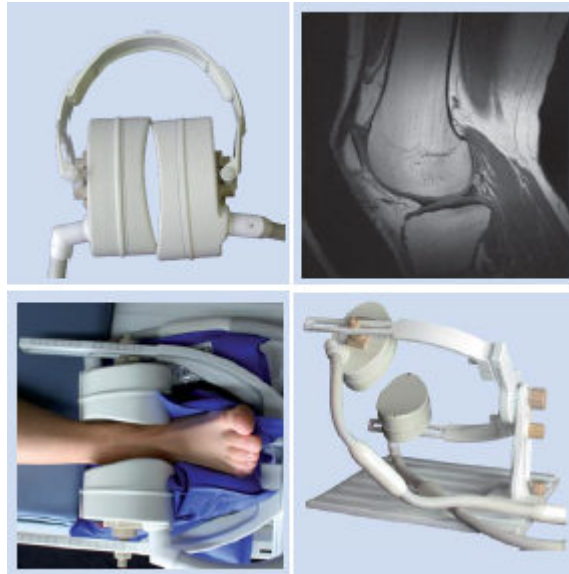


8-Ch Multifunctional Coil Clothespincoil (CPC)

for Diagnostic Imaging with
Siemens MR8150 (113471) / MR8300 (113495)



Operator's Manual
Revision 05



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1 General Information


To ensure safe and failure-free operation of this high quality medical device, please carefully read and follow the instructions of this Operator's Manual and pay particular attention to the following information:

- The **CPC 8-Channel Multifunctional coil** can be used with the following MRI systems:

MR8150 (113471) Siemens **1.5T**: Avanto, Espree, Sonata, Symphony, Aera

MR8300 (113495) Siemens **3T**: Trio, Trio a Tim System, Verio a Tim System, Skyra, Prisma


- Prior to using this device for patient examinations, you should complete a training with the device using a phantom.
- Take care, that only the coils have direct contact with the skin of the patient. The coil holder and the base plate have to be covered with clinic clothes cushion or a beanbag.


	Bodily harm of the patient
	Prior to each use of the coil, injured skin surface must be covered with sterile drapes.

- If you would like to receive up-to-date information about the further development of our new accessories for your **CPC 8-Channel Multifunctional Coil**, please send an e-mail with the serial number of your coil to mri@noras.de.

General Information

- The application conditions have a major impact on the life time of the product. Since these conditions can vary greatly from user to user, an estimation of life-time from our point of view is not possible. The most important factors have to be considered are the frequency of use and the preparation processes (cleaning, disinfection and sterilization). In case of inflexible coils the influence parameters are especially the reprocessing and the mechanical wear of moving parts. The reprocessing may cause only a discoloration of the material which has no influence on the material properties and the lifetime. The mechanical wear again depends on the frequency of application and cannot assess quantitatively due to above mentioned reasons.
- As long as the user takes the intended use into consideration and pays attention to the warnings and measures specified in the user manual regarding the visual inspection of all components before each application, there is no significant risk.

	Notice
	Please be sure to pay attention to and comply with the safety information and instructions of the MRI device manufacturer for operators, patients and third parties.

 G18	Prescription use only
	<p>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.</p> <p>This device may only be distributed to persons who are licensed practioners or to persons who have a prescription or other order from a licensed practioner to purchase it.</p>

2 Intended Use / Indication for Use

The **CPC 8-Channel Multifunctional Coil (Clothespin Coil) 1.5T** (Model No. 113471) and 3T (Model No. 113495) has been designed for diagnostic imaging with an MRI system.

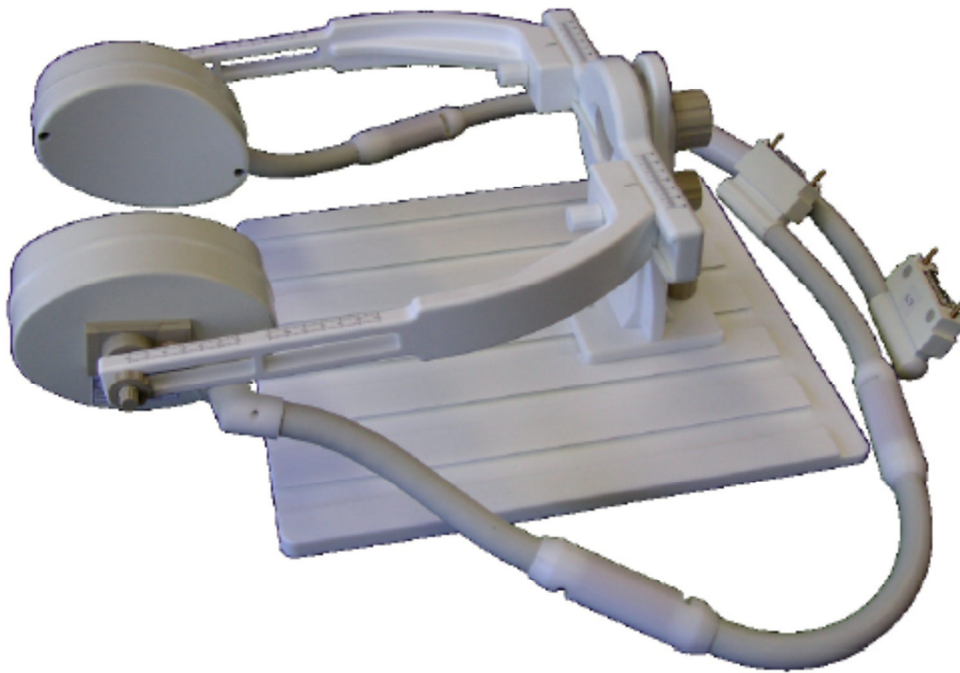


Image similiar


2.1 Function

Diagnostic imaging with an MRI system for detection of lesions and other clinical pictures.

2.2 Contraindication

All patient examinations are contraindicated with this system which is also contraindicated in the proximity of the MRI device according to the information provided by the manufacturer.

Furthermore, the responsibility lies with the examining physician in case of unclear or critical clinical picture.

	Notice
	Please be sure to pay attention to and comply with the safety information and instructions of the MRI device manufacturer for operators, patients and third parties.

3 Operating Principle

The **CPC 8-Channel Multifunctional Coil** described in this document has been designed, depending upon model type, for use with a MRI system with a field strength of 1.5T or 3T. The coil system serves solely as a receiving coil for the reception of high frequency signals from the hydrogen-(¹H) nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRT device. The precessing magnetization induces potential differences in the **CPC 8-Channel Multifunctional Coil** which are digitized and further processed in the MRI system.

Thanks to its variable mechanical support system, this coil can be used for a wide variety of examinations such as the diagnostic imaging of the inner ear, carotid artery, jaw bone, or, in the orthopedic field, of the finger, wrist, elbow, shoulder, knee, ankle or toes.

Parallel diagnostic imaging procedures are made possible by the two 4-channel arrays facing each other on the coil which are able to accelerate diagnostic imaging or increase resolution. The wide range of coil positioning possibilities enables the performance of motion studies such as the imaging of an elbow in stretched and inflected positions.

With its accessibility in three axes, the **CPC 8-Channel Multifunctional Coil** offers significant advantages vs. conventional coils during the examination of patients with rheumatic disease and restricted mobility.







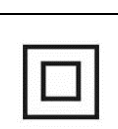

3.1 Safety Concept

The **CPC 8-Channel Multifunctional Coil** is subject to the same multi-stage safety concept as for other MRI local coils and has fuses which minimize the patient hazard as much as possible.










4 Device Description

4.1 Definitions and Symbols

The following symbols are used on the **CPC 8-Channel Multifunctional Coil** or in the Operator's Manual.

	ISO 7000-2493	Item Number
	ISO 7000-2498	Serial Number
	ISO 7000-3082	Manufacturer
	ISO 7000-2497	Date of Manufacture
	EN ISO 7010-M002	Operator's Manual <i>Differ to the requirements of EN ISO 701-M002 all laser engravings can only be executed in grey instead of blue due to technical unfeasibility.</i>
	ISO 7000-0434B	Caution, read the accompanying documents
	IEC 60417-5172	Protective Insulation
	IEC 60417-5333	Type BF

Device Description

	Directive 2002/96/EC	Waste products should not be disposed of with household waste e. g. at a local authority collection point.
	ISO 780 DIN 55402	This way up
	ISO 7000-0621	Fragile, handle with care
	ISO 7000-0626	Store in a dry place
	ISO 7000-0632	Temperature Limit
		Conforms with the essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
		Warning regarding risks that may result in minor physical injury or material damage.
		Warning regarding risks that may result in death or serious physical injury.
		Information regarding the optimal use of the product

On the following page, we describe where you can find our various rating plates on your product. In addition to the above-described symbols, you will also find the model designation as well as the product and serial number.

Device Description

Rating Plates:

Coils

The rating plate is located on the rear side of the coil.



Image similar

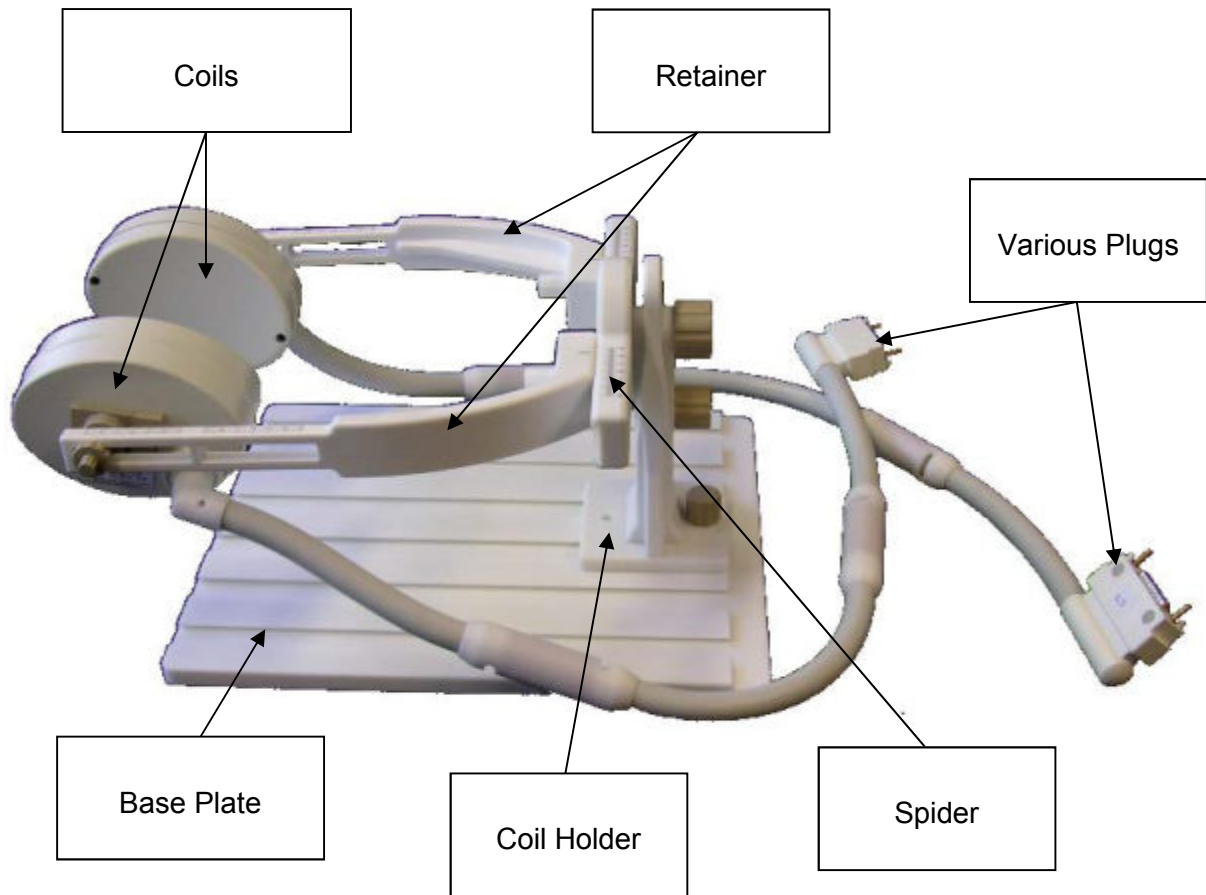
Base Plate


The rating plate is located on the bottom side of the base plate.



Image similar

4.2 System Components



 G34	Device Damage / Coil Error
	<p>Don't carry the coils on their cables or plugs. Furthermore, don't knot the cables.</p> <p>Operating errors may cause permanent damages to the device / coil.</p>

4.3 Combination with other Devices

The **CPC 8-Channel Multifunctional coil** can be used with the following MRT systems:

Siemens **1.5T**: Avanto, Espree, Sonata, Symphony, Aera

Siemens **3.0T**: Trio, Trio a Tim System, Verio a Tim System, Skyra, Prisma

Vacuum Immobilization Mats

We offer different Vacuum Immobilization Mats which are easy to handle and, thanks to its chamber system, always ensure stable immobilization of the patient in the MRI unit. The mats are compatible with all magnetic resonance imaging units and do not cause any artefacts. Our mats are available in many different forms and sizes.

The Vacuum Fixation Mat is filled with a high-quality micro-granulate which cannot slip and therefore also permits fixation in a vertical position. Even the sliding of the pump hose does not cause any vacuum loss. Thanks to the adaptor provided with the Fixation Mat, the latter can be connected to all customary vacuum pumps. The form, which is simultaneously compact and comfortable, offers a very high lateral and longitudinal stability. The Vacuum Fixation Mat can be used as a fixation support for foot, ankle, knee, wrist, elbow, head and babies.

The Vacuum Fixation Mats are not allowed to get in contact with open wounds or sensitive skin areas. We recommend an intermediate located biocompatible blanket.



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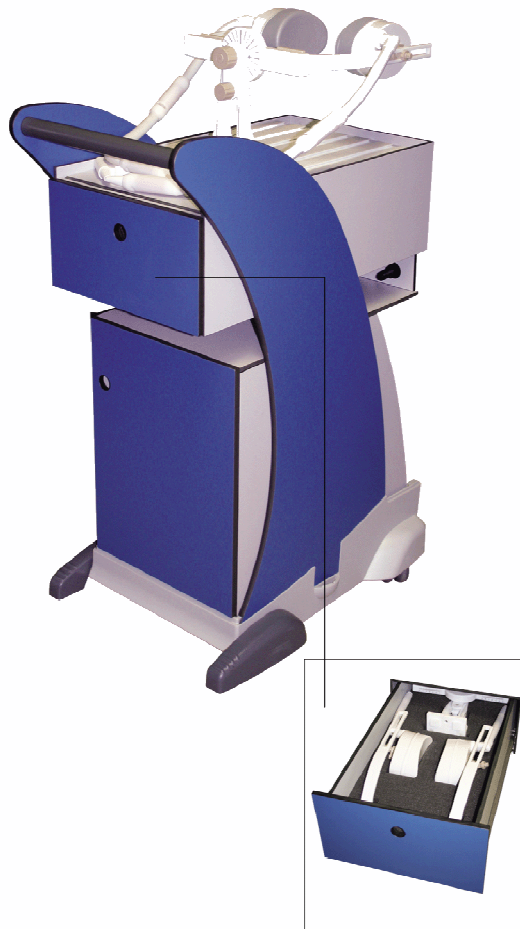
products

Device Description


MRI Trolley


The NORAS MRI Trolley is an equipment vehicle ideal for the MRT area. It serves as storage option for our **CPC 8-channel Multifunctional Coil**. It offers beside its usable work surface a lot of additional storage space and a vacuum pump for the use of our Vacuum Fixation Mats.


We build this Trolley on your request!



Device Description

	Bodily Harm
	<p>For patient comfort, we recommend the use of cushions or beanbags that are attached to your MRI-System.</p> <p>Operating errors may cause bodily injuries to the end user.</p>


 G35	Bodily Harm
	<p>Also MR-compatible accessories can cause injuries to the patient and/or the user. Please follow the instructions of the accessory manufacturer. Non-compliance with these instructions may lead to injuries of the user and/or patient.</p>

 G43	Notice
	<p>The CPC 8-channel Multifunctional Coil may only be used in combination with those indicated in this Operator's Manual and included devices and coils of NORAS MRI products GmbH accessories. Use of other accessories is permitted only with written approval by the NORAS MRI products GmbH.</p>

5 Start-up


 G24/G37	Device Damage / Coil Error
	Only trained personnel may be assigned to handle the CPC 8-Channel Multifunctional Coil . Operating errors may cause permanent damages to the device / coil.
 G25	Device Damage / Coil Error
	The users must be trained before using the device (detailed training of the personnel for existing components).
 G24	Bodily Harm
	Only trained personnel may be assigned to handle the CPC 8-Channel Multifunctional Coil . Operating errors may cause bodily injuries (e.g. contusions) to the user and / or end user.
	Notice
	Please be sure to pay attention to and comply with the safety information and instructions of the MRI device manufacturer for operators, patients and third parties.

Start-up

 G39	Handling
	Incorrect handling can cause damage to the coil and to the connection cables.

The Operator's Manual must be read by each operator prior to using this device. In order to become skilled in the proper handling of this system, you should not only participate in a training with the system but also train with a phantom to become familiar with its use.


Start-up

 G23	Bodily Harm of the End User
	<p>Prior to each patient examination, you should make a careful visual inspection of the system components. In the case of unusual findings and / or damage found, the system must not be used.</p> <p>Damaged coils must not be used. Do not produce images with a defective coil.</p>

Coil installation:

- ✓ Patient is lying on the patient table of the MRI-system.
- ✓ Coil (coil pair) has been installed as described.

Plug in both coil plugs in the connections provided for them in the MRI patient table.

 G28	Notice
	<p>While plugging in the coil pair ensure and check that proper contact has been made.</p>

Start-up



Fig. 1-3: RX Connector Siemens Avanto

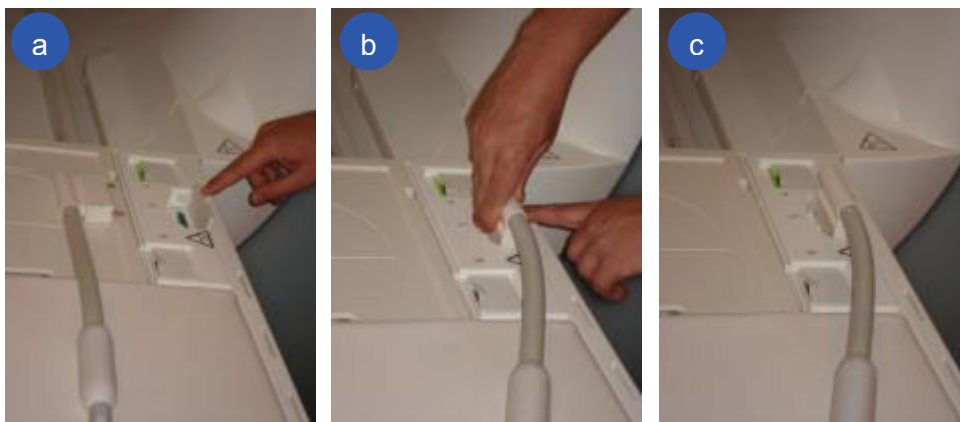



Fig. a-c: RX Connector Symphony


The shield trap should lay as parallel as possible to the magnet bore and not vertical.

Shield Trap




Start-up

 G28	Notice
	While plugging in the coil pair, ensure and check that proper contact has been made.

	External Burns of the End User
	Avoid direct contact between the coil cable and the patient and / or place some absorbent, natural fiber cloths between the patient and the cable. In exceptional cases, the coil cable may become very warm.

The **CPC 8-Channel Multifunctional Coil** is recognized by the MRI software.
The software operation is described in the SIEMENS MRI Operator's Manual.

	Coil Error
	To remove the plugs, only push on the plug-cover themselves, do not pull on the plugs or the cables! Non-respect may cause cable cracks or plug cracks. Defective coils (this includes cables and plugs) must not be used!

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Start-up



Fig. 1-3: RX Connector Siemens Avanto

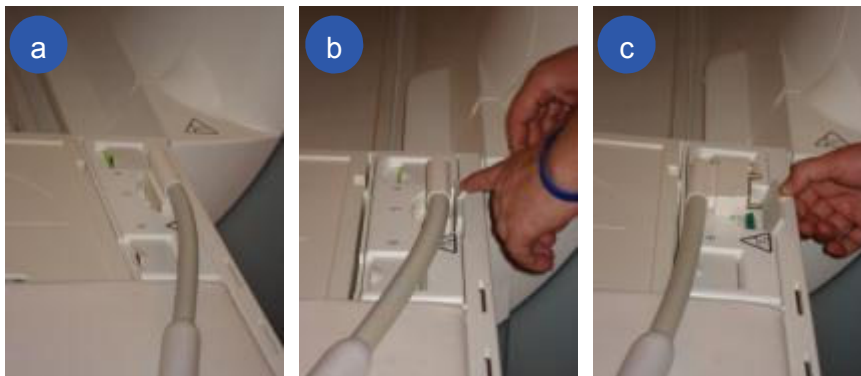




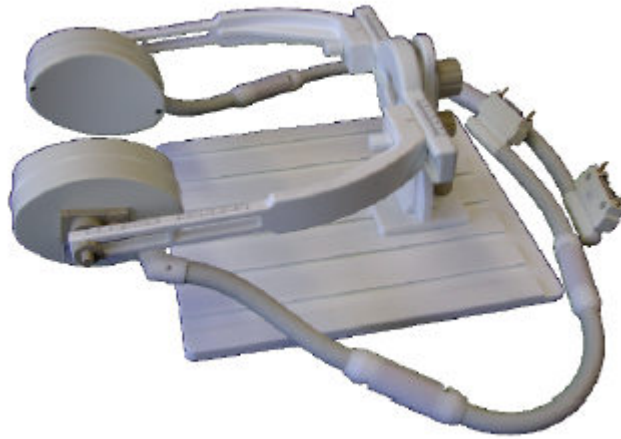
Fig. a-c: RX Connector Symphony

 G32/G38	<p>Danger of Destruction</p>
	<p>The coils must not be cleaned in immersion baths or held under running water.</p> <p>Non-respect of the cleaning instructions may cause the destruction of the coils!</p>

 G03/G04/G05	<p>Notice</p>
	<p>To avoid reduced quality image, use the scales on both retainers. It is to advice to adjust the coils in a distance between 0 cm (min.) to 15 cm (max.) in the same parallel position.</p> <p>Take care that the coils are parallel adjusted and the phase-coding is perpendicularly to the coil level.</p>

5.1 Installation

5.1.1 Installation with Retainers and Spider



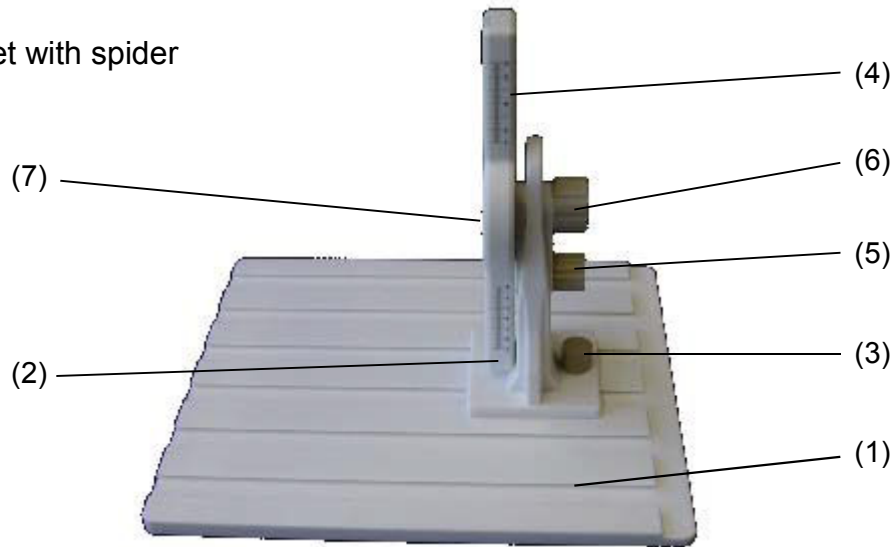
The installation of the coil arm and spider is performed in the following steps:

- Step 1 Install bracket with spider
- Step 2 Install retainers
- Step 3 Attach coils

Start-up

Step 1


Install bracket with spider



- | | |
|------------------------|-----------------------------|
| (1) Base Plate | (5) Height Adjustment Screw |
| (2) Slide with Bracket | (6) Rotation Nut |
| (3) Slide Screw | (7) Rotation Bolt |
| (4) Spider | |

Position the slide with bracket (2) on the base plate (1) by pushing the slide of the bracket into the slide rails of the base plate. Always push the slide all the way into the guide rails of the base plate.

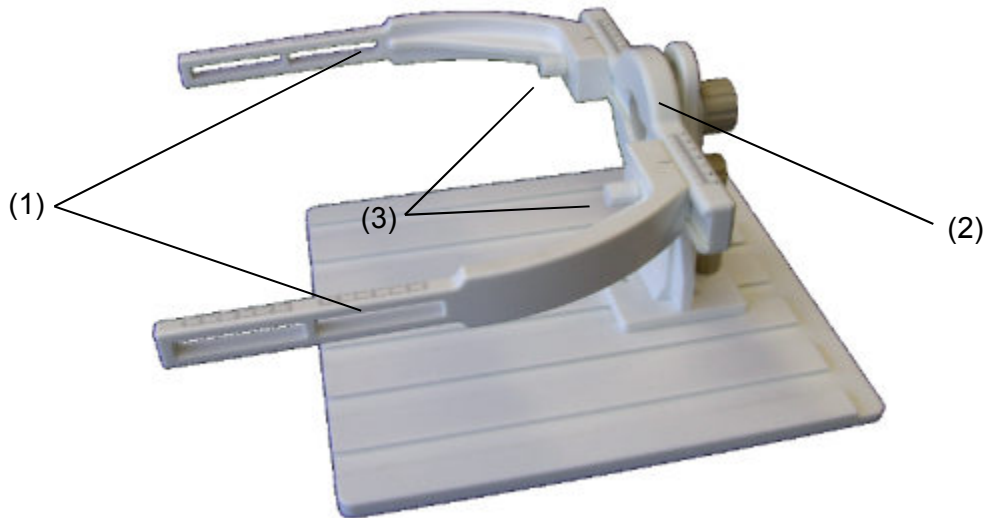
The spider (4) for fastening and aligning the retainers has already been factory installed on the bracket. Fix the slide with bracket to the base plate using the slide screw (3). Tighten the height adjustment screw (5) and the rotation nut (6) on the bracket by hand. By doing so, the spider can be rotated

 G29	Prolongation of the examination
	Take care that the base plate is flat on the patient table. Nonobservance can cause a prolongation of the examination.

Start-up

Step 2

Install retainers




- (1) Retainer
- (2) Spider
- (3) Retainer Slide Screw

Now, push on retainer (1) each into the guide rail on the left and right side of the spider (2) and fix them in position with the corresponding retainer slide screw (3).

Using the scale on both sides of the spider, you can adjust the distance between the two retainers. Tighten the retainer slide screws on the spider by hand.

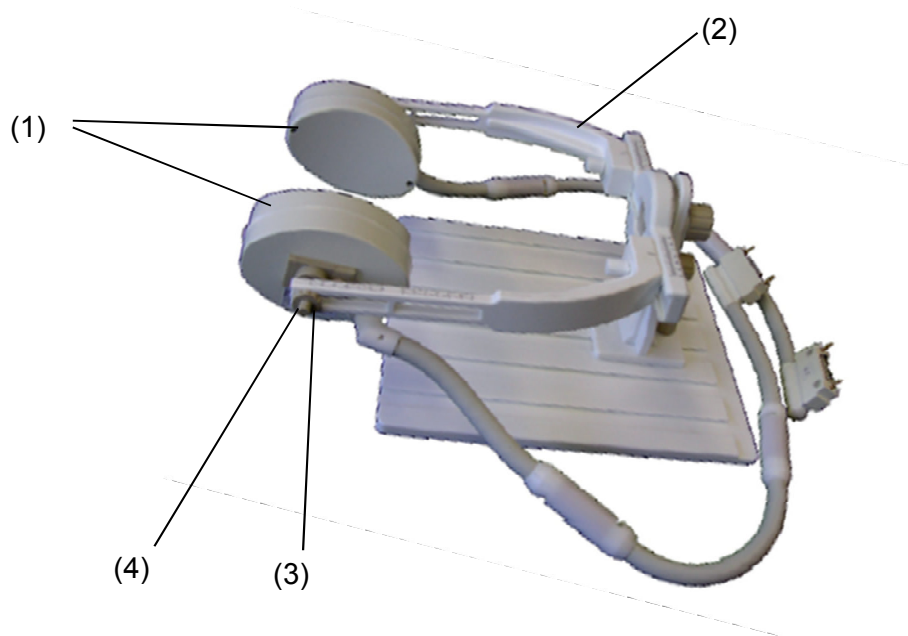
The scale on the spider has not been calibrated and therefore is only used for approximate positioning.

 G30	Prolongation of the examination
	Take care that the guide rail is pushed in completely. Nonobservance can cause a prolongation of the examination.

Start-up

Step 3

Attach coils




- (1) Coil
- (2) Retainer
- (3) Ball Joint Locking Nut (outer)
- (4) Ball Joint Clamping Screw (inner)

Attach one coil (1) each to the left and right retainer (2) and then fix these in position with the ball joint locking nuts (3).

After loosening the ball joint clamping screws (4), the coils can be pivotally moved. To lock the coil in place, tighten the ball joint clamping screw by hand.

Using the scales on both retainers, it is to advice to adjust the coils in a distance between 0 cm (min.) to 15 cm (max.) in the same parallel position.

Start-up

 G27	Prolongation of the examination
	Take care that all screws are tighten by hand. Nonobservance can cause a prolongation of the examination.

Diagnostic Application Fields – Retainers and Spider



Internal medical imaging:
Inner ear, **carotid artery**, jaw bone

5.1.2 Installation with Retainers



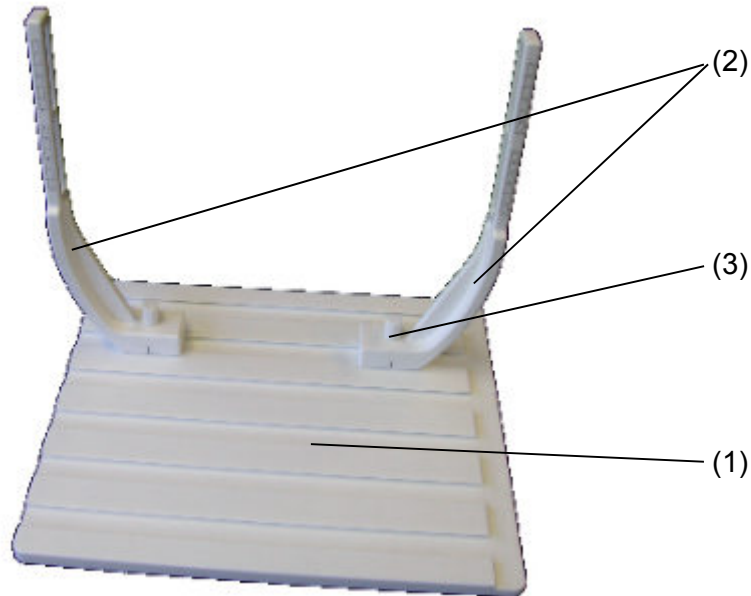
The installation is performed in the following steps:

- Step 1 Install retainers on the base plate
- Step 2 Attach coils

Start-up

Step 1


Install retainers on the base plate



- (1) Base Plate
- (2) Retainer
- (3) Retainer Slide Screw

Install both retainers (2) on the base plate (1) by pushing each retainer into one of the guide rails of the base plate. Always ensure that both retainers are aligned in such a way that the inwardly curved side of each retainer faces the other retainer.

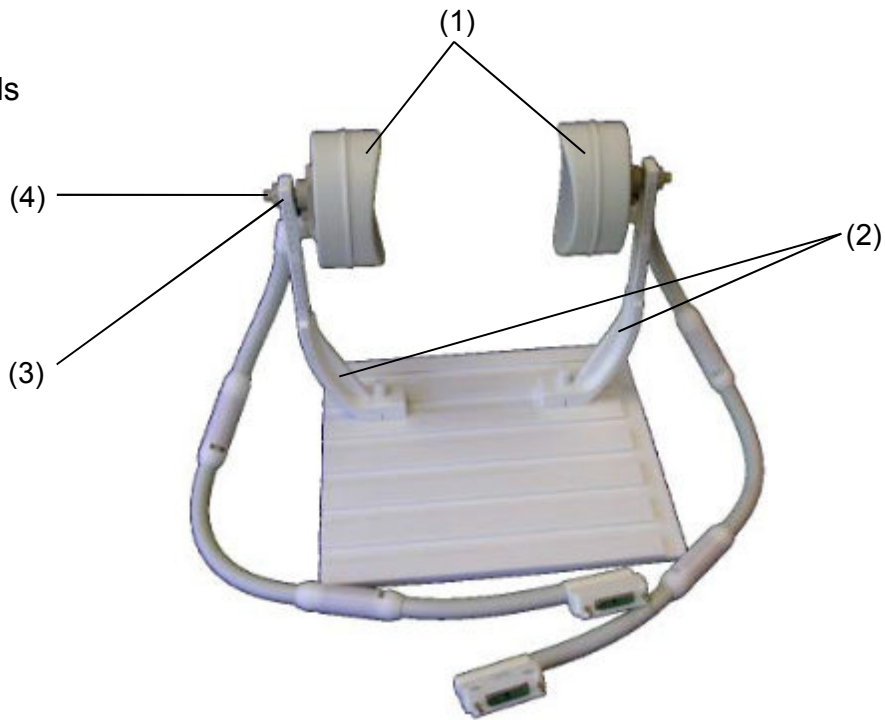
Fix the retainers in place with the retainer slide screws (3).

 G29	Prolongation of the examination
	Take care that the base plate is flat on the patient table. Nonobservance can cause a prolongation of the examination.

Start-up

Step 2

Attach coils




- (1) Coil
- (2) Retainer
- (3) Ball Joint Locking Nut (outer)
- (4) Ball Joint Clamping Screw (inner)

Attach one coil (1) each to the left and right retainer (2) and then fix these in position with the ball joint locking nuts (3).

After loosening the ball joint clamping screws (4), the coils can be pivotally moved. To lock the coils in place, tighten the ball joint clamping screws by hand.

Using the scales on both retainers, it is to advice to adjust the coils in the same height and in a distance between 4 cm (min.) to 20 cm (max.) in the same parallel position.

Start-up

	Prolongation of the examination
	Take care that all screws are tighten by hand. Nonobservance can cause a prolongation of the examination.

Diagnostic Application Fields – Retainers

with Vacuum Immobilization Mat
(available as an option)



Orthopaedic medical imaging:


Knee, ankle, toes

Safety Information


- The **CPC 8-Channel Multifunctional Coil** is **not** suited for operation in areas subject to explosive hazards, in the presence of inflammable anaesthetics or combustible gases, such as anaesthetics.
- The **CPC 8-Channel Multifunctional Coil** has been designed **for use with a MRI device** in the special examination room provided for it (climate controlled, electrically shielded).
- It may only be used by medical technical personnel who are familiar with the operating principle of the MRI device and who have been **instructed** in the function and use of the **CPC 8-Channel Multifunctional Coil** by NORAS MRI products or its responsible company representatives.
- This coil may only be used in combination with accessories supplied by NORAS MRI products. You may only use this coil with accessories supplied by other manufacturers with the express **written approval** of NORAS MRI products.
- Do **not** use a coil showing visible damage to the housing or its connection cables.
- The **CPC 8-Channel Multifunctional Coil** must **not be opened** by the user.
- In case of proper use, all materials subject no significant wear.

6 Cleaning, Disinfection and Sterilization

<p>WARNINGS:</p>	<p>The instructions must be followed as described.</p> <p>In case of inadequate cleaning or disinfection, you have to carry the risk of infection. Non-respect of the disinfection instructions may cause the destruction of the coils.</p> <p>Non-compliance with the cleaning instructions may destroy the system. No warranty service will be provided for damages due to improper disinfecting.</p> <p>Please always wear protective gloves and carefully comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).</p>
<p>Limitations on re-processing:</p>	<p>Frequent processing can have an impact on these products (color changes), but do not affect the function of the product.</p>

 <p>G15</p>	<p>Bodily Harm</p>
	<p>Prior to start up the coils, operators must be informed of the cleaning, disinfection and sterilization requirements of the components.</p> <p>Operating errors may cause bodily injuries to the end user.</p>

Cleaning, Disinfection and Sterilization

	Notice
	<p>Please always wear protective gloves and comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).</p>

INSTRUCTIONS		Individual parts
<u>Point of Use:</u>	Remove excess soil with disposable cloth / paper wipe.	
<u>Containment and Transportation:</u>	No particular requirements. It is recommended to reprocess the product as soon as possible after its use.	
<u>Preparation for Cleaning:</u>	No particular requirements. If necessary, the assembly must be dismantled in its individual components.	

Cleaning, Disinfection and Sterilization

<p><u>Automated Cleaning:</u></p> <p>All parts can be cleaned automatically, excepted the following:</p> <ul style="list-style-type: none"> - coil cables and plugs - CPC coils (right, left) - coil cover 	<p><u>Equipment:</u> Washer / disinfecter</p> <p><u>Detergent:</u> Example alkaline detergent such as Neodisher® MediClean forte 0.2 to 1.0 vol% (2-10 ml/l) (Dr. Weigert) at 50-60°C. For this purpose, all agents, which have been approved and released by the Robert Koch Institute (RKI) can be used in accordance with the instructions on their labels.</p> <p><u>Procedure:</u></p> <ol style="list-style-type: none"> 1. Load the components such that hinges are open and cannulas and holes can drain. 2. Run cycle, wash minimum 5 minutes and rinse 5 minutes. 3. When removing the parts, check the cannulas, holes etc. for visible soil. If necessary, repeat the cycle or clean the parts manually. 	<p>Only for:</p> <p>Mounting rack, ball joint, retainers with scale, bracket, height adjustment screw, slide screw, base plate</p> <p>Ball joint set 1 consisting of: ball joint holder and ball joint inner parts</p> <p>Ball joint set 2 consisting of: ball joint ball, ball joint locking nut, ball joint clamping screw</p> <p>Ball joint set 3 consisting of: ball joint screw, ball joint holder plate</p>
<p><u>Manual Cleaning:</u></p> <p>Coil cables and plugs, CPC coils may not be cleaned in immersion baths and may not be held under running water.</p> <p>The mentioned products above can be wiped cleaned with a moistened cloth (solu-</p>	<p><u>Equipment:</u> -</p> <p><u>Detergent:</u> Example alkaline detergent such as Neodisher® MediClean forte 0.2 to 1.0 vol% (2-10 ml/l) (Dr. Weigert) at 50-60°C. For this purpose, all agents, which have been approved and released by the Robert Koch Institute (RKI) can be used in accordance with the instructions on their labels.</p>	<p>Only for:</p> <p>Mounting rack, ball joint, retainers with scale, bracket, height adjustment screw, slide screw, base plate</p> <p>Ball joint set 1 consisting of: ball joint holder and ball joint inner parts</p>

Cleaning, Disinfection and Sterilization

<p>tion of 30% of the above mentioned cleaning agent and 70% water).</p> <p>Due to possible material incompatibility, abrasive cleaners or other organic solvents and solvent-based cleaning agent (e.g. benzene, alcohol, stain-removers) may not be used.</p>	<p>The cleaning of the parts could be done manually in immersion or ultrasonic bath for 5-10 minutes, preferably at temperatures of up to 50°C.</p> <p><u>Procedure:</u></p> <ol style="list-style-type: none"> 1. Rinse excess soil from components. 2. Using soft brush, apply detergent solution to all surfaces ensuring that hinged components are cleaned in both open and closed positions. <p>Note: Clean cannulas and holes using an appropriate brush ensuring that full depth of the feature is reached.</p> <ol style="list-style-type: none"> 3. Rinse under clean running water for 5 minutes. Ensure that running water passes through cannulas and that blind holes are repeatedly filled and exhausted. 4. The parts must be cleaned as long as no viewable blood or tissue residues are visible on the products. 	<p>Ball joint set 2 consisting of: ball joint ball, ball joint locking nut, ball joint clamping screw</p> <p>Ball joint set 3 consisting of: ball joint screw, ball joint holder plate</p>
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Cleaning, Disinfection and Sterilization

<p><u>Automated Disinfection:</u></p> <p>All parts can be cleaned automatically, excepted the following:</p> <ul style="list-style-type: none"> - coil cables and plugs - CPC coils (right, left) - coil cover 	<p><u>Disinfectant:</u> example Sekusept PLUS ® (Ecolab) 4.0 vol% 3.0 vol% Korsolex ® Plus with exposure time of 15 minutes. For this purpose all aldehyde-free surface disinfectants, which have been approved and released by the Robert Koch Institute (RKI), can be used in accordance with the instructions on the label.</p> <p><u>Procedure:</u></p> <p>If automated disinfecting is employed, a final rinse at 50°C for 5 minutes may be used to effect thermal disinfection. The assembly should be dis-assembled into its individual components so that an optimal disinfection is guaranteed.</p>	<p>Only for:</p> <p>Mounting rack, ball joint, retainers with scale, bracket, height adjustment screw, slide screw, base plate</p> <p>Ball joint set 1 consisting of: ball joint holder and ball joint inner parts</p> <p>Ball joint set 2 consisting of: ball joint ball, ball joint locking nut, ball joint clamping screw</p> <p>Ball joint set 3 consisting of: ball joint screw, ball joint holder plate</p>
<p><u>Manual Disinfection:</u></p> <p>Coil cables and plugs, CPC coils may not be disinfected in immersion baths and may not be held under running water.</p> <p>The mentioned products above can be wiped disinfected with a moistened cloth (solution of 30% of the above mentioned disinfectant and 70% water).</p>	<p><u>Disinfectant:</u> example Sekusept PLUS ® (Ecolab) 4.0 vol% 3.0 vol% Korsolex ® Plus with exposure time of 15 minutes. For this purpose all aldehyde-free surface disinfectants, which have been approved and released by the Robert Koch Institute (RKI), can be used in accordance with the instructions on the label.</p> <p><u>Procedure:</u></p> <p>For manual disinfection, it is advisable to insert the parts in the solution immediately after use.</p>	<p>Only for:</p> <p>Mounting rack, ball joint, retainers with scale, bracket, height adjustment screw, slide screw, base plate</p> <p>Ball joint set 1 consisting of: ball joint holder and ball joint inner parts</p> <p>Ball joint set 2 consisting of: ball joint ball, ball joint locking nut,</p>

Cleaning, Disinfection and Sterilization

<p>The solution is distributed on the surfaces by a cloth. The disinfectant permeates the dirt particles and because of mechanical forces (pressure, abrasion), this ensures effective cleaning.</p> <p>Additionally, the wiping motion ensures that the spores which are resistant to the disinfectant will be removed.</p> <p>The cloth must be replaced after the disinfection in order to prevent the spreading of the spores on other areas.</p> <p>Moreover, it is essential that the wiping solution is renewed regularly.</p>	<p>Ensure that the parts are completely submerged in the solution. Take the parts from the solution after the described time (5 minutes) and rinse by water (the quality of water must be at least equal to drinking water, better would be using aqua. Demineralized water.</p> <p>Changing in color due to continuous disinfection cannot be excluded but can be largely prevented by sufficient rinsing after each use.</p>	<p>ball joint clamping screw</p> <p>Ball joint set 3 consisting of: ball joint screw, ball joint holder plate</p>
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Cleaning, Disinfection and Sterilization


<p><u>Drying:</u></p>	<p>When drying is achieved as part of washer disinfectant cycle do not exceed 50°C.</p>	
<p><u>Maintenance, Inspection and Testing:</u></p>	<p>Blunt or damaged parts should be discarded. Hinged parts: Check for smooth movement of hinge without excessive „play“. Locking (ratchet) mechanism should be checked for action. All parts: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check components with long slender features (particularly rotating components) for distortion. Where components form part of a larger assembly, check assembly with mating components.</p>	
<p><u>Packaging:</u></p>	<p><u>Singly:</u> A standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.</p> <p><u>In sets:</u> The parts may be loaded into dedicated instrument trays, or general purpose sterilization trays. Ensure that cutting edges are protected and do not exceed the maximum loading per tray. Wrap the trays using appropriate method.</p>	


Cleaning, Disinfection and Sterilization


<p><u>Sterilization:</u></p> <p>The CPC coils 114371 & 114395) may be only sterilized according to <u>STERRAD® 100S</u> procedures.</p>	<p><u>Hydrogen Peroxide Gas Plasma Sterilization:</u></p> <p><u>(STERRAD® procedure)</u></p> <p>Only the following items may be subjected to STERRAD® sterilization:</p> <p>▶ (P008) CPC coils</p> <p><u>Procedure:</u></p> <p>STERRAD® 100S: 7 cycles Total cycle time: 55 minutes Cycle Temperature: Less than 131°F / 55°C</p>	
<p><u>Storage:</u></p>	<p>No special requirements.</p>	

<p><u>Additional Information:</u></p>	<p>When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded</p>
<p><u>Manufacturer Contact:</u></p>	<p>See chapter 9</p>


Cleaning, Disinfection and Sterilization


	Danger of Destruction
	<p>The coils must not be cleaned in immersion baths or held under running water.</p> <p>Non-respect of the cleaning instructions may cause the destruction of the coils!</p>

	Notice
	<p>Please always wear protective gloves and comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).</p>

	Danger of Destruction
	<p>The coils must not be cleaned in immersion baths or held under running water.</p> <p>Non-respect of the disinfection instructions may cause the destruction of the coils!</p>
	<p>No warranty service will be provided for damages due to improper disinfection. Improper disinfection may result in malfunction of the device</p>

Cleaning, Disinfection and Sterilization

	Danger of Destruction
	<p>No warranty service will be provided for damages due to improper sterilization.</p> <p>Non-respect of the sterilization instructions may cause the destruction of the system!</p> <p>Steam sterilization will destroy the coils.</p>

	Notice
	<p>The sterilization agent can cause variations in terms of color. This has no influence on the quality of the product.</p>

7 Maintenance, Storage and Waste Disposal

7.1 Maintenance

7.1.1 General Maintenance

Prior to each use, all components of the **CPC 8-Channel Multifunctional Coil** must be visually inspected. The coils and all parts have to be tested regarding breaks and cracks.

Defective products must not be used. In such a case, please contact the NORAS MRI products Service Department.

Comply with the cleaning, disinfection and sterilization instructions!

We recommend that you have a single channel test of the coils performed on a monthly basis using the specified test program of the MRI system as described and shown during the product training. The data regarding the test performance and its results must be recorded in the medical devices log book.

7.1.2 Functional Tests

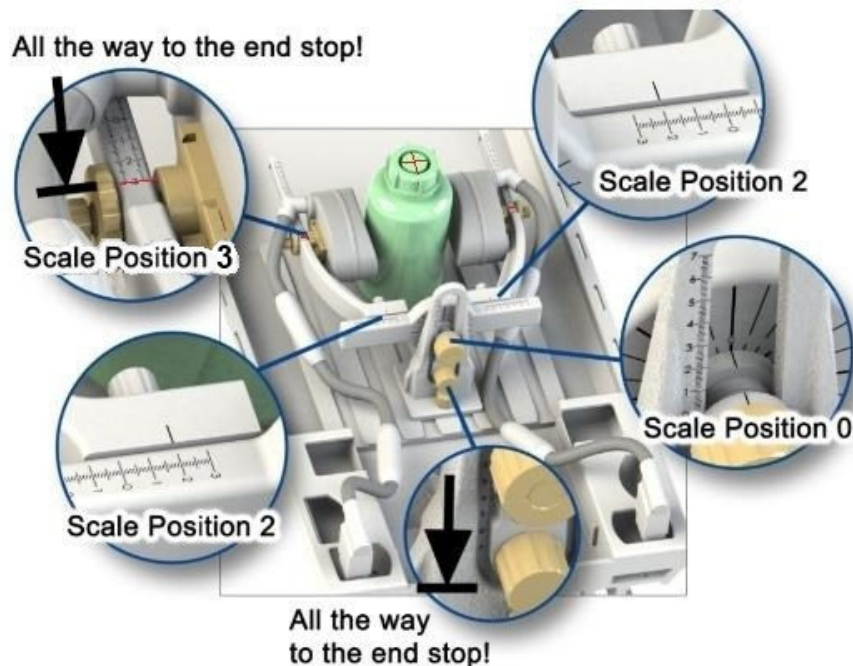
In case that coil malfunctions are suspected, the operator may perform the functional test described below.

Insert the standard Siemens 2l phantom bottles into the coil as shown on the illustration and connect the coil to the MRI scanner. Pay attention that the coils are parallel and straight as shown in the picture below.

Make sure the bottles are positioned in the center of the coils.

To prepare for the measurement, first align the laser sight on the bottles centrally and transport the coil into the iso-center.

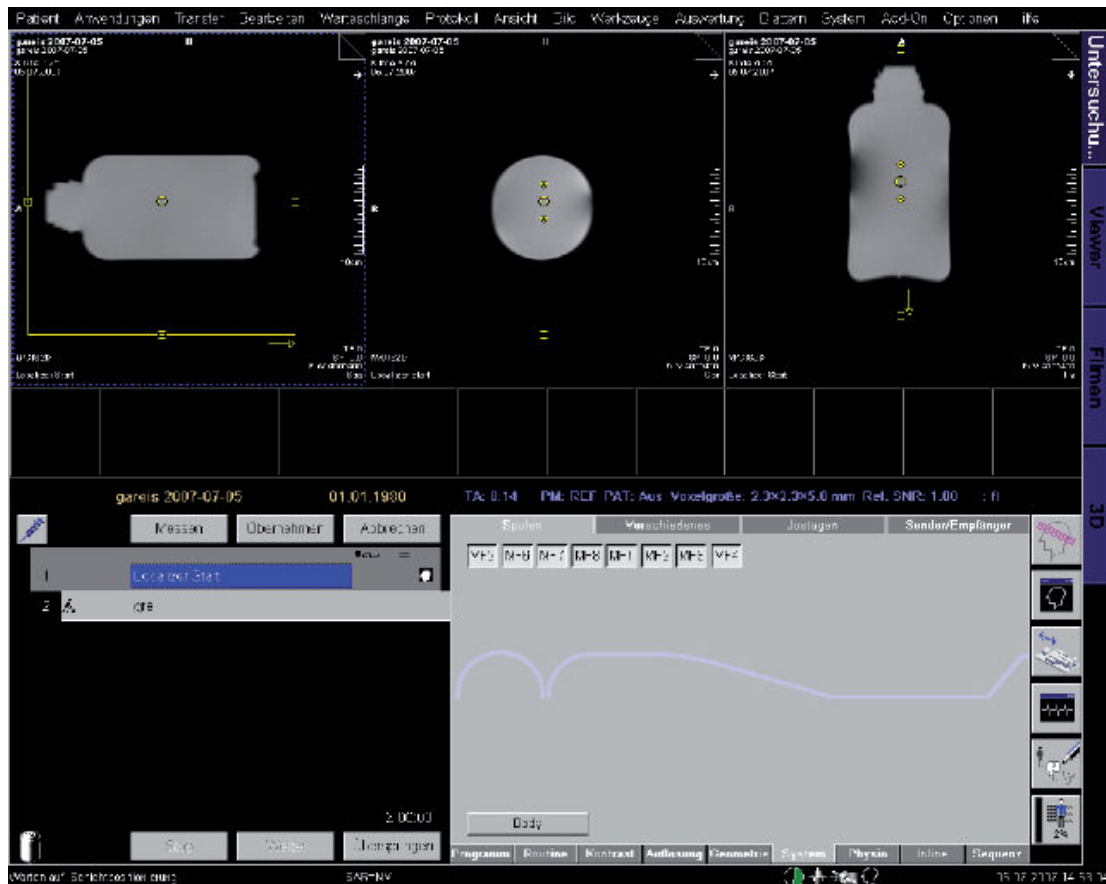
Position the 8ch Multi Function coil (Noras) and the plastic bottle 2000 ml in the center of the measurement field as shown on the picture below. Take care that cable outlets are positioned as in the picture. Position the laser marker at the middle of the phantom and along scale position 3 of the coil holder.



Maintenance, Storage and Waste Disposal

Take a normal localizer sequence measurement and then position the slice of a standard Siemens “gre” (gradient echo sequence) axially centered through the bottles.

You can find this sequence under “Siemens/Sequence Region/Siemens Sequences/Default Protocols/gre”.

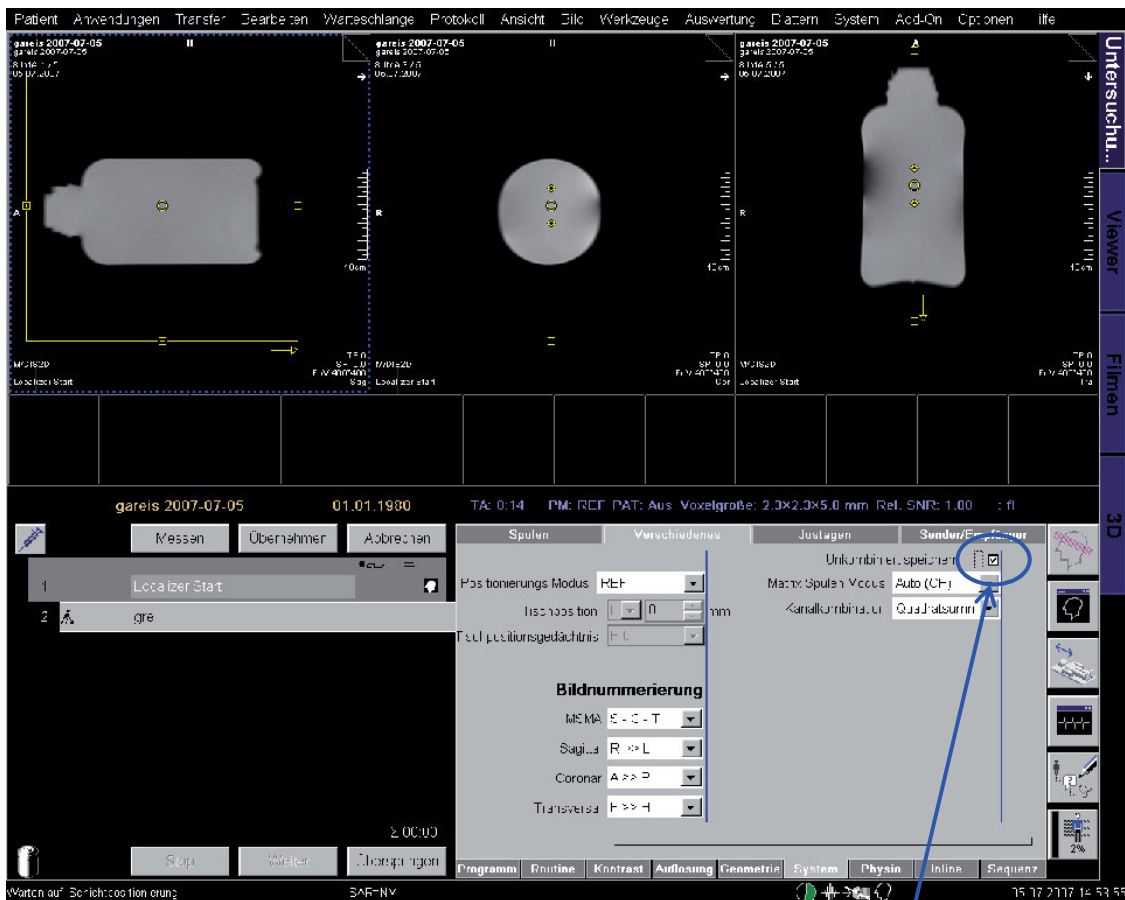


Sequence:

Siemens/Sequence Region/Siemens Sequences/Default Protocols/gre

Maintenance, Storage and Waste Disposal

Choose the option “save uncombined”.



save uncombined

Now, you can start the measurement.

Maintenance, Storage and Waste Disposal

If the signal of each channel is shown, approximately following result should arise:



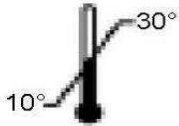
combined signal

The illustration shows that eight coil channels are producing a good quality, artifact-free signal. The picture down to the right shows the combined signal.

If the images produced during your measurement appear significantly different from the above (e.g. the image contains band or one channel with a clearly weaker signal, then a coil may be defective. In this case, please contact the NORAS MRI products GmbH.

7.2 Storage

When the **CPC 8-Channel Multifunctional Coil** is not in use, we recommend that it be stored on the shelves provided for this purpose in MRT room.



After use, the device should be stored dry and at room temperature (min. 10°C, max. 30°C) in a dust-free, UV radiation-protected location.

- Relative Humidity: Min.10%, Max. 95%
- Air Pressure: Min. 500 hPa, Max.1060 hPa

7.3 Waste Disposal

All of the materials used in the production of the system components can be conveniently recycled and therefore do not present any particular or unusual hazards during their disposal.


Prior to disposal, the system must be disinfected as described above to eliminate any risk of infection.

Disposal of **CPC 8-Channel Multifunctional Coil** are to be handed back to the manufacturer.

We would be happy to provide you with additional information about disposal upon request.

8 Technical Specification

8.1 Device Data

<p>Designation (Model / Type)</p> <p>8Ch-Multifunctional Coil CPC 1.5T 113471 / 3T 113495</p>	<p>Product Type / Device Type (according to UMDNS / DIMDI)</p> <p>Surface coil, MR (17-542)</p>
<p>Manufacturer</p> <p>NORAS MRI products GmbH Leibnizstrasse 4 97204 Hoechberg Germany</p>	
<p>Device Type</p> <p>active <input checked="" type="checkbox"/> non-active <input type="checkbox"/></p>	<p>Test / Control (Time limit / Type)</p>
<p>Product Class / Device Class</p> <p>Class IIa (MDD Annex IX, Chapter III, Clause 3, Paragraph 3.2, Rule 10)</p>	<p>Intended Purpose according to Information provided by the Manufacturer:</p> <p>2 x 4-channel coil system for diagnostic imaging in MRT</p>
<p>Identification no. of Notified Body (CE - Marking)</p> <p>0123</p>	<p>Serial Number</p>

8.2 Performance Data

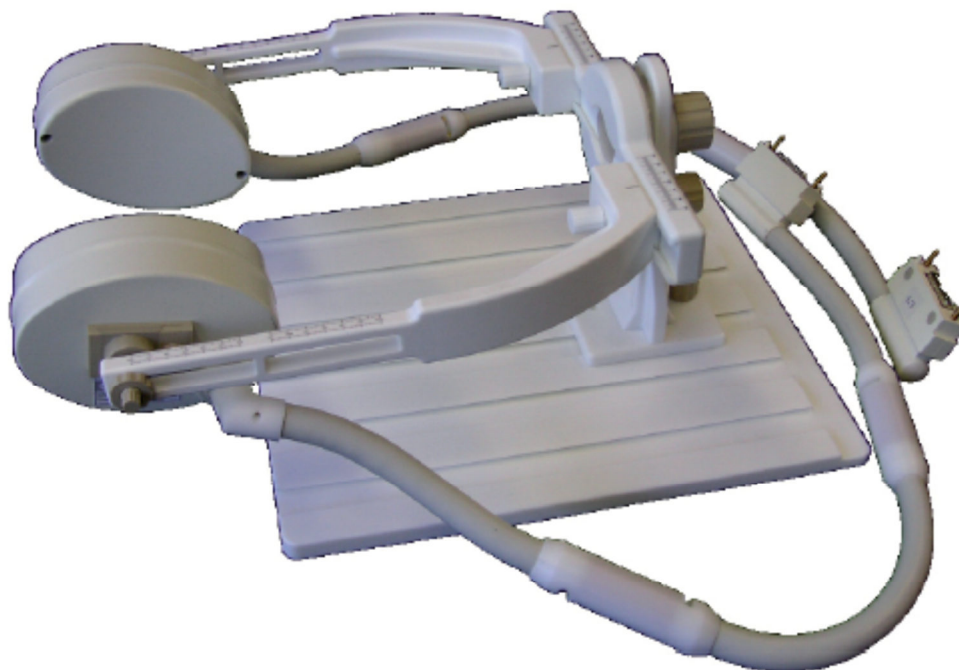
Operating Temperature	Corresponding with the air-conditioned room temperature of the MRI room
Storage Temperature	see 7.2
Protection Class	II
Weight	8 kg (net)
Resonance frequency	1.5T: 63.6 MHz 3.0T: 123.2 MHz
Rated Electrical Input / Output	Maximum 5 W
Interfaces	Electrical: SIEMENS MRI Mechanical: MRI Patient Cradle
Maximum Operating Time of Coils	Continuous operation

Technical Specifications:

CPC 8-Channel Multifunctional Coil consisting of two 4-channel arrays with integrated amplifiers

CPC Type	1.5T	3.0T
Frequency	63.6 MHz	123.2 MHz
Penetration Depth per Coil System	130 mm	130mm

8.3 Parts List



CPC Coils

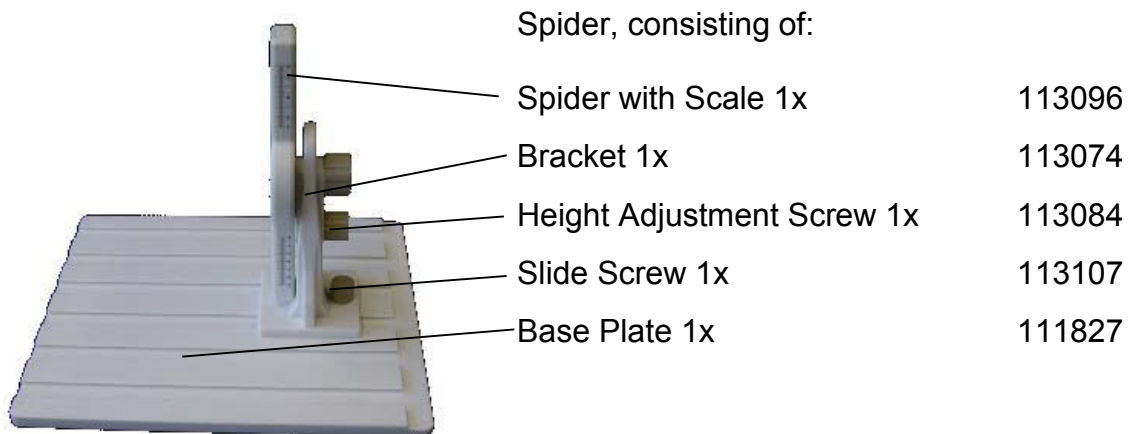
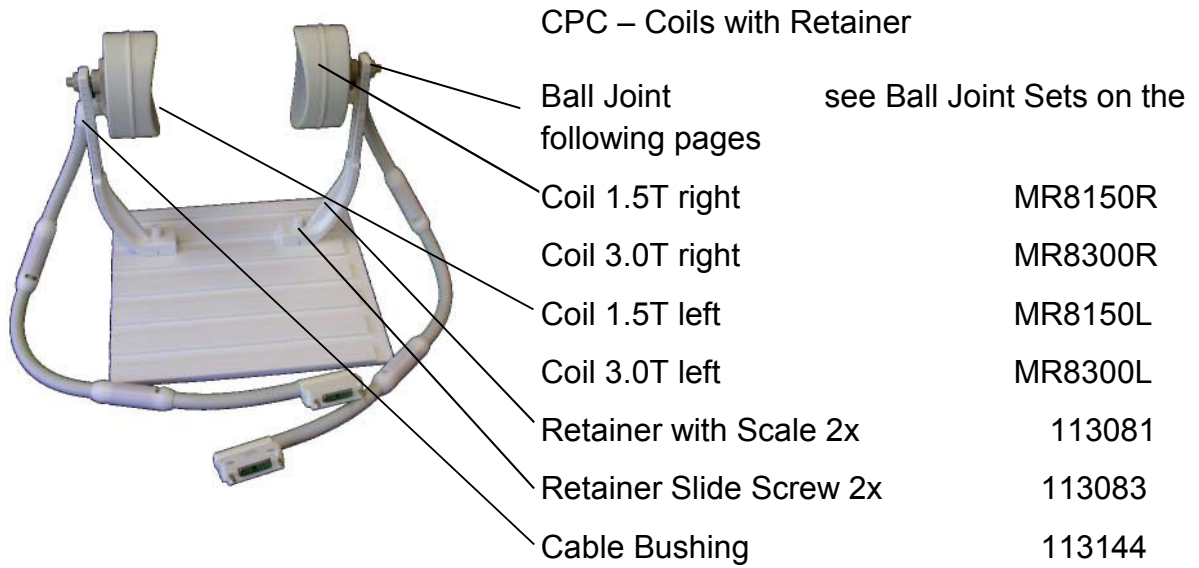
Article No.: MR8150L (left)
Left Coil for 1.5 Tesla Siemens MRI systems

Article No.: MR8150R (right)
Right Coil for 1.5 Tesla Siemens MRI systems

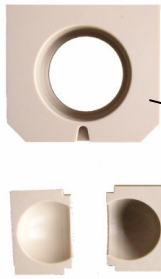
Article No.: MR8300L (left)
Left Coil for 3 Tesla Siemens MRI systems

Article No.: MR8300R (right)
Right Coil for 3 Tesla Siemens MRI systems

Technical Specification



Technical Specification



Ball Joint Set 1

MR8030

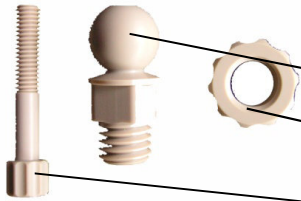
consisting of:

Ball Joint Holder

113116

Ball Joint Inner Parts

113117



Ball Joint Set 2

MR8031

consisting of:

Ball Joint Ball

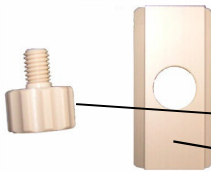
113114

Ball Joint Locking Nut

113115

Ball Joint Clamping Screw

113118



Ball Joint Set 3

MR8032

consisting of:

Ball Joint Screw

111831

Ball Joint Holder Plate

111833

9 Important Addresses

Manufacturer (Development and Production)

 The logo for NORAS MRI products features the word "NORAS" in a bold, blue, sans-serif font. To its right, "MRI" is written in a smaller, blue, sans-serif font, and "products" is written in a smaller, blue, sans-serif font below it. A blue line graphic resembling an ECG trace starts from the right side of "NORAS", goes up, then down, then up again, ending under "MRI".	<p>NORAS MRI products GmbH</p> <p>Leibnizstraße 4</p> <p>97204 Hoechberg / Germany</p> <p>Phone: +49 (0)931/2 99 27-0</p> <p>Fax: +49 (0)931/2 99 27-20</p> <p>E-Mail: mri@noras.de</p> <p>www.noras.de</p>
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10 Operator Training Outline

I have reviewed the NORAS 8-Channel Multifunctional Coil Clothespincoil (CPC) and understood the topics discussed, and verify that the training outlined is co

The training delivered was reflective of the details in the NORAS 8-Channel Multifunctional Coil Clothespincoil (CPC). I will read (or have read) this appropriate manual including the Cleaning, Disinfecting and Sterilization section of the manual.

I understand...

the intended use and the functionality of the NORAS 8-Channel Multifunctional Coil Clothespincoil (CPC)	<input type="checkbox"/>
and I am aware of the components of the 8-Channel Multifunctional Coil Clothespincoil (CPC)	<input type="checkbox"/>
the installation of the 8-Channel Multifunctional Coil Clothespincoil (CPC)	<input type="checkbox"/>
the set-up of the 8-Channel Multifunctional Coil Clothespincoil (CPC)	<input type="checkbox"/>
the connection with the MRI system	<input type="checkbox"/>
the intended use of the medical device	<input type="checkbox"/>
the cleaning instruction	<input type="checkbox"/>
the disinfection instruction	<input type="checkbox"/>
the sterilization instruction	<input type="checkbox"/>
that it is NOT NORAS' responsibility for timely replacement of worn out parts.	<input type="checkbox"/>

Operator Training Outline

Title	Name	Department
Date and Signature		
<input type="checkbox"/> Contact Person E-Mail Address: Phone No.:		
Customer		
Trained by:	NORAS Application Trainer	
Date and Signature		

