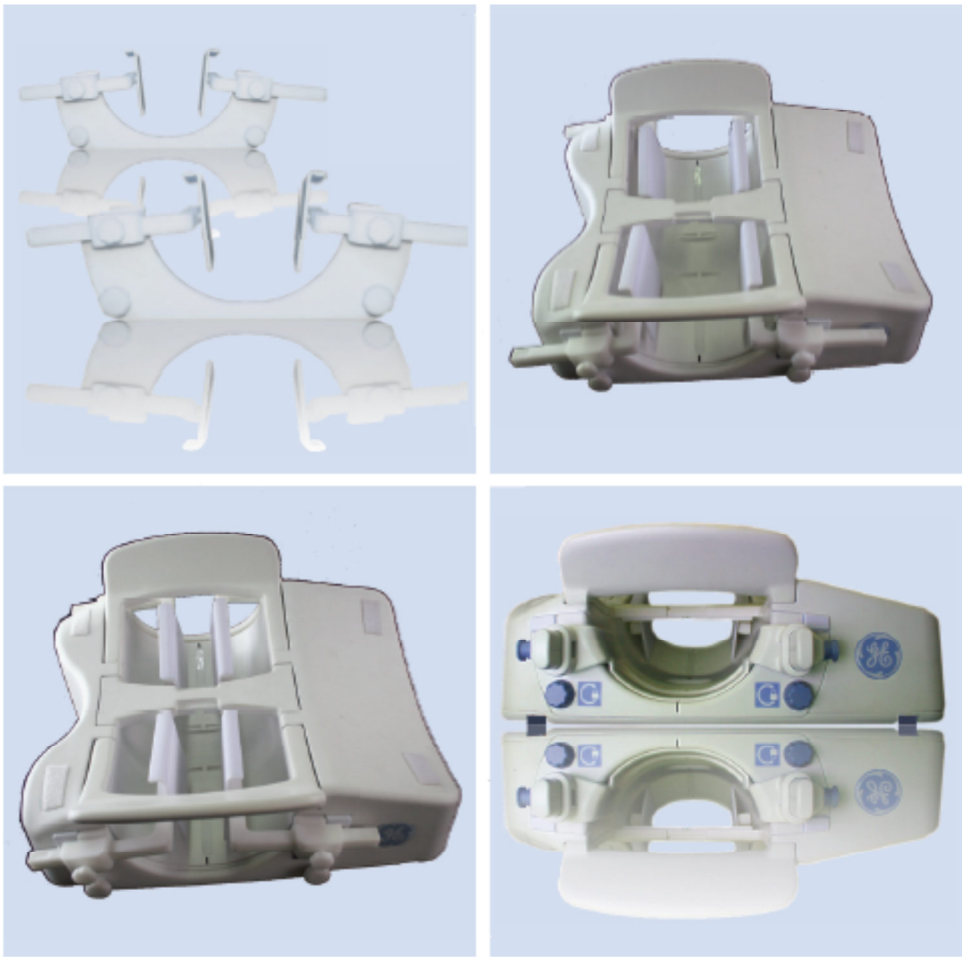
Cranio caudal Fixation Unit CC-GE

Cranio-caudal Fixation Unit
CC-GE
MR10063-CC-GE

for Immobilization with the
GE 8 channel breast coil



Operator's Manual
Revision 04

CE

NORAS MRI products

Issued Date: August 2015

Contents

1 General Information

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

The **Cranio-caudal Fixation Unit CC-GE** can only be used with the GE High Density 8Ch Breast Coil.

	**Infection of the patient**
	Place a sterile tissue on the base plate. Not covering the base plate with a sterile tissue may lead to infection of the patient.

If you would like to receive up-to-date information about the further development or new accessories for your **Cranio-caudal Fixation Unit CC-GE**, please send an e-mail with the serial number of your system to mri@noras.de.

The application conditions have a major impact on product life. 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 in influencing product life are the frequency of application and processing method (cleaning, disinfection and sterilization).

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.

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General Information

 G06	**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 practioners or to persons who have a prescription or other order from a licensed practioner to purchase it.

2 Intended Use / Indication for Use

The **Cranio-caudal Fixation Unit CC-GE** is am medical product and it is indicated for the cranio-caudal fixation of the female breast. The application must only be performed by trained medical personal.

Contraindication

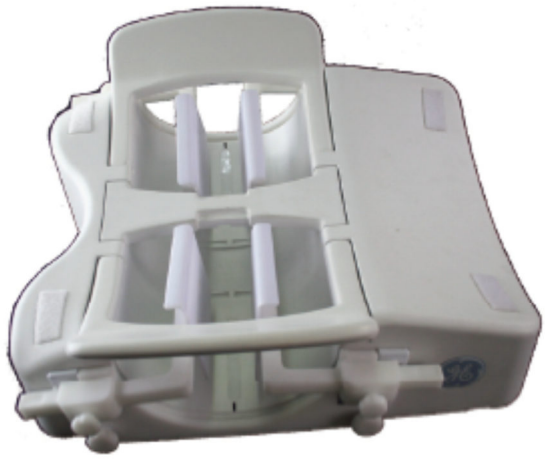
All patient examinations are contraindicated with this system which is also contraindicated in the proximity of the MRI device according to the information provided by the manufacturer.

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

	**Note**
	Please be sure to pay attention to and comply with the safety information and instructions of the MRI manufacturer for operators, patients and the third party.

3 Operating Principle

The immobilization of the breast in the GE 8Ch Breast Coil is performed in cranio-caudal direction.



After a diagnostic examination with the **Cranio-caudal Fixation Unit CC-GE**, the MR-guided breast biopsy, wire localization of the lesion or a minimal invasive intervention can be performed with the NORAS Biopsy Unit (Post&Pillar or Grid) in combination with the GE Breast Coil.

4 Device Description

4.1 Definitions and Symbols

The following symbols are use on the **Cranio-caudal Fixation Unit CC-GE** and in this manual.

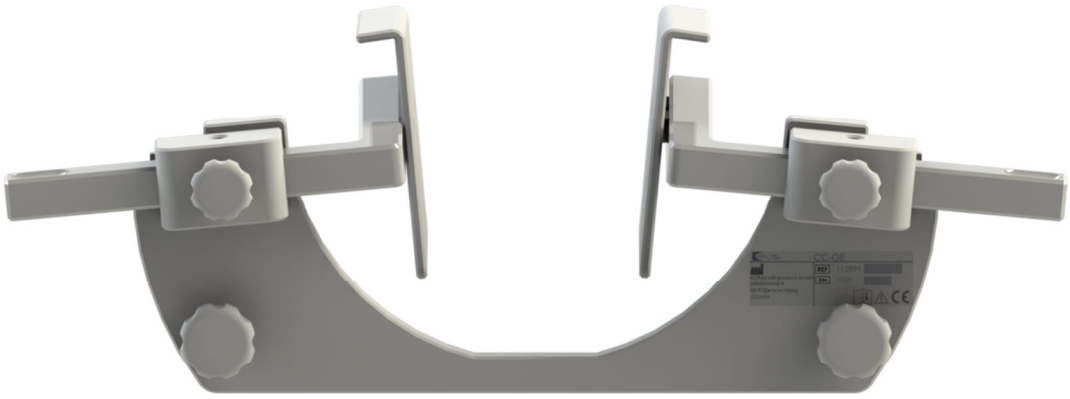
	ISO 7000-2493	Item Number
	ISO 7000-2498	Serial Number
	ISO 7000-3082	Manufacturer
	ISO 7000-2497	Date of Manufacture
	EN ISO 7000-1641	Operator's Manual
	ISO 7000-0434B	Caution, read the accompanying documents
	Directive 2002/96/EC	Waste products should not be disposed of with household waste e. g. at a local authority collection point.
	ISO 780 DIN 55402	This way up

Device Description

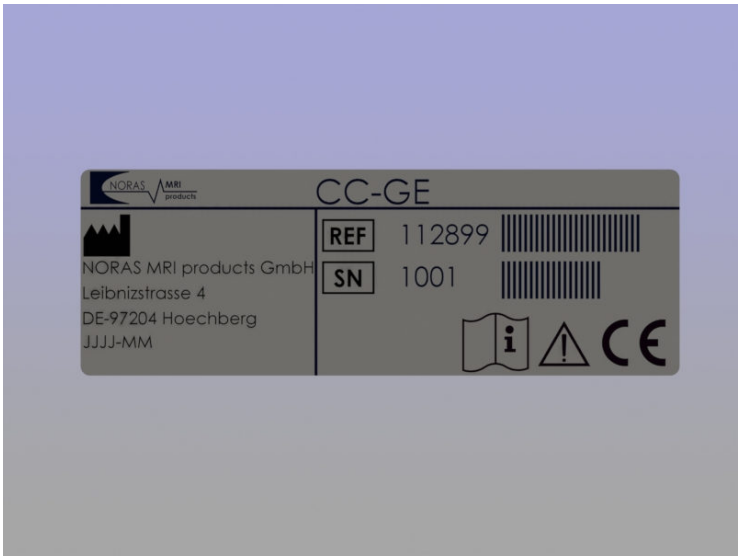
	ISO 7000-0621	Fragile, handle with care
	ISO 7000-0626	Store in a dry place
	ISO 7000-0632	Temperature Limit
CE		Conforms with the essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
		Warning regarding risks that may result in minor physical injury or material damage.
		Warning regarding risks that may result in death or serious physical injury.
		Information regarding the optimal use of the product

4.1.1 Rating Plates

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.

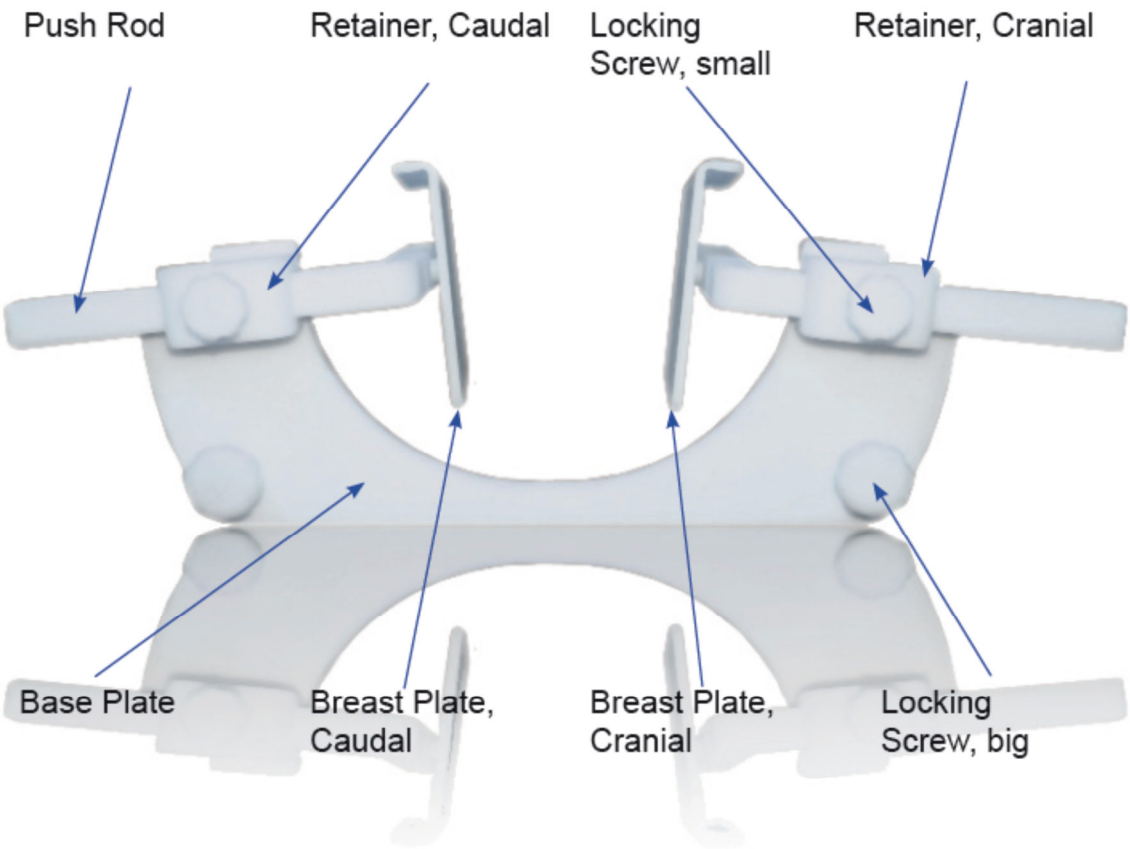


The rating plates are located on the base plate of both fixation units.



4.2 System Components

The **Cranio-caudal Fixation Unit CC-GE** consists of the following components:



5 Start-Up

 G12	**Device Damage**
	The users must be trained before using the device. Operating errors may cause permanent damages to the device.

	**Staff Instruction**
	The users must be trained before using the device (detailed training of the personnel for existing components).

 G11	**Device Damage**
	Only trained personnel may be assigned to handle the **Cranio-caudal Fixation Unit CC-GE**. Operating errors can cause permanent damages of the device.

 G17	**Bodily Injuries**
	Only trained personnel may be assigned to handle the **Cranio-caudal Fixation Unit CC-GE**. Operating errors may cause bodily injuries (e.g. contusions) to the user and/or the patient.

	**Danger of Infection**
	Prior to start-up of the devices or parts thereof, all components must be treated as described in chapter 7 “Cleaning and Disinfection”. Noncompliance with the above instructions may lead to infection of the patient.

 G15	**Bodily Harm**
	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.

 G20	**Use of wrong components**
	The use of components not listed and described in this Operator’s Manual, provided by NORAS, is expressly prohibited.

	**Note**
	Please be sure to pay attention to and comply with the safety information and instructions of the MRI manufacturer for operators, patients and the third party.

Start-Up

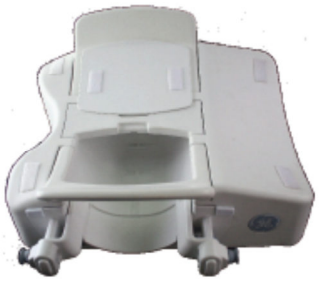
The Operator‘s Manual must be read by each operator prior to using this device. In order to become skilled in the proper handling of this system, you should, in addition to participation in training, use a phantom.

 G10	**Bodily harm of the patient and/or user**
	Prior to each patient examination, you should make a careful visual inspection of the system components. Damaged parts can be sharp-edged and cause injuries to the patient and/or to the user. In the case of unusual findings and/or damage found, the system must not be used.

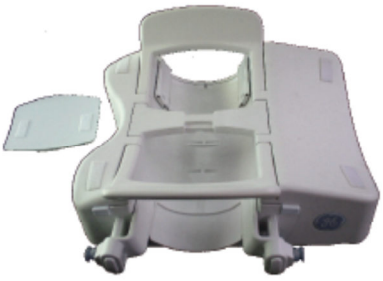
 G18	**Danger of destruction**
	Pay attention and comply with the cleaning and disinfection instructions contained in the Operator’s Manual (chapter 7). Noncompliance with the instructions of the coil manufacturer regarding chapter ‘Cleaning and Disinfection’ may destroy the coils.

Start-Up

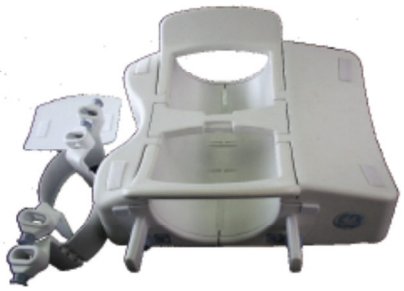
To be able to use the **Cranio-caudal Fixation Unit CC-GE** remove the cover plate as well as the left and the right retainer of the coil housing. These can be dismounted easily by unfastening the screws.



GE Breast Coil

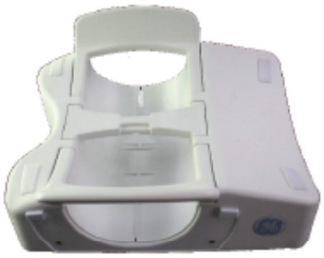


Remove Cover Plate



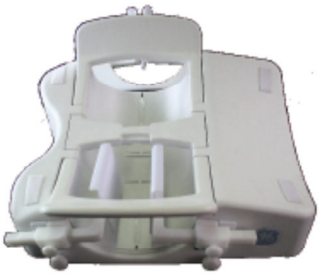
Dismount both retainers of the coil housing

Afterwards you can mount the NORAS parts.



GE Breast Coil

Position Fixation Unit



Screw in the locking screws

The premounted unit is being inserted into the coil.

Position the coil containing the immobilization and biopsy unit, according to the manufacturer's instructions, on the MR table.

To fixate the breast, unfasten the small locking screw of the appropriate fixation unit and relocate the breast plates using the push rods. To lock the fixation unit, fasten the screws by hand.

Follow the instructions of the breast coil manufacturer.

WARNING	**Prolongation or termination of the treatment**
	While plugging in the coil, ensure and check that proper contact has been made. Check the display of the MRI. If the coil pair is not properly plugged in, no images can be produced.

WARNING G14	**Correct Breast Immobilization**
	The breast must be correctly immobilized. Please check this. If the breast is not immobilized properly, it might slip and the data delivered by the MRI will be incorrect.

6 Application

MR-Mammography

	**Permanent damage of the system**
	The system may only be assembled by trained medical stuff. Incorrect assembly and operator errors made by untrained personal can permanently damage individual parts of optional components and of the device itself.

Following the imaging process using axial slices with two immobilizations units for simultaneous diagnosis on the left and right mamma is described.

- The Cranio-caudal Fixation Unit must be assembled and inserted in the coil such as described in chapter ‘Start-Up’.
- Position the patient on the GE Breast Coil and immobilize the mamma to be examined by pressing the breast plates against the mamma on the variable position bars (loosening or fixation of the breast plates is done using the locking screws).Be careful to ensure that the patient can lie as comfortable as possible during the entire procedure.
- It is important to ensure that as much breast tissue as possible is engaged by the breast plates.
- Use the toolbox in your MRI for determination of ROI, FOV and type of sequence imaging.
- Perform the MR-mammographic procedure.

	**Danger of bruising**
	Be absolutely sure to loosen the breast plates before withdrawing the mamma. That way bruises or injuries to the patient can be avoided.

	**Danger of injury**
	Before loosening and withdrawing the mamma, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

7 Cleaning and Disinfection

	**Danger of destruction**
	Regardless to the cleaning and disinfection instructions in this manual, the cleaning instructions of the coil manufacturer are to be followed strictly. Noncompliance with the cleaning instructions of the coils manufacturer may cause the destruction of the coils.

WARNINGS: 	The instructions must be followed as described. In case of inadequate cleaning or disinfection, you have to carry the risk of infection. Non-compliance with the cleaning instructions may destroy the system. No warranty service will be provided for damages due to improper disinfecting. 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).
Limitations on reprocessing:	Frequent processing can have an impact on these products (color changes), but do not affect the function of the product. .

Cleaning and Disinfection

	**Danger of infection**
	Prior to start-up of the devices or parts thereof, all components must be treated as described in chapter 'Cleaning and Disinfection'. Non-compliance with the above instructions may lead to infection of the patient.

	**Note**
	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).

INSTRUCTIONS	
Point of Use:	Remove excess soil with disposable cloth / paper wipe.
Containment and Transportation:	No particular requirements. It is re-commended to reprocess the product as soon as possible after its use. The products should be transported in a closed container.
Preparation for Cleaning:	No particular requirements.

7.1 Cleaning

Immobilization and Fixation Unit	Water bath, possible using a soft brush

After each patient examination the **Cranio-caudal Fixation Unit CC-GE** must be cleaned as described above.

The products used should be cleaned within 30 minutes after use to minimize the danger of the drying of contaminants prior to cleaning. We recommended that the components are cleaned immediately after the examination. Disassemble the cranio-caudal fixation unit into its individual parts so that they can be thoroughly cleaned.

Note

Follow the cleaning instructions of the GE Breast Coil.

7.2 Disinfection

All components of the **Cranio-caudal Fixation Unit CC-GE** must be disinfected after each use. Patient examinations may only be performed with disinfected components.

As during the cleaning process, leave the immobilization and fixation unit in its individual parts so that optimum disinfection can be ensured.

Cleaning / Disinfection Manual:	**Equipment:** **Detergent:** Example: **Sekusept® PLUS (Ecolab) 4,0 vol %, Korsolex® Plus 3,0 vol % with exposure time of 15 minutes. For this purpose all aldehyde-free surface disinfectants, which have been approved and released by the RKI and the VAH** can be used in accordance with the instructions on the label. The cleaning of the parts could be done manually in immersion or ultrasonic bath for **10-30 minutes,** preferable at temperatures of up to **50°C.** **Procedure:** 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. 3. The part is held under running water for 5 minutes. In this case, the running water must flow through the cannulas. The blind holes must be repeatedly filled and emptied. 4. The parts must be cleaned as long as no visible blood or tissue residues more on the products to be seen.

Cleaning and Disinfection

	For manual disinfection, it is advisable to insert the parts (for expected parts see left column) in the solution immediately after use. Ensure that the parts are completely sub-merged in the solution. Take the parts from the solution after the described time 15 minutes and rinse by water (the quality of water must be at least equal to drinking water, better would be using aqua. Demineralized water). Changing in color due to continuous disinfection cannot be excluded, but can be largely prevented by sufficient rinsing after each use. The solution is distributed on the surfaces by a fluff-free cloth. The disinfectant permeates the dirt particles and because of mechanical forces (pressure, abrasion), this ensures effective cleaning. Additionally, the wiping motion ensures that spores, which are resistant to the disinfectant, will be re-moved. The cloth must be re-placed after the disinfection in order to prevent the spreading of the spores on other areas. Moreover, it is essential that the wiping solution is renewed regularly (daily

	**Note**
	Follow the disinfection instructions of the GE Breast Coil.

	**Note**
	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).

Cleaning and Disinfection

	**Danger of Destruction**
	Non-respect of the cleaning instructions may cause the destruction of the device. No warranty service will be provided for damages due to improper cleaning. Improper cleaning may result in malfunction of the device.

 G04	**Danger of Infection**
	The instructions of disinfection must be followed. In case if inadequate disinfection, the operator and/or the patient may be infected.

Maintenance, Inspection and Testing:	Damaged parts should be discarded. All parts: Visually inspect for damage and wear.
Storage:	Safe, dry, dust-free and protected from light. Constant temperature {min.50 F (10°C) / max. 86 F (30°C)} Constant air humidity (min. 10% / max. 95%)
Manufacturer Contact:	See Chapter 10

8 Maintenance, Storage and Waste Disposal

8.1 Maintenance

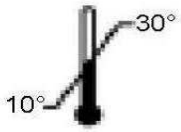
Prior to each use, all components of the **Cranio-caudal Fixation Unit CC-GE** must be visually inspected. Check the immobilization and fixation unit for breaks and cracks.

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

Comply with the cleaning and disinfection instructions!

 G10	**Injury of the patient**
	Prior to each patient examination, a visual inspection of all components is mandatory. In case of unusual findings and /or damage, the coil must not be used. Damaged parts can be sharp-edged and can cause injuries to the patient and/or the user.

8.2 Storage



After use, the device should be stored dry and at room temperature {min. 50 F (10°C), max. 86 F (30°C)} in a dust-free, UV radiation-protected location.

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

8.3 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 **Cranio-caudal Fixation Unit CC-GE** are to be handed back to the manufacturer.

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

9 Technical Specification

9.1 Historical Device Data

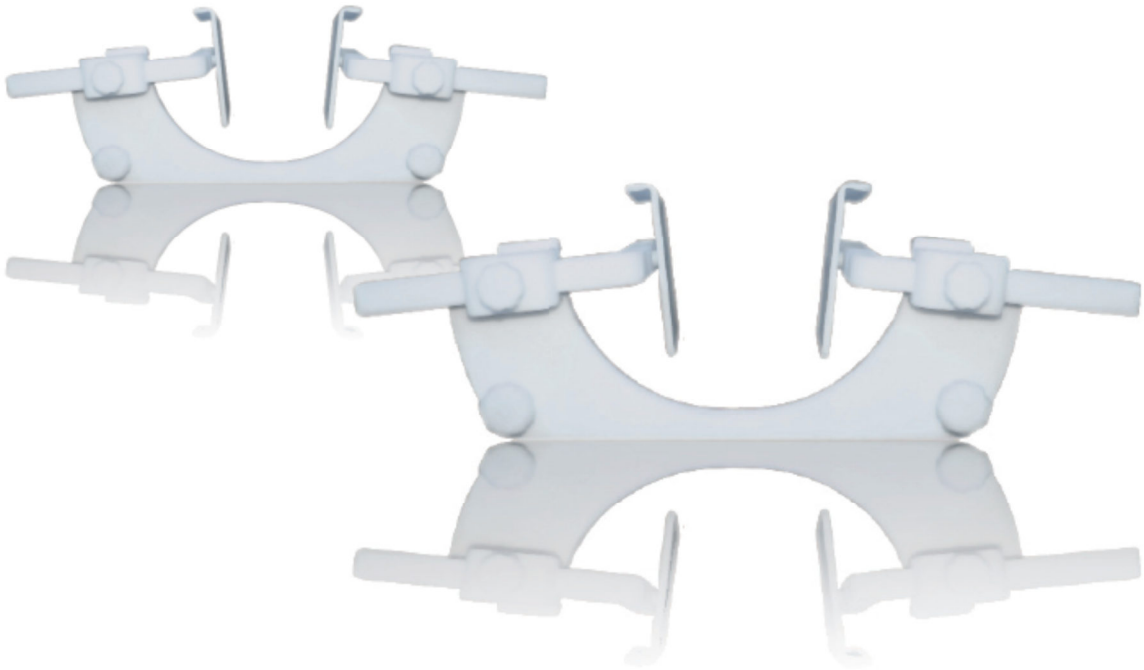
Designation (Model/Type) Cranio-caudal Fixation Unit CC-GE	**Product Type / Device Type (according to UMDNS / DIMDI)** Biopsy System Mammography (17-833)
Manufacturer NORAS MRI products GmbH Leibnizstraße 4 97204 Höchberg Germany	
Operation Type ☐ aktiv ☒ nicht aktiv	**Test / Control (Time Limits / Type)**
Product Class / Device Class Class I (MDD Annex IX, Chapter III, Clause 1, Paragraph 1.1/1.4, Rule 1 and 4)	**Intended Use according to information provided by the Manufacturer:** Cranio-caudal fixation of the female breast (both breasts) for MRI diagnostic examination.
Identification no. of Notified Body (CE-marking):	**Serial Number** 1001 incremental

9.2 Performance Data

Operating Temperature	Corresponding with the air-conditioned room temperature of the MRI room
Storage Temperature	See 8.2
Protection Class	I
Dimensions	Width: approx. 460 mm Height: approx. 140 mm Depth: approx. 160 mm

9.3 Part List

Designation	Order Number
2 x Cranio-caudal Fixation Unit CC-GE	MR10063-CC-GE

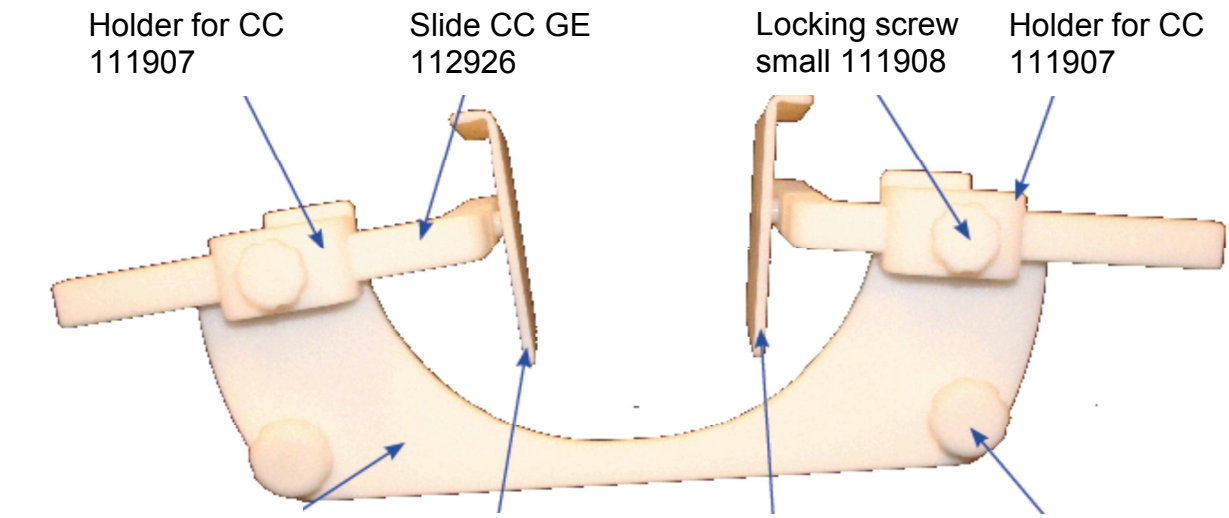


9.4 Combination with other devices

	Note
	The system **Cranio-caudal Fixation Unit CC-GE** 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.

9.5 Accessories

Designation	Order Number
Base Plate CC-GE	112898
Locking screw, big, CC-GE	112897
Locking screw, small, CC-GE	111908
Slide CC-GE	112926
Holder for CC	111907
Breast plate, left	112960
Breast plate, right	112961



10 Important Addresses

Manufacturer (Development and Production)

NORAS MRI products GmbH
Leibnizstraße 4
97204 Hoechberg / Germany
Phone: +49 (0)931/2 99 27-0
Fax: +49 (0)931/2 99 27-20
E-Mail: mri@noras.de
www.noras.de

11 Training Outline

I have reviewed the Training Outline and understand the topics discussed, and verify that the training outlined is complete.

The training delivered was reflective of the details in the **Cranio-caudal Fixation Unit CC-GE** user manual. I will read (or have read) this appropriate manual, including the Cleaning and Disinfecting section of the manual.

I understand

the intended use and the functionality of the **Cranio-caudal Fixation Unit CC-GE**	☐
and I am aware of the components of the **Cranio-caudal Fixation Unit CC-GE**	☐
the installation of the **Cranio-caudal Fixation Unit CC-GE**	☐
the complete setup of the **Cranio-caudal Fixation Unit CC-GE**	☐
the application on patients	☐
the cleaning instructions	☐
the disinfection instructions	☐
that it is NOT NORAS' responsibility for timely replacement of worn out parts	☐

Training Outline

Title	Name	Department

Date & Signature:

☐ **Contact Person**

E-Mail Address:

Phone No:

Customer:	
Trained by:	**NORAS Application Trainer**

Date & Signature:

Notes

Notes