



# MAGNETOM Terra.X

Operator Manual – 8Tx30Rx Knee 7T

## Legend

In this manual, the following symbols are used to indicate safety and other important instructions. The signal words and their meanings are defined below.



Indicates the solution to a problem

Provides troubleshooting information or answers to frequently asked questions



Indicates a list item



Indicates a prerequisite

A condition that has to be fulfilled before starting a particular operation



Indicates a single-step operation

1  
2  
3

Indicates steps within operating sequences

*Italic*

Used for references and for table or figure titles



Used to identify a link to related information as well as previous or next steps

**Bold**

Used to identify window titles, menu items, function names, buttons, and keys, for example, the Save button

Used for on-screen output of the system including code-related elements or commands

**Orange**

Used to emphasize **particularly** important sections of the text

**Courier**

Identifies inputs you need to provide

**Menu > Menu Item**

Used for the navigation to a certain submenu entry

**<variable>**

Identifies variables or parameters, for example, within a string



INFORMATION

Emphasizes important details or provides information on how to avoid operating errors or other potentially hazardous situation, which, if not observed, may result in property damage.



 **CAUTION**

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**CAUTION**

Caution is necessary to avoid a hazardous situation, which, if not avoided, could result in minor or moderate injury.

 **WARNING**

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**WARNING**

Warning must be heeded to avoid a hazardous situation that could result in death or serious injury.

## Warranty and liability

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product. The warranty does not cover the following items, even during the warranty period:




- Damage or loss due to misuse or abuse.
- Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
- Damage or loss caused by failure to meet the specified conditions for this equipment, such as inadequate power supply, improper installation, or unacceptable environmental conditions.
- Damage due to changes or modifications made to the product.

In no event shall QED be liable for the following:

- Damage loss or problems caused by relocation, modification, or repair performed by personnel not explicitly authorized by QED.
- Damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operation manual.

## Transportation and storage conditions

This equipment shall be transported and stored under the following conditions:

	Temperature	-20°C to +60°C
	Relative humidity	10% to 90%
	<b>CAUTION</b> If the coil packaging is exposed to environmental conditions outside of the transportation and storage conditions, the packaging is damaged, or the packaging is opened prior to delivery, complete Quality Assurance testing prior to actual use. If the coil passes QA testing, it may be used normally.	


## United States Federal Law

### CAUTION

Federal law restricts this device to sale, distribution, and use by or on the order of a physician. The device is limited by Federal Law to investigational use for indications not in the Indications Statement.

## About this manual

This manual contains detailed information on the safety precautions, use and care of the RF coil.

	<b>CAUTION</b> For safety and accuracy in using the product, read this manual as well as the MRI system operation manual carefully prior to operation of the product. This manual does not include instructions or safety information on equipment not provided by QED, such as the MRI system. Please consult Siemens Healthineers for information regarding non-QED equipment.	
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**REF**

Model Numbers:

- Siemens Healthineers: 11371529
  - QED: Q7000204
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# 1 Introduction

## 1.1 Description

The 8Tx30Rx Knee 7T coil is an accessory to the MRI system with the intended use for examinations of the left or right knee.

## 1.2 Operating principle

Transmit/receive RF coils transmit an RF pulse and then receive magnetic resonance signals generated in hydrogen nuclei (protons) in the human body. The received signals are amplified and transmitted to the MRI system, where they are processed into tomographic images by the computer.

## 1.3 Operating environment and compatibility

The 8Tx30Rx Knee 7T coil is intended to be used in conjunction with the MAGNETOM Terra.X MR system in a specialized healthcare facility.

## 1.4 User profiles

- **Operator** (all applicable laws in the relevant country must be followed):
  - Radiological technologists
  - Laboratory technologists
  - Physicians
- **User training:**

No special training is required to use this coil. However, Siemens Healthineers provides a comprehensive training course for MRI systems in order to instruct operators on the correct use of MRI system.

## 1.5 Patient information

Age, health, condition - No special limitations beyond the system limitations of the MR system. Consult the [Operator Manual - MR System and Coils](#) for the MR system.

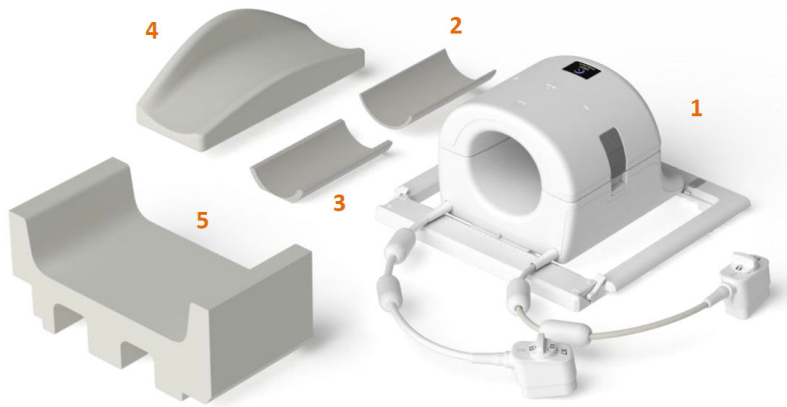
Weight - Patient weight must be greater than 30 kg and less than 200 kg. Consult the [Operator Manual - MR System and Coils](#) for the MAGNETOM Terra.X MR system. If the maximum weight of the patient for the patient table is lower than the maximum weight for this coil, priority must be given to the maximum weight for the patient table.

## 1.6 Clinical benefits

Local RF coils are accessories of the MRI system and are optimized for imaging of specific body regions, improving the image quality and image resolution produced by MRI systems. As an accessory of an MRI system, the clinical benefit of the RF coil is inherited from the MRI system. MRI can assist in diagnosis of a variety of patient conditions when interpreted by trained healthcare professionals.

## 2 8Tx30Rx Knee 7T coil set components

The 8Tx30Rx Knee 7T coil set is shipped with the parts shown below. Upon receipt, please ensure that all parts are included in the shipment. Please contact your Siemens Healthineers representative for replacement or replenishment of any accessories listed here.



8Tx30Rx Knee 7T coil set 7T [Q7000204] components

Item #	Description	Quantity	Siemens Healthineers Part #	QED Part #
1	8Tx30Rx Knee 7T	1	11371529	Q7000204
2	Thin knee support cushion	1	10185454	3000737
3	Thick knee support cushion	1	10185455	3000736
4	pTx knee other leg pad	1	11371690	3008787
5	Both feet pad	1	11371689	3008811

## 3 Safety







This section describes the general precautions and safety information that must be observed when this coil is used.

















### CAUTION

Before using the coil, review the safety information in the **Operator Manual - MR System and Coils** for a full list of safety considerations.

### 3.1 Symbols

Symbol	Number	Standard	Title, meaning
	0434A	ISO 7000 IEC 60417	Caution, caution is necessary when operating the device and/or the situation described needs operator awareness or operator action in order to avoid undesirable consequences
	5.4.3	ISO 15223-1	Operator Manual Consult electronic instructions for use before operating the device
	5172	ISO 7000 IEC 60417	Class II equipment
	5333	ISO 7000 IEC 60417	Type BF applied part
	3082	ISO 7000 IEC 60417	Manufacturer and date of manufacture
	6192	ISO 7000 IEC 60417	RF coil, transmit and receive

Symbol	Number	Standard	Title, meaning
	N/A	IEC 60601-2-33 IEC 62570	MR Safe
	5.1.2	ISO 15223-1	Authorized representative in the EU
	5.1.2	ISO 20417 ISO 15223-1	Indicates the UK responsible person
	5.1.2	SwissMedic ISO 15223-1	Indicates the authorized representative in Switzerland
	2493	ISO 7000 IEC 60417	Catalog number
	2498	ISO 7000 IEC 60417	Serial number
	0632	ISO 7000 IEC 60417	Temperature limit
	2620	ISO 7000 IEC 60417	Humidity limitation
	5.7.7	ISO 15223-1	Medical device
	5.7.10	ISO 15223-1	Unique device identifier
	6049 5.1.11	IEC 60417 ISO 15223-1	Country of manufacture – US
	5.1.8	ISO 15223-1	Importer

Symbol	Number	Standard	Title, meaning
	5.1.9	ISO 15223-1	Distributor
	N/A	EN50419 EU2012/18/EU	<p>The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.</p> <p>For more detailed information concerning the return and recycling of this product, please consult the supplier from whom you purchased the product.</p>



## 3.2 Indications





The 8Tx30Rx Knee 7T coil is intended to be used in conjunction with a MAGNETOM Terra.X MR system to produce diagnostic images of the knee of patients that can be interpreted by a trained physician.

## 3.3 Contraindications







None.

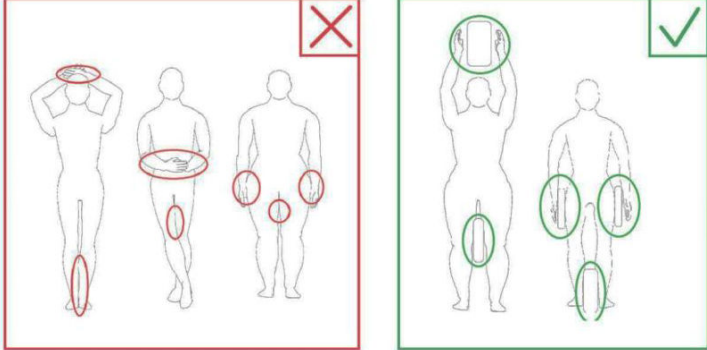
## 3.4 Precautions

	Patients with increased likelihood of seizures or claustrophobia may require special care. Consult the <b>Operator Manual - MR System and Coils</b> .
	Patients who are unconscious, heavily sedated, or in a confused mental state are at increased risk of burn injury because they may not be able to notify the operator of heat or pain due to excessive heating and tissue damage.

	Patients with an inability to maintain reliable communications are at increased risk of burn injury because they may not be able to notify the operator of heat or pain due to excessive heating and tissue damage.
	Patients with loss of feeling in any body part are at increased risk of burn injury because they may not be able to notify the operator of heat or pain due to excessive heating and tissue damage.
	Patients who have difficulty regulating their body temperature or who are particularly sensitive to increases in body temperature (for example, patients with fever, cardiac failure, or impaired perspiration) are at increased risk of burn injury or their body temperature may increase.
	Ensure that the patient does not wear clothing that is wet or dampened by perspiration. The presence of moisture increases the risk of burn injury.

### 3.5 Cautions – RF coil

	<p>Do not place any disconnected devices (RF coils, cables, etc.) in the gantry during scanning. Remove not needed RF coils from the table and confirm that RF coils in use are connected to the connector port before scanning.</p> <p>Disconnected RF coils present during scanning can cause a high-frequency induction current loop to form, resulting in burn injury to the patient. In addition, devices may be damaged.</p>	
	Connect only the designated RF coils to the RF coil connection port.	
	Do not use a defective RF coil, especially if the outer covering has been damaged or if metal parts are exposed. There is a risk of electric shock.	
	Do not attempt to change or modify the coil. Unauthorized modifications could result in burn injury, electric shock, or decreased image quality.	
	Do not cross or loop coil cables. A high-frequency current may form and burns may occur.	

⚠	Ensure that the patient does not make direct contact with the coil cables. Burn injuries may result due to the electric field that is generated in the RF coil when a high-frequency magnetic field is transmitted.
⚠	Do not allow the patient to form a loop with any body parts. Use pads to ensure that the patient's hands and legs do not touch the coil, MRI system, patient table, or another body part that may form a loop. A high-frequency current may form and burns may occur.
	
⚠	Do not allow the patient or RF coil to contact the gantry inner wall. Separate the patient from the gantry inner wall by at least 10 mm using foam pads. Separate the patient from the RF coil cable using foam pads. Burn injuries may result due to the electric field that is generated in the RF coil etc. when a high-frequency magnetic field is transmitted.
⚠	Confirm that the coil cable is on the table before sending the patient into the gantry. If the table is moved with the cable protruding, the cable may interfere with the MRI system main unit, which could result in shifting of the coil position or in the patient being caught and injured by the system.
⚠	Stop the scan immediately if the patient complains of warming, tingling, stinging, or similar sensations. Contact a physician before continuing with the scan.
⚠	Ensure that the coil does not get in touch with liquids such as water or medications.

⚠	The enclosure of the coil and the parts inside the coil may appear in the images under certain imaging conditions (for example, when a sequence with a short echo time (TE) is used or when the pixels are large).
⚠	If a coil is found to be defective, stop using the coil immediately and contact your Siemens Healthineers representative.
⚠	Use the coil only with the accessories described in this manual.
⚠	Use the coil only for examinations as specified in the corresponding intended use.

### 3.6 Residual risks and undesirable side-effects

All known risks associated with RF coils have been controlled as far as possible. The benefit of the device has been determined to far outweigh the risk and the residual risks are low. Residual risks are communicated through cautionary statements within this manual.

RF coils have no known undesirable side-effects aside from those attributed to the MRI examination. Refer to the [Operator Manual - MR System and Coils](#).

### 3.7 Emergency procedures and incident reporting

In case of an emergency during the scan, stop the scan immediately, remove the patient from the room, and obtain medical assistance, if necessary.

If a serious incident occurs in the EU, it should be reported to QED and the competent authority of the member state in which the user facility is established.

## 4 Receptacle locations

8Tx30Rx Knee 7T coil is a transmit and receive coil. To properly use the coil, ensure both system interface connectors are connected to X7 and X5 receptacles on the system.

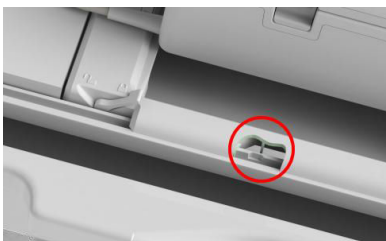


## 5 Quality assurance and scanner verification

- 1 Setup the baseplate with the coil support, and 8Tx30Rx Knee 7T coil in the center of the baseplate as shown below. Connect the coil cable connectors to the X5 and X7 receptacles of the system.



Align the notch on the side of the base plate with the “V” groove as shown below.



To align the coil in the center of the baseplate:

- Move the levers on the two sides to the unlocked position. (The levers are connected – moving the lever on one side causes the lever on the other side to move in the same manner.)



- Adjust the coil position by sliding the coil to the left or right.



- Return the levers to the locked position. When the coil is set at the desired position, move the levers on the two sides back to the locked position. Confirm that the coil is locked in position by trying to move it to the left and right.

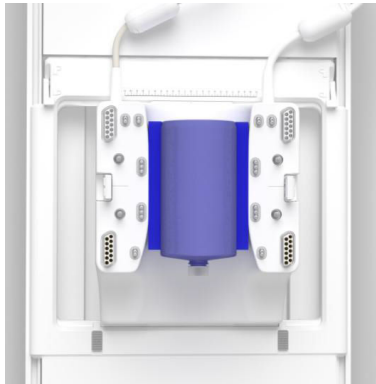
**CAUTION**

Be careful not to pinch a finger when locking the coil.

- 2 Open the coil by pulling up on the latches on both sides of the anterior.



- 3 Place the knee coil phantom holder (Siemens Healthineers PN: 11250950) in the lower part of the coil. Position the 1900 ml Marcol oil phantom (Siemens Healthineers PN: 10496430) on the phantom holder, so that the bottom of the bottle is facing the magnet bore and aligned with phantom holder end edge.



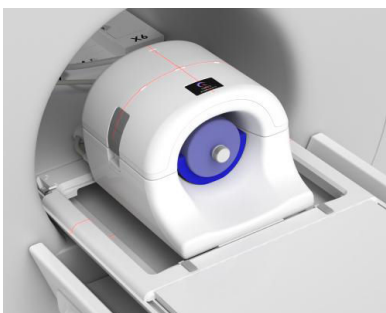
- 4 Place the upper part of the coil onto the lower part of the coil, so that it locks into place.



**CAUTION**

- Be careful not to pinch a finger when locking the coil.
- Do not begin a QA or patient scan without the anterior coil attached.
- Confirm that the anterior coil is securely attached to the posterior coil before starting scanning.

- 5 Align the laser-light localizer with the center marking of the coil.



- 6 Move the 8Tx30Rx Knee 7T coil into the magnet isocenter with the controls on the gantry.
- 7 Start the QA scan for the 8Tx30Rx Knee 7T coil listed in the QA tools section of the system software.
- 8 When the QA scan is complete, remove the coil from the bore and then remove the phantom from the coil.

## 6 Coil setup and use

### 6.1 Carrying the coil

- ◆ When moving the coil, use the handles provided on the right and left sides of the base frame.



- Do not subject the coil to physical shock (for example, by dropping it on the floor).
- Be sure to use the handles on the base frame when lifting the coil. If the coil is lifted by holding only the anterior section, the posterior section may come loose and fall, risking damage to the coil.
- Do not lift the coil by holding the cable. Doing so will subject the coil to excessive stress, possibly resulting in damage.
- Do not allow the cable to hang freely when carrying the coil. This could cause damage to the cable or connector.



## 6.2 Coil setup

- 1 Remove all RF coils that are connected to the connector ports on the gantry and RF coils that are not connected to the connector ports on the table.



### CAUTION

Ensure all other coils are removed from the table. If an unplugged RF coil is left on the table during scanning, burn injury, abnormal images, or coil failure may result.

- 2 Place the coil on the table. If the coil is transported by hand, be sure to carry the coil with both hands, using the handles on the left and right sides of the base frame.



Position the RF coil so that the arrow on the pictogram label shown below points towards the gantry.



### 3 Slide the posterior section to the desired position.

To do this:

- Move the levers on the two sides to the unlocked position. (The levers are connected – moving the lever on one side causes the lever on the other side to move in the same manner.)



- Adjust the coil position by sliding the coil to the left or right. From the direction of the table as pictured below: slide to the right to scan the patient's left knee or to the left to scan the right knee, or to the center for a phantom QA scan.

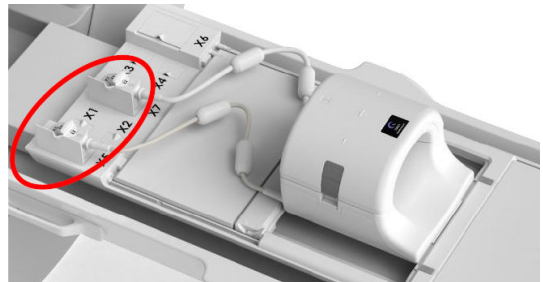


- Return the levers to the locked position. When the coil is set at the desired position, move the levers on the two sides back to the locked position. Confirm that the coil is locked in position by trying to move it to the left and right.

**CAUTION**

Be careful not to pinch a finger when locking the coil.

- 4 Position the base plate in the recess on the patient table that corresponds to the area of examination.
- 5 Connect the coil plugs from the posterior to coil sockets X5 and X7. Turn the end of the connectors around such that it exhibits the locked position.

**CAUTION**

Do not cross or loop coil cables.

Ensure that the patient does not come into direct contact with the coil cables.

### 6.3 Patient positioning and scanning



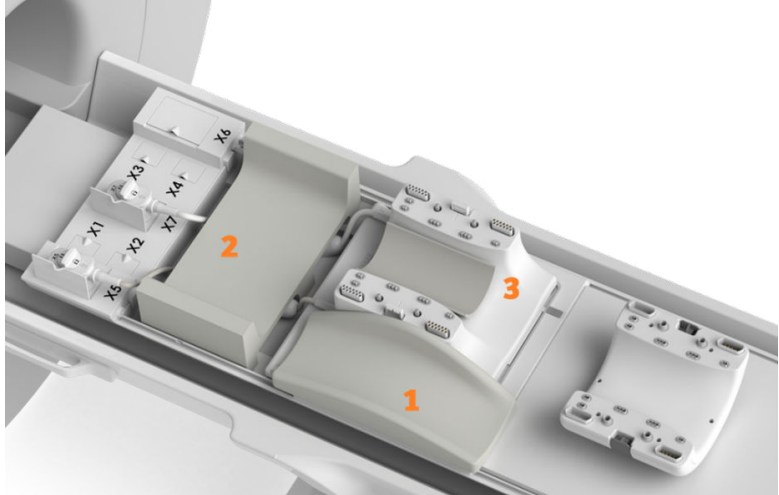
#### CAUTION

- Be sure to read this manual and the **Operator Manual - MR System and Coils** supplied with the MRI system before operating the system.
- Be sure to correctly enter the patient's weight, height, and anatomical region to be scanned. Incorrect information could result in a significant error in the SAR estimation and excessive RF energy may be applied to the patient. The RF coil could also be damaged or become hot due to excessive RF energy. Refer to the **Operator Manual - MR System and Coils** for all relevant SAR precautions.

- 1 Open the latches on both sides by pulling the latch flaps as shown below and remove the anterior section.

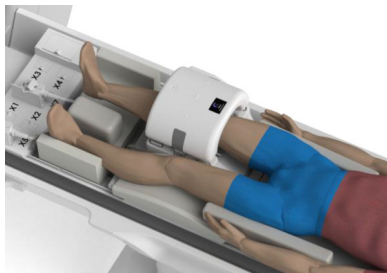


- 2 Position the pads supplied with the coil on the table as shown below.



Number	Pad
1	Other leg pad
2	Both feet pad
3	Bottom liner Pad: a. Thin pad (0.64 cm) b. Thick pad (1.27 cm)

- 3 Position the patient's knee to be scanned into the coil, and the other knee on the other leg pad.

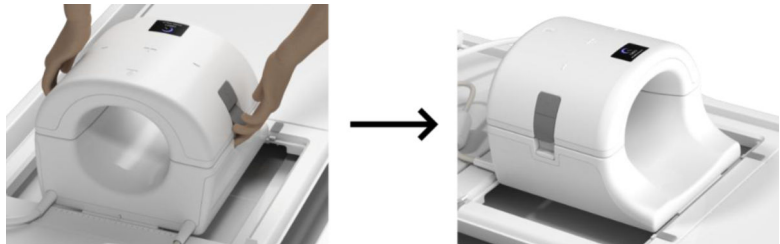


**CAUTION**

Ensure that pads are placed between hands and torso and between feet, so that no loops are created through the body, to prevent high frequency current loops.

- 4 Connect the anterior section to the posterior section and secure the sections together using the latches.

Confirm that the anterior and posterior sections are fully connected and that the latch flaps are pushed in.



- 5 Advance the patient into the magnet and landmark the coil using the reference mark on the anterior of the 8Tx30Rx Knee 7T coil for the desired imaging mode.



- 6 Confirm that no parts of the coil, cable, or mats extend out from the table, and then move the patient into the gantry.
- 7 Register the patient and start scanning using the instructions in the **Operator Manual - MR System and Coils**.



When removing the coil from table, rotate the coil to facilitate access to the handles and then lift the coil using the handles.

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# 7 Cleaning, maintenance, service, and disposal

## 7.1 Cleaning the RF coil

Surfaces that could have contacted the patient, the personnel, or bodily fluids, should be cleaned and disinfected after each use.

Use a peroxide-based disinfectant with proven cleaning efficacy that is certified by relevant national authorities (for example, EPA, VAH) for cleaning and disinfection.

The cleaning and disinfection instructions below were validated using the following product:

- **Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes**

### 7.1.1 Cleaning and disinfection precautions



- Do not pour or spray cleaning fluids onto surfaces.
- Do not immerse objects in water or cleaning fluids.
- Do not place into any type of sterilizer.
- Ensure that no liquids seep into the openings of the product, for example, gaps between covers.
- Do not use hard or sharp objects (for example, knives or tweezers) to remove residue.
- Do not insert any objects into areas that are hard to reach.
- Do not wipe electrical contacts or outlets. Cover electrical contacts before cleaning, if possible.
- Avoid wiping affixed hook and loop surfaces; detachment may occur.
- Wear appropriate personal protective equipment per the cleaner or disinfectant manufacturer's instructions.
- Use only commercially available cleaning and disinfectant solutions. Follow the instructions provided by the manufacturer of the cleaning or disinfectant agent.
- Use only the recommended cleaning agents; incompatible cleaning agents may cause surface damage or discoloration.

### 7.1.2 Preparation

- 1 Disconnect the device before cleaning the coil.
- 2 If any parts of the device are detachable, detach them and clean and disinfect separately.
- 3 Wipe off any dirt on the surface using a dry cloth. If dirt is difficult to remove, clean it according to the procedures below.

### 7.1.3 Cleaning

- 1 Thoroughly wipe all surfaces with sufficiently saturated cleaner disinfectant wipes until they are completely wet and all visible contamination is removed.
  - Use as many wipes as necessary to remove all visible signs of contamination.
  - Pay attention to hard-to-clean areas, such as crevices and mated surfaces. Use extra wipes as needed for hard-to-clean areas. Use a sterile cotton swab to push the wipe into crevices.
- 2 Check all surfaces for cleanliness. If soiling is still visible, repeat the cleaning steps above.
- 3 To remove cleaner residue, moisten at least one lint-free cloth with water and thoroughly wipe the cleaned surfaces.
- 4 Allow surfaces to air dry completely before use.
- 5 Dispose of cleaning materials according to federal, state, and local regulations.

### 7.1.4 Disinfection

- 1 Thoroughly wipe all surfaces with sufficiently saturated cleaner disinfectant wipes until they are completely wet.
  - Use as many wipes as necessary to wet all the surface.
  - Pay attention to hard-to-clean areas, such as crevices and mated surfaces. Use extra wipes as needed for hard-to-clean areas. Use a sterile cotton swab to push the wipe into crevices.
- 2 Ensure that the areas to be disinfected remain visibly wet for at least two minutes.

Additional wipes may be used to keep surfaces wetted with the disinfectant.
- 3 To remove disinfectant residue, moisten at least one lint-free cloth with water and thoroughly wipe the disinfected surfaces.
- 4 Allow surfaces to air dry completely before use.

- 5 Dispose of cleaning materials according to federal, state, and local regulations.

## 7.2 Maintenance

No regularly scheduled maintenance is required for the RF coil.

## 7.3 Service

Please contact your Siemens Healthineers representative for questions regarding service of the RF coil.

## 7.4 Disposal

Please follow local regulations for the disposal of electrical equipment. Do not dispose of the RF coil in unsorted waste bins. Contact your Siemens Healthineers representative for questions regarding the return or disposal of the RF coil.

## 7.5 Expected service life

This RF coil is designed for an expected service life of at least six years under normal usage conditions. The coil is safe to use beyond the expected service life as long as information in the Safety section is followed and Quality Assurance tests pass.

# 8 Performance characteristics

## 8.1 Technical specifications

Number of channels	<ul style="list-style-type: none"> <li>• Transmit: 8</li> <li>• Receive: 30</li> </ul>
RF coil type	Transmit-Receive
Field strength	7.0 T
Frequency	297.18 MHz
Conformance	<ul style="list-style-type: none"> <li>• IEC 60601-1</li> <li>• IEC 60601-1-2</li> <li>• IEC 60601-2-33</li> <li>• NEMA MS9</li> <li>• NEMA MS14</li> <li>• ISO 14971</li> </ul>

## 8.2 Guidance and manufacturer's declaration – Electro-magnetic compatibility (EMC)

This coil requires special attention regarding EMC and must be installed and used in accordance with the EMC guidelines provided in this manual. Only use the RF coil in the environment specified below; electromagnetic compatibility is not ensured in environments other than those specified.

### 8.2.1 Classification

This RF coil is classified as group 2, class A per CISPR 11 when it is used in combination with an MRI system.



The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

## 8.2.2 Environment and compatibility

This RF coil is intended to be used in combination with an MRI system that resides in an RF-shielded scan room within a specialized healthcare facility. All cables and accessories are part of the RF coil and cannot be removed or replaced by the user.



### CAUTION

- Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment, or interference with radio services.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories and cables other than those specified or provided in this manual could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the RF coil, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

### 8.2.3 Electromagnetic emission

The RF coil can only function when connected to the MRI system, which is contained within an RF-shielded environment. Therefore, IEC 60601-1-2 clause 7 regarding electromagnetic emission does not apply.

### 8.2.4 Electromagnetic immunity

This RF coil complies with IEC 60601-1-2 clause 8 when used in the specified electromagnetic environment.

Immunity test	Test and compliance level
Electrostatic discharge (ESD), contact discharge	IEC 61000-4-2 ±2kV, ±4kV, ±6kV, ±8 kV
Electrostatic discharge (ESD), air discharge	IEC 61000-4-2 ±2kV, ±4kV, ±8kV, ±15kV

## 9 Address information



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