. Do you allow high local SAR for the current patient?



Read about 1st level controlled operating mode for SAR.

This message pops up upon **Start Scan** when 1st level controlled operating mode for SAR and local high SAR are not confirmed for the current examination.

- Confirm and Start** immediately starts the scan.

All scans for the current patient which require medical supervision due to high SAR are allowed.

- Cancel** sets the scan back to **ready to run** and allows you to adjust parameters.

Cancel is the default value.

**High Local SAR**

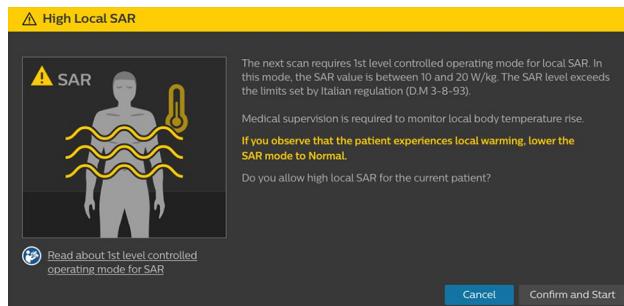
The next scan requires 1st level controlled operating mode for local SAR. In this mode, the SAR value is between 10 and 20 W/kg. The SAR level exceeds the limits set by Italian regulation (D.M 3-8-93).

Medical supervision is required to monitor local body temperature rise.

If you observe that the patient experiences local warming, lower the SAR mode to Normal. Do you allow high local SAR for the current patient?



Read about 1st level controlled operating mode for SAR.

**Automatic Tabletop Movement**

English

Your language

Automatic Tabletop Movement**Automatic Tabletop Movement**

The tabletop will move. Check that the patient, patient extremities, clothing, equipment, cables and intravenous lines cannot get trapped.

Verify that nothing can get trapped during the tabletop movement.

Allow the tabletop to move automatically for

- this scan?
- all scans?



[Read about tabletop movement.](#)

**Automatic Tabletop Movement**

The tabletop will move. Check that the patient, patient extremities, clothing, equipment, cables and intravenous lines cannot get trapped.

Verify that nothing can get trapped during the tabletop movement.

Allow the tabletop to move automatically for

- this scan?
- all scans?



[Read about tabletop movement.](#)

This message pops up when the scan requires tabletop movement after **Start scan**.

- To not initiate tabletop movement, click **Cancel**.

The scan will be aborted if it the scan status is dispatched. The scan will be cancelled if the scan status is **ready to run**.

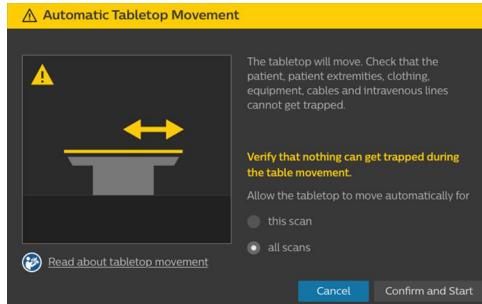
Cancel is the default value.

- To start tabletop movement and then start the scan, click **Confirm and Start**.
 - If you select for **this scan**, tabletop movement takes place only for the current scan.

The message pops up again for the next scan that requires tabletop movement.

- If you select for **all scans**, tabletop movement takes place for all scans where it is required or recommended.

Allow for all scans is the default value.

**Low Bore Ventilation**

English

Your language

Low Bore Ventilation

Low Bore Ventilation

The bore ventilation is below the recommended level and may cause patient discomfort. Increase the bore ventilation level.

Level 3 or higher is recommended.



[Read about bore ventilation](#)

Low Bore Ventilation

The bore ventilation is below the recommended level and may cause patient discomfort. Increase the bore ventilation level.

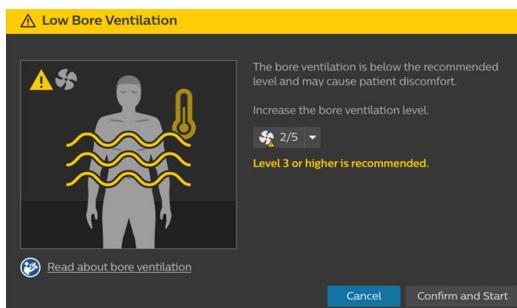
Level 3 or higher is recommended.



[Read about bore ventilation](#)

This message pops up when the bore ventilation is below the recommended level after **Start scan**.

- **Confirm and Start** immediately starts the scan.
 - **Cancel** sets the scan back to **ready to run** and allows you to adjust parameters.
- Cancel** is the default value.



Fast Tabletop Movement

English



Fast Tabletop Movement

The tabletop will move fast. Check that the patient, patient extremities, clothing, equipment, cables and intravenous lines cannot get trapped.

Verify that nothing can get trapped during the table movement.

Do you allow the tabletop to move fast for this scan?



[Read about tabletop movement.](#)

Your language



Fast Tabletop Movement

The tabletop will move fast. Check that the patient, patient extremities, clothing, equipment, cables and intravenous lines cannot get trapped.

Verify that nothing can get trapped during the table movement.

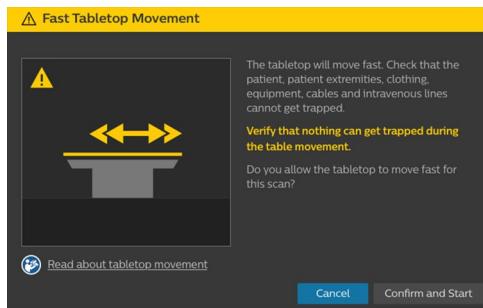
Do you allow the tabletop to move fast for this scan?



[Read about tabletop movement.](#)

This message pops up when the scan requires fast tabletop movement.

- To not initiate tabletop movement, click **Cancel**.
The scan will be aborted if the scan status is dispatched. The scan will be cancelled if the scan status is **ready to run**.
Cancel is the default value.
- To start tabletop movement and then start the scan, click **Confirm and Start**.



High Sound Level For Pediatric Patients

English

High Sound Level For Pediatric Patients

The predicted sound pressure level exceeds the recommended maximum level of 99 dB for pediatric patients. This may result in temporary or permanent loss of hearing.

Verify that the patient or others in the examination room wear appropriate hearing protection.

Do you allow a high sound level for the current patient?



Read about high sound levels.

Your language

High Sound Level For Pediatric Patients

The predicted sound pressure level exceeds the recommended maximum level of 99 dB for pediatric patients. This may result in temporary or permanent loss of hearing.

Verify that the patient or others in the examination room wear appropriate hearing protection.

Do you allow a high sound level for the current patient?



Read about high sound levels.

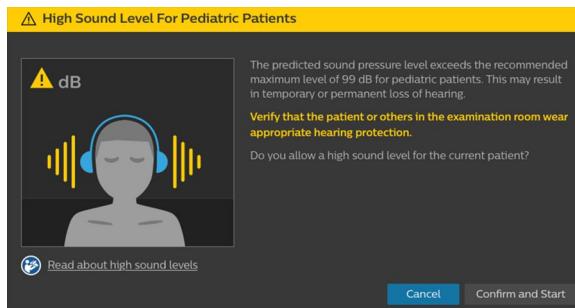
The message pops up

when the predicted sound pressure level of the scan to be started is above the allowed level for pediatric patients (age < 3 years).

- The sound pressure level starts for each patient at 99 dB. It can be increased to higher value via this pop-up.
- **Cancel** sets the scan back to **ready to run** and allows you to adjust the parameters.
- **Confirm and Start** immediately starts the scan.

The allowed limit is set to the new, higher, value.

- **Cancel** is the default value.



High Peripheral Nerve Stimulation

English



High Peripheral Nerve Stimulation

The next scan requires 1st level controlled operating mode for Peripheral Nerve Stimulation (PNS). In this mode the PNS value is above 80%. Medical supervision is required to monitor patient comfort.

If you observe that the patient feels a tingling sensation or superficial twitch, lower the PNS mode to Normal.

Do you allow a high PNS level for the current patient?



Read about 1st level controlled operating mode for PNS.

Your language



High Peripheral Nerve Stimulation

The next scan requires 1st level controlled operating mode for Peripheral Nerve Stimulation (PNS). In this mode the PNS value is above 80%. Medical supervision is required to monitor patient comfort.

If you observe that the patient feels a tingling sensation or superficial twitch, lower the PNS mode to Normal.

Do you allow a high PNS level for the current patient?



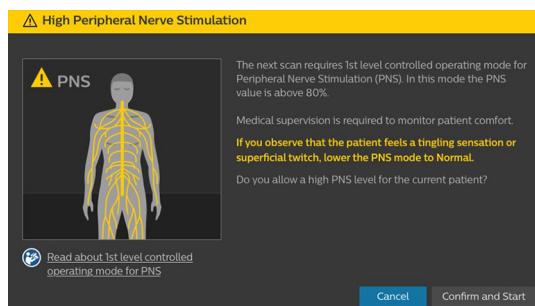
Read about 1st level controlled operating mode for PNS.

The message pops up when the PNS exceeds 80%, and high PNS was not confirmed for the current examination.

- **Cancel** sets the scan back to **ready to run** and allows you to adjust the parameters.
- **Confirm and Start** immediately starts the scan.

All scans for the current patient which require medical supervision due to high PNS are allowed.

- **Cancel** is the default value.



High Total SED

English

Your language

High Total SED**High Total SED**

The performed scans and the remaining scans together exceed the recommended Specific Energy Dose (SED) levels with xx kJ/kg. Patient discomfort due to body temperature rise can be observed at values greater than the recommended SED of 7.0 kJ/kg.

If you observe that the patient is feeling warm, reduce the scan time or the SAR of the remaining scans. Do you allow to exceed the recommended SED for the current patient?



Read about SED.

**High Total SED**

The performed scans and the remaining scans together exceed the recommended Specific Energy Dose (SED) levels with xx kJ/kg. Patient discomfort due to body temperature rise can be observed at values greater than the recommended SED of 7.0 kJ/kg.

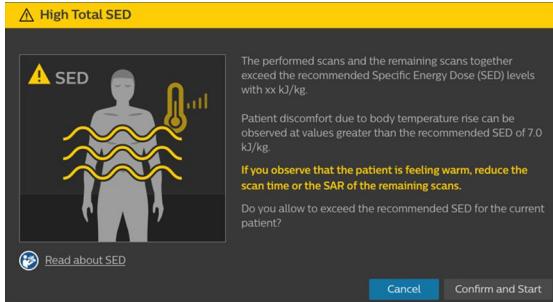
If you observe that the patient is feeling warm, reduce the scan time or the SAR of the remaining scans. Do you allow to exceed the recommended SED for the current patient?



Read about SED.

This message pops up when the total SED for the current patient exceeds 7.0 kJ/kg when the scan is started.

- **Confirm and Start** immediately starts the scan.
 - **Cancel** sets the scan back to **ready to run** and allows you to adjust parameters.
- Cancel** is the default value.

**Recommended Maximum SED Will Be Exceeded**

English

Your language

Recommended Maximum SED Will Be Exceeded**Recommended Maximum SED Will Be Exceeded**

In the next scan and the remainder of the examination the SED exceeds 7.0 kJ/kg, which leads to patient discomfort. Medical supervision is required to monitor the patient temperature rise. Specific Energy Dose (SED) is a comfort measure about the RF energy delivered to the patient. Serious discomfort is reported at values greater than 7.0 kJ/kg.

If you observe that the patient is feeling warm, stop scanning to avoid serious discomfort. Confirm that the clinical benefit exceeds the risk of high SED. Do you allow to exceed the recommended SED for the current patient?



[Read about SED.](#)

**Recommended Maximum SED Will Be Exceeded**

In the next scan and the remainder of the examination the SED exceeds 7.0 kJ/kg, which leads to patient discomfort. Medical supervision is required to monitor the patient temperature rise. Specific Energy Dose (SED) is a comfort measure about the RF energy delivered to the patient. Serious discomfort is reported at values greater than 7.0 kJ/kg.

If you observe that the patient is feeling warm, stop scanning to avoid serious discomfort. Confirm that the clinical benefit exceeds the risk of high SED. Do you allow to exceed the recommended SED for the current patient?



[Read about SED.](#)

This message pops up when the Delivered SED for the current patient exceeds 7.0 kJ/kg when the scan is started.

- To continue scanning, click **Confirm and Continue Scanning**.
- To stop scanning, click **Stop Scanning**.

Stop Scanning is the default value.

**Recommended Maximum SED Will Be Exceeded**

[Read about SED](#)

In the next scan and the remainder of the examination the SED exceeds 7.0 kJ/kg, which leads to patient discomfort.

Medical supervision is required to monitor the patient temperature rise.

Specific Energy Dose (SED) is a comfort measure about the RF energy delivered to the patient. Serious discomfort is reported at values greater than 7.0 kJ/kg.

If you observe that the patient is feeling warm, stop scanning to avoid serious discomfort.

Confirm that the clinical benefit exceeds the risk of high SED.
Do you allow to exceed the recommended SED for the current patient?

[Stop Scanning](#)

[Confirm and Continue Scanning](#)

Phantom Scanning Only

English

Your language

Phantom Scanning Only**Phantom Scanning Only**

The PNS of this scan exceeds the allowed limits on patients. The system enters second level controlled operating mode.

Patient scanning is not allowed with these settings.

I understand the implication of scanning in the second level controlled operating mode.



[Read about 2nd level controlled operating mode for PNS.](#)

**Phantom Scanning Only**

The PNS of this scan exceeds the allowed limits on patients. The system enters second level controlled operating mode.

Patient scanning is not allowed with these settings.

I understand the implication of scanning in the second level controlled operating mode.

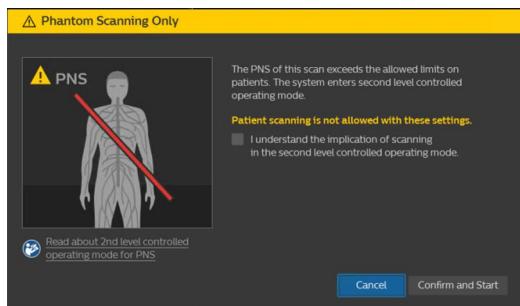


[Read about 2nd level controlled operating mode for PNS.](#)

The message pops up

when the scan exceeds the PNS limits of 1st level controlled mode.

- **Cancel** sets the scan back to **ready to run** and allows you to adjust parameters.
- **Confirm and Start** immediately starts the scan.
- **Cancel** is the default value.

**Smoke detected**

English

Your language

Smoke detected	
Smoke detected - Evacuate the patient	Smoke detected - Evacuate the patient
	
Smoke is detected in the Examination Room. Evacuate the patient from the Examination Room.	
Check Examination Room for a developing fire.	Check Examination Room for a developing fire.
Adhere to established fire emergency procedures, which may include switching off power to the complete system and/or removing of the magnet field by using the Emergency Magnet Off button.	Adhere to established fire emergency procedures, which may include switching off power to the complete system and/or removing of the magnet field by using the Emergency Magnet Off button.
Scanning is disabled until Philips Service has checked the system. Do not attempt to continue scanning.	Scanning is disabled until Philips Service has checked the system. Do not attempt to continue scanning.
Contact Philips Service	Contact Philips Service
Critical temperature	
English	Your language
Critical temperature reached - Evacuate the patient	Critical temperature reached - Evacuate the patient
	
Parts in the Gradient Coil reached critical temperature. Evacuate the patient from the Examination Room.	Parts in the Gradient Coil reached critical temperature. Evacuate the patient from the Examination Room.
Scanning is disabled until Philips service has checked the system. Do not attempt to continue scanning.	Scanning is disabled until Philips service has checked the system. Do not attempt to continue scanning.
Contact Philips Service	Contact Philips Service

10.2 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.

Applied part symbols	Source	Meaning
	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.
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.	Metallic implants prohibited.
	ISO 7010-P014	No access for people with metallic implants.
	ISO 7010-P008	No metallic articles or watches.

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

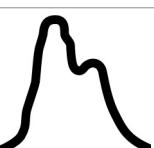
Warning symbols	Source	Meaning
	ISO 7010-W001	General warning sign.
	ISO 7010-W006	Warning: Magnetic field.
	ISO 7010-W005	Warning; Non-ionizing radiation.

Warning symbols	Source	Meaning
	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.
	IEC 60417-5307	Medium priority alarm.
Other symbols	Source	Meaning
	IEC 60417-6193	RF coil, receive only
	IEC 60417-6192	RF coil, transmit and receive

Other symbols	Source	Meaning
	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
	ETL listed	Intertek ETL recognized component
	ISO 7000-1641	Consult Instructions for Use or consult electronic Instructions for Use
	2017/745/EU	Medical Device
	European Commission	CE Marked Device

Other symbols	Source	Meaning
	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	UDI
	2017/745/EU	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
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

Philips Markings	Meaning
	N.A. Magnetic Field Strength
Safety marking plate	Explanation
 <p>1 This 1.5T magnet is ALWAYS ON</p> <p>2 System use and scanning room access for MR Authorized personnel ONLY</p> <p>3 ONLY screened and approved devices allowed in scanning room</p> <p>4 While scanning: RF fields and acoustic noise</p> <p>Safety Marking Plate 12NC 4598 005 25651 www.philips.com/mrisafety</p>	<p>Examination room door safety marking plate.</p> <p>The individual symbols are explained in other parts of this section.</p> <p>Text on the safety marking plate:</p> <ol style="list-style-type: none"> 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

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>

www.philips.com/healthcare



Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands



© 2024 Koninklijke Philips N.V.

All rights reserved. Reproduction or transmission in whole or in part, in any form or by any means, electronic, mechanical or otherwise, is prohibited without the prior written consent of the copyright owner.

Printed in The Netherlands
3000 113 87602/ 782 * 2024-10 - en-US

