31P/1H TxRx Flex Loop 7TI

REF 11371305

Important Document: Read Carefully and Keep in a Safe Place

CE 0197

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PART A PREFACE

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A.1. Scope

The Instructions For Use are an integral part of each device provided by RAPID Biomedical GmbH (RAPID Biomedical). They describe the intended purpose of the device. They are meant for all users, who operate, install or commission the device. It is mandatory to read the Instructions For Use carefully prior to first use. Contact RAPID Biomedical in case of any questions regarding the Instructions For Use. The Instructions For Use have to be made available to all users of the device at all times during its use life. The Instructions For Use have to be passed on to any subsequent owner/user of the device.

1.1. Product Safety Signs and Labels

Device safety signs and labels are described as follows.

⚠CAUTION
Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

CAUTION consists of the following elements:

Situation	Information about the nature of a hazardous situation.
Hazard	Consequences of not avoiding a hazardous situation.
Prevention	☞ Methods of avoiding a hazardous situation.

NOTICE
Indicates information considered important, but not hazard-related (e.g. messages relating to property damage).

NOTICE consists of the following elements:

Situation	Information about the nature of a situation.
Hazard	Consequences of not avoiding the situation.
Prevention	☞ Methods of avoiding the situation.

Indicates useful advice or recommendation.

1.2. Limitation of Liability

The content of the Instructions For Use were correct at the time of going to print. RAPID Biomedical GmbH does not accept liability and is also exempted from all claims by third parties arising from damage incurred with the device due to inappropriate or unauthorized use, operational errors or disregarding the Instructions For Use, especially the safety instructions contained herein. The warranty and liability conditions contained in the standard terms and conditions (AGB) of RAPID Biomedical GmbH or in the individually agreed contractual terms are not affected.

1.3. Provision of Instructions For Use

The instructions for use of the device are provided in either printed or electronic form. For information on the form of the Instructions For Use that came with the model, see Part D “Model Specific Information”.

1.3.1. Printed Edition

- Instructions For Use in paper form are included in the scope of delivery.
- Replacement of delivered Instructions For Use in paper form can be ordered from RAPID Biomedical via email (see email address on page 2).

1.3.2. Electronic Edition

- CD-ROM/USB flash drive: A CD or a USB flash drive with electronic Instructions For Use in different languages is being delivered together with the product. For further information refer to the eIFU Leaflet supplied.
- Electronic Instructions For Use can be downloaded in different languages and all available editions from the RAPID Biomedical website (see page 2).
- A replacement CD/USB flash drive or a paper copy of the Electronic Instructions For Use can be ordered from RAPID Biomedical free of charge via email (see page 2).

A.2. Glossary

2.1. Symbols

Symbol	Symbol Title & Definition
	For indoor use only. To identify electrical equipment designed primarily for indoor use.
	Temperature limit. To indicate the temperature limit values to which the device can be safely exposed.
	Humidity limitation. To indicate the range of relative humidity to which the device can be safely exposed.
	Atmospheric pressure limitation. To indicate the the range of atmospheric pressure to which the device can be safely exposed.
	Manufacturer. To identify the manufacturer of a device.
	Country of manufacture. To identify the country of manufacture of the device (“DE” means Germany).
	Article number. Indicates the article number of the manufacturer so that the device can be identified.
	Serial number. Indicates the manufacturer's serial number so that a specific device can be identified.
	Batch code. To identify the manufacturer's batch or lot code.
	RF coil, transmit. To identify the radio frequency (RF) coil for transmit only.
	RF coil, transmit and receive. To identify the radio frequency (RF) coil for both transmit and receive.
	RF coil, receive. To identify the radio frequency (RF) coil for receive only.
	Refer to instruction manual/booklet. To signify that the instruction manual/booklet must be read.
	Caution. To indicate that caution is necessary when operating the device or control close to where the symbol is placed.
	Type B applied part. To identify a type B applied part complying with IEC 60601-1.
	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.
	Class II equipment. To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	Body weight. To identify the control or the indicator to enter or call up the body weight of a person. Range of weight may vary.
	Indicates that the product must not be disposed of with household waste.

Symbol	Symbol Title & Definition
	People's Republic of China Electronic Standard: Marking and labeling standard for the environmental protection characteristic of a product, namely that the product does not contain any hazardous substances.
	General symbol for recovery/recyclable. To indicate that the marked item or its material is part of a recovery or recycling process.
	Fragile, handle with care. Indicates a device that can break or be damaged if handled carelessly.
	This way up. To indicate correct upright position of the transport package.
	Store in a dry place. Indicates a product that must be protected against moisture.
	CE marking of Conformity for Medical Devices Class I.
	CE marking of Conformity with the number of the Notified Body to the right of the symbol for Medical Devices ≠ Class I.
	Medical Device. Indicates the item is a medical device.
	Unique Device Identifier. Indicates a carrier that contains Unique Device Identifier information.
	Distributor. To indicate the entity distributing the device into the locale
	Consult instructions for use or consult electronic instructions for use. To identify the location where the operator's manual is stored.
	Authorized Representative. Indicates the Authorized Representative in the target country.

TableA1 Explanation of symbols

2.2. Technical Terms, Acronyms and Abbreviations

Item	Explanation
AGB	Standard Terms and Conditions
C	Carbon
CD	Compact Disk
CFR	Code of Federal Regulations (USA)
CMDR	Canadian Medical Devices Regulations
EC	European Community
ECG	Electrocardiogram
EEC	European Economic Community
eIFU	Electronic Instructions For Use
EU	European Union
F	Fluor
FID	Free Induction Decay
He	Helium
IEC	International Electrotechnical Commission
IFU	Instructions For Use
Li	Lithium
MDD	Council Directive 93/42/EEC
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council
MR	Magnetic Resonance
Na	Sodium
NEX	Number of excitations; equivalent to number of signal acquisitions (NSA)
P	Phosphorus
PET	Positron Emission Tomography
PPE	Personal Protective Equipment
PN	Part Number
pTx	Parallel transmit
QA	Quality Assurance
PROPELLER	Special MR imaging sequence (Pipe 1999); integrated on GE MR systems as PROPELLER sequence, Siemens MR systems as BLADE, on Philips MR systems as MultiVane
REF	Reference Number (Part Number)
RF	Radio Frequency
RMS	Root Mean Square = average (e.g. used in contrast to peak power)
RoHS	Restriction of Hazardous Substances
ROI	Region of Interest
Rx	Receive Function
SAR	Specific Absorption Rate
SN	Serial Number
SNR	Signal-to-Noise Ratio
Tx/Rx	Transmit/Receive
Tx	Transmit Function

Item	Explanation
UDI	Unique Device Identification
USB	Universal Serial Bus
WALTZ	Wideband, Alternating-phase, Low-power Technique for residual splitting – is a broadband decoupling MR sequence
WEEE	Waste of Electronical and Electrical Equipment
Xe	Xenon

Table A2 Explanation of technical terms, acronyms and abbreviations

PART B GENERAL INSTRUCTIONS

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B.1. Safe Operation

Proper and safe operation of the device in combination with the MR system requires operating personnel with technical knowledge and a high degree of familiarity with both the Instructions For Use of the device and the Instructions For Use of the MR system. The Instructions For Use of the MR system remain entirely applicable. Pay particular attention to all warnings.

1.1. General Safety

⚠CAUTION	
Situation	Maloperation of the device.
Hazard	Target subject and / or user can be harmed, device and / or other equipment can be damaged.
Prevention	☞ The device may only be operated by qualified personnel. ☞ It is mandatory to follow these Instructions For Use closely. ☞ Follow the Instructions For Use of the MR system, additional devices and facilities.

⚠CAUTION	
Situation	Emergency that needs the target subject to be evacuated.
Hazard	Target subject can be harmed, device and / or other equipment can be damaged.
Prevention	☞ Before MR examinations on human subjects, the user has to familiarize himself with the necessary steps for a quick evacuation. ☞ It is mandatory to follow these Instructions For Use closely. ☞ Follow the Instructions For Use of the MR system, additional devices and facilities.

⚠CAUTION	
Situation	Defective device.
Hazard	Target subject and / or user can be harmed, device and / or other equipment can be damaged.
Prevention	☞ The operational reliability of the device must be checked and ensured prior to each use. ☞ The device must not be used in the event of damaged labels. ☞ The device must not be used in the event of any defect. Notify your local service representative immediately.

Checking the operational reliability of the device also includes checking the housing, checking the cable connections and checking all device labels.

Missing or damaged labels may only be amended or replaced by the service representative.

⚠CAUTION	
Situation	Unauthorized repair of a defective device.
Hazard	Target subject and / or user can be harmed, device and / or other equipment can be damaged.

Prevention	☞ Only a representative authorized by RAPID Biomedical is entitled to repair the device.

	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the state in which the user is established.

1.2. Diagnostic Error

⚠CAUTION	
Situation	Disturbed signal detection by low SNR or image artifacts.
Hazard	Imaging Artifacts can be misinterpreted.
Prevention	☞ Proper function of the device has to be checked and ensured prior to each use. ☞ The device is not to be used if failure of proper function is detected. ☞ The device may only be operated by qualified personnel.

⚠CAUTION	
Situation	When using in PET / MR system, PET signal is attenuated by the device.
Hazard	Displayed PET signal might be decreased and/or dislocated which can lead to misinterpretation.
Prevention	☞ Use of a PET attenuation correction is recommended.Ensure that the cable of the device runs directly out of the PET detection area.

1.3. Error Indicators

The device has no error indicators. Operators have to rely on other means of error indication. In this regard they should:

- constantly observe the error information provided by the MR system.
- regularly check on the functionality of the device (e.g. for unexpected examination results, for degraded MR image quality, changed Tx power consumption, etc.).

1.4. Off-label Use

The device has been developed for use in conjunction with the specific MR system indicated in document “MRSysComp”.

The situation of an off-label use is not applicable for devices targeting non-human target subjects.

⚠CAUTION	
Situation	The device is not used according to the Instructions for Use.
Hazard	Target subject can be harmed, device can be damaged.
Prevention	☞ The device is to be used as intended being described by the Instructions for Use.

⚠CAUTION	
Situation	Device is used in combination with non-approved device.
Hazard	Target subject can be harmed, device and / or other equipment can be damaged.
Prevention	☞ Use device only in combination with devices specified in document “MRSysComp”. ☞ Use only device approved for combined usage with the device.

	Check for MR system receive coils integrated into the patient table; e.g. Siemens Spine Array Coil, Philips Posterior Array, GE Posterior Array. It might be necessary to lock them in park position or remove them completely as specified in Part D “Specific Model Information”.

	Observe Instructions For Use of the MR system as well.

	Prescription Use only Country specific laws restrict this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioner licensed by the law of the country in which he practices to use or order the use of the device. This device may only be distributed to persons who are licensed practitioners or to persons who have a prescription or other order from a licensed practitioner to purchase it.

B.2. RF Safety

2.1. Risk Factors

⚠CAUTION	
Situation	Exposure of the target subject to RF magnetic fields may involve the following risk factors: o Presence of conductive (metallic) objects or implants within the sensitivity region of the RF transmit coil. o Presence of medicinal products in transdermal patches. o Skin-to-skin contact of different parts of the body. o Presence of damp clothing. o Placement of target subject's body or extremities against the RF transmit coil surface. o Contact between target subject and RF coil cable and the routing of the RF coil cable in proximity to the RF transmit coil. o Formation of loops with RF receive coil cables and the ECG leads. o Use of MR conditional ECG electrodes and leads. o MR examination of sedated or unconscious target subjects or target subjects with loss of feeling in any body parts. o Presence of unconnected RF coils or electric cables remaining in the RF transmit coil during MR examination.
Hazard	Target subject may experience local excessive RF heating and even RF burning.
Prevention	☞ All removable conductive objects are to be removed from the target subject; e.g. all clothing containing metallic thread or components, watches, coins, jewelry, etc. ☞ Do not perform MR examinations on target subjects with conductive implants. ☞ Do not perform MR examinations on target subjects with medicinal products in transdermal patches. ☞ Check the position and posture of the target subject to avoid conductive loops; e.g. calf-to-calf, hand-to-hand, etc. ☞ Do not perform MR examinations on target subjects with damp clothing. ☞ Check the position of the target subject to avoid contact with the RF transmit coil surface. ☞ Check the position of the target subject to avoid contact between target subject and RF coil cable when the routing of the RF coil cable is in proximity to the RF transmit coil. ☞ Check the routing of RF coil cables and ECG leads to avoid loops. ☞ Observe Instructions For Use of ECG electrodes and leads. Pay close attention to expiration dates. ☞ Continuously monitor sedated or unconscious target subjects or target subjects with loss of feeling in any body parts closely during MR examinations. ☞ Remove disconnected coils or cables prior to the MR examination.

2.2. Specific Absorption Rate

The target subject is exposed to RF energy during a MR examination, which can heat the body and hence is of concern. The Specific Absorption Rate (SAR) is the RF power absorbed by the target subject's body per unit mass expressed in Watts per kg (W / kg) and serves as a stress indicator.

SAR correlates with the average RF deposition into the target subject, also denoted as RMS RF power.

The maximum SAR value allowed for a MR examination is determined by target subject parameters (weight, sex, etc.) and MR examinations parameters (application, table position, target subject orientation, etc.).

The maximum RMS RF power allowed for a MR examination is determined by the RF coil chosen for transmit of the RF field.

The device itself does not feature a monitoring function of SAR and RMS RF power. SAR and RMS power limits are observed by a monitoring function of the MR system. The device features coil configuration files, which contain information on SAR and RMS power limits specific for the device. These coil configuration files have to be installed on the MR system and will be loaded into the monitoring function of the MR system as soon as the coil is connected and successfully recognized.

Devices targeting non-human target subjects might not feature coil configuration files and therefore information on SAR and RMS power limits are not available for the device.

⚠CAUTION	
Situation	SAR and / or RMS power limits set incorrectly or MR system's monitoring function of SAR and / or RMS RF power not active.
Hazard	Target subject can be harmed, device and/or other equipment can be damaged.
Prevention	☞ SAR relevant data has to be entered correctly. ☞ The RF monitoring or the SAR control system of the MR system is not to be switched off. ☞ SAR relevant parameters in the configuration files are not to be changed.

⚠CAUTION	
Situation	In the case of using pTx arrays, a special dedicated SAR monitoring is not used.
Hazard	Target subject can be harmed.
Prevention	☞ The use of a SAR monitoring is essential, which is especially approved for pTx arrays. ☞ SAR relevant data has to be entered correctly. ☞ The RF monitoring or the SAR control system of the MR system is not to be switched off. ☞ SAR relevant parameters in the configuration files are not to be changed.

⚠CAUTION	
Situation	Scanning of target subject with weight below "minimum patient weight".
Hazard	Target subject may experience local excessive RF heating and even RF burning.
Prevention	☞ Scanning of target subjects with a "minimum patient weight" as specified in Part D "Specific Model Information".

⚠CAUTION	
Situation	Scanning of target subject while user / MR worker is inside the MR room.
Hazard	Target subject and / or user / MR worker can be harmed, device and / or other equipment can be damaged.
Prevention	☞ The device is not to be operated if a user / MR worker is inside the MR room.

Observe information on SAR and RMS in Instructions For Use of the MR system.

B.3. Initial Setup

Coil configuration files have to be installed on the MR system before the device is allowed to be initially connected to the MR system.

Devices targeting non-human target subjects might not feature coil configuration files and therefore an initial setup of these devices is not applicable.

⚠CAUTION	
Situation	Incorrect installation of the device.
Hazard	Target subject and / or user can be harmed, device and / or other equipment can be damaged.
Prevention	☞ The device may only be installed by qualified personnel. ☞ It is mandatory to follow these Instructions For Use closely. ☞ Follow the Instructions For Use of the MR system, additional devices and facilities.

The coil configuration files might already be installed by your local service representative.

A successful completion of this installation procedure is essential for the first use of the device.

3.1. Installation of Configuration Files

The procedure for the installation of the coil configuration files varies based on the MR system model and the installed software version.

For Siemens MR systems:

- Refer to the instructions in the readme file on the coil configuration files CD/USB flash drive.

For GE MR systems:

- Contact your GE field engineer for installation of the coil configuration files.
- Refer to the instructions in the readme file on the coil configuration files CD/USB flash drive.

For Philips MR systems:

- Contact your Philips service technician and/or clinical scientist for installation of the coil configuration files.
- Refer to the instructions in the readme file on the coil configuration files CD/USB flash drive.

Contact RAPID Biomedical in case of any issues during the installation of the coil configuration files.

Check the proper operation of the device after installation of the coil configuration files according to chapter B.4 “First Use”.

3.2. Upgrade of the MR system

An upgrade of the software or of the hardware of the MR system may require the installation of new coil configuration files and a new compatibility evaluation by RAPID Biomedical.

Proceed as follows in order to prepare for the upgrade of the MR system:

- Before the upgrade, record the performance of the device according to B.5 “Regular Use”.
- Keep the QA data available as a reference.
- Contact RAPID Biomedical at least 3 weeks prior to the upgrade providing information on
  - the device and serial number,
  - the new software version of the MR system,
  - the change in hardware of the MR system,
  - the date of the upgrade and
  - the QA data.

B.4. First Use

The device needs to be prepared for the first use after delivery, service or repair as described in the following.

4.1. Acclimatization

First use of the device is only allowed after a reasonable period of acclimatization.

NOTICE	
Situation	Device is operated before being acclimatized.
Hazard	Damage of device due to condensation.
Prevention	☞ Store the unpackaged device under operating conditions for 24 hours prior to first use. ☞ Observe the permissible environmental conditions listed in Table B1.

⚠CAUTION	
Situation	Device is not operated within the limits of specified operating conditions.
Hazard	Target subject and / or user can be harmed, and the device can be damaged.
Prevention	☞ Ensure that environmental conditions of the MR room are within the limits of permissible environmental conditions listed in Table B1.

Description	Symbol	Environmental Condition
Application Environment		Indoor use only
Operating Conditions: Temperature Range		+15°C to +24°C / +59°F to +75.2°F
Relative Humidity		30 % to 80 % RH
Air Pressure		70 kPa - 107 kPa
Transport & Storage Conditions: Temperature Range		-25°C to +60°C / -13°F to +140°F
Relative Humidity		5 % to 95 % RH

Table B1 Environmental Conditions

4.2. Proper Operation

First use of the device on a target subject is only allowed after assuring proper operation:

1. Connect the device to the MR system and check whether the device is successfully recognized.
2. Check the functionality of the device by model specific tests according to Part D “Specific Model Information”, e.g.
    a. Detection of ^{1}H signal
    b. Detection of signals from all other supported nuclei (^{31}P, ^{13}C, etc.)
    c. Image homogeneity
    d. ^{1}H decoupling capability, etc.
3. Record the results of the functionality tests.
4. Check the performance of the device by running a QA check according to chapter B.5 “Regular Use”.
5. Record the results of the QA check.

Proper operation of the device might already be assured by your local service representative.

Devices targeting non-human target subjects might not feature coil configuration files and therefore the device might not be recognizable by the MR system.

4.3. Application

First use of the device on a target subject is only allowed after proper preparation.

⚠CAUTION	
Situation	Device not prepared according to intended use.
Hazard	Target subject can be harmed.
Prevention	☞ Prepare the device before use according to intended use as described in chapter C.4 “Reprocessing of the Device”

B.5. Regular Use

5.1. Handling

NOTICE	
Situation	Sensitive electronic device, not handled with care.
Hazard	Device can be damaged.
Prevention	☞ Handle and use with appropriate care. ☞ Avoid jolts or impacts which can affect the device. ☞ Only carry the device by its housing. ☞ Treat any attached cables and plugs with due care and do not use them for carrying the device.

⚠CAUTION	
Situation	Device not handled with care.
Hazard	Target subject can be harmed, device can be damaged.
Prevention	☞ Do not carry the device by its cables and / or plugs. ☞ Ensure that devices parts are correctly connected and connecting cables are routed safely before driving the patient table into the bore of the MR system. ☞ Closely mind the target subject for potential harm while closing any device parts and/or driving the patient table into the bore of the MR system.

5.2. Reprocessing

5.2.1. General Information

Cleaning

Cleaning is an essential step before an 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.

Disinfection

Disinfection is the inactivation of diseasecausing microorganisms.

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

⚠CAUTION	
Situation	Use of other cleaning solution, disinfectants, special accessories, and / or cleaning and disinfection procedures other than described in these Instructions For Use.
Hazard	Target subject and / or user can be harmed, device can be damaged.
Prevention	☞ The device may only be reprocessed by qualified personnel. ☞ Only use a cleaning solution and disinfectants specified in these Instructions For Use. ☞ Only use special accessories specified in these Instructions For Use. ☞ Only use reprocessing procedures described in these Instructions For Use.

Refer to chapter C.4 “Reprocessing of the Device” for classification of the device with regard to reprocessing and the level of disinfection, which has to be achieved.

5.2.2. General Workflow

- Wear appropriate personal protective equipment when handling cleaning solutions, disinfectants and the device. PPE may include gloves, eye protection, impervious gown, face shield or simple surgical mask, etc.
- Properly discard expendable items like gloves, wipes etc.
- Automated reprocessing is not feasible for this device. Follow procedures for manual reprocessing of the device as described below.

The Instructions For Use of the PPE, special accessories, cleaning agent and disinfectants are also to be observed.

5.2.3. Storage

Store the device away from potential sources of contamination and mechanical impacts in a dry cool place, which is not subject to strong variations in temperature (see Table B1).

5.3. Service

5.3.1. Performance / Quality Assurance

A regular (e.g. weekly) execution of a defined MR examination with the device is recommended enabling early detection of any performance deterioration.

MR examination for quality assurance of the device is a combination of

- a suitable MR sequence (i.e. imaging or spectroscopy) with specific parameters,
- a well-defined setup of coil and MR phantoms (QA setup) and
- a well-defined procedure / workflow (setup in MR system, setting of sequence parameters, adjustments as frequency, shim, Tx power, etc.).

An appropriate MR phantom contains adequate quantities of each targeted nucleus. It is of comparable size and electrical conductivity as the target subject in the intended application.

Refer to Part D “Specific Model Information” for information on a quality assurance setup recommended for the specific model.

Ensure that the device is set up and used according to these Instructions For Use.

Significant parameters for evaluation of the performance may be

- SNR,
- required pulse power/voltage/attenuation for a 180° rectangular pulse of a defined length,
- etc.

It is advisable to record detailed results, such as:

- description of MR phantom(s),
- positioning of coil and MR phantom(s),
- shim parameters and achieved line width,
- MR sequence and parameter settings,
- raw data.

A procedure for assuring the quality of the device (QA check) might already be installed on the MR system. Contact RAPID Biomedical for further information.

5.3.2. Maintenance

No maintenance is required.

5.3.3. Returning of Devices

RAPID Biomedical devices are shipped in dedicated packaging, which can be reused.

NOTICE	
Situation	Inadequate packaging and / or improper means of transport.
Hazard	Device can be damaged.
Prevention	☞ The original packaging is supposed to be used for returning the device.

Returning of devices might be handled by your local service representative. Contact RAPID Biomedical for further information.

B.6. End of Product Life Cycle

6.1. Disposing of Devices

RAPID Biomedical hereby confirms that its devices conform to the guidelines, regulations and laws of the European Union concerning the disposal of waste electrical and electronic equipment (WEEE) in its applicable version.

⚠CAUTION	
Situation	Improper disposal.
Hazard	Others can be harmed and / or there might be danger of environmental pollution. environment hazard.
Prevention	☞ This device must not be disposed of as domestic waste. ☞ RAPID Biomedical will take care of disposal of old device. ☞ Contact RAPID Biomedical for further information.

RAPID Biomedical accepts the return of packaging material and of old devices.

6.2. Environmental Protection

RAPID Biomedical assures observing the environmental protection regulations of the applicable EU Directives over the entire life cycle of its devices from development through manufacturing and disposal.

PART C GENERAL MODEL INFORMATION

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C.1. Description

The Surface Coil is intended to be used on humans. Its qualification as a medical device for the target country depends on

1. The qualification of the device itself.
   This is shown on the rating plate of the device by symbol “MD”. Check Part D “Specific Model Information” for detailed information.
2. The qualification of the device for the target country:
   Check for an additional labelling (on the device, on the IFU, etc.) which might limit the information on the rating plate to the qualification of the device in the target country.

In case that the rating plate qualifies the device as a medical device and there is no additional restrictive labelling, ignore chapter 1.2 “Device For Research Purposes only”.

In case that there is additional restrictive labelling, ignore chapter 1.1 “Medical Device” and proceed with chapter 1.2 “Device For Research Purposes only.

1.1. Medical Device

Intended Purpose	The Surface Coil is intended to be used for diagnostic imaging/ spectroscopy with a MR system (MRI, MRS).
Indications for Use	The Surface Coil is indicated for use as diagnostic device extension for MR systems to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, displaying the internal structure of human anatomy. These images when interpreted by a trained physician yield information that may assist in diagnosis.
Contraindications	The Surface Coil does not alter the general contraindications for MR examinations of the corresponding MR system. No additional contraindications are identified.
Application	Multi-Purpose (might differ; see Part D “Specific Model Information”).
Intended Population	Specified in Part D “Specific Model Information”.
Applied Parts	The whole device is considered being an Applied Part but only under the aspect of electrical safety.
MR System	Specified in Part D “Specific Model Information”.

Table C1 General model description

Refer to Part D “Specific Model Information” to find, e.g.:

- Configuration (nucleus, transmit, receive, transmit/receive)
- Design (linear, quadrature, phased-array, multi-channel transmit, 1H decoupling (waltz), etc.)
- Characteristics (geometry, dimensions, location of coil elements frequencies, etc.)

1.2. Device For Research Purposes only

Intended Purpose	The Surface Coil is intended to be used for imaging/ spectroscopy with a MR system (MRI, MRS).
Indications for Use	The Surface Coil is indicated for use as device extension for MR systems to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, displaying the internal structure of the target subject.
Contraindications	The Surface Coil does not alter the general contraindications for MR examinations of the corresponding MR system. No additional contraindications are identified.
Application	Multi-Purpose (might differ; see Part D “Specific Model Information”).
Intended Population	Specified in Part D “Specific Model Information”.
Applied Parts	The whole device is considered being an Applied Part but only under the aspect of electrical safety.
MR System	Specified in Part D “Specific Model Information”.

Table C2 General model description

Refer to Part D “Specific Model Information” to find, e.g.:

- Configuration (nucleus, transmit, receive, transmit/receive)
- Design (linear, quadrature, phased-array, multi-channel transmit, 1H decoupling (waltz), etc.)
- Characteristics (geometry, dimensions, location of coil elements frequencies, etc.)

C.2. Model Types

The Surface Coil is available in various designs with different configurations and characteristics. From an application perspective, the Surface Coil can be divided into three types of models:

2.1. Device Setup before Target Subject Positioning

- These models are designed to be positioned into the patient table of the specified MR system.
- They feature a robust design for carrying the weight of the target subject.
- According to the intended application, a Surface Coil might offer a mechanism for target subject fixation.
- For more specific information, please refer to Part D “Specific Model Information”.

Figure C1: Surface Coil 01476 – Example of a rigid Surface Coil to be positioned into the patient table of a Siemens MR system.

2.2. Device Setup after Target Subject Positioning

- These models are designed to be positioned after positioning of the target subject.
- They offer some flexibility in positioning.
- Some models feature a flexible housing design and can be bent around the target subject.
- Some models feature options for fixation.
- For more specific information, please refer to Part D “Specific Model Information”.

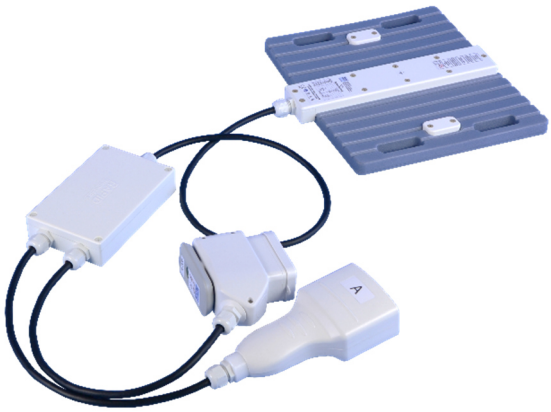

Figure C2: Surface Coil 01765 – Example for a flexible Surface Coil for a GE MR system, which is setup after target subject positioning and allows for being bent around the target subject.

2.3. Device Setup with Dedicated Interface

- These models are designed as a coil part combined with a dedicated interface.
- The interfaces are designed to be setup into the patient table of the specified MR system.
- After positioning of the target subject, the coil part is positioned and connected to the interface.
- These models offer some flexibility in positioning.
- Some models feature a flexible housing design and can be bent around the target subject.
- Some models feature options for fixation.
- For more specific information, please refer to Part D “Specific Model Information”.

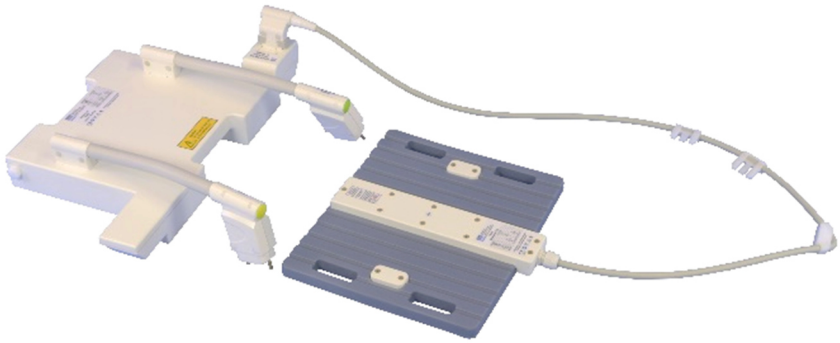

Figure C3: Surface Coil 01781 – Example of a flexible Surface Coil with a dedicated interface for a Siemens MR system.

2.4. Device Setup with Dedicated Coil Support

- These models are designed as a coil part combined with a dedicated coil support.
- The coil supports are designed to be setup into the patient table of the specified MR system.
- After positioning of the target subject, the coil part is positioned and fixated by the coil support.
- These models offer some flexibility in positioning.
- Some models feature a flexible housing design and can be bent around the target subject.
- For more specific information, please refer to Part D “Specific Model Information”.

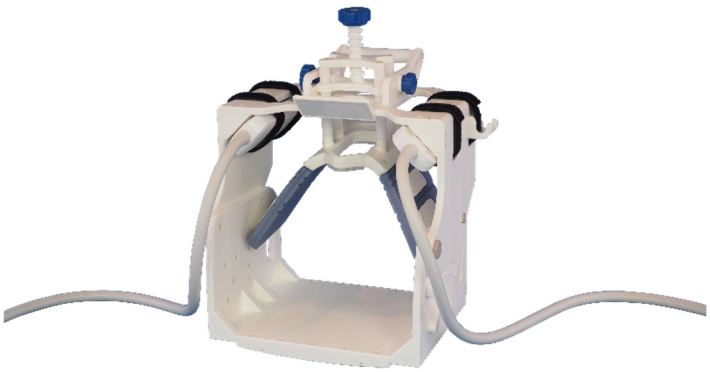

Figure C4: Surface Coil 02172 – Example of a flexible Surface Coil with a dedicated holder.

C.3. Regular Use

3.1. Positioning of Target Subject and Device

3.1.1. Models setup before Target Subject Positioning

1. Remove cushions and/or other not compatible coils, which are integrated into the patient table.
2. Position the Surface Coil into the patient table.
3. Connect the device to the MR system as described in chapter 3.3 “Connecting to the MR system”.
4. Fill open gaps with cushions provided together with the Surface Coil or with cushions of the MR system.
5. In order to avoid direct contact between the target subject skin and the device cover the corresponding parts of the device by e.g. suitable cloths.
6. Position the target subject on the patient table according to the IFU of the MR system.
7. According to the specific model, use the offered a mechanism for target subject fixation (refer to details in Part D Specific Model Information).

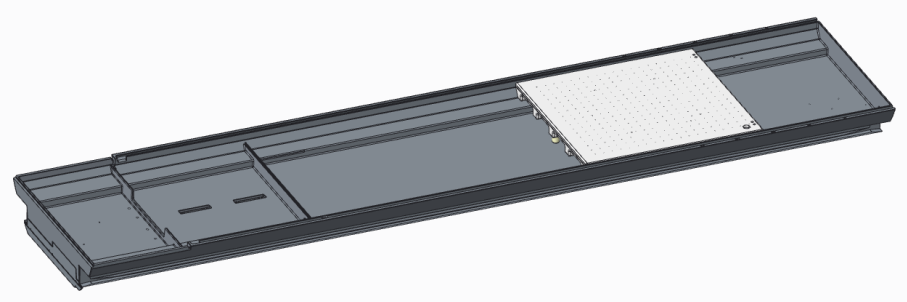

Figure C5: Surface Coil – Example for positioning of the device into the patient table.

3.1.2. Models setup after Target Subject Positioning

1. Remove other not compatible coils, which are integrated into the patient table.
2. Fill open gaps with cushions of the MR system.
3. Position the target subject on the patient table according to the IFU of the MR system.
4. In order to avoid direct contact between the target subject skin and the device cover the corresponding parts of the device by e.g. suitable cloths.
5. Connect the device to the MR system as described in chapter 3.3 “Connecting to the MR system”.
6. Position the Surface Coil over or bent around the anatomical region of interest.
7. Fixate the Surface Coil in position by means like velcro straps, etc.

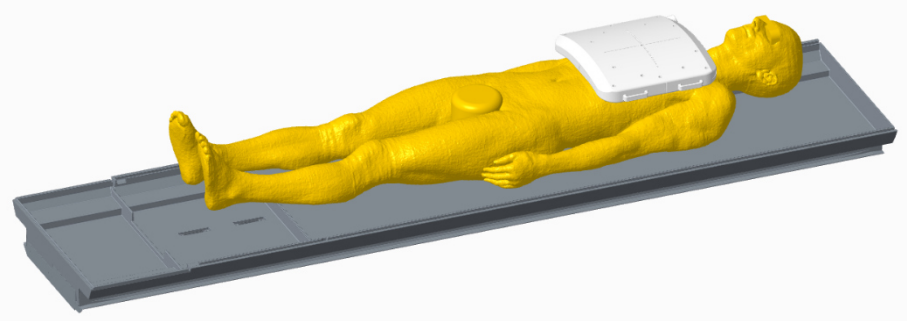

Figure C6: Surface Coil – Example for positioning the device after target subject positioning.

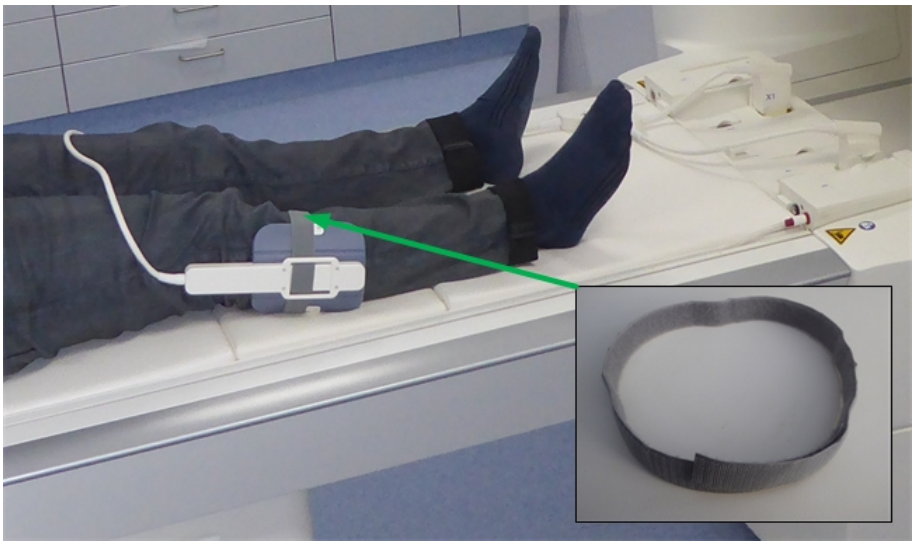

Figure C7: Surface Coil – Example for fixation of the device using velcro straps.

3.1.3. Models with Dedicated Interface

1. Remove cushions and/or other not compatible coils, which are integrated into the patient table.
2. Position the interface into the patient table.
3. Connect the device to the MR system as described in chapter 3.3 “Connecting to the MR system”.
4. Fill open gaps with cushions provided together with the Surface Coil or with cushions of the MR system.
5. In order to avoid direct contact between the target subject skin and the device cover the corresponding parts of the device by e.g. suitable cloths.
6. Position the target subject on the patient table according to the IFU of the MR system.
7. In order to avoid direct contact between the target subject skin and the device cover the corresponding parts of the device by e.g. suitable cloths.
8. Position the coil part over or bent around the anatomical region of interest.
9. Fixate the coil part in position by means like velcro straps, etc.
10. Connect the coil part to the interface.

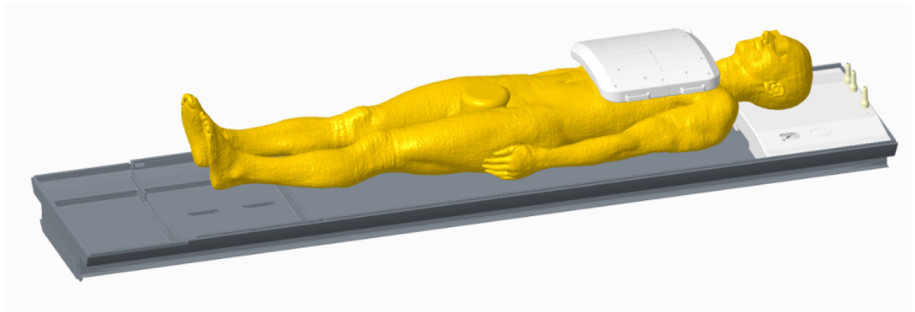

Figure C8: Surface Coil – Example for positioning of the device with the dedicated interface.

Do not operate the coil part on the interface.

3.1.4. Models with Dedicated Coil Support

1. Attach the coil part to the coil support.
2. Remove cushions and/or other not compatible coils, which are integrated into the patient table.
3. Position the coil support with the attached coil part into the patient table.
4. Connect the device to the MR system as described in chapter 3.3 “Connecting to the MR system”.
5. Fill open gaps with cushions provided together with the Surface Coil or with cushions of the MR system.
6. In order to avoid direct contact between the target subject skin and the device cover the corresponding parts of the device by e.g. suitable cloths.
7. Position the target subject on the patient table according to the IFU of the MR system.
8. Use the coil support to position the coil part over or bent around the anatomical region of interest (refer to details in Part D “Specific Model Information).

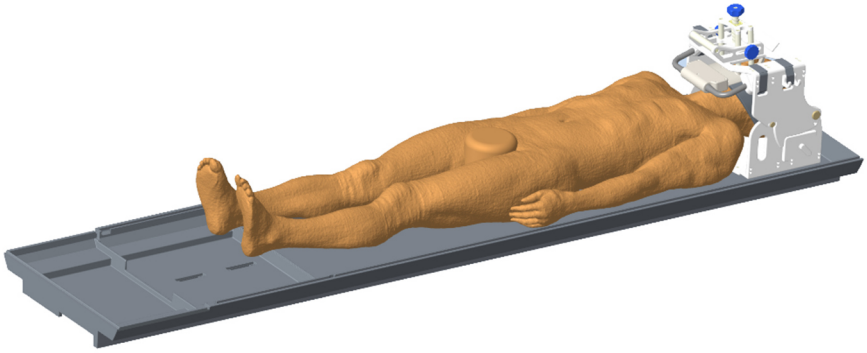

Figure C9: Surface Coil – Example for positioning of the device with the dedicated coil support.

⚠CAUTION	
Situation	Using the coil support to position the coil part.
Hazard	Patient or user can be harmed by squeezing.
Prevention	☞ Use coil support carefully.

3.1.5. All Model Types

- The RF center of all the coils is indicated by respective markings on the housing.
- The target subject should be positioned that the ROI of the intended application is arranged as close to the RF center of the coil as possible.
- Use the position aids on the coil housing to align the device with the laser alignment lights for target subject land marking.
- Drive the patient table carefully into the MR system.

Long lasting direct contact between the device and target subject skin can lead to perspiration. Sweat is electrically conductive allowing the absorption of RF power.

⚠CAUTION	
Situation	Long lasting direct contact between the device and target subject skin.
Hazard	Target subject can be harmed by RF burning and / or biological interactions.
Prevention	☞ Avoid direct contact between the target subject and the device, e.g. by using suitable cloths.

3.2. Application Restrictions

The application of some models is restricted due to SAR evaluation. Check Part D “Specific Model Information”, if any application restriction described in the following paragraphs is applicable to this specific model.

3.2.1. Keep distance to Eyes!

This paragraph is applicable for models with the application restriction “Keep distance to Eyes!”.

⚠CAUTION	
Situation	Device is positioned too close to the eyes of the target subject.
Hazard	Eye of the target subject can be harmed up to blindness.
Prevention	☞ Keep a distance to the eyes of at least 6 cm (2.5 inches) in all directions.

3.2.2. Do not use on the Head!

This paragraph is applicable for models with the application restriction “Do not use on the Head!”.

⚠CAUTION	
Situation	Device is positioned too close to the eyes of the target subject.
Hazard	Eye of the target subject can be harmed up to blindness.
Prevention	☞ Do not use the coil on the head of the target subject.

3.3. Connecting to the MR system

The Surface Coil is only to be connected to the MR system specified in Part D “Specific Model Information”.

The Surface Coil features dedicated system connector(s), which have to be connected to the corresponding socket(s) of the MR system.

The MR system’s software will either display select option(s) for the Surface Coil or select the Surface Coil automatically if it is properly connected. The Surface Coil is not properly connected to the MR system if the select option(s) do not appear.

Refer to Part D “Specific Model Information” for detailed information on the wiring of the Surface Coil and the select option(s), which ought to be presented by the MR system.

	Ensure that connecting cords/cables are run directly to specified socket(s) of the MR system. Do not guide them around the product or the target subject.

⚠CAUTION	
Situation	Examinations with the device not connected according to these Instructions For Use.
Hazard	Target subject can be harmed, device and/or other equipment can be damaged.
Prevention	☞ The device has to be connected as specified in these Instructions For Use. ☞ Follow the connecting instructions given in the Instructions For Use of the MR system. ☞ Prior to examinations make sure all connections have been completed. ☞ Proper connection between the coil and the MR system needs to be checked in the user interface of the software prior to each exam. ☞ Examinations are not to be performed if the coil is inside the magnet and disconnected from the MR system.

3.4. Removing Target Subject and Device

After finishing the MR examination proceed as follows:

3.4.1. Models setup before Target Subject Positioning

1. Move the patient table out of the magnet bore.
2. According to the specific model, loosen any target subject fixation carefully.
3. Help the target subject off the patient table.
4. Remove any cloths.
    a. Properly dispose of the cloths.
5. Disconnect the Surface Coil from the MR system.
    a. Attach cover onto coil connector (see Figure C10) if applicable.
6. Remove the Surface Coil from the patient table.
    a. Start reprocessing immediately according to chapter C.4 “Reprocessing of the Device”.

3.4.2. Models setup after Target Subject Positioning

1. Move the patient table out of the magnet bore.
2. Disconnect the Surface Coil from the MR system.
    a. Attach cover onto coil connector (see Figure C10) if applicable.
3. Loosen any straps used to fixate the Surface Coil.
4. Remove the Surface Coil from the target subject carefully.
    a. Start reprocessing immediately according to chapter C.4 “Reprocessing of the Device”.
5. Remove any cloths.
    a. Properly dispose of the cloths.
6. Help the target subject off the patient table.

3.4.3. Models with Dedicate Interface

1. Move the patient table out of the magnet bore.
2. Disconnect the coil part from the interface.
3. Loosen any straps used to fixate the coil part.
4. Remove the coil part from the target subject carefully.
    a. Start reprocessing immediately according to chapter C.4 “Reprocessing of the Device”.
5. Remove any cloths.
    a. Properly dispose of the cloths.
6. Help the target subject off the patient table.
7. Disconnect the interface from the MR system.
    a. Attach cover onto coil connector (see Figure C10) if applicable.
8. Remove the interface from the patient table.
    a. Start reprocessing immediately according to chapter C.4 “Reprocessing of the Device”.

3.4.4. Models with Dedicated Coil Support

1. Move the patient table out of the magnet bore.
2. Loosen the coil support used to fixate the coil part into position.
    a. Control the coil part the whole time.
3. Use the coil support to remove the coil part from the target subject carefully.
4. Help the target subject off the patient table.
5. Remove any cloths.
    a. Properly dispose of the cloths.
6. Disconnect the Surface Coil from the MR system.
    a. Attach cover onto coil connector (see Figure C10) if applicable.
7. Detach the coil part from the coil support.
    a. Start reprocessing immediately according to chapter C.4 “Reprocessing of the Device”.
8. Remove the coil support from the patient table.
    a. Start reprocessing immediately according to chapter C.4 “Reprocessing of the Device”.

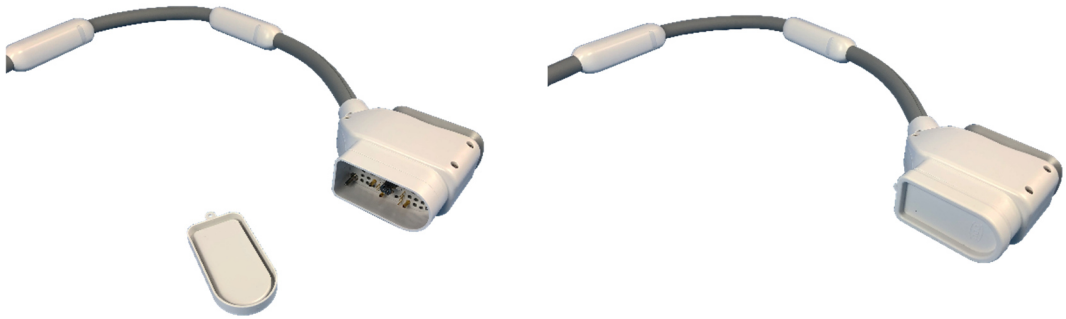

Figure C10: Surface Coil 01765 – Example of attaching cover onto coil connector (only models for GE (example shown) or Philips MR systems).

C.4. Reprocessing of the Device

4.1. General Information

The Surface Coil is classified as a non-critical item with regard to reprocessing. Therefore disinfection of the Surface Coil is not required.

The Surface Coil allows for an optional low level disinfection step during reprocessing of the device according steps (2) and (3).

4.2. Reprocessing Workflow

4.2.1. Summary of steps

(1) Cleaning	☞ Clean device with rotating movements from connector up to the end of the housing. ☞ Rinse with wipes moistened with water. ☞ Dry with dry wipes. ☞ Visual inspection of cleanliness.
(2) Low Level Disinfection (LLD) - [optional]	☞ Use disinfectant wipes to disinfect all areas of the device. ☞ Rinse thoroughly.
(3) Drying - [optional]	☞ Dry surfaces, holes and threads.
(4) Inspection	☞ Visual inspection for damages. ☞ Check all connections. ☞ Check connector.
(5) Storage & Transportation	☞ Store the device.

4.2.2. Steps in detail

(1) CLEANING	
Accessories	• pH-neutral enzymatic cleaning detergent; e.g. B. Braun Helizyme 1 % solution. • Soft, lint-free wipes soaked with cleaning solution; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO. • Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO.
Steps	• Wring a wipe soaked with cleaning solution. • Clean cable areas with rotating movements. Avoid back and forth movements. Move from connector towards coil housing. • Clean coil area starting at the cable inlet(s) to the end of the housing. Avoid back and forth movements. • Ensure that all areas of the device come into contact with the wipe. • Allow the cleaning solution to take effect for the minimum exposure time according to its IFU. • Rinse thoroughly with moistened wipes soaked with clean, fresh tap water. • Dry with dry wipes. • Check that the device is visibly clean. Repeat the process if the device is determined not to be visibly clean.

(2) Low Level Disinfection (LLD) – [optional]	
Accessories	• Low-level disinfectant wipes, alcohol based, concentration 60%–80% alcoholic solution; e.g. Schülke & Mayr GmbH, mikrozid® AF wipes. • Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO
Steps	• Use disinfectant wipes to disinfect all surfaces of the device. • Allow the disinfectant to take effect for the minimum time according to IFU of disinfectant; e.g. 5 minutes for mikrozid® AF wipes. • Rinse thoroughly with moistened wipes soaked with clean, fresh tap water.

(3) Drying – [optional]	
Accessories	• Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO.
Steps	• Dry the device with dry wipes.

(4) Inspection	
Accessories	No special accessories required.
Steps	• Visually inspect for damages and other signs of material deterioration. • Check coil connector and connections to ensure that no fluid has penetrated. • In case of any findings see chapter B.1 “Safe Operation”.

(5) Storage and Transportation	
Accessories	No special accessories required.
Steps	• Transport to defined storage location. • Store under specified conditions (see chapter B.4 “First Use”).

Only use a cleaning solution specified in these Instructions For Use.

PART D SPECIFIC MODEL INFORMATION

Table of Contents

D.1. REF 11371305 - 31P/1H

1.1 Description

Item	Entry
Device trade name	31P/1H TxRx Flex Loop 7T
Device reference number (REF)	11371305
Rapid Biomedical product number	O-XL-HL-070-01882
Model type	Setup after Patient Positioning
MR system(s)	Siemens 7.0T MR systems Refer to attached document for details “734 FO11 Declaration of MR system compatibility”
Required Tx coil(s)	none
Required Rx coil(s)	none
Lock/remove of Rx coil in patient table required	no
Devices approved for combined use	Refer to attached document “734 FO11 Declaration of MR system compatibility”
Field strength of MR system	7 T
MR nuclei	1H 31P
Frequencies	1H: 297,2 MHz 31P: 120.3 MHz
RF coil type	1H: transmit/receive (detachable) 31P transmit/receive (detachable)
Design	1H TxRx: linear 31P TxRx: linear
Configuration	X-TR_H-TR
Suited for 1H decoupling	no

1.2 Scope of Delivery

No.	Item	Illustration
Item 1	Surface Coil	
Item 2	Instructions For Use (printed edition)	

1.3 Specifications

Item	Entry
Intended Population	Adolescent (from 12 years to 18 years of age) Transitional Adolescent A (18 through 21 years of age) Transitional Adolescent B (18 through 21 years of age) Adults (greater than 21 years of age)
Application	Multi-Purpose
Application restrictions	Do not use on the Head!
Maximum allowed patient weight	Maximum load allowed for patient table
Minimum required patient weight	30 kg
Maximum allowed Tx peak power	1H: 1800 W 31P: 1800 W
Maximum allowed rms power	1H: 9 W 31P: 9 W

1.4 Characteristics

Item	Entry
Dimensions coil housing (x – y – z)	Width: 14 cm Height: 2 cm Length: 26 cm
Resonator shape	1H: Loop 31P: Loop
Resonator dimensions	1H: Diameter 11 cm 31P: Diameter 12 cm
Weight	0.8 kg
Length of cable	18 dm
Required interface(s)	none
Connector(s)	2x Tx/Rx connector for Siemens MAGNETOM Terra X
Required connector adapters (not included in the scope of delivery).	none

1.5 Connections

Mind the pictograms on the coil connectors indicating the socket number and the correct orientation for being plugged in.

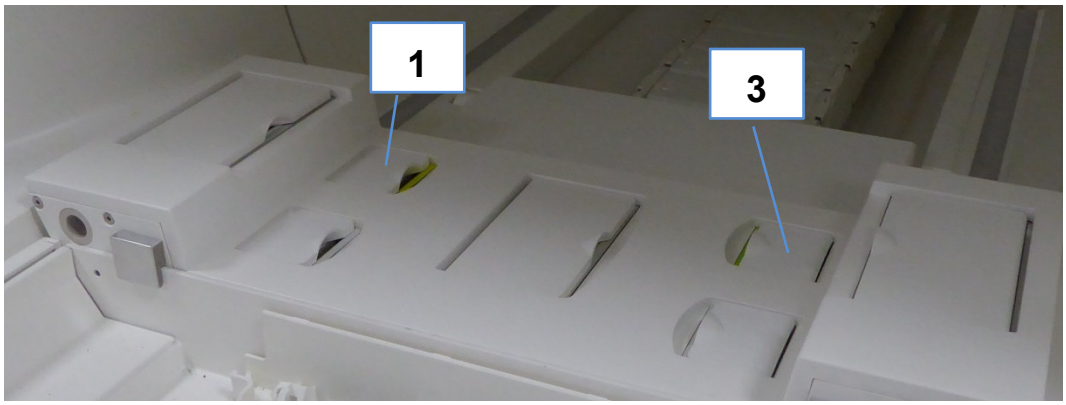

Figure D1: Wiring of the device to numbered sockets.

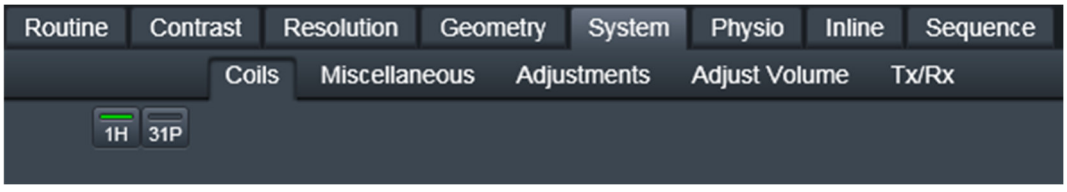

Figure D2: Example screenshot of Siemens Syngo Workspace – System-Coils tab

1.6 Labels

Ensure that device labels have not become illegible or missing.
In case of any findings see chapter B.1 “Safe Operation”.

The following list shows all items which have to be present on the device label(s).

Label purpose	Device Marking		Remarks
	Symbol	*Inscription*	
Manufacturer		RAPID Biomedical GmbH Kettelerstr. 3-11 97222 Rimpar Germany	--
Distributed by		Siemens Healthineers AG	
Device trade name	n/a	31P/1H TxRx Flex Loop 7T	--
Magnetic field strength	n/a	7T	
Device reference number		11371305	--
Device serial number		XXXX	--
Medical Device		--	Indicates the device as a medical device
Country and date of manufacture (YEAR-MONTH-DAY)		YYYY-MM-DD	--
Unique Device Identifier		--	Indicates the adjacent inscriptions as for unique device identification
UDI code (sample)		--	Data matrix following GS1 Standard
UDI human readable	n/a	(01) 04260487680157	GS1 AI (01) - Global Trade Item Number (GTIN)
UDI human readable	n/a	(21) xxx	GS1 AI (21) – Serial Number (SN)
UDI human readable	n/a	(20) xx	GS1 AI (20) – Internal product variant
UDI human readable	n/a	(240) 11371305	GS1 AI (240) – Additional product identification
UDI human readable	n/a	(422) 276	GS1 AI (422) – Country of origin
RF coil type		Tx/Rx	Transmit and receive
Follow the Instructions For Use		--	--

Label purpose	Device Marking		Remarks
	Symbol	*Inscription*	
Caution		--	Indicate that caution is necessary when operating the device.
CE marking		--	--
Applied part type		--	Type BF
Equipment safety		--	Class II equipment according to IEC 61140.
Disposal		--	The product must not be disposed of with household waste.
Patient weight		> 30 kg	--
IVK	n/a	--	**I**nstalled **V**olume Component (**K**)
RF center		--	molded into the housing
Caution		--	The coil must not be used on the head.
Identification of correct connection		--	Coil connector 1
Identification of correct connection		--	Coil connector 3

1.7 Tests for functionality approval

Item	Entry			
MR system				
Test 1	The MR system has recognized the device	Passed	Yes ☐	No ☐
Test 2	The MR system has presented select options	Passed	Yes ☐	No ☐
Test 3	1H image successfully recorded	Passed	Yes ☐	No ☐
Test 4	31P signal detected	Passed	Yes ☐	No ☐

1.8 Setup for QA test

Nucleus	Phantom
1H and 31P	• Plastic bottle 500ml • Solution: Phosphate buffer Siemens part number: 10963553

An automatic Coil QA Procedure is accessible in the Siemens Syngo Workspace menu under "Exam\Options\Service\CustomerQA\FlexLoop" (c.f. Figure D3)

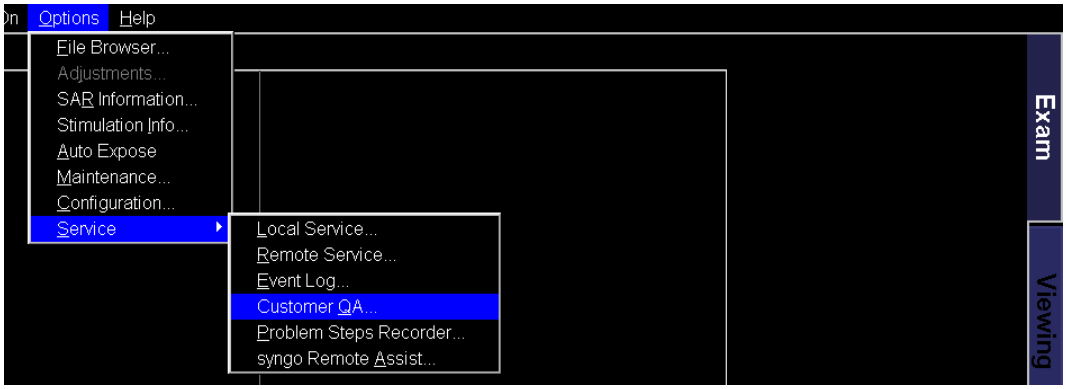

Figure D3: Access to automatic Siemens Customer QA procedure.

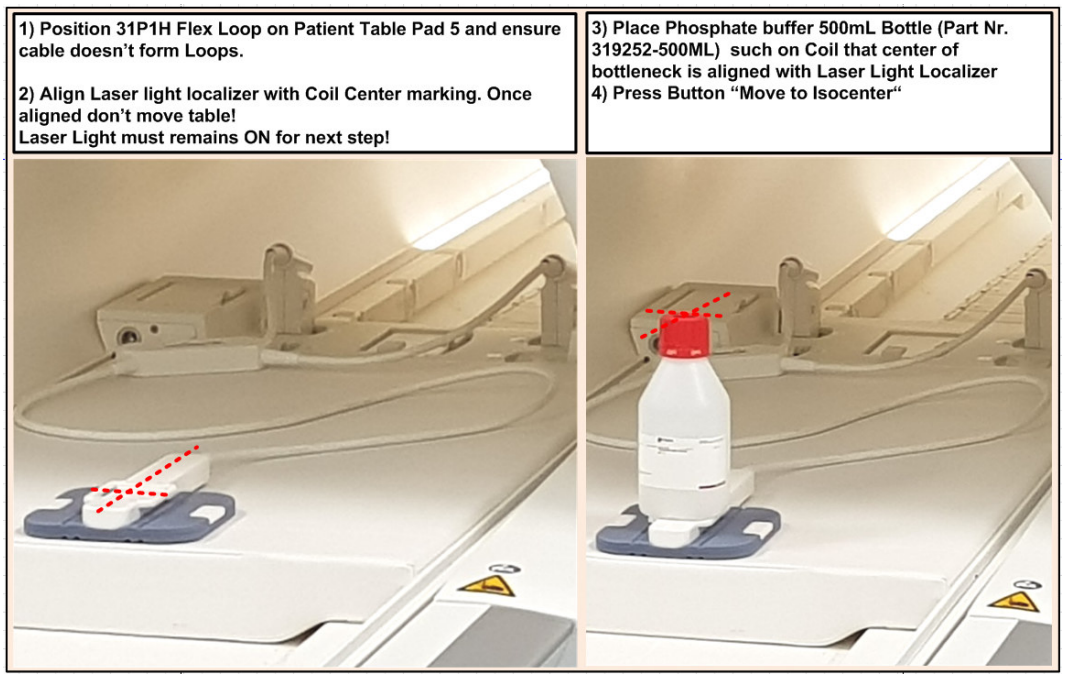

Figure D4: QA setup.