Instructions for Use

English

dS TorsoCardiac 1.5T/dS MSK S 1.5T/dS MSK M 1.5T

IFU Coils

PHILIPS

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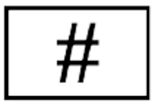
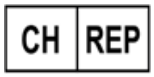
1 Introduction

Safety

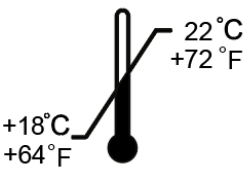
Other symbols	Source	Meaning
	European Commission	CE Marked Device
	ETL listed	Intertek ETL recognized component
	ISO 7010-M002	Refer to instruction manual/booklet.
	ISO7000 3500	To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.
	ISO 15223-1-5.4.4	Caution
	IEC 60417-5333	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417-5172	Class II Equipment
	IEC 60601-1	Splash proof safety rating

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Other symbols	Source	Meaning
	Directive 2012/19/EU WEEE Symbol	Waste electrical and electronic equipment.
	IEC60878-6050	Model Number
	2017/745/EU	Medical Device
	ISO7000-3082	Manufacturer
	ISO7000-6049	Country of Manufacture
	ISO7000-2498	Serial number
	ISO7000-2493	Catalogue number
	ISO15223-1-5.1.2	Authorized representative in the European Community
	2017/745/EU	UDI
	ISO15233-1-5.1.2	Swiss authorized representative

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Other symbols	Source	Meaning
	ISO 7000-3725	Importer To indicate the entity importing the medical device into the locale
	IEC 62570	MR Safe
	IEC 60417	RF coil receive
	None-Internal symbol	Indicates the appropriate magnetic field strength of MR scanner (1.5T or 3.0T) that the medical device is intended for use with.
	None-Internal symbol	CHINA RoHS
	ISO 15223-1	Humidity limitation
	ISO 15223-1	Temperature limit
R_x Only	FDA Guidance Document "Alternative to Certain Prescription Device Labeling Requirement".	Prescription Device Caution: US Federal law restricts this device to sale by or on the order of a clinician.

CAUTION: US Federal law restricts this device to the sale, distribution and use by or on the order of a physician.

Coil Name	Channel number
dS TorsoCardiac 1.5T	8

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Coil Name	Channel number
dS MSK S 1.5T	8
dS MSK M 1.5T	8

Tab. 1: Product-Specific indications for use

Contraindications

Contraindications for the MRI scanner apply when using any coil. Refer to the Instructions for Use for the compatible MRI scanner for more information.

Intended Purpose / Intended use / Indications for use

Intended Purpose / Indications for use

The Magnetic Resonance (MR) coil is used with an MR scanner. A trained physician interprets the diagnostic images(of the anatomy of interest) produced.

Intended users

The target users of the device are individuals who have been trained and educated in the broader aspects of MR safety issues, including, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients.

MR operator

The MRI operator is the person operating the MRI machine. The operator is the person who performs the patient examinations. He/she sits behind the console to perform the necessary scans and acquire the images. Most importantly, the operator is the patient's coach for the MRI examination. The following users belong to the MR Operator group:

- Medical imaging Technician
- Radiologist
- Researcher
- Physicist

MR Supervisor

The MRI supervisors are responsible for scanning patients and supervising their MRI team members. The MRI supervisor will be responsible for communication to department staff, teaching and training, and working directly with MRI physicians to continuously improve examination procedures and departmental processes. The MRI supervisor will serve as a pacesetter for the MRI team members in education, skill level, and flexibility within the department. The following users belong to the MR Supervisor group:

- Medical imaging Technician
- Radiologist
- Physicist

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MR Radiologist

MRI radiologists are the qualified medical experts that order and review MRI examinations. His needs are:

- Order an MR examination from RIS.
- Monitor the progress of the MR examination, and (remotely) see the scanning status when called for advice by the MR operator.
- Review black and white and color MR image, and annotations/measurements, on a Medical Workspot, with a qualified Medical Display.

CAUTION

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

Target population

Philips MR systems are designed to create images of the head, body or extremities of any patient (prenatal to geriatric) referred to an MR study by a trained physician.
Exceptions to admissible patients relate to their physical characteristics (circumference, mass) in relation to system capabilities (magnet bore size: 60 cm or 70 cm; mechanical strength of the patient support, allowing 150 kg or 250 kg) and taking into account pre-screening results and contraindications.

Use And Operation

Use and operation of the coil is subject to the law in the jurisdiction(s) in which the coil is being used. Both users and operators must only use and operate the coil 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.

Clinical benefits and undesirable side effects

The following clinical benefit descriptions are representative for all Philips MRI coils and are included in the associated Risk-Benefit Analysis documents as part of the Risk Management file.

The clinical benefits of MR imaging are:

- Images, spectra, and measurements of physical parameters obtained by an MR scan may, when interpreted by a trained physician, provide information that may assist patient diagnosis and therapy planning.
- Image contrasts can be tailored to specific clinical applications required for a specific patient, to emphasize dedicated types of pathology.
- Images can be obtained in numerous planes without repositioning the patient.

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- Patients do not need to be subjected to ionizing radiation in order to obtain an MR scan and there is no need to administer contrast agent to patients in order to generate tissue-specific contrasts.

Clinical benefits are expressed in Quality Adjusted Life Years (QALYs) and are based on the relevant industry accepted clinical practice guidelines. Since RF coils are accessories, i.e. they only work in conjunction with an MRI system, they do not have clinical benefits by themselves. RF coils affect the spatial and temporal resolution, sensitivity, and uniformity of MR images. They can also target specific anatomies and make it possible to achieve the highest possible signal-to-noise ratio (SNR) through suitable fit and field of view, thereby playing an important role in MR image quality.

No undesirable side effects have been identified with the use of coils. Refer to the MR System Instructions for Use/Operations manual for any undesirable side effects related to the use of MR scanners.

MR Scanner Compatibility

Coils are compatible with specific MR scanners at the magnetic field strength listed on the coil label. The following precautions are taken before using any MR coil with an MR scanner:

- Refer to the MR scanner-specific operator manual for detailed instructions about proper use of the coil with the MR Scanner being used.
- Refer to the Coil-specific operator manual (in addition to the general coil IFU) for detailed instructions about the coil being used and the compatible MR scanners.

The coil and accessories require special conditions regarding electromagnetic compatibility. The coil is installed and used with the MR magnet systems for which it was designed. MR scans are performed in the shielded rooms provided with the MR magnet system. Failure causes reciprocal interference with portable and mobile RF communications equipment, affecting the performance of the MR coil and such equipment.

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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.

Coil maintenance frequency	One time per half year

Coil Classification

EQUIPMENT CLASSIFICATION	
Classification according to IEC-60601-1	
According to the type of protection against electrical shock:	Class II equipment.
According to the degree of protection against electric shock:	Type BF applied parts.
According to the degree of protection against harmful ingress of water:	Ordinary equipment (Protection against vertically falling water drops, IPX1).
According to the methods of sterilization or disinfection:	Non-sterilizable. Use of Liquid surface disinfectants only.

Incident Reporting

NOTICE

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

In the European Economic Area (EEA), the incident should also be reported to the Competent Authority that the Member State, in which the user and/or patient is established, has designated responsible for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

In the United States of America, the Medical Device Reporting regulation contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA.

Follow the applicable laws or regulations on reporting device-related incidents or adverse events in the jurisdiction(s) in which the system is being used.

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2 Cautions

The following general warning statements apply to scanning with a magnetic resonance system. For further details, review the warnings in your MR system operator manual:



WARNING

Indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.



CAUTION

Indicates a hazard with a low level or risk which, if not avoided, could result in minor or moderate injury.

NOTICE

Used to highlight information that is considered important but that is not hazard related, such as unusual points or hints for efficiency.



WARNING

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



WARNING

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

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WARNING

Prevent patients from touching the contacts of separable coils. When connected to the system a voltage of 12 volt DC is present at the contacts of the coil base. Under normal conditions, this voltage is not hazardous to patients. However for critically ill cardiac patients this low DC voltage may have serious consequences.

Always close the coil before connecting it to the system.

Always disconnect the coil from the system before opening the coil.

Do not leave unused coils or coil parts on the tabletop.

Connect all coils on the tabletop to the system before scanning, even if the coils are not used for scanning.

Background: IEC60601-2-33: 201.7.9.2.101.j: Exposure of the PATIENT to radio frequency magnetic.

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.

WARNING

Never use surface coils, cable traps and cables which 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

Never position heavy objects or let patients sit on RF receive coils.

Heavy weight load can damage the coils, which may result in excessive heating and patient burns when scanning.

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.

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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

Infectious residue

Risk of cross-infection

- **Always clean and disinfect the coils and cables after each examination of (injured or infectious) patients where contamination may have occurred.**
- **Use proper personal protection and precautions when removing blood or residual contrast medium.**



WARNING

Do not leave coils unconnected in the bore.

(Do not leave unused coils or coil parts on the tabletop. Connect coil on the tabletop to the system before scanning, even if the coil is not used for scanning).



WARNING

Do not simultaneously touch the coil connector pins and the patient to prevent potential harm for the patient.



WARNING

Ignition of disinfecting spray.

Risk of serious injury or death.

- **Do not use flammable or potentially explosive disinfecting sprays.**

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WARNING

Electrical conductive path due to excessive liquid

Risk of electric shock

- **Never allow water or other liquids to enter the system, system components, coils, coil contacts (of separable coils) and connectors.**
- **Verify that all parts of the system, coils and positioning aids are completely dry before starting an examination.**

If liquid has entered the system, contact your Philips service engineer.

CAUTION

The coil and accessories require special conditions regarding electromagnetic compatibility. The coil should only be installed and used with the MR magnet systems for which it was designed. MR scans should only be performed in the shielded rooms provided with the MR magnet system.

Failure to do so may cause reciprocal interference with portable and mobile RF communications equipment, affecting the performance of the MR coil and/or such equipment.

CAUTION

After unpacking the coil, allow it to remain under stable atmospheric conditions for several hours prior to use.

Extreme temperature and/or humidity during storage and/or transportation allowed condensation to form inside the coil.

CAUTION

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

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3 Scanning

Refer to the system manual for installation instructions and proper use of the coil in conjunction with the scanner.

Emergency Procedures

In the unlikely event that a coil creates smoke, sparks, or makes an unusually loud noise, or if the patient requires emergency assistance:

- Stop the scan if one is in progress.
- Remove the patient from the scan room if the medical treatment is required.

Technical Considerations

- No modification of this equipment is allowed. There are no user serviceable components and is not user repairable.
- The coil should only be used with the cable and accessories specified in the system operator manual.
- The use of accessories other than those specified in the system operator manual results in decreased ESD immunity of the coil or MR system, causing damage to the coil and/or system.
- The equipment should not be used with other coils or equipment present in the MR scanner except as specified in the system operator manual.
- Tampering with the cable pins and connector damages the connector and affects the coil or system performance. Verify that connector and pins are not damaged before use.
- The coil should not be left unplugged in the system during body coil scanning.
- Reference the MR system or supplied application guide for coil positioning requirements, specific operating conditions and routine maintenance.
- At the end of its service life, dispose the coil in accordance with local regulation.
- For split coil designs, the user should avoid touching any exposed connector pins and the patient at the same time.
- Users must be trained on the safe and effective use of the MRI scanner before attempting to operate the coil.
- After unpacking the coil, allow it to remain under stable atmospheric conditions for several hours prior to use. Extreme temperature and humidity during storage and transportation is allowed condensation to form inside the coil.
- The RF coils are considered suitable for direct contact with the patient in normal use conditions, that is, considered Applied Parts per IEC60601-1

Guidance and manufacturer's declaration – electromagnetic immunity

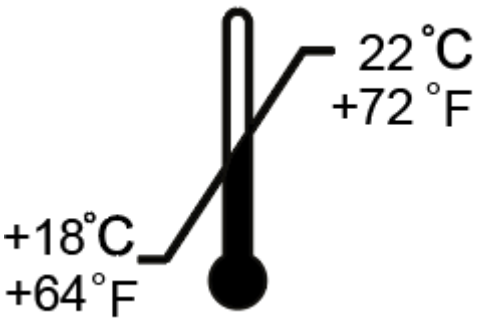
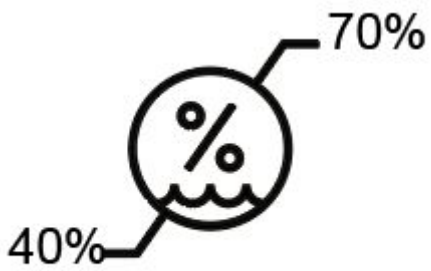
The MRI coil is intended for use in an electromagnetic environment specified below. The customer of the device should assure that is used in such an environment.

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Immunity test	EN 60,601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact	Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30 %.
EN 61000-4-2	±15 kV air	±15 kV air	

Ambient Operating Conditions

	The system is specified for use with examination room temperatures 18–22 °C (64–72 °F).
	The system is specified for use with examination room. Relative humidity must be kept to 40 - 70%.

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4 Cleaning and Disinfection

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

- Cleaning and disinfection may only be performed by appropriately trained personnel. Before cleaning coils, it is essential that you read and familiarize yourself with all Warnings and Cautions given in this Instructions for Use.
- 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. Cleaning is an essential prerequisite for effective disinfection.
- Cleaning agents: Only use the cleaning agents that are listed in this section. Philips cannot be held liable for damage caused by the use of different products or compositions.

Coils cleaning and disinfection procedure frequency	After each patient **
Coil connectors and sockets cleaning and disinfection	Weekly *

NOTICE

* required

** recommended

General cleaning instructions

- Use soft cloths, disposable tissues and wipes.
- Only use commercially available MR Safe and MR Conditional equipment and tools. Strictly follow the manufacturer's instructions.
- Never use cleaning equipment that contains ferromagnetic material.

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WARNING

Always detach coil from scanner before attempting to clean.

Do not pour any cleaning solution directly on the coil or baseplate.

Care must be taken to avoid contact with any electrical connections during cleaning. Spraying the contacts may cause the devices to malfunction or reduce the life expectancy of the interconnect and will void warranty. Avoid direct use of cleaning agents on any connector contacts and interfaces.

Under no circumstances should the coil be placed into any type of sterilizer. Sterilization and exposure to fluids may damage the electrical components of the device. Do not autoclave any components of the coil. Do not heat above 70°C.

Do not submerse any of the coils in fluids. Submersing in fluids may cause the device to malfunction and will void the warranty.

Do not allow pooling of cleaning agents after cleaning. Coil, pads and other accessories must be completely dry before use.

Use only recommended cleaning solutions, or you may void the manufacturer's warranty.

Disinfection

Disinfection is the process of eliminating or reducing harmful microorganisms from inanimate objects and surfaces.

Levels of disinfection

The level of disinfection required for a device is dictated by the type of tissue with which it is in contact during use. The table below shows which level of disinfection needs to be performed depending on the classification of the device.

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

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

NOTICE

Recommended for disinfection. Only the described disinfectants are tested and recommended by Philips.

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Tested and recommended disinfectant	Disinfection Level
Isopropanol 70%	Intermediate
Ethanol 70%	Intermediate
Chlorhexidine 0.5% in 70% ethanol	Intermediate
1:200 Bleach solution (250 ppm chlorine) (5 ml household bleach in 1 L water)	Low

Cleaning: Regular procedure

1. Take a soft damp cloth. Do not apply large amounts of water.
2. Use a swab or toothpick to remove dirt from hardware joints and parts difficult to reach.
3. Wipe hard surfaces with the soft cloth until all visible signs of surface contaminants are removed.
4. Remove remaining particulate and cleaning residue with a cloth dampened with clean water.
5. Towel dry with a soft cloth.
6. Dispose any used cleaning materials in accordance with your facility's disposal protocols

Disinfecting: Regular procedure

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 bleach solution is used:
   - Allow at least 1 minute contact time for bleach solution.
   - Always wipe surfaces with a cloth dampened with clean water to remove the bleach solution.
   - Air dry or dry with a clean cloth.
5. Dispose any used disinfection materials in accordance with your facility's disposal protocols.

NOTICE

Be aware that the use of sheets and paper without actual cleaning and disinfection does not prevent the spread of infectious agents.
Protecting yourself and others as an operator, wash and disinfect your hands (hand sanitizer) after each patient.

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5 Disposal

Final disposal: The coils are disposed in such a way that it cannot be used for its intended purpose.

The user is responsible for proper disposal of the coils.

Philips MRI coils are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the coils are properly operated and maintained, they pose no environmental risks. However, the coils contain materials that are harmful to the environment if disposed incorrectly.

Do not dispose the MRI coils, or any parts of the coils, with industrial or domestic waste. Philips can assist in:

- Recovery of reusable parts.
- Recycling of useful materials by competent disposal companies.
- Effective and safe disposal of the MRI coils.

If this product passes to another user, it must be in its **Complete** state, including all the product support documentation.
Provide awareness to the user about Philips support services that assists in installing, commissioning and maintaining the product.

Once the product is passed to a new user, a previous user receives the 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 unable or prepared to do this, must inform Philips about the new user, so that Philips can provide the new user with safety-related information.

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China RoHS declaration table

Name and content of hazardous substances in products

Name of the parts	Pb	Hg	Cd	Cr(VI)	PBB	PBDE
RF-Coils	X	O	O	O	O	O

Tab. 2: Hazardous substances or elements

This table is developed according to the provisions of SJ/T 11364.

O: The content of such hazardous substance in all homogeneous materials of such component is below the limit required by GB/T 26572.
X: The content of such hazardous substance in at least one homogeneous material of such component is beyond the limit required by GB/T 26572.

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.

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