Ingenia

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1 Introduction

About these Instructions for Use

These Instructions for Use are intended to assist users and operators in the safe and effective operation of your Philips Ingenia MRI system. The 'user' is considered to be the body with authority over the system; 'operators' are those persons who actually handle the system.

Before attempting to operate the system, you must read, note and strictly observe all DANGER notices and safety markings on the systems.

Before attempting to operate the system, you must read these Instructions for Use thoroughly, paying particular attention to all WARNINGS, Cautions and Notes incorporated in it. You must pay special attention to all the information given and procedures described in the SAFETY section.

⚠ **WARNING**

WARNINGS are directions which if not followed could cause fatal or serious injury to an operator, patient or any other person, or could lead to a misdiagnosis.

⚠ **CAUTION**

Cautions are directions which if not followed could cause damage to the system described in these Instructions for Use and/or any other equipment or goods, and/or cause environmental pollution.

NOTICE

Notices are intended to highlight unusual points as an aid to an operator.

This manual may contain descriptions regarding the features and functionalities that are not implemented on the current equipment shipped for Japan and/or the product(s) that is/are not currently sold in Japan due to limitations and restrictions under the applicable local laws and regulations in Japan.

Contact your local Philips representative for an overview of available options, accessories and other supporting materials.

Volumes of these Instructions for Use

These Instructions for Use consist of three volumes:

1. Your MRI System

Volume 1 of these Instructions for Use contains the introduction to your MRI system including information about e.g. intended use, general MR safety, maintenance and product disposal.

2. Operation in the Magnet Room

Volume 2 of these Instructions for Use contains information on how to operate the system in the magnet room, e. g. patient positioning in the system.

3. Operation at the MR console

Volume 3 of these Instructions for Use contains information on how to operate the MR console, e.g. scanning of examinations, viewing and postprocessing of MR data.

Help System

On the MR system you can also access a Help system. This Help system gives you basic and advanced scanning information. The Technical Description describing the magnet, gradient and RF field characteristics can also be found in the Help system. A summary of the relevant information is available as an About function at the same location of the UI.

The MR system software includes a context sensitive Help functionality. This functionality will lead you directly to the related topic of the Help system.

Other Instructions for Use

Certain other pieces of equipment may be used with the MR system, and each may have their Instructions for Use.
On the MR system you can also access a Help system. This Help system gives you basic and advanced scanning information.
The MR system software includes a context sensitive Help functionality. This functionality will lead you directly to the related topic of the Help system.

MR-RT and MR-OR systems

When the device is used in combination with Philips MR-RT oncology configuration, refer to Ingenia MR-RT Instructions for Use for additional information.
When the device is used in combination with Philips MR-OR solution, refer to the Ingenia MR-OR Instructions for Use for additional information.

Technical Description

Apart from the Instructions for Use, Philips also produces a Technical Description. It provides additional data essential for safe operation and measures or conditions necessary for installing the MR system. The Technical Description can be found in the user documentation section of your system and on the user documentation DVD.

Addendum

With these Instructions for Use a separate addendum may be available. This addendum contains latest information about your system, which is not included in these Instructions for Use. Therefore it is of great importance to read and familiarize yourself with the content of this addendum.

About the system

General

Philips Ingenia Release 5 systems are Philips' digital broadband Magnetic Resonance Imaging systems.

Principle of operation

The operation of Magnetic Resonance Imaging systems 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 a radio 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.

Intended use

The Philips Ingenia Magnetic Resonance Medical Electrical Systems indicated for use as a diagnostic device.
The systems can produce cross-sectional images, spectroscopic images and/or spectra in any orientation of the internal structure of the head, body or extremities.

Magnetic Resonance images represent the spatial distribution of protons or other nuclei with spin. Image appearance is determined by many different physical properties of the tissue and the anatomy, and the MR scan technique applied. The image acquisition process can be synchronized with the patient's breathing or cardiac cycle. The systems can use combinations of images to produce physical parameters, and related derived images.
Images, spectra, and measurements of physical parameters, when interpreted by a trained physician, provide information that may assist the diagnosis and therapy planning. The accuracy of determined physical parameters depends on system and scan parameters, and must be controlled and validated by the clinical user. For some studies the use of contrast agents can be essential. Their application is subject to local medico-legal regulations and to their appropriateness to assist the diagnosis and therapy planning as judged by a trained physician.

In addition the Philips MR systems provide imaging capabilities, such as MR fluoroscopy, to guide and evaluate interventional and minimally invasive procedures in the head, body and extremities. MR Interventional procedures, performed inside or adjacent to the Philips MR system, must be performed with MR Conditional or MR Safe instrumentation as selected and eval-

uated by the clinical user for use with the specific MR system configuration in the hospital. The appropriateness and use of information from a Philips MR system for a specific interventional procedure and specific MR system configuration must be validated by the clinical user.

The Instructions for Use of any applied equipment, other than the MR scanner, shall be considered as integral part of the safety and operational requirements, beyond those described in the Instruction for Use of the Philips MR system.

During an MR examination energy is transferred to the patient in the form of Radio Frequency waves, switching magnetic fields and acoustic noise. The energy levels as well as the level of the static magnetic field are controlled following international safety standards. For a static magnetic field at values over 2T, patients and operators may experience effects such as dizziness, vertigo and a metallic taste in the mouth.

Use and operation of this system is subject to the law in the jurisdiction(s) in which the system is being used. Both users and operators must only use and operate the system in such ways as do not conflict with applicable laws or regulations which have the force of law. Both users and operators must be trained appropriately and have taken notice especially of the safety paragraphs in these Instructions for Use.

NOTICE

In the United States, Federal law restricts this device to sale by or on the order of a physician.

Compatibility

The system described in these Instructions for Use should not be used in combination with other equipment or components unless such other equipment or components are expressly recognized as MR safe or MR conditional with the system by Philips Healthcare.

Changes and/or additions to the system should only be carried out by Philips Healthcare or by third parties expressly authorized by Philips Healthcare to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.

Changes and/or additions to the system that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Philips Healthcare warranty being voided. As with all complex technical systems, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the system and of personal injury.

Specific technical information needed to enable testing of the proper operation of peripheral equipment is described in the Technical Description.

Philips Healthcare

Compliance

Philips Ingenia Release 5 systems comply with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips Healthcare representative.

In particular, the MR system is designed in compliance with IEC60601-2-33 (Basic Safety and Essential Performance of MR Systems), which includes IEC60601-1 (Basic Safety and Essential Performance of Medical Electrical Equipment and Systems) and its collaterals.

IEC-60601-2-33 is the MR Safety standard published by the International Electrotechnical Commission.

Philips Ingenia Release 5 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.

Training

Users of the system must have received adequate training on its safe and effective use before attempting to operate the system described in these Instructions for Use. Training requirements for this type of device will vary from country to country. Users have to make sure that operators receive adequate training in accordance with local laws or regulations which have the force of law.

If you require further information about training in the use of this system, please contact your local Philips Healthcare representative. Alternatively contact the manufacturer.

Philips provides application training for safe use of general system functions, and for dedicated application packages.

Installation, Maintenance and Repair

Installation and Repair Instructions

Installation and repair instructions for the system described is supplied by Philips Healthcare in separate documentation. Installation and repair must be performed by appropriately trained personnel.

Installation, maintenance and repair instructions for the system described are supplied by Philips Healthcare in separate documentation.
Installation, maintenance and repair must be performed by appropriately trained personnel.
The user is responsible to (at least weekly) check the integrity of system and coil covers, coil cables, and accessories. Contact Philips Healthcare for information on the system maintenance program.

Philips Healthcare

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

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

WARNING

The MR 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.

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.

The following (electrical component containing or weight bearing) parts of the system are considered suitable for direct contact with the patient in normal use conditions, i.e. are considered Applied Parts per IEC60601-1:

- Tabletops.
- VCG sensors and module.
- PPU sensors and module.
- All cord-connected RF coils.

2 Safety

Philips Healthcare products are all designed to meet stringent safety standards.

Safe operation of the MR equipment, as installed and maintained according to Philips' instructions, requires adherence to all warnings in this IFU. When adhered to, the residual safety risk of the use of Philips MR equipment is evaluated by the manufacturer to be acceptable.

It is vital:

- that you read, note, and strictly observe all DANGER notices and safety markings on the system.
- that you follow strictly all safety directions under the heading SAFETY and all WARNINGS and Cautions throughout this manual, to help ensure the safety of both patients and operators.

NOTICE

This Safety chapter covers general Safety warnings.

Specific warnings for specialized workflows or accessories can be found in other chapters and volumes of these Instructions for Use

In particular, you must read, understand and know the chapter "Emergency procedures" on page 48 before attempting to use the system for any examination.

Definitions

IEC operating modes

Three operating modes are defined by IEC 60601-2-33 to which this manual refers. Therefore they are briefly explained below.

Operating mode	Explanation
Normal	In the normal operating mode no physiological stress factors are to be expected. It is recommended that all patients receive routine patient observation.
First level controlled	In the first level controlled operating mode some conditions may cause physiological stress to patients. Particular caution must be taken for patients at risk by adding medical supervision in addition to routine patient observation.
Second level controlled	The second level controlled operating mode can not be entered on the system.

Tab. 1: Operating modes

The scan protocol indirectly determines the operating mode.

The levels of exposure for the Normal Operating Mode and the First Level Controlled Operating Mode are specified in IEC 60601-2-33 and are based on current scientific literature related to safety.

NOTICE

The decision to operate the system in first level controlled operating mode, and the possible need for physiological monitoring of patients, shall be a medical judgment as to the patient's benefit versus potential risk. Supervision of the medical condition of patients, especially those at risk as identified in chapter "Specific Absorption Rate (SAR)" on page 25 and chapter "Contra-indications and MR Conditional implants" on page 58, is subject to procedures established in the hospital.

NOTICE

The system will alert the operator when it is about to operate in the first level controlled mode. The operator will be required to deliberately accept this mode of system operation and will be instructed to implement medical supervision. Upon acknowledgment, the system will provide feedback at any time whether the actual operating conditions are in the first level controlled mode.

Medical Supervision

In the IEC 60601-2-33 standard Medical Supervision is defined as:

MEDICAL SUPERVISION requires a positive assessment by a qualified medical practitioner of the RISK versus benefit for a particular scan, or a decision by a qualified surrogate of the practitioner that the PATIENT satisfies a set of objective criteria, formulated by a qualified medical practitioner, for the parameters of the scan and the condition of the PATIENT. MEDICAL SUPERVISION may entail physiological monitoring of the PATIENT by means of devices designed to measure or assess various physiological states (e.g. heart rate, ECG trace, blood pressure, pulse oximetry; but see cautions in reference auxiliary devices MR Conditional requirement.

General safety directions

Safety awareness

WARNING

Do not use the system for any application until you have read, understood and know all the safety information, safety procedures and emergency procedures contained in this SAFETY chapter.

Operation of the system without a proper awareness of how to use it safely could lead to fatal or serious personal injury and to clinical misdiagnoses.

WARNING

When a patient is supported by a ventilator or under anaesthesia, any error condition detected by the auxiliary device shall immediately be followed by stopping the MR scan, and moving the patient outside the MR system until the error condition is removed.

NOTICE

In some countries legislation may exist covering occupational limits for exposure to EMF (Electro Magnetic Fields).
These regulations may be stricter than those adopted by the IEC (International Electrical Committee) and used to design the MR systems.

Refer to the Technical Description for applicable EMF exposure values in and around the MR system.

Adequate Training and Screening of Personnel

WARNING

A safety officer must be appointed for ensuring that proper procedures are in effect, enforced, and updated to ensure safety in the MR environment.

The safety officer shall be responsible for training and authorization of staff.

⚠ **WARNING**

Do not use the system for any application until you have received adequate and proper training in its safe and effective operation.

Training is needed for physicians and operators to operate the MR system safely and effectively.

Training shall include emergency procedures related to emergency medical procedures, access to the controlled access area, the handling of emergency field shut down unit, procedures in case of fire and the emergency actions in the event of a quench.

⚠ **WARNING**

Do not use the system if you are unsure of your ability to operate this system safely and effectively.

Operation of this system without proper and adequate training could lead to fatal or serious personal injury and to clinical misdiagnoses.

For information about training, please refer to chapter "Training" on page 11.

NOTICE

All personnel that need to enter the MR examination room must be screened and instructed concerning the risk factors associated with working in the MR environment. Specific risk factors include magnetic materials, pacemakers, pregnancy and sensitivity to movement in high magnetic fields.

For further guidance concerning contra-indications, refer to chapter "Contra-indications and MR Conditional implants" on page 58. Working near the magnet during scanning may cause mild peripheral nerve stimulation.

Whereas no epidemiological evidence exists to date concerning adverse health effects on the fetus, it is prudent for pregnant workers to minimize exposure to the magnetic fields.

NOTICE

Local regulations may consider the fetus as member of the general public, and strict exposure limits may prohibit pregnant workers to approach the MR System.

Workers shall be informed that occupational exposure to RF and gradient fields is limited to those present in the examination room when the system is scanning.

Current scientific evidence does not indicate harm related to occupational exposure, but exposure can be limited by keeping distance from the MR system.

Similarly, keeping distance when possible will limit exposure to the main magnetic field.

Intended use & compatibility

⚠ **WARNING**

Do not use the system for any purposes other than those for which it is intended.

Operation of the system for unintended purposes could lead to fatal or serious injury and to clinical misdiagnoses.

See also chapter "Intended use" on page 9.

⚠ **WARNING**

Do not use the system with any system/devices/accessories other than those which Philips Healthcare recognizes as tested.

Operation of the system with untested equipment, could lead to fatal or serious injury and to clinical misdiagnoses.

See also chapter "Compatibility" on page 10.

NOTICE

Specific application warnings and notes are described in the online help system.

These warnings and notes involve:

- Intravenous lines application.
- Coil application, correct use and cable handling.
- Patient positioning.
- Possible misinterpretation related to scan techniques.

Maintenance, faults and modifications

⚠ **WARNING**

Do not use the system for any application until you are sure that the Routine User Checks Program has been satisfactorily completed, and that the Planned Maintenance Program is up to date.

⚠ **WARNING**

If any part of the equipment or system is known (or suspected) to be defective or incorrectly-adjusted, DO NOT USE the system until a repair has been made.

Operation of the equipment or system with defective or incorrectly-adjusted components could expose the operator or the patient to safety hazards. This could lead to fatal or other serious personal injury, or to clinical misdiagnoses.

⚠ **WARNING**

Do not start an examination with the system when the examination-room door is open.

Operation of the system with the examination-room door open can cause malfunction of other (medical) devices outside the examination room and consequently may lead to personal injury.
Other (medical) devices could also interfere with the MR system, possibly resulting in image artifacts.

⚠ **WARNING**

Never use surface coils when coil or cables are damaged.

A damaged cable or connector is hazardous because of high voltage across the cable during the transmit phase of the system. Sharp edges may cause injury to patient's skin.

⚠ **WARNING**

Changes to the system and repairs that are carried out by persons without appropriate training may lead to the Philips Healthcare warranty being voided.

Complex technical equipment maintenance by persons not appropriately qualified carries serious risks of damage to the system and of personal injury.
The owner of this product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Philips Healthcare, or its authorized service personnel.

⚠️ **WARNING**

It is not permitted to log on to the system via a terminal or PC.

This may interfere with the running of the system.

The remote desktop application as described in IFU volume 3 is allowed.

NOTICE

Damaged coils which are returned to Philips Healthcare must be cleaned by the user as well as practically possible.

For Japan: please contact Philips Healthcare Japan for instructions before returning damaged coils.

Information about the Routine User Checks Program and the Planned Maintenance Program can be found chapter "Maintenance and Quality assurance" on page 89.

Devices and controls essential for system safety

Refer to Devices and controls essential for system safety in IFU2.

Cleaning MR equipment and MR rooms

Cleaning and disinfection instructions can be found in chapter "Cleaning and Disinfection" on page 95.

⚠️ **WARNING**

Cleaning and disinfection may only be performed by appropriately MR-trained staff.

⚠️ **WARNING**

Do not use flammable or potentially explosive disinfecting sprays.

The resultant vapor could ignite, causing fatal or other serious personal injury and/or damage to equipment. Also refer to chapter "Explosion safety" on page 37.

⚠️ **WARNING**

Do not bring objects made of iron or other magnetic materials into the Controlled Access Area. See chapter "Access to Controlled Access Area" on page 22 for further guidance.

Such objects will be attracted by the magnet and may lead to serious or fatal injury of the patient or personnel and may cause system malfunctions.

WARNING

Always clean/disinfect the tabletop, mattresses, RF coils and cables, physiology sensors and cables and accessories after examination of (injured) patients where contamination may have occurred.

Cleaning and disinfection will avoid cross-infection.

NOTICE

Always consider and apply the safety instructions of the cleaning agents.

Magnetic safety

NOTICE

In some countries, legislation may exist prohibiting very high magnetic fields (>2T) for routine clinical use.

Static magnetic field

The magnetic field strength of the system can be found in the About function, accessible through the Help menu.

3.0T systems that are compliant with the 2nd edition of IEC60601-2-33 are considered to operate continually FIRST LEVEL CONTROLLED MODE. Additional medical supervision is required when operating in this mode.

NOTICE

Patients and operators may experience transient effects of dizziness, nausea, vertigo or metallic taste in the mouth when moving the head with substantial speed in or near a 3T MR system.

Patients and operators are therefore strongly advised to move slowly in the magnetic field. The distribution of the magnetic field inside the MR Examination Room can be found in the Technical Description.

In addition, patients should be instructed to avoid moving their heads during the examination.

⚠ **WARNING**

Working near or inside the magnet bore (e.g. interventional procedures) may affect task performance of medical staff.

Reduced attention can be the effect of movement in the magnetic field or peripheral nerve stimulation. It is recommended that medical staff will evaluate their sensitivity to such effects, prior to performing the medical procedure.

Controlled Access Area

⚠ **WARNING**

It is the obligation of the user to mark all entries of the Controlled Access area with appropriate safety symbols. See "Strong Magnetic Field" and "No pacemakers" symbol in chapter "Symbols on System, Coils and Accessories" on page 83.

In the Controlled Access Area the stray field will exceed 0.5 mT (= 5 Gauss). Exposure to such fields may cause device malfunction in certain types of pacemakers.

0.5 mT is exceeded up to the following distances from the magnet center:

Field strength	X direction	Y direction	Z-direction
1.5T	2.4 m	2.4 m	3.8 m
3.0T	3.1 m	3.1 m	4.9 m

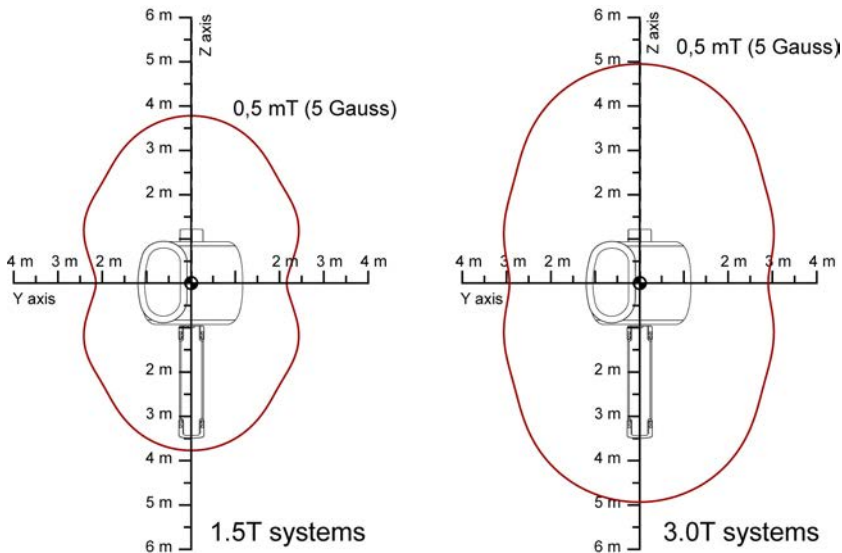**Tab. 2:** Static magnetic field

Fig. 1: Top view with 0.5 mT (5 Gauss) lines for 1.5T and 3.0T systems.

Access to Controlled Access Area

WARNING

Do not bring objects made of iron or other magnetic materials into the Controlled Access Area.

These objects will be attracted by the magnet and may lead to serious or fatal injury of the patient or operating personnel and may cause system malfunctions.

Objects of concern include but are not limited to:

- **Scissors, pocket knives, lighters, keys, coins, hair pins, glasses, etc.**
- **Vacuum cleaners, floor polishers, etc.**
- **Mobile phones, pagers, tablets.**
- **Magnetic wheel chair, magnetic trolley, iron stretchers, etc.**
- **MR unsafe fire extinguishers.**
- **Life supporting, vital sign monitoring, or emergency equipment**

WARNING

Approaching or entering the MR system is a significant risk for persons fitted with metallic implants or electrically, magnetically, or mechanically activated implants (such as cardiac pacemakers).
Do not allow such persons to enter the Controlled Access Area.
The magnetic and electromagnetic fields produced by the MR system can exert strong forces on these devices or interfere with their operation.

Note that some implants may be labeled MR Conditional and persons can be permitted entrance under the responsibility of the hospital and the operator. The operator is responsible to ensure that all conditions are strictly adhered to.

NOTICE

Compatibility of tools and devices will depend on the magnetic field strength of the MR system.

Contact the supplier when using tools or devices at different systems than specified.

NOTICE

It is advised to carefully secure monitoring equipment to the wall of the examination room, using a chain and/or other anchorage device of sufficient strength.

This will prevent the equipment to be pulled into the system.

Portable metal detectors or ferromagnetic detectors (FMD) pillars can be used to check patients and other persons for metal objects. These detectors are only additional aids and cannot replace screening procedures by the medical staff.

⚠️ **CAUTION**

Do not bring magnetic media into the Controlled Access Area.

Information on magnetic media, such as magnetic strips on credit cards, diskettes and tapes, may be erased by a magnetic field strength higher than 0.5 mT (= 5 Gauss).

The perimeters of the Controlled Access Area usually coincide with the walls of the RF room shield. Inside this shield:

- Elevated RF levels or the magnetic fringe field may disturb electronic equipment other than equipment tested by Philips.
- The presence of such equipment may interfere with the operation of the MR system.

NOTICE

It is the responsibility of the user to establish adequate rules and emergency procedures for controlling access to the Controlled Access Area in terms of the potential risk to patients and staff.

Magnet Emergency Stop button

Fig. 2: Magnet Emergency Stop button

Pressing an Emergency Stop button will initiate a quench of the magnet within a few seconds.

Design	Red button with 'Emergency stop' label.
Location	Emergency stop buttons are located: • In the examination room. • Outside the examination room.
Purpose	Immediate removal of the magnetic field. Operation of this button will de-energize the magnet.
Reason for use	**ONLY use in case of emergency** when: • Objects are attracted by the magnet, causing injury to patient or personnel. • Fire or some other unexpected event occurs that demands immediate action and entry of emergency personnel into the examination room. • In any other situation that requires immediate removal of the magnetic field as opposed to the normal, controlled ramp-down of the magnetic field. In any other situation that requires immediate removal of the magnetic field, as opposed to normal controlled ramp-down of the magnetic field.
Limitation	An emergency removal of the magnetic field causes a large amount of liquid helium to evaporate. Note that a system restart can only be performed by Philips Customer Service and takes about 2-3 days to complete.
Warning label	A label with the following text is displayed at the button: **Emergency stop button** Operation of this button will de-energize the magnet. **WARNING!** Energizing the magnet is a long and very costly process.

Quench

In case of a quench: stay calm, evacuate patient. Call Philips Service to recover system operation.

During the quench the system will make a loud noise that is caused by the rapid relief of cold helium gas through the quench pipe.
This loud noise is proof that the magnet has actually quenched and that the magnet field has decreased to below 10mT. This will take less than 20 seconds.

When a magnet quenched, MR scans will fail, e.g. with a message that the MR resonance frequency cannot be found. Proof that the magnet is off-field can be obtained by keeping a slightly magnetic coin (US quarter, Euro) close to the magnet, held secure in your hand.

> **WARNING**
>
> It is the responsibility of the hospital to establish emergency procedures for Emergency stops of the magnet.

Mobile telephones & similar products

Philips MR systems comply with the requirements of applicable EMC standards. Other electronic equipment exceeding the limits defined in these EMC standards could, under unusual circumstance, affect the operation of the system. E.g. certain mobile telephones exceed these limits.

> **WARNING**
>
> Do not allow radio frequency transmitting devices (such as mobile telephones) into the examination room. Even when switched off.
>
> These devices could exceed EMC radiation standards and, under unusual conditions, interfere with the proper functioning of the system. This could, in extreme cases, lead to fatal or other serious personal injury or to clinical misdiagnoses.

Specific Absorption Rate (SAR)

The scan procedures always involve the emission of radio frequency (RF) energy. This RF energy can heat the patient, and hence, is of concern. The Specific Absorption Rate (SAR) is the RF power absorbed by the patient per unit mass expressed in Watts per kg (W/kg).

> **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.

For each scan one of these SAR types is the limiting SAR type. The system will control SAR with the applicable limiting SAR type, taking into account patient position and transmit or receive coil applied. When scanning with elevated SAR values, both local warming sensations and core temperature increase can occur, irrespective of limiting SAR type. The operator needs to consider both effects for patient care: the severity of these effects depends on the condition of the patient.

The predicted SAR is calculated for each scan and is a conservative estimate. Information on the limiting SAR type and expected SAR values for the scan is displayed on the Scan Dashboard and on the info page:

• SAR / limiting SAR type:	x %
• Whole body / level:	y W/kg / n

Limiting SAR type = whole body, head, local torso or local extremities.
x % = The predicted SAR expressed as a percentage of the maximum for the limiting SAR type.
y W/kg = The predicted whole body SAR.
n = Operating mode (normal or first level)

SAR correlates with the average RF deposition in the patient, also denoted as B1+RMS. This parameter can be found in the sequence definition user interface. Some labeling of MR Conditional implants may specify an upper limit for this parameter to control the MR exposure conditions.

Operating modes

The system recognizes three operating modes, see chapter "Definitions" on page 13:

IEC Operating mode	SAR limits	Safety measures
Level 0 (Normal)	• Whole body SAR < 2 W/kg • Head SAR < 3.2 W/kg	• Patient observation.
Level I (First level controlled)	• Whole body SAR ≥ 2 W/kg and < 4 W/kg • Head SAR < 3.2 W/kg	• Patient monitoring with medical expertise. • Particular caution for patients at risk.
Level II (Second level controlled)	• Whole body SAR ≥ 4 W/kg • Head SAR ≥ 3.2 W/kg	The system is limited. Level II cannot be reached.
Level 0 (Normal)	• Local torso SAR < 10 W/kg* • Local extremities SAR < 20 W/kg*	• Patient observation.
Level I (First level controlled mode)	**Only for IEC-60601-2-33 3rd edition systems:** • Local torso SAR < 20 W/kg* • Local extremities SAR < 40 W/kg*	• Patient monitoring with medical expertise. • Particular caution for patients at risk.

* Applicable for transmit surface coils.

More information about level 1

The SAR limitations for Level 0 and Level 1 are based on current scientific knowledge that relate RF power deposition (SAR) to increase of core temperature and local temperature. The system is designed to limit SAR values such that core temperature increase does not exceed 0.5 ^{0}C in Level 0, and 1.0 ^{0}C in Level 1.
Core temperature limit values are 39 ^{0}C for Level 0 and 40 ^{0}C for Level 1.
When SAR levels corresponding to Level 1 will be used, a warning message is given and medical supervision of the patient is required. If the patient's condition cannot be monitored, or the risk is too high (for example due to elevated baseline core temperature or reduced thermoregulatory capabilities of the patient, anesthesia, or unconsciousness), the scan parameters must be changed to give a SAR in Level 0 range (e.g. use SAR mode "low").

NOTICE

The temperature rise depends on the total RF energy delivered during the examination (SED). Information on the actual and predicted SED is available at the user interface to support evaluation of the patient's warming.

WARNING

The whole body SAR limits are only valid for room temperatures below 22^{0}C, as specified in the system installation procedures.

When Level 1 is reached a warning message is given and medical supervision of the patient is required:
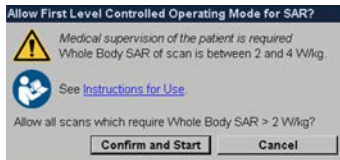
Allow First Level Controlled Operating Mode for SAR?

Medical supervision of the patient is required. Whole Body SAR of scan is between 2 and 4 W/kg.

See Instructions for Use.

Allow all scans which require Whole Body SAR > 2 W/kg?

- Confirm and Start
- Cancel

Medical supervision of the patient is required. Whole Body SAR of scan is between 2 and 4 W/kg.

This message is displayed when the scan exceeds SAR limits of the Normal Operating Mode. The system enters the First Level Controlled Operating Mode and the following safety measures apply:

- Patients need to be monitored with medical expertise.
- Particular caution for patients at risk. Press 'cancel' to lower SAR by modifying the scan(s) and operate within Normal Operating Mode. Press 'Confirm & Start' to continue the examination in First Level Controlled Operating Mode. For more information about SAR please refer to section "Specific Absorption Rate (SAR)".

If the patient's condition cannot be monitored, or the risk is too high, the scan parameters must be changed to lower SAR to normal operating mode. If the risk is acceptable, the scan can be started.

NOTICE

The consequence of SAR-induced increase of the patient's core temperature is that scanning a patient with an initial core temperature >39.5 °C is contra-indicated, while a patient with an initial core temperature >39 °C can only be scanned in Normal Mode. Scan duration shall be limited, and monitoring of the core temperature is recommended.

Particular caution must be exercised for the following classes of patients:

- Patients for whom MR examinations are contra-indicated, chapter "Contra-indications and MR Conditional implants" on page 58.
- Patients with a higher than normal likelihood of requiring emergency medical treatment, e.g. due to their present medical condition.
- Patients with a higher than normal likelihood of requiring emergency medical treatment as a result of the strong fields applied, when the system is operating in first level controlled operating mode, e.g. anesthetized patients, patients with restricted thermoregulatory capacity.

Particular caution for patients at risk

In addition to patient observation, particular caution must be exercised for patients who are sensitive to temperature increases or to RF energy, e.g.:

- Patients at risk of cardiac arrest.

- Pregnant women: The fetus is especially thermally vulnerable during early pregnancy, scanning is not recommended in the first trimester.

- Patients with extensive tattoos. These patients are at serious risk for RF burns.

- Patients susceptible to seizures or claustrophobic reactions.

- Decompensated cardiac patients and febrile patients.

- Patients with impaired ability to perspire e.g. due to age, overweight, diabetes, or hypertension.

- Patients under specific drug regimes that may affect thermoregulatory capabilities, such as diuretics, tranquillizers or vasodilators.

- Patients who are unconscious, sedated or locally anesthetized, confused, or may be unable to sense or communicate heat sensations.

- Patients with fever, reduced thermal regulating capabilities or increased sensitivity to raised body temperature.

- Patients who are thermally insulated. (e.g. in a gypsum cast).

- Patient with MR Conditional implants for which labeling may require SAR to be limited to non-standard values and short examination times.

The temperature of the air in the examination room is continuously monitored by the system.

If these conditions are exceeded, e.g. if the patient is warmed by means of a heated blanket, the whole body SAR must not be greater than 2.0 W/kg and patient's condition must be monitored.

The temperature and humidity of the air in the examination room is continuously monitored by the system. A Warning message is displayed when the room temperature or humidity is high. Too high temperature may lead to patient heating, especially in combination with moderate and high SAR scans. Please verify the ambient temperature and take actions to reduce the temperature in the examination room. Please apply sufficient patient ventilation.

⚠️ **WARNING**

A message is displayed on the screen when the ambient temperature is above 22°C.

Too high temperature may lead to patient heating, especially in combination with moderate and high SAR scans. Please verify the ambient temperature and take actions to reduce the temperature in the examination room. Please apply sufficient patient ventilation.

Interventional procedures

NOTICE

It is advised to scan in normal mode when scanning without patient ventilation during an interventional procedure.

⚠️ **WARNING**

Patient temperature must constantly be monitored during interventional procedures using MR-conditional equipment.

Clothing and environmental conditions

Increased ambient temperature and humidity hinder the body's ability to dissipate excess heat. Likewise, heavy clothing hinders heat dissipation.

Examination room:

- Room temperature must be kept to 18 - 22°C.
  Recommended room temperature is 21°C.

- Relative humidity must not exceed 70%.

⚠️ **WARNING**

Do not scan in first level controlled operating mode when the ambient temperature in the examination room exceeds 22^{0}C. Room temperature must constantly be monitored by the operator using MR-conditional equipment.

Too high temperature may lead to patient heating, especially in combination with moderate and high SAR scans. Please verify the ambient temperature and take actions to reduce the temperature in the examination room. Please apply sufficient patient ventilation.

⚠️ **WARNING**

Do not bring metal parts close to the magnet.

Interaction with RF signal may result in excessive heating of these metal parts which may lead to burn injuries.

WARNING

Take appropriate action to prevent severe perspiration of the patient.

Severe perspiration of the patient may result in the formation of unintended RF circuits between body parts and ultimately in burn injuries.

WARNING

Remove any added insulation (such as blankets).

Added insulation prevents satisfactory dissipation of body heat.

WARNING

Verify that the patient ventilation system is working. Pads and accessories must never obstruct patient airflow in the bore.

Patient core temperature rise can be minimized by adequate ventilation of the patient space.

NOTICE

Avoid direct contact of the patient with the magnet bore covers or Transmit-Receive Coils.

This may cause local heating of the patient.

High SAR scanning

It is advised to use high whole-body SAR levels only if absolutely necessary. For patient comfort lower SAR levels are preferred. Scanning in high SAR mode may result in perspiration and discomfort of the patient.

WARNING

For High SAR scanning it is required to use the patient ventilation system.

WARNING

Patients who are exposed to high SAR values must be dressed in light clothing (e.g. light pajamas, nightshirt or T-shirt).

Philips Healthcare

⚠️ **WARNING**

For scanning a baby in an incubator it is advised to only scan in normal operating mode.

This will avoid a too high SAR value for the baby in the warm and humid incubator environment.

NOTICE

For high SAR scanning it is advised to plan breaks between the scans for the patient to cool down.

Breaks can be created by planning low SAR scans between the high SAR scans.

⚠️ **WARNING**

Medical supervision is required for all scans in first level controlled mode.

Special attention is required for young, pregnant and elderly patients to prevent increase of body core temperature. Select low SAR sequences whenever possible.

Specific Energy Dose (SED)

During an MRI examination, RF energy is transferred to the body, potentially resulting in warming sensations. The patient temperature rise is proportional to the total energy delivered to the patient (SED, expressed as kJ/kg). It is determined by the SAR and scan duration. SAR is the rate of delivered energy expressed in Watts/kg, represented as W/kg. Limiting the amount of RF energy (SED) delivered to the patient, limits the temperature rise in the patient.

The display of Specific Energy Dose is a comfort measure and provides feedback on the exposed energy to the patient. The system will limit to the maximum SED as recommended by the IEC. In general, a delivered SED value > 3.5 kJ/kg may be uncomfortable for some patients. Patient comfort during scanning is affected by the condition of the patient and must be taken into account. A rise in body temperature can be a hazard to a patient with restricted thermoregulatory capacity.

NOTICE

Adequate patient cooling (e.g. patient ventilation fan, system ambient temperature within specified range) is necessary in order to keep patient comfort within desired limits. See chapter "Clothing and environmental conditions" on page 30.

Display of SED on the console

The SED is visible in the Patient Status Area above the 'Stop Scan' button (see figures below). The SED bar has a scale of 0 to 7 kJ/kg. The bar shows the planned SED in grey and the accumulated SED in dark grey. Once the accumulated SED exceeds 3.5 kJ/kg the color changes to yel-

low. Examinations with an accumulated SED above 7 kJ/kg are indicated with an arrow at the end of the SED bar as an indication SED has exceeded twice the recommended value of 3.5 kJ/kg.

- The Accumulated SED (kJ/kg) displays the SED of the completed scans including the SED of the currently running scan.
- Planned SED (kJ/kg) displays the SED of the planned scans in the ExamCard.
- Total SED (kJ/kg) is the total amount of the planned- and accumulated SED.

The information is also available during planning: the SED of that scan is available on the info page.
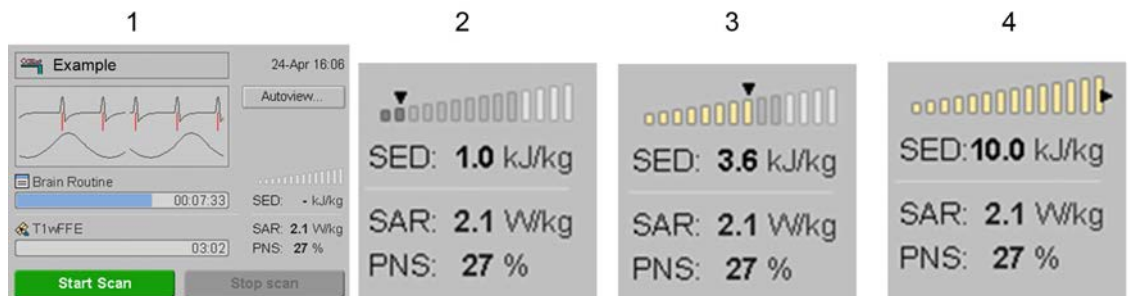

Fig. 3: 1: SED display in Patient Status Area. SED not yet applicable since no scans are selected. 2: Light grey total planned SED for this examination, dark grey accumulated SED of 1.0 kJ/kg. 3: Accumulate SED exceeds 3.5 kJ/kg, color changes to yellow. 4: Black arrow added at the right side of the bar graph, indicating that the accumulated SED exceeds 7.0 kJ/kg.

Messages on the screen

The following message is displayed when the Specific Energy Dose (SED) exceeds the maximum allowed level for the current patient.

Scan will exceed maximum SED level

Cannot start scan.

Execution would exceed the maximum allowed Specific Energy Deposition in the patient.

See Instructions for Use.

|Close|

Scanning cannot be started. Click 'Close' and modify the scan to lower the SAR and/or scan duration.

The following message is displayed when the maximum allowed level Specific Energy Dose (SED) has been reached for the current patient.

Maximum SED level exceeded

Scan aborted.

Maximum Specific Energy Deposition in the patient is reached. Further scanning on this patient is not allowed.

See Instructions for Use.

|Close|

Further scanning cannot be continued. Click 'Close' .

Gradient field strength (gradient output)

The use of fast switching and high gradients may lead to peripheral nerve stimulation (PNS) during the scan. The location and nature of the PNS differs for each individual. PNS can cause a tingling sensation or superficial twitching. Some patients may report such sensations as pain, when scanning in first level controlled operating mode.

NOTICE

Very high gradient output could even cause cardiac nerve stimulation.

Literature indicates that threshold levels for cardiac stimulation are much higher than for peripheral nerve stimulation. Peripheral nerve stimulation is possible. Cardiac stimulation is never induced by the exposures from the gradient switching.

Gradient output

During the scan definition, the gradient output is calculated for this scan (PNS) and compared with mean threshold level. This mean threshold PNS is defined as the onset of sensation, and refers to the level at which 50% of the people start to experience PNS.

During the scan definition, the gradient output is calculated for this scan (PNS) and compared with mean threshold level. This mean threshold PNS is defined as the onset of sensation, and refers to the level at which 50% of the people start to experience PNS.

The expected PNS level is displayed on the info page and expressed as a percentage of the mean threshold level for PNS as calculated by the system for the sequence prepared for the patient.

PNS/level	x % / n

x % = The predicted PNS value is expressed as a percentage of the mean threshold level for PNS.
n = Operating mode ('Normal' or 'Level I')

PNS levels

This MR system employs a Whole Body Gradient System, and the Gradient Output related to potential peripheral nerve stimulation is defined in a cylinder of 20 cm radius around the magnet bore's center line.

The system recognizes three PNS levels, corresponding to chapter "Definitions" on page 13:

IEC Operating mode	Gradient output	Safety measures
Level 0 (Normal)	Gradient output ≤ 80% of the mean threshold level	• Routine patient observation

IEC Operating mode	Gradient output	Safety measures
Level I (First level controlled)	80% of the mean threshold level < Gradient output ≤ 100% of the mean threshold level	• Patient monitoring with medical expertise • Particular caution for patients at risk
Level II (Second level controlled)	Gradient > 100% of the mean threshold level	The system is limited to a maximum gradient output of 100% of the mean threshold level. Level II cannot be reached

More information about Level 0

In Level 0 the probability of PNS is very low.

More information about Level I

When Level I is reached (predicted gradient output exceeds 80% of the mean threshold level) a warning message is displayed:

Allow First Level Controlled Operating Mode for PNS?

Medical supervision of the patient is required. Peripheral Nerve Stimulation of scan is between 80 and 100 %.

See Instructions for Use.

Allow all scans which require PNS > 80%?

• Confirm and Start

• Cancel

Medical supervision of the patient is required. Peripheral Nerve Stimulation of scan is between 80 and 100 %.

This message is displayed when the scan exceeds PNS limits of the Normal Operating Mode. The system enters the First level controlled operating mode and the following safety measures apply:

• Patients need to be monitored with medical expertise.

• Particular caution for patients at risk. Press 'cancel' to lower PNS by modifying the scan(s) and operate within Normal Operating Mode. Press 'Confirm & Start' to continue the examination in First Level Controlled Operating Mode. For more information about PNS please refer to section "PNS levels".

The operator has to decide whether to accept the parameter settings for execution of the scan or to cancel. If cancelled the parameter settings can be modified to decrease the gradient output below the PNS limit.

Safety Measures

For scans which may produce peripheral nerve stimulation attention must be paid to the following:

- Inform the patient that peripheral nerve stimulation may occur and describe the nature of the sensation.
- Maintain permanent contact with the patient during the scan either directly or via an observation monitor and intercom.
- Terminate the scan when the patient calls for attention via the nurse call.
- Patients should be positioned with the arms alongside the body to reduce the likelihood of Peripheral Nerve Stimulation.

NOTICE

Personnel working inside or very close to the magnet during scanning may experience Peripheral Nerve Stimulation. Occupational exposure can be derived from the spatial distribution of the Gradient Output (dB/dt) provided in the Technical Description.

Exposure can be reduced by keeping distance from the magnet or by scanning in Normal Operating Mode.

Defining a scan

The potential for peripheral nerve stimulation depends on the maximum gradient strength, slew rate and timing of the scan. When defining a scan, the parameter 'PNS mode' is used to control the maximum allowed gradient output. The actual gradient output is displayed on the Scan Dashboard and on the Info page and is dependent on other parameters.

Three levels are available:

- "low": the maximum allowed gradient output will be limited to 60% of the mean threshold level, i.e. the system will always operate in normal operating mode and the probability of PNS is very low.
- "moderate": the maximum allowed gradient output will be limited to 80% of the mean threshold level, i.e. the system will always operate in normal operating mode. The probability of PNS is low and if experienced it is mostly not painful.
- "high": the maximum allowed gradient output will be limited to 100% of the mean threshold level, i.e. the system may operate in the first level controlled operating mode. The probability of PNS is about 50% and may be experienced as painful. However, the patient may have more tolerance for PNS when properly informed and motivated.

Electrical safety

Philips MR systems may be operated on a permanent 24-hour basis without adversely affecting its safety or performance.

⚠ **WARNING**

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠ **WARNING**

Do NOT open cabinets. Do NOT remove system covers.

The system and all subsystems remain powered. Danger of an electric shock.

⚠ **WARNING**

Covers, cables or components should only be removed by qualified and authorized Customer Support personnel.

In this context, qualified means those legally permitted to work on this type of medical electrical equipment in the jurisdiction(s) in which the equipment is being used. Authorized means those authorized by the user of the equipment.

⚠ **WARNING**

Do not allow water or other liquids to enter the equipment as they may cause short-circuits or corrosion.

Only use the MR system in rooms or areas that comply with all applicable law (or regulations having the force of law) concerning electrical safety for this type of equipment.

Applied Parts

The following electrical or weight bearing parts of the MR system are designed for patient contact during normal use (known as Applied Parts):

- Tabletop.
- VCG.
- PPU.
- All RF coils, see their respective instructions for further details.
- NVC base plate, when used as head rest.

Explosion safety

This equipment must not be used in the presence of explosive gases or vapors, such as certain anaesthetic gases. Use of electrical equipment in an environment for which it was not designed can lead to fire or explosion.

⚠️ **WARNING**

Do not use flammable or potentially explosive disinfecting sprays.

The resultant vapor could ignite, causing fatal or other serious personal injury and/or damage to equipment.

⚠️ **WARNING**

When scanning anesthetized patients the use of flammable anaesthetic mixtures with air, oxygen or nitrous oxide is not allowed at the system.

Philips Ingenia systems are not AP (Anaesthetic-Proof) or APG (Anaesthetic-Proof Category G) tested.

Mechanical safety

⚠️ **WARNING**

Special care must be taken that no objects or body parts (e.g. patient in a wheelchair) are present near the patient support while lowering the patient support.

Objects can get trapped between patient support and floor which may lead to damage or personal injury.

⚠️ **WARNING**

Do not remove the covers from the patient support as it contains moving parts.

Removing the covers could lead to serious or fatal injury.

Emergency Stop button

Fig. 4: Emergency Stop Button

In case of emergency the Emergency Stop button on the UIM can be used to stop tabletop movement immediately and the tabletop can be moved manually.

Press the emergency button (1) on the UIM to stop and to release tabletop movement. The tabletop can be moved manually out of the magnet.

Pressing this resume button (2) will reset the tabletop after an emergency stop. Operation is re-enabled.

NOTICE

Remote software controlled moves can be stopped by pressing the F12 key.

You can also use the Emergency Stop button on the Audio module.

Tabletop movement in the event of an electrical power failure

In the event of an electrical power failure, the tabletop is automatically released. The tabletop can be moved manually out of the magnet.

When electric power is re-established the tabletop is engaged again.

Please note that there might be events where table movement is not possible even in manual mode, refer to chapter "Moving the patient into the magnet bore" on page 70

Horizontal tabletop movement

If horizontal tabletop movement is not functioning properly the patient support switches automatically into 'manual mode': The Manual mode button on the UIM flashes.

Move the tabletop manually out of the system into its end position. The patient support is reset and the button stops flashing.
Press the 'Manual mode' to switch to motorized movement again: horizontal movement of the tabletop is re-enabled.
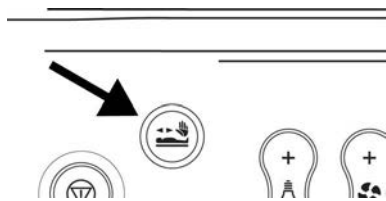

Fig. 5: Manual mode

Manual override switch

If the control electronics break down, it will still be possible to move the patient support to the highest position and continue scanning. The 'Manual override' switch is located at the magnet end under the patient support.

If the switch is activated the patient support will move up and stop at its highest position.

Fig. 6: Manual override switch.

Fire safety

In the event of a fire in the examination room:

Press the magnet 'Emergency stop' button (see chapter "Magnet Emergency Stop button" on page 23) to rapidly remove the magnetic field before bringing fire-extinguishers into the examination room.

General safety measures in the event of fire

- All operators of this medical electrical equipment should be fully aware of and trained in the use of fire extinguishers and other fire-fighting equipment, and in local fire procedures. Fire extinguishers should be provided for both electrical and non-electrical fires.

- Fire regulations for the type of medical area being used should be fully applied, observed and enforced.

- The fire precautions stated in this section should be discussed with the local fire department and fire emergency precaution procedures should be established.

⚠ **WARNING**

It is the responsibility of the hospital to establish emergency procedures in case there is a need for an emergency stop of the magnet.

⚠ **WARNING**

Only use fire extinguishers that are specifically labeled as suitable for electrical or chemical fires.

Using water or other liquids can lead to serious or fatal injury.

Attempt to isolate the equipment from electrical supplies before fighting the fire. This will reduce the risk of electric shocks.

NOTICE

MR safe (non-magnetic) fire extinguishers compatible with a field strength of 3.0T are commercially available and can be used.

The most restrictive local rules must be complied with.

Choose fire extinguishers that best suits your site and make certain that mixing up with MR unsafe extinguishers is not possible.

Safety with Helium

Liquid helium

WARNING

Under no circumstances should a liquid helium container be brought into the magnet area unless it is known to be made of non-magnetic material or the magnet is not energized.

It is extremely dangerous for patients, personnel and equipment to bring any magnetic or ferrous metal objects into the examination room. Special non-magnetic containers are available from liquid helium suppliers and must always be specified and appropriately labeled.

WARNING

Under no circumstances should liquid helium be transferred into the magnet prior to installation of the helium venting system.

Filling with liquid helium

WARNING

Filling with liquid helium should be carried out by trained and authorized persons. See chapter "Topping up liquid helium" on page 90.

⚠ **WARNING**

Always use protective gloves, skin covering clothing, and preferably goggles.
Liquid helium is extremely cold and can freeze human tissue.

Injuries caused by freezing must be washed with water and treated as burns.

⚠ **WARNING**

Always verify that the examination room and the storage room for liquid gases are well ventilated.

There is danger of suffocation as the evaporating helium will dilute or displace the oxygen in the air.

⚠ **WARNING**

If liquid helium is accidentally released in the examination room, accumulation of liquid oxygen may occur, resulting in a potential fire hazard.

Helium gas

Properties of helium gas:

- Odorless

- Non-flammable

- Non-poisonous

- On evaporation of liquid helium a cold mist is formed. Helium gas rises in air.

Normal operating conditions

Philips MR systems are equipped with a zero helium boil-off system. Under normal operating conditions no helium gas evaporates.

For the event that helium is boiling off, Philips MR systems are equipped with a helium venting system, which vents the helium gas from the magnet to the outside of the building. Helium boil-off occurs at an emergency switch-off (quench).

High concentration of helium gas

Note that under well controlled installation conditions helium gas will never be present in the examination room, except for the case of a technical failure.

High concentrations of helium gas in the examination room can lead to suffocation, as it dilutes the oxygen in the air.

A large amount of helium gas is evaporated when the magnet 'Emergency stop' button is used for immediate removal of the magnetic field, or during a spontaneous quench of the magnet.

⚠ **CAUTION**

Always report a magnet quench immediately to Philips Customer Service to take proper action.

Failure to do so may result in the necessity to perform a costly and time-consuming magnet de-icing procedure, or possible permanent magnet damage.

⚠ **WARNING**

It is the responsibility of the hospital to establish emergency procedures in the event of quench of the magnet, especially for situations in which the venting system of the magnet fails and helium gas is released into the examination room.

⚠ **WARNING**

In the 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 could build up in the examination room forming clouds of cold mist.

Open the door of the examination room.
Immediately evacuate the patient and personnel from the examination room.

⚠ **WARNING**

Do not switch-off the air conditioning or air circulation in the room if helium has leaked into the examination room (this is an automatic procedure triggered by a smoke detection alarm for detection of fire) but maintain air circulation and ventilation.

An oxygen detector with audible alarm may be used as a warning device.

Magnet monitoring messages

Magnet helium level

Helium is used to keep the magnet in a pre-defined temperature range. When magnet helium levels are too low, the magnet cannot be kept in optimal conditions and the MR system may be disabled for scanning.

Helium refill message

The helium refill level is defined in Field Service Framework (and may vary per geographic region). The following UI message is displayed at the start of a new examination, once the actual helium level is below the helium refill level. The user is asked to contact their local service representative.
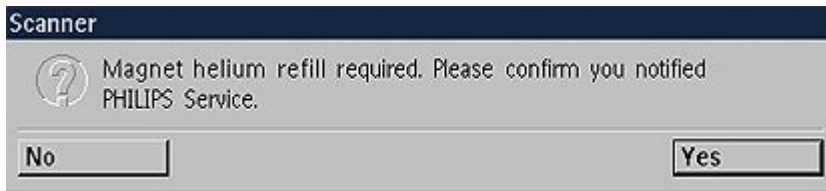
Fig. 7: Magnet helium refill required. Please confirm you notified PHILIPS service.

The user may do the following:

- Keep the message on screen until the local service representative has been contacted.

- Select **no** to confirm that local service representative has not been contacted yet. The pop-up is closed and will be displayed again at the start of a new examination.

- Select **yes** to confirm that local service representative has been contacted. The pop-up is closed and will not be displayed again. An alert message is displayed on the info status line at the start of each new examination until the helium level is above the refill level again "Magnet helium refill required. PHILIPS Service is already notified.
The user selection (**no** or **yes**) is logged in the system's log file.

Helium low level message

In case the helium level drops below the critical level, warning messages will be shown at the start of each examination for 3 consecutive days. To prevent magnet damage, scanning will be blocked on the fourth day. A helium refill is then required.

The following warning messages will be displayed.
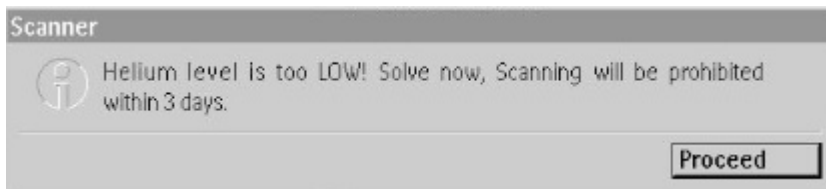
Message on first day of low helium level:

Fig. 8: Helium level is too LOW! Solve now, Scanning will be prohibited within 3 days.
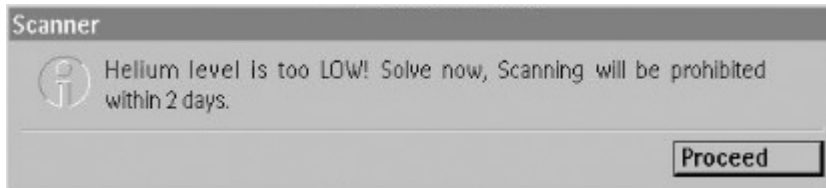
Message on second day of low helium level:

Fig. 9: Helium level is too LOW! Solve now, Scanning will be prohibited within 2 days.

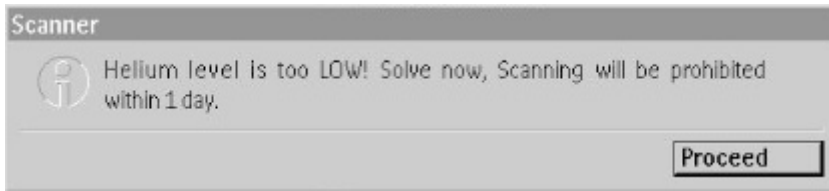Message on third day of low helium level:

Fig. 10: Helium level is too LOW! Solve now, Scanning will be prohibited within 1 days.
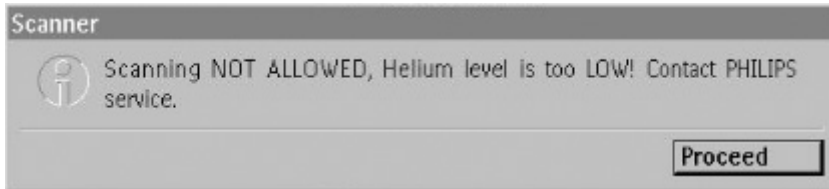
Message after third day of low helium level:

Fig. 11: Scanning NOT ALLOWED, Helium level is too LOW! Contact PHILIPS service.

Cryo compressor messages

Cryo compressor malfunctions may be solved by the user or local hospital engineer. In all other situations please contact your Philips service representative.

The following warning messages, depending on the system type, may be displayed at the start of a new examination. An action from the user is required.
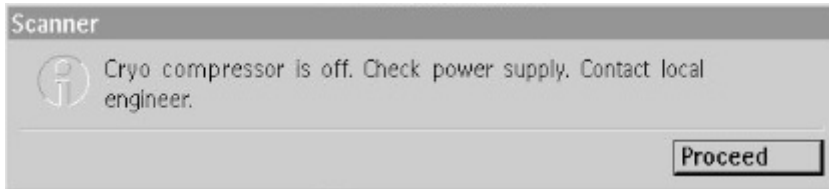
Fig. 12: Cryo compressor is off. Check power supply. Contact local engineer.

Cryo compressor power-off is detected for more than 30 minutes.
Check the power supply. If required, contact your local service representative.

Fig. 13: Cryo compressor temperature alarm. Check water cooling. Contact local engineer.

Cryo compressor temperature alarm is detected for more than 1.5 hours.
Check the water cooling. If required, contact your local service representative.
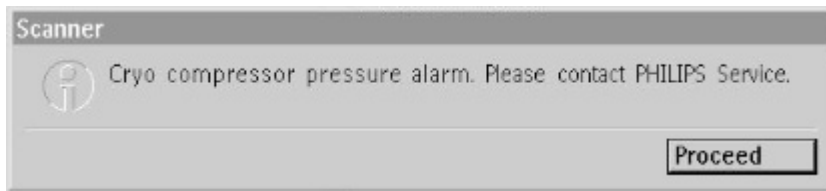
Fig. 14: Cry compressor pressure alarm. Please contact PHILIPS Service.

Cryo compressor pressure alarm is detected for more than 3 hours.
Contact your local service representative.
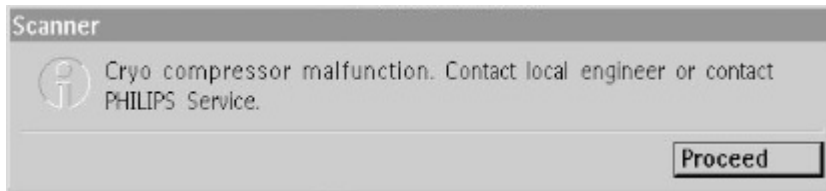
Fig. 15: Cryo compressor malfunction. Contact local engineer or contact PHILIPS Service.

Cryo compressor malfunction is detected for more than 30 minutes.
Check the power supply and water cooling circuit. If required, contact your local service representative.

Fig. 16: Cryo compressor malfunction detected for over 3 hours. Contact PHILIPS Service.

Cryo compressor malfunction is detected for over 3 hours.
Contact your local service representative.

Magnet helium pressure alarm
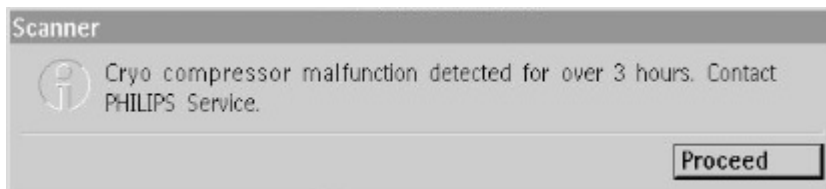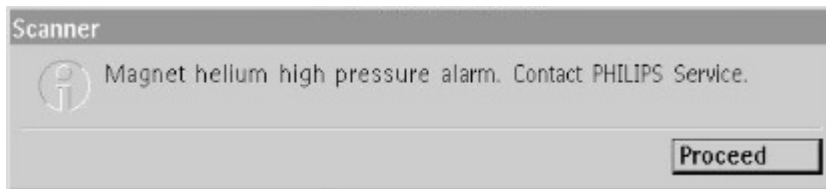

Fig. 17: Magnet helium high pressure alarm.

This message is displayed when the average magnet pressure exceeds the defined level during the last three hours.

Laser light radiation safety (Light visor)

Philips MR systems have a laser type Light visor system.

The laser light visors is in compliance with laser standards *IEC60825-1: 2007* and *21 CFR 1040:10* .

The Light visor should only be used under supervision of medical trained personnel, who are acquainted with hazards implied by the use of laser light.

It is the user's responsibility to meet local safety regulations.

⚠ **WARNING**

Avoid laser light shining in the patient's eyes. The laser is a Class II (FDA) / Class 2 (IEC) laser.

Instruct the patient not to look into the laser beam. Direct laser light may cause irreversible damage to the eyes.

⚠ **WARNING**

Use the Light visor for its intended use only, avoid unnecessary exposure to laser radiation.

⚠ **WARNING**

For non-responsive patients (babies, anesthetized patients) provide adequate protection to avoid direct laser light in the eyes.

⚠ **WARNING**

Use of controls, adjustments or procedures other than those specified in this manual may result in hazardous radiation exposure.

Labeling

The following warning labels are put on the system:

Outside front cover

	Caution label CAUTION Laser radiation Do not stare into beam Max output < 0.35 mW Emitted wavelength 635nm Class II Laser product
	Caution label Laser radiation Do not stare into beam Class 2 Laser product Max output< 0.35 mW Emitted wavelength 635 nm IEC 60825-1: 2007
	Laser warning symbol
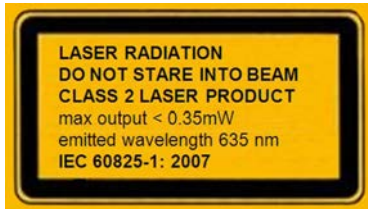
At the laser aperture (outside front cover)

	Label Laser Aperture

Emergency procedures

⚠ **WARNING**

It is required for the hospital to establish emergency procedures for the following situations:

- **Emergency medical procedures.**
- **Unauthorized people entering the controlled access area.**
- **The need for an emergency field shut down.**
- **Fire precautions.**
- **In case of a quench of the magnet.**

In addition, precautions should be taken and an appropriate plan should be established for use of emergency equipment outside the examination room, especially for the following classes of patients:

- Patients at risk of cardiac arrest.
- Patients predisposed to seizures or claustrophobic reactions.
- Patients who are very sick, sedated, confused, or unconscious.
- Patients with whom no reliable communication can be maintained.

A procedure must be established for rapid removal of the patient from the examination room in the event of an emergency, if necessary with an Emergency field shut down, see chapter "Magnet Emergency Stop button" on page 23.

WARNING

Electronic or other metallic emergency equipment must not be brought into the examination room.

WARNING

The system is not designed to withstand cardiac defibrillation procedures. In the event of an emergency, remove the patient from the table, and outside the 5G line.
In the event that a system part or coil has come into contact with a defibrillation pulse: do not use the system until Philips Service has replaced the affected part.

Interventional procedures

WARNING

When the MR system is used for interventional procedures, the hospital must establish procedures to complete the intervention or adequately stabilize the patient in case of MR system failures.
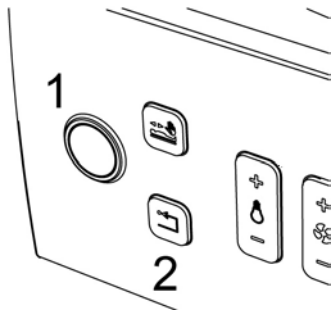
Emergency button

Fig. 18: Emergency button

Press the emergency button (1) on the UIM to stop and to release tabletop movement. The tabletop can be moved manually out of the magnet.

Pressing this resume button (2) will reset the patient support after an emergency stop. Operation is re-enabled.

Image quality

The resulting appearance of anatomical structures on images may be dislocated or distorted. Also non-uniform intensities or contrasts can occur. These image deviations may lead to misinterpretation. More information on typical MR artifacts, including examples, is provided in the MR Help system.

WARNING

MR images may demonstrate structures that are not present in the patient (artifacts), which may lead to misinterpretation.

These structures may occur as a result of technological and physiological factors or can be introduced by metallic or magnetic objects in the patient.
Technological factors can be spurious signal generated by system components or other source in the immediate area of the system.

Intrinsic artifacts

MR technical capabilities and patient physiology may result in artifacts which appear in the image.
These artifacts may be caused by e.g.:

- Magnet homogeneity.
- Gradient non-linearity.
- RF inhomogeneity.
- Truncation.
- Aliasing.

- Motion.
- Flow.
- Chemical shift.
- Susceptibilities.

Extrinsic artifacts

Magnetic objects or non-magnetic metallic objects such as jewelry, hairpins, buttons, prosthetics will disturb the RF signal or will influence the homogeneity of the magnet field and will interfere with the imaging capabilities of the system. This may lead to clinical misdiagnoses.

> **WARNING**
>
> Do not allow magnetic objects or non-magnetic metallic objects to be brought into the magnet, unless this is needed for the specific study and properly controlled (e.g. biopsy needles).

Liquids in phantoms

> **WARNING**
>
> Handle all phantoms with care to prevent damage, and spilling of the liquid contents.
>
> If the phantoms are not used, the phantoms must be placed in the phantom box and closed appropriately.
> Note that the contents of the phantoms may irritate the skin. Washing with water after contact with the human skin is sufficient.

Phantoms for 1.5T systems

Liquid in Body 400 mm and Head 200 mm phantoms	
Personal protection	• Eyes: safety goggles
Constituents in weight percent	• 99.6 - 99.96% water • 0.02 - 0.37% sulfuric acid • 0.03 - 0.08% copper(II)sulphate
Toxicity	• LD-50: 300 mg/kg (ORL-RAT, copper (II) sulfate) • LD-50: 2.14 mg/kg (ORL-RAT, sulfuric acid)
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.

Liquid in Body 400 mm and Head 200 mm phantoms

First aid	• Skin contact: Rinse for a long time with plenty of water, then wash with soap and water.
	• Eyes: Rinse for a long time with plenty of water.

Liquid in Bottle phantoms

Personal protection	• Eyes: safety goggles
Constituents in weight percent	• 99.717% water
	• 0.005% sulfuric acid
	• 0.077% copper(II)sulphate
	• 0.2% sodium chloride
	• 0.001% dialkyl-1-dimethyl ammonium chloride
Toxicity	• LD-50: 300 mg/kg (ORL-RAT, copper (II) sulfate).
	• LD-50: 2.14 mg/kg (ORL-RAT, sulfuric acid).
	• LD-50: 3 g/kg (ORL-RAT, sodium chloride).
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
First aid	• Skin contact: Rinse for a long time with plenty of water, then wash with soap and water.
	• Eyes: Rinse for a long time with plenty of water.

Liquid in AC-PC Bottle phantoms

Personal protection	• Eyes: safety goggles
Constituents in weight percent	• >99.0% water
	• >0.25<1.0% Nickel Chloride-6-Water
Toxicity	• LD-50: 175 mg/kg (ORL-RAT, Nickel Chloride-6-Water).
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.

Liquid in AC-PC Bottle phantoms	
First aid	• Skin contact: immediately remove contaminated clothes. Immediately remove residue substance (e.g. rinse with plenty of water). In case of serious exposure call a doctor.
	• Ingestion: Let victim drink 1 or 2 glasses of water. In case of general disorder call a doctor.
	• Inhalation: Bring victim immediately into fresh air, let rest and if necessary call a doctor.
	• Eyes: Rinse for a long time with plenty of water. In case of eye-sight disturbance consult a doctor.

Phantoms for 3.0T systems

Liquid in Head 200 mm phantom	
Personal protection	• Eyes: safety goggles
Constituents in weight percent	• 99.6 - 99.96% water
	• 0.02 - 0.37% sulfuric acid
	• 0.03 - 0.08% copper(II)sulphate
Toxicity	• LD-50: 300 mg/kg (ORL-RAT, copper (II) sulfate)
	• LD-50: 2.14 mg/kg (ORL-RAT, sulfuric acid)
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
First aid	• Skin contact: Rinse for a long time with plenty of water, then wash with soap and water.
	• Eyes: Rinse for a long time with plenty of water.

Liquid in 400 mm Body phantom and Bottle phantoms	
Personal protection	• Eyes: safety goggles
Constituents in weight percent	• 100% Spectrasyn 4 (ExxonMobil Chemical: http://www.exxonmobilchemical.com)
Toxicity	• Oral: LD50: > 15 g/kg Practically non-toxic.
	• Dermal: LD50: > 5 g/kg Practically non-toxic.
	• Inhalation: LD50: > 5 mg/l Practically non-toxic.
	• Eye irritation: Practically non-irritating.
	• Skin irritation: Practically non-irritating.

Liquid in 400 mm Body phantom and Bottle phantoms	
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
	• Clothing: Remove contaminated clothing. Launder contaminated clothing before re-use.
First aid	• Skin contact: Wash with soap and water.
	• Eyes: Rinse for a long time with plenty of water.
	• Inhalation: Not expected to be a problem.
	• Ingestion: Not expected to be a problem.

Liquid in AC-PC Bottle phantoms	
Personal protection	• Eyes: safety goggles
Constituents in weight percent	• >99.0% water
	• >0.25<1.0% Nickel Chloride-6-Water
Toxicity	• LD-50: 175 mg/kg (ORL-RAT, Nickel Chloride-6-Water).
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
First aid	• Skin contact: immediately remove contaminated clothes. Immediately remove residue substance (e.g. rinse with plenty of water). In case of serious exposure call a doctor.
	• Ingestion: Let victim drink 1 or 2 glasses of water. In case of general disorder call a doctor.
	• Inhalation: Bring victim immediately into fresh air, let rest and if necessary call a doctor.
	• Eyes: Rinse for a long time with plenty of water. In case of eye-sight disturbance consult a doctor.

Spectroscopy phantoms

Proton Phantoms

Liquid in proton sphere phantoms A	
Personal protection	• Eyes: safety goggles

Liquid in proton sphere phantoms A	
Constituents	• 5 ml/l 98% acetate (CH3COOH) • 10 ml/l 80% ethanol (CH3CH2OH) • 8 ml/l 98% Phosphorus acid (H3PO4) • 1 ml/l 1% arquad solution + 120 mg/l CuSO4 in demi water.
Total contents	• 524 ml
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
First aid	• Skin contact: Rinse for a long time with plenty of water, then wash with soap and water. • Eyes: Rinse for a long time with plenty of water.

Phosphorus phantoms

Liquid in phosphorus sphere phantoms B	
Personal protection	• Eyes: safety goggles
Constituents	• 30 g/l Methyl phosphoric acid P(OH)2O(CH3) in demi water
Total contents	• 524 ml
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
First aid	• Skin contact: Rinse for a long time with plenty of water, then wash with soap and water. • Eyes: Rinse for a long time with plenty of water.

Liquid in phosphorus disk phantoms A	
Personal protection	• Eyes: safety goggles
Constituents	• 300 mM H3PO4(phosphor acid) solution
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
First aid	• Skin contact: Rinse for a long time with plenty of water, then wash with soap and water. • Eyes: Rinse for a long time with plenty of water.

Liquid in phosphorus disk phantoms B	
Personal protection	• Eyes: safety goggles

Liquid in phosphorus disk phantoms B	
Constituents	• 300 mM H3PO2(phosphoric acid) solution
Emergency actions	• Spillage: Absorb the liquid in dry sand, diatomite, vermiculite etc. Shovel the mixture into plastic bags and remove to a chemical waste depot.
First aid	• Skin contact: Rinse for a long time with plenty of water, then wash with soap and water. • Eyes: Rinse for a long time with plenty of water.

Liquid in Gradient System

Gradient amplifier	

Constituents	• Distilled water 50%
	• Dowtherm SR1 9 (dyed pink) 50%, consisting of:
	  – Ethylene glycol CAS#000107-21-1 (>95%)
	  – Dipothassium Phosphate CAS#007758-11-4 (<3%)
	  – Water CAS#007732-18-5 (<3%)

Toxicity	The coolant may irritate the skin by contact.
Emergency actions in case of a leakage	• Absorb the liquid with an appropriate absorbent (e.g. powersorb, dry sand, diatomite etc.). • Dispose the used absorbent of (in plastic bags) according local legislation for chemical waste. • After a leakage, the gradient amplifier cooling system needs topping up. Contact Philips Customer Support.
First aid	• Skin contact: Immediately remove contaminated clothing and rinse the skin with plenty of water. • Eyes: Rinse for a long time with plenty of water.

Gradient coil coolant	
Constituents	• Distilled water (approximately 30 l) • Inhibitor, AZ8104 from Betz Dearborn (6ml) • Biocide, Spectrus NX 1164* or Spectrus 1106* from Betz Dearborn (2.7 ml)
Toxicity	The coolant may irritate the skin by contact.

Gradient coil coolant	
Emergency actions in case of a leakage	• Absorb the liquid with an appropriate absorbent (e.g. powersorb, dry sand, diatomite etc.).
	• Dispose the used absorbent of (in plastic bags) according local legislation for chemical waste.
	• After a leakage, the gradient coil cooling system needs topping up. Contact Philips Customer Support.
First aid	• Skin contact: Immediately remove contaminated clothing and rinse the skin with plenty of water.
	• Eyes: Rinse for a long time with plenty of water.

* Biocide, Spectrus NX 1164 or Spectrus 1106 is depending on your region.

Safety directions concerning a routine MR examination

General

⚠️ **WARNING**

The operator must inform the patient about the possibility of some system components (RF coils, interface boxes) warming up during scanning as a result of the applied energy.

Warm elements may frighten the patient when touched. All system components fulfill the requirements as defined in the IEC standards.

⚠️ **WARNING**

The operator must inform parents who are accompanying their child in the examination room, that during scanning physical contact with the child in the scanner is to be avoided.

Physical contact may result in excessive local tissue heating.

Screening prior to MR examination

Screening of patients prior to an MR examination is essential. This is especially important for those who could be at risk due to their occupation, past medical history, present medical condition or the physical environment of the MR system.

Particular caution must be exercised for the following classes of patients:

• Patients for whom MR examinations are contra-indicated, chapter "Contra-indications and MR Conditional implants" on page 58.

- Patients with a higher than normal likelihood of requiring emergency medical treatment, e.g. due to their present medical condition.
- Patients with a higher than normal likelihood of requiring emergency medical treatment as a result of the strong fields applied, when the system is operating in first level controlled operating mode.

⚠ **WARNING**

If in doubt, do not scan.

Contact the referring doctor.

Contra-indications and MR Conditional implants

⚠ **WARNING**

This chapter contains very important information about MR safety: In principle a qualified physician has to evaluate the risk/benefit ratio of the MR examination for every patient.

To date, there is no scientific proof that MR examinations are harmless for pregnant women, the unborn and children under two years of age.

Metallic implants

In general, an MR examination is contraindicated for patients with electronic or electronically conductive implants of metals, especially those containing ferromagnetic foreign matter.

These contraindications are based on effects caused by RF energy, the static magnetic field, and switching gradients. Potential hazards are displacement of the device in the body or device malfunction.

In addition, presence of implants may cause significant MR image artifacts or excessive (local) heating with potential loss of physiological function of vital organs or other serious injury.

Exceptions:
Certain implantable medical devices have been cleared, approved and/or licensed by the Competent Governmental Authorities and/or labeled by the manufacturer as "MR Conditional". For such devices, the general contra-indications may not be applicable in its entirety:
It is the responsibility of the implant manufacturer to declare an implant as MR Conditional if appropriate and to define the conditions (constraints) for safe MR scanning. The MR operator must be aware of any such conditions for MR scanning. It is the obligation of the MR operator to assure that these conditions are strictly adhered to. To obtain these specific conditions the operator may refer to the labeling of the implant or contact the implant manufacturer.
Philips does not assume responsibility or liability for the operation of the MR with any implantable medical device. Especially Philips is not responsible for controlling technical parameters of

the MR system other than those defined by the normal operating mode and the first level controlled operation mode, and the data provided in the Technical Description, such as spatial field gradient plots.

WARNING

The magnetic and electromagnetic fields may exert strong forces on metallic implants.

This may result in heating of the components of the implants.

WARNING

Do not allow persons fitted with metallic implants or electrically, magnetically, or mechanically activated implants (such as cardiac pacemakers) to enter the Controlled Access Area.

The magnetic and electromagnetic fields produced by the MR system can exert strong forces on these devices or interfere with their operation.

The magnetic and electromagnetic fields may exert strong forces on metallic implants.
This may result in heating of the components of the implants or may interfere with the operation of these devices.

Examples:

- Cardiac pacemakers and Conductive wires. The magnetic and electromagnetic fields may exert strong forces on the metallic implants or may interfere with the operation of these devices.

- Insulin pumps, nerve stimulators, cochlear implants.
  These are not necessarily contra-indications, but the examination may damage or impair them. Consult the referring doctor or radiologist.

Refer to the table below for additional technical information relevant to evaluating the risk of MR Conditional implants.

WARNING

The maximum dB/dt on the info page does not display the maximum dB/dt for automatically inserted pre-scans to calibrate the system. Please refer to the Gradients paragraph of the Technical Description.

Conditional information	What it is	Where to find / how to control
Main field strength (B0; T)	Strength of the magnetic field at iso-center.	Magnet façade or system manual. The Technical Description also contains a map of the varying field strength around the magnet, including the 5G line.
Static Field Gradient (SFG, MSG; G/cm or T/m)	The fringe field of the magnet varies with spatial location inside and around the magnet. The static field gradient is a measure of how quickly the field changes over a given distance. 1 T/m = 100 G/cm Note that the static field gradient is not related to the switching gradient used for imaging (mT/m/ms).	Spatial plots of the fringe field are provided in the Technical Description.
dB/dt (T/s)	The strength of the switching gradient used for imaging. The value is specified at a radial distance of 20 cm about central axis of the magnet bore. Note: this value varies spatially, but the 20 cm nominal value is used for implant labeling	The dB/dt value is calculated for every sequence and displayed on the info page of the parameter editor during scan definition. See warning above this table for pre-scans. The value can indirectly be controlled by setting the sequence parameters "gradient mode" to "regular" and "PNS mode" to "low". Note: Expect sequences with REST pulses to have high dB/dt values.

Conditional information	What it is	Where to find / how to control
Max SAR: Whole Body SAR and/or Head SAR (W/kg, for 15 min)		The SAR values are quoted differently on the Info page of the sequence definition UI.
		If Head SAR is the limiting SAR type, the actual Head SAR exposure can be obtained by multiplying the displayed percentage and the limit value of 3.2 W/kg.
		Setting the "SAR mode" parameter to low, limits the scan to the normal mode. (Whole Body SAR < 2 W/kg) Evaluate exposure per scan, and ensure that it does not exceed the values quoted in the MR Conditional labeling of the implant.

Implants of magnetic material

Examples:

- Intracranial aneurysm clips.
- Other surgical clips and staples.
- Artificial cardiac valves.
- Joint prostheses Contra-indication depends on the amount of ferromagnetic material and the possibility of heating and/or movement.
- Limb prostheses containing ferromagnetic materials.

WARNING

Most metallic implants are only tested for field strengths up to 1.5T.

For 3.0T systems extra care is necessary.

Metal splinters

Danger of movement of the splinters.
Danger of movement depends on location, size and time in situ. Movement can be limited by fibrosis. Small splinters of 1 mm or less can cause image artifacts and/or patient discomfort. Splinters are a potential hazard to the patient (if located in the orbit, for example). Ask the patient if he/she has ever worked in a metal industry or has had shrapnel injuries.

Pregnancy

Although there have been no documented adverse fetal effects reported, it is the responsibility of the physician to judge the risks/benefits of scanning a pregnant patient.

NOTICE

The fetus is especially thermally vulnerable during early pregnancy, scanning is not recommended in the first trimester or if pregnancy status is unknown.

NOTICE

Local regulations may consider the fetus as member of the general public, and strict exposure limits apply. The fetus is especially thermally vulnerable during early pregnancy.

When scanning a pregnant patient it is advised that the SAR level be limited to below 2W/kg (normal mode of operation).

Spine stabilizing devices

There is a risk to patients who require stabilization of the spine with a halovest or other similar device e.g. bracelets or prostheses.
RF interaction with the conductive metal parts of such devices could cause electrical arcing or undue local heating.

Patches

Medicinal products in transdermal patches (e.g. nitroglycerin transdermal delivery patch) may cause burns to the underlying skin due to absorption of RF energy. The supplier of the patches should be consulted or the patch should be removed to avoid burns.
A new patch should be applied after the examination.

⚠ **WARNING**

Tattoos, permanent (tattoo) eye-liner and facial make-up may contain ferromagnetic particles that could penetrate the tissues around the eye. This may also cause a "heating" effect.

High RF levels

High RF levels can be harmful to certain patients.

Metallic objects and clothing containing metallic parts

All clothing containing metallic thread, metallic components or conductive wires and all metallic objects must be removed from the patient.

Failure to do so may result in excessive local heating due to absorption of RF energy and may also influence the homogeneity of the magnetic field and lead to clinical misdiagnoses.

Examples:

- spectacles, dentures
- prostheses, hearing aids, arch supports
- watches, jewelry, medallions
- piercings
- buttons, hairpins, safety pins, buckles
- wigs, hair pieces
- clothing with zips and/or metal buttons
- bra

Damp clothing

Wearing damp clothing may result in excessive local heating.

NOTICE

Other contra-indications may be specified by local regulations.

Patient support and tabletop

The safe working load is 250 kg for the Ingenia FlexTrak trolley, Height Adjustable FlexTrak trolley and 250 kg for the patient support.

NOTICE

The safe working load as labelled on patient support and trolley is based on the sum of the maximum allowable patient weight and the mass of accessories and coils. The weights mentioned above are equal to the safe working load.

- The maximum weight load allowed for horizontal and vertical movement of the tabletop on the patient support is 250 kg.
- The maximum allowed weight load of the tabletop on the FlexTrak is 250 kg.

⚠ **WARNING**

Verify that patient's hands are on the tabletop before moving the tabletop into the magnet to avoid finger pinching.

Fingers can get pinched between tabletop and the system covers.

1. The special arm supports of the accessory set can be used to avoid finger pinching. The arm supports prevent the patient from grabbing around the table sides avoiding finger pinching during tabletop movement.
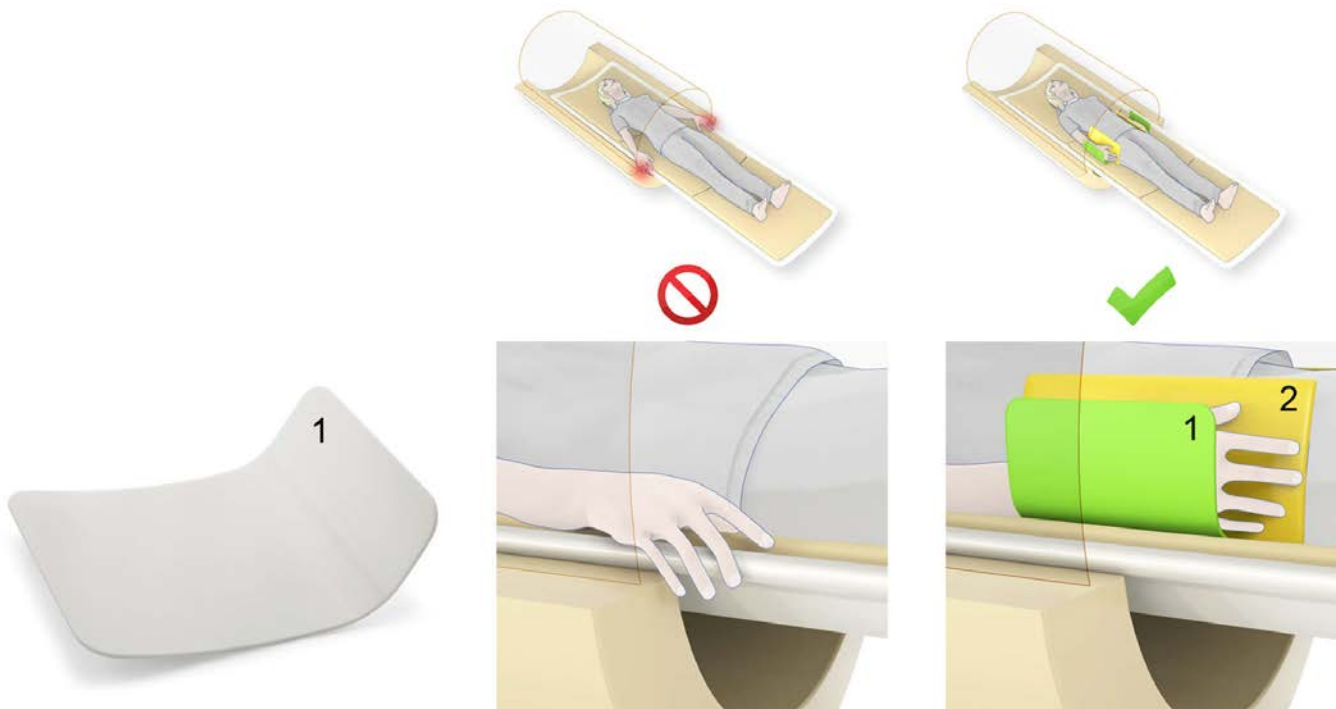
Fig. 19: Left: Arm support. Middle: Incorrect patient positioning. Right: Advised patient positioning with arm support (1) and padding (2).

⚠ **WARNING**

In prone position support the lower legs in such a way that the patient's toes are positioned higher than the tabletop surface.

If the patient's feet are positioned over the end of the tabletop, verify that the feet cannot be caught between tabletop and system parts when moving into the magnet.

⚠ **WARNING**

Take special precautions for anxious patients and patients in panic.

Use the accessories to immobilize a patient.

Communication

⚠️ **WARNING**

The 'Nurse call pinch ball' must be given and demonstrated to every patient.

This allows for communication between the patient and the operator at all times.
Check correct functioning of the 'Nurse call system' before each examination.

Pressing the 'Nurse call pinch ball' activates a buzzer that can be heard as long as the ball is squeezed. When the pinch ball is pressed more than once within 4 seconds or for more than 1.5 seconds, a flashing yellow light will also be activated in the control room to draw the personnel's attention.

It is advised to communicate when the system gradients are off.

⚠️ **WARNING**

Instruct the patient on using non-verbal communication signs.

Because of acoustic noise levels in the examination room verbal communication with the patient may be impaired.

Acoustic noise protection

Basic hearing protection must be worn by the patient during scanning. Such hearing protection is provided by appropriately fitted earplugs with sufficient damping (>30 dB).

NOTICE

Typical damping characteristic of the Philips' headset is 20 dB in the 1 kHz range.

⚠️ **WARNING**

Always apply hearing protection to the patient and anyone else present in the examination room before start scanning.

Without hearing protection, noise levels may be high enough to cause discomfort or result in temporary or even permanent loss of hearing.

⚠ **WARNING**

Hearing protection shall be used for the safety of the Patient. This hearing protection shall be sufficient to reduce the A-weighted r.m.s. sound pressure level below 99 dB(A); Pay special attention to the correct placement of the earplugs. Positioning of the headset is also critical for additional acoustic damping.

For scanning of patients to whom the earplugs or headset cannot be applied adequately (e.g. neonates and babies), special attention is required to use other means to obtain maximum hearing protection for these patients.

⚠ **WARNING**

It is MANDATORY to use earplugs which provide acoustic damping of 30 dB, or better.

⚠ **WARNING**

Acoustic noise protection
Hearing protection, e.g. earplugs or a headset, must be worn by the patient during scanning.

Without hearing protection, noise levels may be high enough to cause discomfort or result in temporary or even permanent loss of hearing.

⚠ **WARNING**

Always apply hearing protection to the patient and anyone else present in the examination room before start scanning.

⚠ **WARNING**

Always apply hearing protection to anesthetized patients.

Anesthetized patients are more sensitive to high sound pressure, so that hearing protection for these patients must not be omitted.

⚠ **WARNING**

Pay special attention to patients to whom the headset or earplugs cannot be applied adequately.

For scanning of patients to whom the headset or earplugs cannot be applied adequately (e.g. neonates and babies), special attention is required to use other means to obtain maximum hearing protection for these patients.

WARNING

It is MANDATORY to use earplugs when scanning with the gradient mode set to maximum.

For maximum patient comfort it is recommended to use both earplugs and headset.

WARNING

Special training for the operator is required for fitting earplugs for optimal hearing protection.

Follow the fitting instructions of the earplug manufacturer to assure maximum noise protection.

WARNING

Only use hearing protectors which contain no metal parts.

WARNING

Due to increased anxiety, accepted sound level may still be of concern to pregnant women, to neonates, infants and young children and to elderly patients.

WARNING

The sound level in the control area must comply with local regulations concerning exposure to noise at work.

WARNING

Personnel must wear hearing protection when present in the MR examination room during scanning.

NOTICE

It is advised to apply SofTone to reduce the noise level.

Message on the screen

The following message is displayed when the predicted sound level exceeds the maximum level for pediatric patients (age < 3 years).

Verify that appropriate hearing protection is applied to the patient.

The predicted sound pressure level of this scan is xx dB higher than recommended for pediatric patients (99 dB).

xx = the calculated sound pressure level for current scan - 99dB

This message is displayed when the predicted sound level exceeds the maximum level for pediatric patients (age < 3 years).

Click:

- Cancel to modify the scan.

- Confirm & start to accept the higher sound level and to start the scan.

Acoustic noise burden is characterized by the measurement method from NEMA MS 4:2010, to establish A-weighted RMS sound pressure levels, Laeq. Representative measurements for maximum acoustic noise are performed on an MR system installed according to specifications. Resulting acoustic noise levels comply with regulations from IEC 60601-2-33.

Sound level meter settings:

- Detector: r.m.s.

- Time weighting: fast or slow.

- Frequency weighting: A-weighting.

- Measurement duration: >20s.

Coil and cable positioning

Risk factors

The MR system dissipates energy from various sources. This can lead to a temperature rise of components surrounding the patient such as cables and RF coils. Usually the end temperature of these components do not exceed body temperature. In these situations there is no concern regarding patient safety.

The most important source of energy is the RF energy emitted by the transmit coil. Safety issues on the direct deposition of RF energy into the patient are described in chapter "Specific Absorption Rate (SAR)" on page 25.

When electrical cables are close to the patient (e.g. RF coil cables) or connected to the patient by electrodes (e.g. ECG cables), care must be taken to avoid situations of components heating up to high end temperatures.

WARNING

Never position heavy objects or let patients sit on the posterior coil cover of the patient support.

Heavy weight load can damage the coil, which may result in excessive heating and patient burns when scanning. The posterior coil cover is visible when the tabletop is removed or moved into the magnet bore.

WARNING

Avoid placing cable loops and twisted cables (RF coil cables and ECG leads) inside the body coil (RF area).

Loops can cause excessive heating of the cables which may result in burns upon contact to patient's skin. The cables must be routed parallel to the axis of the bore.

WARNING

Avoid routing of the RF coil cable assembly in proximity to the RF transmit coil. Avoid direct contact of the patient's skin with the RF coil cable assembly.

Failing to do so may result in excessive local heating and ultimately in skin burns. Positioning of the RF coil cable assembly must be done with care. Keep a distance to the patient's skin of at least 2 cm. Use the special spacer or pads of the standard accessory set where the cable assembly may touch the skin.

WARNING

The combined use of RF coils, high SAR levels and direct skin contact of the coils cables may cause local cable heating and can lead to skin burns.

WARNING

Ensure sufficient distance (> 2 cm at all positions) between coil cables when routed in parallel at the same side of the patient.

WARNING

Never attempt to bend or force the coil into an abnormal shape.

WARNING

Do not place the coil perpendicular to the main magnetic field.

WARNING

Always run the cable directly away from the region of interest.

⚠ **WARNING**

Position and secure the cable in the grooves of the tabletop.

⚠ **WARNING**

Do not leave unconnected coils on the tabletop.

All coils present on the tabletop must be connected to the system regardless whether the coils are being used for imaging or not. RF energy may cause heating of the coils, skin burns to the patient and destruction of the preamplifiers inside the coil.

NOTICE

Combination of receive coils is restricted by the software.

In case of combination of RF receive coils, cable handling is even more critical to avoid excessive local heating.

⚠ **WARNING**

Always position the cables of the coils parallel to the direction in which the table moves. A minimum of 2 centimeters clearance must be secured between the cable and the bore covers (as well as between the cable and the patient).

NOTICE

Always use dedicated pads and mattresses provided with the coils.

Moving the patient into the magnet bore

⚠ **WARNING**

In manual mode move the table slowly into the magnet bore.

Fast movement can cause mispositioning and may result in misdiagnoses.

WARNING

Before starting a scan which initiates tabletop movement, always check that nothing can get caught or hit during tabletop movement.

Check patient, patient extremities, clothing, equipment and positioning aids. Guide cables and intravenous lines. This especially applies when Transmit/Receive (T/R) coils are used, which are connected to the T/R socket at the UIM.

WARNING

Verify if an urine bag is present at the patient. Empty the urine bag before starting an examination.

Spilled urine can form a conductive path possibly resulting in an electric shock.

WARNING

Verify that no blankets, sheets, pillows or clothing hang over the front and end side of the tabletop or are wrapped around it.

These objects may get caught between tabletop and patient support during table movement. This can block tabletop movement even when in manual mode.

WARNING

Avoid contact of the patient's body or extremities with the RF transmit coil or system body coil surface.

This may result in excessive local heating.

WARNING

Due care must be taken to verify that no part of the patient's body, hair, clothing, cables or infusion lines can get trapped or injured by any part of the equipment.

NOTICE

The operator must be aware that the patient may have claustrophobic reactions when moved into the magnet.

A panicking patient may hurt itself or damage equipment.

Messages on the screen

The following message is displayed before table movement is initiated.

Verify that the tabletop can move without harm to the patient. This scan can only start if the table is moved.

Verify that nothing can get trapped or caught when starting table movement: Infusion lines, leads, extremities, hair, blankets etc.

Click:

- Cancel to modify the patient preparation.
- Select one of the two options:
  - Allow the tabletop to move for this scan only.
  - Allow the tabletop to move with normal speed for all scans.
- Followed by clicking Confirm & Start to initiate table movement and to start the examination. Depending the previous selection the:
  - Examination is paused after the first scan, the message is displayed again for the next scan.
  - Examination is started with automatic table movement for all scans.

The following message is displayed before table movement is initiated.

Careful positioning of the patient is required.

This scan can also start without table movement. However, for optimal image quality table movement is advised.

Verify that nothing can get trapped or caught when starting table movement: Infusion lines, leads, extremities, hair, blankets etc.

- Cancel to modify the patient preparation.
- Select one of the three options:
  - Allow the tabletop to move for this scan only.
  - Allow the tabletop to move with normal speed for all scans.
  - Do not allow tabletop movement.
- Followed by clicking Confirm & Start to initiate table movement and to start the examination. Depending the previous selection the:
  - Examination is paused after the first scan, the message is displayed again for the next scan.
  - Examination is started with automatic table movement for all scans.

The following message is displayed before table movement is initiated.

Verify that the tabletop can move fast without harm to the patient. Be aware that the tabletop can make long strokes.

Verify that nothing can get trapped or caught when starting table movement: Infusion lines, leads, extremities, hair, blankets etc.

Click:

- Cancel to modify the patient preparation.
- Confirm & Start to initiate table movement and to start the current scan.

The following message is displayed while the tabletop is moving.

The tabletop is moving automatically.

Click: Stop movement to immediately stop tabletop movement in case something unexpected occurs.

Observation of the patient.

WARNING

Visual observation and medical supervision is required for all patients who cannot attract the operator's attention (e.g. pediatric, unconscious or sedated patients).

WARNING

Pay special attention to scanning of sedated or unconscious patients or patients with loss of feeling in any body part, e.g. paralysis of arms or leg.

These patients are unable to sense excessive local heating, excessive sound or peripheral nerve stimulation and are unable to alert the operator.

Scanning Sedated and Anesthetized Patients

Anesthetized and sedated patients can have compromised thermoregulatory performance, particularly in the extremities. In addition, they are unable to notify the operator of any adverse events that may take place during scanning. If it is necessary to scan such patients then, in addition to the required medical supervision and physiological signs monitoring activities, observe the following:

- Avoid scanning in 1st level controlled mode.
- Keep the SED low, preferably below 3.5 kJ/kg.
- Keep the whole examination duration as short as possible.
- Use low SAR scans as much as possible while avoiding back to back high SAR scans.
- Examine the patient between individual scans to detect potential burns before they progress.

BOLD imaging package

The BOLD imaging package contains a Functional Brain Imaging box. Its intended use is to synchronize external devices to create functional imaging protocols/paradigms by means of a galvanic separated trigger pulse generated by the functional imaging pulse sequence.

⚠ **WARNING**

Manufacturer recommends the proper use of the Functional Brain Imaging box in connection with external devices that are compliant with IEC 60950 class I or class II equipment.

Only devices that are compliant with the aforementioned IEC standards may be connected to the box outside the examination room.

⚠ **WARNING**

The EMC immunity of the Functional Brain Imaging box complies with IEC 60601-1-2. The maximum level of discharges is 2.5 kV at a distance of 50 cm from the box and must not be exceeded.

Under certain circumstances when static discharges occur in the direct vicinity of the Functional Brain Imaging box, false trigger pulses may occur which may distort the synchronization of the functional imaging protocol or paradigm and the functional imaging sequence. Consequently, such a false trigger may compromise the image quality of the functional brain study.

Imaging Techniques

General

⚠ **WARNING**

Applying imaging techniques must always be done with great care to avoid any unwanted effects like artifacts.

Correct parameter optimization is essential for optimal image quality.

SENSE

The SENSE/CLEAR parallel imaging technique must be applied carefully to avoid unexpected and possibly unidentified image artifacts. The technique can be used successfully to speed up the scan technique, get a ideal homogeneity correction or optimize the protocol in a number of other ways (SAR reduction, acoustic noise reduction, resolution improvement, etc.).

A number of specific warnings and notes are given in the following.

⚠ **WARNING**

With CLEAR and SENSE significant artifacts may occur in case of gross patient motion between the reference scan and the CLEAR or SENSE scans.

The patient must to be instructed not to move head or limbs between scans.

WARNING

Artifacts may occur if the SENSE or CLEAR scan is performed with inspiration breath hold.

NOTICE

Both SENSE reduction factors will decrease the actually encoded field-of-view (FOV) in P and S direction, respectively. This implies increased k-space steps.

Geometry compensation

WARNING

For comparing images the same type of geometry compensation must be used.

Erroneous distance, area and volume measurements may lead to misinterpretations. Stereotaxy guidance can be distorted which may lead to personal injury.

k-t BLAST

WARNING

The k-t BLAST acquisition technique assumes repeated cyclic behavior of the moving tissue in time. Changes in this behavior can result in incorrect interpretation of details.

Spectroscopy

NOTICE

The system supports export to a proprietary file format. However, since this is not a published standard, Philips makes no claims about the correctness of this file.

CAUTION

Do not use the coils in an unloaded situation.

When the load (normally the patient) is removed from the coil, or vice versa, the voltages may damage the capacitors of the spectroscopy coils.

> **WARNING**
>
> In 3.0T applications, distortions in spatial shift of the CSI PRESS box may lead to misdiagnoses.
>
> Analogous to the fat-water slice shift in imaging, the voxel volume localized using STEAM or PRESS for one metabolite is displaced relative to that for a different metabolite with a different chemical shift. The relative size of this spatial displacement is greater at higher field strengths, because chemical shift differences in Hz scale with the main magnetic field. In chemical shift imaging (CSI), the displacement of localization volumes will give rise to distorted relative intensities and incorrect peak area ratios in spectra from voxels at the edges of the region of interest, where the volumes do not overlap.

The PlanScan Metabolite and Shifted Metabolite boxes displayed during scan set-up, can be used to determine which voxels lie in the overlap region for two metabolites of interest, both in-plane (for 2D and 3D CSI) and in the slice direction for 3D CSI. Choosing higher bandwidth RF pulses (such as the "sharp" excitation pulse) can help to minimize the mismatch.

An alternate for 2D CSI is to use spin-echo slice localization (plus multiple REST slabs if necessary) instead of PRESS or STEAM volume localization, this method eliminates in-plane chemical shift displacement and associated peak ratio distortions, and is recommended for 3.0T.

Another approach for 3.0T is "overprescription", using a set of high bandwidth REST pulses (power level 3 or 4) applied with negative gap values to saturate signal from non-overlapping regions, effectively redefining the actual localized volume. Whatever the technique, it should be noted that SpectroView does not apply any correction factors for chemical shift displacement.

On Planscan and Review planscan

Since the actual contents of "processed data" in multi voxel experiments can be changed by the order of processing and the actual commands used, the following must be taken into account:

Double volume

The planscan and review planscan show the correct volume numbers only after postprocessing with the available postprocessing batch DOUBLE.scom.

Network safety, security and privacy

Customer Role in the Product Security Partnership

We recognize that the security of Philips Healthcare products is an important part of your facility's security-in depth strategy. However, these benefits can only be realized if you implement a comprehensive, multilayered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The actual implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, authentication technologies, etc.

As with any computer-based system, protection must be provided such that firewalls and/or other security devices are in place between the medical system and any externally accessible systems.

Although the system incorporates state-of-the-art protection mechanisms to protect it against the intrusion of malware (viruses etc.) a remote probability remains that a system can become infected. In all circumstances system safety remains secure, but the user might notice unfamiliar system behavior and/or performance. If this happens repeatedly, e.g. also after the system has been switched off and on again, the user is advised to call Philips Customer Service to have the system checked and if needed cleaned from malware.

The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

NOTICE

The internal electronic log files generated by this product as a part of its normal operations, will contain the names of storage folders created by the user, and therefore will include any patient, clinician or other personal identifying information used in such folder names.

In the course of maintenance, monitoring or repair of this product or of related development and other product-related activities, Philips may access, store or otherwise use those log files.

Any connection of a device to a hospital network should be done with appropriate risk management for safety, effectiveness, and data and systems security. For guidance on risk management, see the IEC-80001-1 standard.

Additional security and privacy information can be found on the Philips product security website at *http://www.philips.com/productsecurity*. Please review Philips product security policies regarding remote service, patch management, anti-virus software and more in the "Product Security Policy Statement" and additional information sources available through this website.

CAUTION

The internal electronic log files generated by this product as a part of its normal operations, will contain the names of storage folders created by the user, and therefore will include any patient, clinician or other personal identifying information used in such folder names. In the course of maintenance, monitoring or repair of this product or of related development and other product-related activities, Philips may access, store or otherwise use those log files.

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Alarms Overview

The following auditory alarms can occur:

1. Nurse Call
   This alarm is triggered when the patient presses the nurse call button twice or longer than 1.5 sec. This way, the patient on the table can call attention to discomfort or a potentially harmful condition.

   The proper functioning of the nurse call button should be tested during patient preparation, for each new patient. The function of the nurse call button should be explained to the patient.

The sound pressure of the Nurse call is designed to be at least 80 dB(A).

The following visual alarms can occur at the console:

1. Automatic table movement
   This alarm is triggered before automatic table movement is started.

2. High SED
   This alarm is triggered when the current scan exceeds the maximum SED level for the patient.

3. High SAR scan
   The alarm is triggered when an scan is selected that requires SAR 1st level controlled mode. This may lead to increased body temperature.

4. High dB/dt scan
   This alarm is triggered when a scan is selected that requires PNS 1st level controlled mode. This may lead to perceived peripheral nerve stimulation (PPNS)

5. High sound pressure level for pediatric patient
   This alarm is triggered when a scan is selected for a pediatric patient that requires high sound pressure level

6. Patient ventilation
   This alarm is triggered when the patient ventilation is below the recommended level for the selected scan.

7. Remote Desktop
   This alarm is triggered when a remote desktop session is initiated.

8. Helium overpressure
   This alarm is triggered when the Helium overpressure is too low.

Important messages and indications

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

Messages	
English	**Translation**
Allow First Level Controlled Operating Mode for SAR?	**Allow First Level Controlled Operating Mode for SAR?**
Medical supervision of the patient is required. Whole Body SAR of scan is between 2 and 4 W/kg.	Medical supervision of the patient is required. Whole Body SAR of scan is between 2 and 4 W/kg.
See Instructions for Use.	See Instructions for Use.
Allow all scans which require Whole Body SAR > 2 W/kg?	Allow all scans which require Whole Body SAR > 2 W/kg?
• Confirm and Start • Cancel	• Confirm and Start • Cancel
Allow First Level Controlled Operating Mode for PNS?	**Allow First Level Controlled Operating Mode for PNS?**
Medical supervision of the patient is required. Peripheral Nerve Stimulation of scan is between 80 and 100 %. See Instructions for Use.	Medical supervision of the patient is required. Peripheral Nerve Stimulation of scan is between 80 and 100 %. See Instructions for Use.
Allow all scans which require PNS > 80%?	Allow all scans which require PNS > 80%?
• Confirm and Start • Cancel	• Confirm and Start • Cancel
Scan will exceed maximum SED level	**Scan will exceed maximum SED level**
Cannot start scan. Execution would exceed the maximum allowed Specific Energy Deposition in the patient. See Instructions for Use.	Cannot start scan. Execution would exceed the maximum allowed Specific Energy Deposition in the patient. See Instructions for Use.
• Close	• Close
Patient Ventilation Warning	**Patient Ventilation Warning**
The patient ventilation is below the recommended level.	The patient ventilation is below the recommended level.
Press <Modify…> to modify the patient ventilation level. Refer to the Instructions for Use for information about patient ventilation.	Press <Modify…> to modify the patient ventilation level. Refer to the Instructions for Use for information about patient ventilation.
Press <Proceed> to proceed with the current patient ventilation level.	Press <Proceed> to proceed with the current patient ventilation level.
Press <Cancel> to cancel the scan.	Press <Cancel> to cancel the scan.
• Modify • Cancel • Proceed	• Modify • Cancel • Proceed
Moving TableTop	**Moving TableTop**
The tabletop is moving automatically.	The tabletop is moving automatically.
• Stop	• Stop

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

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

Auxiliary Medical equipment

Only use Philips-approved Multiple Socket Outlet (MSO) to power auxiliary equipment, as approved for connection through MSO by Philips.

⚠ **WARNING**

Assessment of compatibility and use of auxiliary devices for physiological monitoring or sensing inside the MR Examination room is the resposibility of the hospital. Always involve your local Safety Officer in this process and follow the equipment manufacturer's guidance.

⚠ **WARNING**

All accessories used with the MR system must be labeled MR safe or MR conditional safe, see table below for labeling.

Third parties claims about MR compatibility of accessories must be interpreted with care: Philips does not verify these claims.

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WARNING

After an upgrade of the system, e.g. to higher gradients, do not use auxiliary medical equipment approved for use with the system configuration before the upgrade, unless recognized as tested for use with this configuration after the upgrade.

WARNING

Changes and/or additions to the MR system that are carried out using untested auxiliary medical equipment may lead to the Philips Healthcare warranty being voided. Do not use unapproved auxiliary medical equipment.

This equipment carries serious risks to cause damage to the system or personal injury.

WARNING

Third party RF coils cannot be used in combination with Philips RF coils nor with SENSE and CLEAR.

WARNING

The physiology sensing devices of the MR scanner are only intended for sequence triggering purposes.

Patient monitoring of physiological signals and application of sensing devices is subject to requirements and specifications of the monitoring equipment manufacturer.
It is the responsibility of the hospital and the operator to implement necessary safety provisions and to understand potential interferences with monitoring reliability introduced by the MR scanner.

WARNING

The use of auxiliary equipment, such as physiological monitoring and gating equipment and radio frequency coils, which have not been specifically tested and approved for use with Philips MR systems may result in burns or other injuries to the patient.

WARNING

Auxiliary devices labeled as MR conditional may cause injury if the manufacturer's instructions, especially with respect to electrically conducting lead positioning, are not followed.

WARNING

Auxiliary devices labeled as MR conditional may only be used in combination with Philips MR systems when the conditions specified in the manufacturer's instructions for use are fulfilled.

WARNING

Auxiliary devices not labeled as compatible with MR equipment may be affected by electro-magnetic interference (EMI).

This may influence the proper functioning of the Auxiliary device.

NOTICE

For description and further Instructions for Use on compatibility test protocols, see the Technical Description of the system.

MR compatibility labels on third party equipment

The compatibility of third party equipment in combination with the MR systems is regulated via special warning labels (see below). These warning signs indicate whether the third party equipment is MR safe, MR unsafe or MR conditional.

When the equipment is marked as MR conditional these conditions must be described in the Instructions for use of this equipment.

Warning label	Category
	MR safe
	MR conditional
	MR unsafe

Symbols on System, Coils and Accessories

The following symbols are used with on system if applicable.

General symbols	Meaning
	Type B applied part (IEC 60601-1)
	Type BF applied part (IEC 60601-1)

Mandatory Action symbols	Meaning
	Consult manual (Instructions for use)
	Hearing protection required
	ONLY screened and approved devices allowed in scanning room

Prohibition symbols	Meaning
	Active implants, metallic implants prohibited
	Metallic implants prohibited
	Metallic body implants prohibited
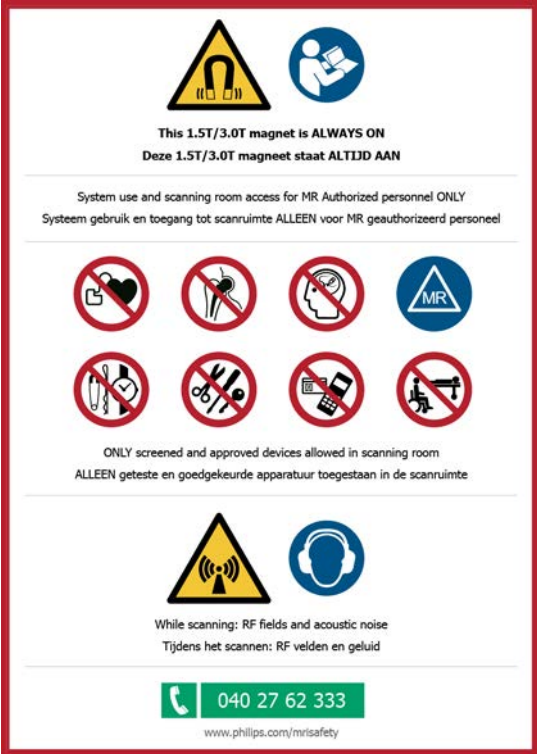
Prohibition symbols	Meaning
	Loose ferromagnetic objects and mechanical watches prohibited
	Loose ferromagnetic tools prohibited
	Wheel chairs and equivalent metal objects prohibited
	Magnetic media prohibited (credit cards, diskettes, magnetic tapes)
	Loading prohibited
	Label on (dS) T/R Knee 16ch 3.0T coil: Scanning pediatric patients is not allowed with this coil

Hazard Identification symbols	Meaning
	Warning, consult manual (Instructions for use)
	Strong magnetic field
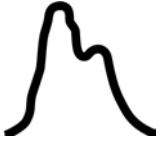
Hazard Identification symbols	Meaning
	High frequency electromagnetic field
	Danger of pinching
	Laser light

Safety marking plate	Explanation
	Examination room door safety marking plate. For explanation of symbols see other tables in this chapter.

Medical symbols	Meaning
	ECG

Medical symbols	Meaning
	Peripheral pulse/blood pressure

Disposal symbol	Meaning
	Dispose of in accordance with your local regulation.

Environmental symbol	Meaning
	The environment-friendly use period of this product is 50 years. (according to People's Republic of China Electronics Industry Standard SJ/T11364-2006)

Accessories list

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

- VCG module.
- Respiratory module.
- FlexTrak patient transportation system, fixed height (FH) and height adjustable (HA).
- Tabletop.
- Arm support.
- Breast Support iRF.
- FlexTilt tilting device.
- All RF coils.
- dStream Interface.

3 Maintenance and Quality assurance

Planned maintenance, Quality assurance and routine user checks are necessary to keep the system operating safely, effectively and reliably.

Planned maintenance

The operator should always take all practical steps to make sure that the planned Maintenance Program is fully up to date and that all routine user checks have been satisfactorily completed before using the system to examine a patient.

Planned maintenance 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 are available from your Customer Support Organization.

Routine user checks program

The scheduled 'routine user checks program' is as follows:

Routine check	Daily	Weekly	Time (min.)
Nurse call	+	+	1
Check emergency stop button on both UIM's	+	+	1
Patient support	+	+	5
Coils and patient accessories	+	+	10
Magnet check		+	5
Check virus scanner definition date. The last update should not be older then one week.	+		2
Operator's Console		+	5
Printer		+	5
Periodic Image Quality Test		+	15

Also refer to the section on 'Cleaning'.

Miscellaneous checks

- Check the function of the red Emergency stop buttons on both UIM's. When pressed, the button is lit red. Press the resume button to exit the stop mode. When a failure occurs the following message appears on the console: Possible failure of Stop button at magnet. Please call Philips Service.
- Inspect coils for damage to coverings and connectors.
- Check the ink cartridge for correct printing and replace it if necessary.

Weekly magnet check

This magnet check must also be performed during holiday periods.
Measure the helium level in the magnet cryostat and note the measured values in the logbook.

- Check if the sound of the compressor is still normal.

⚠️ **CAUTION**

The compressor for the helium refrigerator must always be running.

Excessive helium boil-off occurs if this unit is switched off.

- Measure the helium level in the magnet cryostat and note the measured values in the log book:
    - Logon to the system.
    - Click the Windows |Start| button and select |All Programs|, |MR User| and |Display Helium Level|.
    The Helium Level is displayed in a pop-up window.

NOTICE

The helium level is displayed with a delay of 20 seconds. Do not use the |Enter| key during that time.

NOTICE

Please contact your local Philips service if significant helium boil-off is observed.

Philips MR systems are equipped with a zero helium boil-off cooling system. Under normal operating conditions no helium gas evaporates.

Topping up liquid helium

Once a year (or less, depending on the magnet type) the liquid helium in the magnet must be topped up by an authorized Customer Support engineer.

The minimum acceptable helium level is 30%. This is because the magnet coils must be immersed in liquid to ensure that they remain superconductive. If the helium level is 30% or lower you have to contact the local Customer Support Organization.

Anti-virus updates

The MR system is equipped with anti-virus software which is designed to detect viruses on your system and to deny access to infected files, before they can do any damage.

Anti-virus definitions should be updated on a regular basis, usually every day. The Anti-virus definitions update mechanism automatically looks for updated virus definition files at a pre-configured time (as set by service engineer or hospital administrator) and installs them, if available.

NOTICE

It is the responsibility of the system operator to daily check if the anti-virus definitions are up to date.

Check the anti-virus definirions date

- Right-click on the virus scan icon in the tray of the windows task bar and select 'About...'.
- In the displayed window check the "DAT Created ON" date.

An update is neccessary if the date of the definitions is older than 7 days (compare with current date).

Update the anti-virus definitions

- Right-click on the virus scan icon in the tray of the windows task bar and select 'Update Now ...'.
  The anti-virus definitions are automatically updated.
- After the update has finished recheck the date of the definitions.

Periodic Image Quality Test (PIQT)

NOTICE

It is advised to use the PIQT over any other quality assurance program.

PIQT offers an automated and consistent test procedure.

A regular (weekly) execution of predefined scans to monitor the system performance enables early detection of any system deterioration.

PIQT is based on three scans made with the 200 mm head phantom. The scans and analyses are performed automatically and the results are stored. The service engineer can (remotely) access the results of the PIQT.

The scans are performed with the following coils:

Possible Coils	
1.5 T systems	**3.0 T systems**
dS Head	dS Head

Possible Coils	
1.5 T systems	**3.0 T systems**
Q-Body	Q-Body

NOTICE

Apart from the automatic evaluation, it is recommended that the images are visually inspected by the operator or a physicist.

NOTICE

Further options for evaluation and inspection are available in PIQT. For more information please contact your Philips service representative.

Performing PIQT scans

The PIQT test will take approximately 15 minutes. ExamCards are not supported in the applications PIQT and SPT (System Performance Test).

1. Select 'SPT' from the System menu.

2. Click the 'PIQT' icon or select |File| followed by |Perform PIQT| on the main menu bar. The PIQT windows opens.

3. Follow the instructions on the PIQT window:
    position the phantom in the head section of the coil and move the coil to the isocenter.

4. Click |Proceed| to start the scans.
    The PIQT procedure will run automatically making survey scans, making PIQT scans and evaluating the results.

Remove the phantom when the scans are finished. The system is available for routine use. The PIQT program will analyze the images in the background.

Quality Assurance (QA) Tool for (BOLD) Stability

In order to make sure that the very small BOLD (fMRI) signal is not superimposed by noise, all noise contributions need to be minimized for optimum BOLD results.

The QA Tool provides means to measure stability based on an ACR method. It calculates all *Function Biomedical Informatics Research Network (FBIRN)* metrics based on a predefined protocol according to FBIRN guidelines:
Friedman L, and Glover GH. "Report on a multicenter fMRI quality assurance protocol" JMRI 23:827–839 (2006) .

NOTICE

It is advised to run the QA Tool on a regular base, preferably once a week.

Items needed for QA Tool Stability

The following items are needed:

- Sphere A phantom

  The Sphere A phantom is a 10 cm diameter sphere with a water-based solution. The second choice is the FBIRN gel phantom which is a bigger (17 cm diameter) sphere.
  The air bubble in the phantom needs to be as small as possible.

- dS HeadSpine coil solution (Base coil and Head top coil)
- Foam Pads
- Straps
- Sandbags

Fig. 20: Items needed for QA tool for Stability, Ingenia system.

Workflow QA Tool Stability

▶ Select 'SPT' from the System menu.
  The System Performance Tool window opens.

▶ Click '+' to expand the 'Batch files' and '+' again to expand the 'FMRI' folder.

▶ Right-click on the coil folder and select 'Run Batch'.
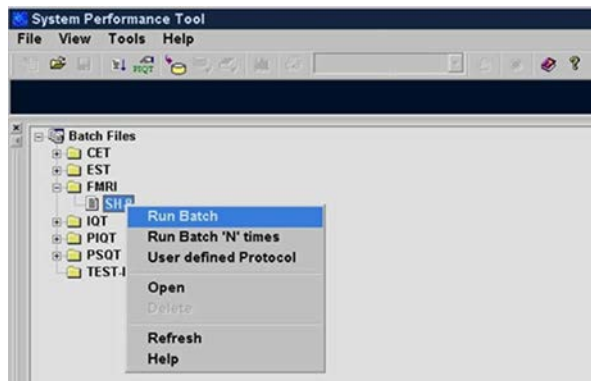
Fig. 21: System Performance Tool window: right-mouse menu with 'Run Batch' selected.

► Follow the instructions in the window:

   • Set up the phantom in the Head coil, using foam pads to raise it close to the center of the coil.

   • Secure it with foam wedges or straps.

   • Do not use a sandbag in the Head coil. A sandbag can be used on top of the coil to ensure proper connection of the coil.

   • Landmark to the center of the phantom and move the table to the scan plane.

Fig. 22: Set up Ingenia.

► Start the acquisition: Click |Proceed| to start the scans.
The procedure will run automatically making all scans needed.

NOTICE

The scan starts after a waiting period to avoid fluid motion artifacts. Do not skip this waiting time

Skipping the waiting time can result in automatic plan scan problems and can have negative influence on the IQ results.

► Press 'Analyze' to analze the results and to display and evaluate the results.

► Remove the phantom when the scans are finished. The system is available for routine use.

The following results will be provided:

- Residual Noise graph

  RMS Stability graph

- SFNR image

- Static spatial noise

- numeric results, e.g. Drift, Standard deviation, SNR summary value, SFNR summary value, Noise spectrum peak
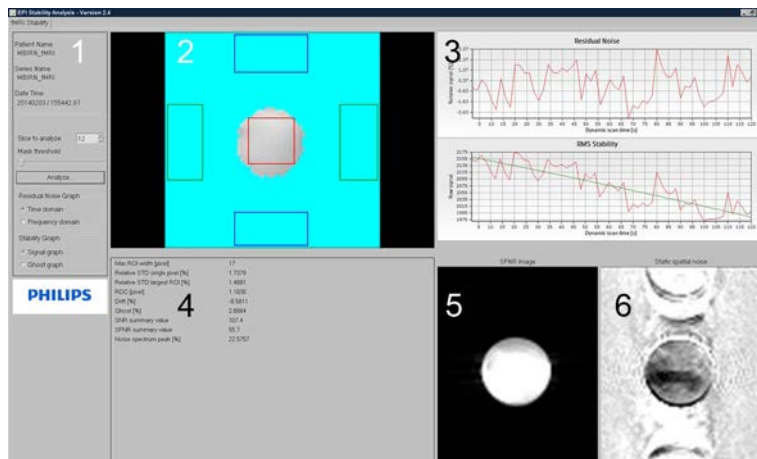
Fig. 23: QA results of a poorly performing system where 1 - Control Area, 2 - Threshold mask overlaid to image with ROIs as used for the calculation, 3 - Residual Noise and RMS Stability graphs, 4 - numeric results, 5 - SFNR image, 6 - Static Spatial Noise image. The Static Spatial Noise image shows many ghosts which is an indication for a poorly performing system.

Cleaning and Disinfection

Introduction

This section contains information on cleaning and disinfection of the system, system components and accessories.

Cleaning and disinfection must comply with all applicable laws and regulations which have the force of law within the jurisdiction(s) in which the system is located.

NOTICE

Perform a routine system cleaning cycle before first use, and after maintenance.

WARNING

Before cleaning and disinfection of the system, system components and accessories, it is essential that you read and familiarize yourself with all Warnings and Cautions given in the safety chapter.

WARNING

Clean up spilled liquids immediately.

WARNING

Never allow water or other liquids to enter the system.

Contact your service technician if liquid has entered the system.

WARNING

It is important that all parts of the system, coils and accessories are completely dry before starting an examination.

NOTICE

Do not use aggressive detergents, organic solvents or abrasive cleaning agents to clean the equipment.

Aggressive detergents, alcohol, and organic cleaners may damage the finish and also cause structural weakening. If you are not sure about the properties of a disinfectant agent, do not use it.

NOTICE

It is recommended to clean and disinfect the bore, mattresses, accessories and coils that have been in contact with the patient after each patient.

NOTICE

It is recommended for the entire staff to wash and disinfect their hands (hand sanitizer) after each patient.

NOTICE

It is recommended to use sheets or MR compatible examination table paper to cover the tabletop before positioning a patient. However the use of sheets and paper without actual cleaning and disinfection will not prevent spread of infectious agents.

Cleaning

Cleaning is an essential step before effective disinfection.

Cleaning is the physical removal of foreign material, e.g. dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning generally removes rather than kills microorganisms. Cleaning is accomplished with water, detergents and mechanical action.

Use only mild household cleaning detergents, diluted in water. Use a soft damp cloth. Do not apply large amounts of water in cleaning.

WARNING

Do not immerse or allow any type fluid to enter the system, system components, coils, coil contacts (of separable coils) and connectors.

Liquids may cause electrical short-circuits or metal corrosion.

WARNING

If fluids are suspected to have entered inside system covers, contact your local Service for support.

WARNING

Never clean electrical parts, such as the UIM and connectors, with a damp or wet cloth unless the system or system parts are switched off.

WARNING

Use proper personal protection and precautions when removing blood or residual contrast medium. Blood and contrast medium are potentially infectious.

See the table in section **Components, procedures and frequency** for cleaning frequencies.

Disinfection

Disinfection is the inactivation of disease producing microorganisms. Disinfectants are used on inanimate objects in contrast to antiseptics, which are used on living tissue.

Levels of disinfection.

The table below shows the different classifications of disinfection. The level of disinfection required for a device is dictated by the type of tissue it will contact during use.

Classification	Definition	Level of disinfection
Critical	Device enters otherwise sterile tissue (for example, intraoperative applications)	Sterilization
Semi-critical	Device contacts mucous membranes (for example, intra-cavity applications)	High
Noncritical	Device contacts intact skin	Intermediate or low

The disinfection of the MR system, components and accessories is classified as non-critical and requires an intermediate or low level disinfection.

Low level disinfectants kill most vegetative bacteria and some fungi as well as enveloped (lipid) viruses (e.g., hepatitis B, C, hantavirus, and HIV). Low level disinfectants do not kill mycobacteria or bacterial spores.
Intermediate level disinfectants kill vegetative bacteria, most viruses and most fungi but not resistant bacterial spores.

NOTICE

In some countries disinfection is not differentiated in low, intermediate and high level.

The following factors will affect the efficiency of a disinfectant solution:

- Duration of exposure.
- Age of the solution.
- Concentration and potency of the disinfectant.
- Quantity and location of the contamination.
- Resistance of the contaminant.
- Organic matter on the item to be disinfected.

Disinfectants and compatibility

The following disinfectants should be used because of their chemical compatibility with the product materials.

Disinfectant	Disinfection level
Isopropanol 70%	Intermediate
Ethanol 70%	Intermediate
Chlorehexidine 0,5% in 70% Ethanol	Intermediate

⚠️ **CAUTION**

Only the described disinfectants are tested and recommended by Philips Healthcare.

Philips Healthcare cannot be held liable for damages caused by using different products or compositions.

⚠️ **CAUTION**

Do not mix different disinfecting solutions.

Hazardous gases may develop.

⚠️ **CAUTION**

Do not use iodine or colored disinfectants.

Iodine or colored disinfectants may cause a discoloration of the affected material.

⚠️ **CAUTION**

If a premixed solution is used, be sure to observe the solution expiration date.

The use of bleach (Chlorine) as disinfectant

Bleach is widely used as a disinfectant because of its price, availability and effectiveness.

⚠️ **CAUTION**

A Bleach solution of more than 250 ppm is not recommended by Philips Healthcare because the chemical compatibility with the product materials has not yet been tested.

A bleach solution of 250 ppm has been tested as compatible with the system materials. Philips Healthcare cannot be held liable for damages caused by using higher bleach concentrations .

NOTICE

Check the concentration of bleach products before use.

Different bleach products may contain different concentrations of available chlorine.

- A bleach solution of 500 ppm is used for disinfecting surfaces.
- A bleach solution of 5000 ppm is a strong and effective disinfectant for cleaning up blood or body fluid spill.

⚠️ **CAUTION**

Chlorine 5000 ppm solution is caustic. Avoid direct contact with skin and eyes.

Equipment and tools

⚠️ **WARNING**

Do not use cleaning and disinfection equipment and tools that contain ferromagnetic material, e.g. pails made of metal and spray aerosols.

Only use MR safe equipment and tools.

Commercially available MR-safe equipment and tools can be used. Strictly follow the manufacturers instructions.

Use soft cloths, disposable tissues and wipes.

Components, procedures and frequency

The following table gives an overview of system components and procedures concerning cleaning and disinfection.

Four different procedures have been identified for cleaning and disinfection. Procedures for:

- Hard surfaces.
- Soft closed surfaces.
- Surfaces with an open structure.
- Other.

Component	Cleaning	Disinfection	Procedure/Surface	Frequency
Magnet covers / Gantry	Yes	As required	Hard	Weekly *
Magnet bore	Yes	Yes	Hard	After each patient **
Ambient ring	Yes	As required	Hard	Weekly *
Patient support	Yes	As required	Hard	Weekly *
Tabletop	Yes	Yes	Hard	After each patient **
Mattress	Yes	Yes	Soft closed	After each patient **
Rigid coils	Yes	Yes	Hard	After each patient **
Surface coils	Yes	Yes	Soft closed	After each patient **
Leads and cables	Yes	Yes	Soft closed	After each patient **
Pads, wedges, sand bags	Yes	Yes	Soft closed	After each patient **

Component	Cleaning	Disinfection	Procedure/Surface	Frequency
Straps	Yes	No	Open structure	After each patient **
Nurse call	Yes	Yes	Soft closed	After each patient **
Headset	Yes	Yes	Soft closed	After each patient **
FlexTrak	Yes	As required	Hard	Weekly *
Cabinet	Yes	As required	Hard	Weekly *
Printer	Yes	No	Other	Weekly *
Examination room floor	Yes	No	Other	Weekly *
Scanner controls (UIM)	Yes	As required	Other	Weekly *
Operator's console	Yes	No	Other	Weekly *
Monitor displays	Yes	No	Other	Weekly *
Keyboard	Yes	Yes	Other	Weekly *

* Or as required.
** Recommended.

Hard surfaces

Inspection

Inspect coils and cables for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the coils or cables and contact Philips Customer Service.

Cleaning

1. Wipe hard surfaces with a soft cloth dampened in a mild soap or detergent solution (preferably liquid soap based, rather than antiseptics) until all visible signs of surface contaminants are removed.

2. Remove remaining particulate and cleaning residue with a cloth dampened with clean water.

3. Towel dry with a soft cloth.

4. Dispose of any used cleaning materials in accordance with your facility's disposal protocols.

Disinfection

1. Clean the surface according to the instructions above.

2. Wipe the surface with a soft cloth dampened in a recommended disinfectant.

3. When alcohols are used: air dry the surface.

4. When Chlorine is used: wipe the surface with a cloth dampened with clean water to remove the chlorine. Air dry or dry with a clean cloth.

5. Dispose of any used disinfection materials in accordance with your facility's disposal protocols.

Special cleaning instructions

Tabletop

Thoroughly remove any solid matter in the grooves of the tabletop using a soft cloth or a tissue. Clean and disinfect as described in this paragraph.

Hardware joints and parts difficult to reach

Clean these parts as described in the paragraph. Use a swab or toothpick for the difficult areas.

Soft closed surfaces

Inspection

Inspect the surface of accessories like pads, wedges, mattresses and sand bags regularly for breaches, tears or frays.

WARNING

Remove and replace breached, torn or frayed mattresses, pads, wedges, and sand bags immediately.

The internal spongy structure cannot be disinfected adequately.

WARNING

Do not use patches to repair tears and holes.

Patches do not provide an impermeable surface.

Black light

It is recommended to inspect the surfaces using a black light.

A black light provides ultraviolet light that is especially sensitive in detecting biological material such as blood, prints and body fluid. This material will light up under black light exposure.

NOTICE

If biological material remains after proper cleaning, it may indicate the surface is breached, frayed or torn allowing fluids to enter the structure.

Cleaning

1. Wipe soft closed surfaces with a soft cloth dampened in a mild soap or detergent solution (preferably liquid soap based, rather than antiseptics) until all visible signs of surface contaminants are removed.

2. Remove remaining particulate and cleaning residue with a cloth dampened with clean water.

3. Towel dry with a soft cloth.

4. Dispose of any used cleaning materials in accordance with your facility's disposal protocols.

Disinfection

1. Clean the surface according to the instructions above.

2. Wipe the surface with a soft cloth dampened in a recommended disinfectant.

3. When alcohols are used: air dry the surface.

4. When Chlorine is used: wipe the surface with a cloth dampened with clean water to remove the chlorine. Air dry or dry with a clean cloth.

5. Dispose of any used disinfection materials in accordance with your facility's disposal protocols.

Open structure surfaces

Straps have an open structure surface and can not be disinfected.

1. Wash the straps in a mild soap or detergent solution (preferably liquid soap based, rather than antiseptics).

1. Rinse with clean water.

2. Air dry the straps until they are completely dry.

NOTICE

Straps are also machine washable at 40 °C using a mild detergent.

FlexConnect sockets and connectors

For proper functioning of dStream coils it is essential that the lenses of FlexConnect sockets and coil connectors are clean.

Clean the lenses by using the special cleaning kit, which is provided with the system.

Endo coil with disposable probe

Cleaning and disinfection

Discard the probe in a hazard waste container. The probe (endo-coil) is for single use only.

- Discard the probe in a hazard waste container.

- Clean the interface device after each use with one of the following solutions:
  - distilled water, mild dish detergent.
  - 10% bleach/90% distilled water solution.
  - hydrogen peroxide.
  - isopropyl alcohol.
  - formula 409.
  - Lysol disinfectant.
  - methylated spirits (90% ethanol, 9.5% methanol, .5% pyridine).

⚠️ **CAUTION**

To avoid possible damage to the Endo coil Interface Device, DO NOT use solutions containing amines, strong alkalis, esters, iodine, aromatic or chlorinated hydrocarbons, or ketones.

⚠️ **CAUTION**

Do not sterilize any part of the coil.

Sterilizing may damage the coil.

Endo-Cavitary coil for 1.5T systems

Cleaning and disinfection

⚠️ **CAUTION**

Do not use a Endo-cavitary coil for more than 3 months, more than 50 times nor after the expiration date printed on the coil and its storage box.

⚠️ **WARNING**

Do not sterilize any part of the Endo-cavitary coils.

If biosoil/residues are still visible, cleaning must be repeated. After cleaning, the coil must be rinsed thoroughly with water. Disinfectants may get cemented to the coil if it is not cleaned properly.

Cleaning instructions

- Always close the air valve during cleaning to prevent ingress of liquid.

- After each patient the coil must be cleaned with a cloth dampened with detergent. Clean the coil from the balloon up to the grip. Follow the instructions of the detergent manufacturer.

  It is recommended to remove biosoil (blood, mucous, etc.) with a cloth and rinse the coil before cleaning it with a cloth dampened with detergent.

Disinfection instructions

It is important to clean the coil thoroughly before disinfection.

- After cleaning, disinfect the coil by immersing it vertically from the balloon up to the last mark of the ruler on the grip in a high-level disinfectant solution per recommendation below. Do not use low- or intermediate-level disinfectants.

  Follow the instructions of the disinfectant manufacturer.

- Remove any disinfectant solution residue with a soft cloth dampened with water. Do not allow disinfectant solution to air-dry on the coil.

For disinfection, the following high level disinfectants can be used:

- Cidex© OPA, see www.cidex.com

- Steranios© 2% NG, see www.anios.com

Based on material compatibility testing these agents have been found to be chemically compatible with the coil.

PPU sensor and reusable clips

Cleaning and disinfection

To clean the sensor (cable) and the reusable clips complete the following steps:

1. Remove the accessory from use.

2. Remove dirt and dust from the accessory using a lint-free cloth, moistened with warm water (40°C/104°F maximum) gently wiping all surfaces to be cleaned briefly (30 seconds to 1 minute) as needed to ensure proper cleaning. Stains can be removed from the accessory by scrubbing briskly with the moistened cloth.

3. Inspect the accessory for any cracks, holes, tears, cuts, etc. that could affect operation and replace as necessary.

4. If disinfection is required, use only the recommended liquid surface disinfectants. Recommended surface disinfectants include dilute solutions of any of the following:

   - CaviWipes.

   - Alcohol (70%).

   - Antibacterial Soap (10% Triclosan).

⚠ **CAUTION**

Do not autoclave (sterilize) any parts of the equipment or use bleaches containing hypochlorite (e.g. Clorox ™).

Disinfect the accessory as determined by your institution's policy.

Other

Keyboard and UIM

1. Remove any solid matter around keys and buttons with a swab or toothpick.

2. Clean by wiping the keys and the sides with a soft cloth or tissue dampened in a mild soap or detergent solution and wipe dry.

3. Disinfect the surface by wiping the keys and the sides with a soft cloth or tissue dampened in a recommended disinfectant.

4. When alcohols are used: air dry the surface.

5. When Chlorine is used: wipe the surface with a cloth dampened with clean water to remove the chlorine. Air dry or dry with a clean cloth.

Monitor displays

▷ Before cleaning turn off the display and unplug the power if possible.

► Wipe with a soft cloth moistened with soap and water. Alternatively a window cleaner can be used.

Chrome parts

► Clean by rubbing down with a dry woolen cloth. Never use abrasive polishes but a non-abrasive wax.

Printer

Clean the printer according to the manufacturer's instructions.

Examination Room

► Clean the floor according to your facilities cleaning protocol.

4 Product Disposal

About product disposal

Philips Healthcare is concerned to help protect the natural environment, and to help ensure continued safe and effective use of this product through proper support, maintenance and training.

Therefore Philips equipment is designed and manufactured to comply with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained, it presents no environmental risks. However, the equipment may contain materials which could be harmful to the environment if disposed of incorrectly. Use of such materials is essential to performing the functions of the equipment, and to meeting statutory and other requirements.

The equipment stores sensitive personal information of e.g. patients and operators. Disposal of the product is therefore subject to privacy related (local) legislation.

This section of this manual is directed mainly at the user/owner of the product - the body with legal authority over the product. Operators are not usually involved in disposal, except in the case of batteries of the ECG sensor device.

For advice and information, contact your local Philips Healthcare Customer Support Organization first, Philips Healthcare at the address below or the Philips' Magnetic Resonance Recycling Passports internet site at http://www.healthcare.philips.com/main/about/sustainability/recycling/mr.wpd .

Philips Medical Systems

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5680 DA BEST

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Passing the product on to another user

If this product passes to another user, it must be in its complete state, including all product support documentation.
Make the new user aware of the support services that Philips Healthcare provides for installing, commissioning and maintaining the product.
Before passing on the product or taking it out of service, all patient data must be (backed up elsewhere if necessary, and) unrecoverable deleted on the product.

It must be remembered by all existing users that passing on medical electrical products to new users may create serious technical, medical and legal (e.g. on privacy) risks. Such risks can arise even if the product is given away. Existing users are strongly advised to seek advice from their local Philips Healthcare representative before committing themselves to passing on any product. Alternatively, contact the manufacturer.

Philips Healthcare

Once the product has been passed on to a new user, a previous user may still receive important safety-related information, such as bulletins and field change orders. In many jurisdictions, there is a clear duty on the previous user to communicate such safety-related information to new users. Previous users who are not able or prepared to do this should inform Philips Healthcare about the new user, so that Philips Healthcare can provide the new user with safety-related information.

Final disposal of the product

Final disposal is when the user disposes of the product in such a way that it can no longer be used for its intended purpose.

NOTICE

Recycling passports needed as a result of the European Directive WEEE (waste on Electric and Electronic Equipment) are available via the Philips Healthcare web site.

Please contact your local Philips representative.

WARNING

The product contains privacy sensitive information which should be properly removed.

It is advisable to contact your Philips Service Organization before disposing of the product.

WARNING

Do not dispose the product (or any parts of it) with industrial or domestic waste.

This product contains hazardous material(s) which require(s) special disposal. Incorrect disposal of these materials may lead to serious environmental pollution.

Special attention should be paid to:

- Cooling fluids.
- Phantom fluids.
- Batteries.
- Helium.

NOTICE

Lithium battery cells of type CR2032 used in the host computer contain perchlorate material, special handling may apply.

See www.dtsc.ca.gov/hazardouswaste/perchlorate/index.cfm.

Philips Healthcare

Philips supports users in:

- Recovering reusable parts.
- Recycling of useful materials by competent disposal companies.
- Safe and effective disposal of equipment.

China RoHS declaration table

Marking styles for names and contents of toxic or hazardous substances or elements

Name of the parts	Hazardous/toxic substances or elements					
	Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Magnet + peripherals	X	O	X	O	O	O
System cabinets	X	X	O	X	O	O
RF-coils	X	O	O	O	O	O

O: Means the hazardous substances in all the homogeneous materials are below the concentration limits defined in the Standard.

X: Means the hazardous substances in at least one of the homogeneous materials of the Unit exceed the concentration limits defined in Standard.

Toxic or hazardous substances and elements

REACH Declaration

REACH requires Philips Healthcare (PH) to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the article weight.

Components within electric and electronic equipment may contain phthalates above the threshold Bis(2-ethylhexyl)phthalate (DEHP), CAS nr.: 117-81-7 .

The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold: http://www.philips.com/about/sustainability/REACh.page

5 Error procedures, Security and Privacy

Error procedures

NOTICE

Error Messages concerning recoverable errors can usually be accepted by pressing the Return key.

Scan not possible

When scanning is not possible, various error messages may appear on the text screen, either during the preparation phase or during measurement. Proceed as follows:

- Correct errors such as: Incorrect coil... , Connector not in... .
- Write the Error message and/or number, date and time in the system logbook.

Computer malfunction

When the application software does not respond (hang-up), stop the application.

1. This can be done by clicking |System| -> |Exit| on the main menu bar, or: Select |system| -> |show taskbar| or press the 'windows' key on your keyboard to show the windows task-bar.

2. Click |Start| -> |Shut down|.

3. Select |Restart|.

On occasion, it may be necessary to restart the system by pressing the reset button on the computer.

If measurement is still not possible, notify your local Philips Customerr Service representative.

Malware detection

If the virus scanning software has detected infection by malware, there is no possibility to use automatic repair utilities because the integrity of the repaired software cannot be guaranteed.

In case of infections, always contact your local Philips Customerr Service representative to assess and repair the system.

Be sure to also adhere to local procedures regarding malware infection of customer systems (this may e.g. include disconnect from the network).

Logging

Logging is a tool, which helps the Customer Support engineers analyze operational problems. Logging can be accessed via the Windows start menu.

1. Select |system| -> |show taskbar| or press the 'windows' key on your keyboard to show the windows taskbar.

2. Click |Start| -> |MR User| -> |Diagnostics| -> |Logging Application UI|. The logging application will be opened.

Security and Privacy features implemented

It is the policy of Philips Healthcare to adhere to all required standards and regulations. To assist the hospital, the following functionality has been added to the system:

Access control

Intended to restrict access to the system to authorized users only:

- Customizable on/off, a user log-on/log-off procedure is required to gain access to the system.
- Access to the system is granted according to a customizable list of authorized users.
- Username/Password authentication is supported for Active Directory and Local users. 2-Factor authentication is supported for Philips Engineers only.
- The system provides functionality to synchronize with customer central user account administration, LDAP only.
- The system supports only single user sessions. It does not provide functionality to register multiple simultaneous users or to switch between users other than via log-off / log-on.
- The system does not support single sign-on for situations where the system works together with other (optional) systems or is part of another system, e.g. extra workstations. Single sign-on is also not for some optional software components that require additional login.

Audit trail

Required to log user activities which are information-security critical:

- Applies to logging-on, reading and/or modifying clinical information.
- Requires that means be provided for auto-backup on a hospital server, e.g. the use of an external standard 'Syslog' server.
- The creation of an audit trail on the local system is not supported.

Network time synchronization

Intended to synchronize system time to an external time-standard:

- "uses a standard Network Time Protocol (NTP)
- "the coupling is configured by Field Service during system installation.

Security and node authentication

Intended to secure the exchange of clinical data and restrict this exchange to pre-determined nodes:

- Applies to RIS/CIS and PACS nodes, e.g. archives and viewers
- Does not apply to Field Service access
- Uses standard Transport Layer Security Protocol
- The user can decide at installation to use encryption on a per node basis (this may result in reduced performance).

Computer systems cannot be guaranteed to be safe in an insecure network. The user should provide some level of network protection e.g. installing firewalls.

Implementation

In order to meet the requirements described above, the system implements the solution defined by the Integrating the Healthcare Enterprise (IHE) year 4 Basic Security profile.

- The Basic Security Integration Profile establishes security measures which, together with the Security Policy and Procedures of the Enterprise, provide patient information confidentiality, data integrity and user accountability. For more information see the DICOM Conformance Statement.

Field Service

Field Service is used to enable the following configuration items based on information supplied by the hospital:

- Authentication and encryption
- Time synchronization
- Configuration of the 'Syslog' server
- Configuration of any other programs, e.g. tools used to install certificates.

Certificates

Certificate requests should be handled by the hospital. The hospital should decide on a procedure to create the Certificate request and import the certificates.

The hospital should also define the types of certificates required, for example:

- The certificate of the machine itself
- The certificates of the machines it chooses to trust
- The certificate of the Certificate Authority (CA).

Certificates should always be signed by someone else, i.e. no self-signed are allowed. However, the signer of the certificate need not be present on the system. Self-signed certificates are the certificates required by the Integrating the Healthcare Enterprise (IHE).

The following should also be specified:

- The location of the certificates (local machine)

- The location of the tools for certificate installation.

Certificates should be used between nodes to enable them to validate the identity of each other.

It is the responsibility of the Healthcare Enterprise (HE) to define the maximum validity period of certificates in its security policy.

Other Security and Privacy features addressed

HIPAA defines a number of physical and technical safeguards which are either required or addressable. Some features that could implement these functions are differently or not implemented for reasons mentioned below.
This section also lists other information related to security features that are not implemented and that the owner of the systems should be aware of.

Backup procedure

It is not the intended use of the system to permanently store (sensitive) personal information. Information should be exported to a storage device as soon as possible.

Emergency Access Procedure

The system allows the creation of multiple users. A user account that serves as a generic emergency account can be created. However the user should be aware that the knowledge of this generic account and access to the system should be restricted to avoid unwanted access to (sensitive) personal information. Note that there is no built in function that will allow or enforce the user of such an account to enter their real name. Also it is not possible to clearly mark data output (e.g. screen, print-out, exported data to DVD) as being created during emergency access operation.

Automatic logoff

An auto-logoff feature is not implemented since it contradicts the intended use of the system. Manual logoff using a 'short-cut' key combination is not implemented for the same reason. A configurable screen save function with password protection is available.

Encryption

The system supports encryption of personal data on hard-drive and removable media (USB devices). Hard drive encryption can be activated by Philips Service Engineers.

Physical access to system

Some parts of the systems are located in the technical area of a system. Access to these locations is assumed to be restricted. Usually, the components in the operator or examination room are more readily accessible and therefore the following characteristics shall be taken into account for system operation and access control:

- The computer case is 'service friendly'; opening and removal of e.g. hard disk without use of tools may be possible; computer case can be locked (e.g. by cable lock etc.); there are no front side accessible drives etc.

- The boot order for the system is DVD - Hard Disk. By inserting a bootable CD/DVD the system may start up from those and thus access may be gained to the system including information stored in it.

- There is no detection of unauthorized physical access into the system e.g. via tamper proof seals.

- The integrity of most of the Philips application software is checked when the systems starts, for data this is not done.

- By default the system BIOS is not password protected and can be accessed during startup of the system if unauthorized access to the system is possible.
  On request Philips Service Engineers are instructed by guidelines how to password protect the BIOS

Network firewall configuration

If the system is placed behind a network firewall (this is preferred), then the following ports should be allowed to pass through for the system to operate correctly in a network under normal operating conditions:

- Clinical use: ICMP:Echo, ICMP:Echo-Reply, TCP:104[1)]

- emote service: TCP:22[2)], TCP:5900[2)], TCP:9903, TCP:9044 or outbound: TCP:443[2)]

[1)] *default port might be reconfigured. It is assumed that outbound traffic is unrestricted.*
[2)] *depending on configuration of the system (ISSLLink or VPN) .*

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