User Manual
Technical Manual

NHAC
8-channel Neonatal Head Array Coil

Neonatal Head Array Coil

Trademark and copyright

This document contains copyrighted information. This information is property of LMT Medical Systems GmbH (hereinafter “LMT”) and may not be reproduced in whole or in part without the express written permission of LMT.

Repairs and modifications

This coil contains no user serviceable parts. All repairs must be performed by LMT.
Product modification can be dangerous. LMT will not be responsible for injury to persons or damage to property arising directly or indirectly out of unauthorized repairs and modifications to this device.
Furthermore, any unauthorized repairs or modifications will void any warranty extended by LMT.

Scope of application

This instructions for use applies solely for the following devices:

NHAC

REF: _____

SN: _____

Interface (if applicable)

REF: _____

SN: _____

which are compatible with the following MRI scanner:

❑ Siemens _____

❑ Philips _____

❑ GE _____

with a magnetic field strength of:

❑ 1.5T ❑ 3.0T

Note: When no serial number is filled in by LMT, this User Manual is only for information. It will not be exchanged or updated without request.

This manual consists of 30 pages.

CE 0123

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Contents

List of Abbreviations

NHAC	Neonatal Head Array Coil
SNR	Signal-to-Noise Ratio
ROI	Region of Interest
QA	Quality Assurance
PACS	Picture Archiving and Communication System
OEM	Original Equipment Manufacturer
EMI	Electromagnetic Interference
MRI	Magnetic Resonance Imaging
MRT	Magnetic Resonance Tomograph

GE	GE Healthcare
PH	Philips Healthcare
SMS	Siemens Healthineers

Scope of Supply

For all MRI systems

1 × NHAC
2 × “Neo wedge pad set” (3 foam pads in different sizes per set)
1 × Phantom Holder

Philips Ingenia MRI systems only

1 × Interface Ingenia

Philips Prodiva MRI systems only

1 × Interface Prodiva

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

For your and your Patient's Safety

Important instructions in this manual are especially highlighted.

⚠ WARNING!

… indicates information on dangerous situations which could result in serious injury or death.

⚠ CAUTION!

… indicates information on dangerous situations which could result in personal damage.

NOTICE!

… indicates information on dangerous situations which could result in property damage.

Be sure to follow these instructions to avoid accidents, personal injury and property damage.

In this manual paragraphs with further information and advice on efficient and trouble-free handling of the device start with **"Note:"**.

This equipment is only to be used for the purpose specified under „Intended Use". Observe all warnings and precautions included in this manual and in the device labeling.

Never operate the coil if it has suffered physical damage or does not seem to operate properly. Please contact LMT or an authorized dealer.

Product modification or misuse can be dangerous. LMT disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by LMT or by other manufacturers if such a combination is not endorsed by LMT.

Periodically check the imaging performance of the coil as described in this manual. It is recommended to perform these quality assurance tests once a year - e.g. as part of maintenance performed by LMT-authorized personnel.

The device has to undergo an inspection by LMT-authorized personnel once a year. Use only LMT spare parts.

The design of this device, the accompanying literature, and the labelling on the equipment take into consideration that the use of this equipment is restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings and caution statements are limited, therefore, largely to the specifics of the LMT design.

This publication excludes references to various hazards which are obvious to a medical professional and operator of this equipment, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions.

Assembly of medical electrical systems ("ME Systems") and modifications to the system during its actual servicelife require checks for the system's continued compliance with the requirements of IEC 60601-1 for medical electrical equipment.

⚠ **WARNING!** Strictly follow this Instruction for Use Manual. Any use of the product requires full understanding and strict observation of all portions of these instructions.

Intended Purpose

The NHAC is a local coil (receive only) and is intended to be used in conjunction with a magnetic resonance imaging (MRI) system and can be used in conjunction with the MR Diagnostic Incubator System nomag® IC Advanced.

Intended User

This device may only be used by properly trained personnel under the supervision of qualified medical personnel with the currently known risks and benefits of infant incubators and MR Imaging.

Intended Environment

The device is intended to be used during MR examinations in hospital environments.

Target Treatment Population

The NHAC is suitable for patient up to approx. 40 cm head circumference.

Medical Indications

Used in a compatible MR Scanner or used in the nomag® IC Advanced MR Diagnostic Incubator, the NHAC is indicated to be used within MRI examinations of the intended patient group, when such MRI examination is clinically indicated.

Medical Contraindications

The operator should be aware of the following contraindications for use related to the strong magnetic field of the MRI system.

General contraindications for MRI should be considered:

- Metallic implants e.g. cochlear implants
- Pacemakers or other neurostimulators
- Prosthetic limbs or joints
- Ferromagnetic surgical clips and staples
- Artificial heart valves
- Metal fragments in critical locations

Clinical Benefits

The clinical benefit is established by the state of the art since MRI coils represent standard devices to improve the image quality during MRI. NHAC have no direct medical benefit but can be considered as technical aids that enable adequate MRI examination in the intended patient population based on their technical characteristics.

Improved image quality (compared to not using a coil) requires proximity to the anatomic region of interest. NHAC is designed with physical dimensions tailored to the anatomy of the intended patient population, allowing simultaneous use of the MR Diagnostics Incubator System nomag® IC Advanced crucial for vulnerable infants undergoing MRI.

An acceptable image quality ensured post installation by determining an initial signal to noise ratio (see QA Measurement).

Note: The coil is designed to withstand the climate of the incubator: Temperatures of up to 40 °C (104 °F) and relative humidity of up to 80 %.

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Safety Instructions

General precautions

Inspection according to LMT protocol has to be carried out once a year.
Product modification or misuse can be dangerous. LMT disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by LMT or by other manufacturers if such a combination is not endorsed by LMT.

⚠ **WARNING!** This device may only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of infant incubators and MR Imaging (e.g. radiological technologists, laboratory technologists, physicians).

⚠ **WARNING!** Do not use a coil which has sustained mechanical damage. Return the damaged coil to LMT for service/repair.

⚠ **WARNING!** This coil is only to be used with MRI scanners listed as compatible on page 2.

⚠ **WARNING!** This coil contains no user serviceable parts. All repairs must be performed by LMT.

Electromagnetic compatibility

The NHAC is subject to special precautions regarding electromagnetic compatibility (EMC). It must be installed and put into service in accordance with the EMC information provided in the technical documentation (see „Electromagnetic compatibility“ from page 26).

Portable and mobile RF communications equipment can affect medical electrical equipment.

Note: Other devices may cause interferences, even if these other devices comply with the relevant applicable emission requirements of CISPR.

MR Imaging precautions

⚠ **WARNING!** When the coil is used in conjunction with MR Diagnostics Incubator System nomag® IC, there is a possibility of incubator proton signal backfolding onto patient images, thus creating misinterpretable artifacts. Therefore any diagnosis shall be based on at least two different acquisitions, these acquisitions being different in orientation.

⚠ **WARNING!** In case of MR application with short spin echo time (TE < 4 ms), the material of the respiration tube system may become visible in MR imaging. This can lead to a possible misdiagnosis. Select a longer TE time to avoid these artifacts.

⚠ **WARNING!** When the coil is used in conjunction with MR Diagnostics Incubator System nomag® IC, the patient in the incubator has only limited ability to dissipate heat from inside the body. It is therefore advised to only perform MR scans in ‘normal’ mode (SAR << 2 W/kg) to avoid any dangerous increase in body temperature.

⚠ **WARNING!** Use only MR compatible accessories to avoid negative influences on MR imaging.

MR Safety

Pre-use check

Inspect the coil for mechanical breakage/damage everytime before usage.

⚠ **WARNING!** Do not put any metal parts or accessories into the coil. Do not attach any metal parts or accessories to the coil.

⚠ **WARNING!** Improper use of coils may cause patient burns and other hazards. Read and understand all of the information contained within section one of this manual.

⚠ **WARNING!** Before each MRI scan ensure that the coil plug is well connected to the MRI system's interface socket. Coil damage, ensuing imaging artefacts due to intermittent contact, need to be prevented.

⚠ **CAUTION!** Route the cables out of the magnet so that they don't touch the wall of the patient tunnel.

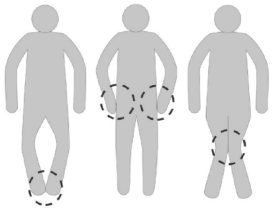
⚠ **CAUTION!** Avoid loops in ECG and RF coil cables as well as the presence of any unconnected receiving coils or unconnected electric cables during the MRI scan in order to prevent excessive local heatup of the aforementioned parts.

For further details, review the warnings in your MRI system's Operator's Manual.

⚠ **WARNING!** MR scanning is contraindicated for patients who have electrically, magnetically or mechanically activated implants (for example, cardiac pacemakers), because the magnetic and electromagnetic fields produced by the MRI system may interfere with the operation of these devices.

⚠ **WARNING!** MR scanning of patients with intracranial aneurysm clips is contraindicated.

⚠ **WARNING!** Always separate the legs from each other and the arms from the body with insulating material (e.g. cloth) to avoid eddy currents which can cause burns.



UTM NHAC,en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Device description

The Coil

The NHAC in Figure „Ergonomic features“ is an 8-channel coil (receive only) and is intended to produce high resolution images of the neonate head and brain.

The „Ergonomic features“ Figure is provided to illustrate the NHAC and basic ergonomic features.

The NHAC serves solely as a receiving coil for the reception of high frequency signals from the hydrogen nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRI system. The precessional movement of the nuclei's magnetisation induces potential differences in the NHAC which are processed in the MRI system.

NOTICE! Pull or carry the coil only by its handle. Do not use the cables as handles.

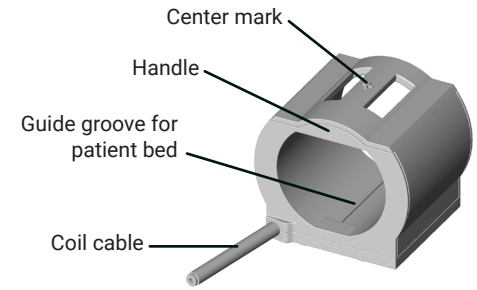


Figure 1: Ergonomic features

The Pads

The differently sized foam pads are provided to position the patient's head in the coil center comfortably. The head wedge pads are included to centrally locate the head in the L-R direction.

The pads are coated to prevent fluids from seeping into the foam. The pads can be cleaned by following the instructions in the section „Decommissioning and Cleaning“.

Figure 2: “Neo wedge pad set”

Interface description (Philips Ingenia MRI systems only)

The Interface Ingenia is an adapter unit, specifically designed to connect LMT coils to Philips Ingenia MRI systems.

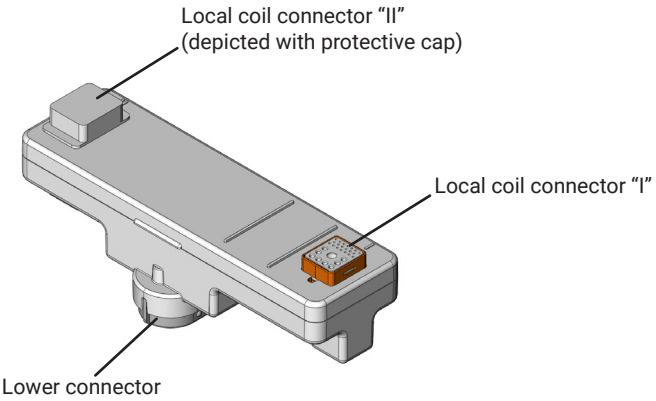


Figure 3: “Interface Ingenia”

Quality Assurance (QA)

Coil hook-up Siemens

TIM coil interface

Place the coil on the patient table of the MRI system. Insert the coil connector in the MR table's socket (see Figure).

NOTICE! Ensure that the coil plug is well connected to the interface socket. Coil damage, ensuing imaging artefacts due to intermittent contact, need to be prevented.

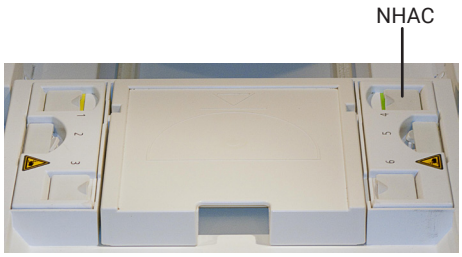


Figure 4: Siemens

TIM4G coil interface

Apply "Tim Coil Interface" adapters to sockets 1 and 2 of the MRI patient table (see Figure 4). Make sure to follow the adapters' and MRI system's Instructions for Use.

Connect the plug of Coil cable 1 to the adapter on socket 1. Connect the plug of Coil cable 2 to the adapter on socket 2. Make sure to follow the adapters' Instructions for Use.

NOTICE! Do not cross the coil cables!

NOTICE! Interruptions of power and signal transmission can cause damage to the coil and image artifacts. Make sure that the plug and socket are correctly connected.

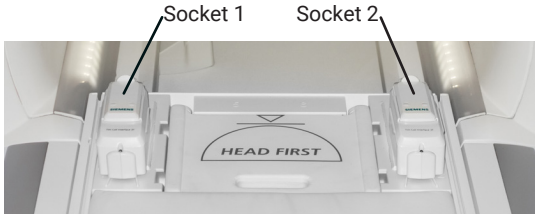


Figure 5: Connection via Tim Coil Interface

Coil hook-up GE

Place the coil on the patient table of the MRI system. Insert the coil connector into a socket at the MR table that matches the coil's plug (see Figure 6, 7).

Figure 6: GE

Figure 7: GE

Make sure that the rotary latch on the coil connector is in the unlocked position (red).

Connect the coil connector to the „P2" connector on the patient table of the MR system (see Figure 8).

Figure 8: Example for connector „P2"

NOTICE! Ensure that the coil plug is well connected to the interface socket. Coil damage, ensuing imaging artefacts due to intermittent contact, need to be prevented.

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Coil hook-up Philips Ingenia

Connect the Philips dStream interface (dSI) to the patient table. Observe the manufacturer's instructions.

Figure 9: Philips dStream Interface (dSI) by itself

There is a protective cap in the middle of the bottom side of the Interface Ingenia (see Figure). Pull off this cap to access the lower connector.

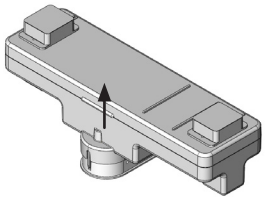


Figure 10: Protective cap on lower connector

Put the rounded side of the lower connector to the protection tab in the center of the dSI. Then move the Interface Ingenia towards the MRI scanner - thereby sliding open the dSI's protective tab.
When the dSI's protective tab has completely opened, press the housing of the Interface Ingenia as far as possible down into the slot of the dSI.
Position the lower connector's protective cap on top of the interface housing (see Figure).

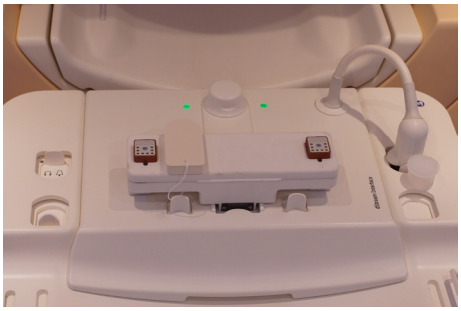


Figure 11: Philips dSI with Interface Ingenia

Place the coil on the patient table of the MRI system. Remove the protective caps from the connectors on top of the Interface Ingenia and then connect the coil cable(s) with them.

NHAC coil cable will be connected to the coil connector "II".

Figure 12: Interface Ingenia with connected local coils

NOTICE! Ensure that the coil plug is well connected to the interface socket. Coil damage, ensuing imaging artefacts due to intermittent contact, need to be prevented.

QA Measurement

During the first installation of the coil an "Initial QA" was performed with one specific phantom from your scanner site. The phantom's identifying information together with the coils performance data were recorded on page 15.

For the periodic QA test results to be conclusive, use the same phantom for every test run.

Phantom set-up

Place the phantom with the aid of the phantom holder - included within scope of delivery - in the middle of the coil (see „Phantom set-up"). Position the coil in the middle of the MR table with the aid of the positioning laser and the center marking (see „Center mark").

After moving the coil to the isocenter of the MRI system wait for the phantom's filling to settle. Wait at least 2 minutes for oil phantoms and 5 minutes for water phantoms to reliably prevent artifacts caused by movement of the phantom filling.

Run a localizer (survey) protocol.

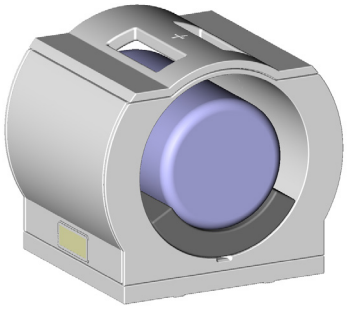


Figure 13: Phantom set-up

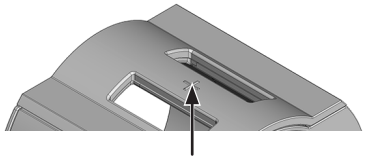


Figure 14: Center mark

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

QA protocol settings

Parameter	Value	Unit
Pulse sequence name	Spoiled Gradient Echo	e.g.: T1-FFE, FLASH, SPGR, FE_fc (RF spoiling = on)
Field of view	300 × 300	millimeters
Data acquisition matrix size	256 × 256	…
Voxel dimensions	1.17 × 1.17	millimeters
Slice thickness	5	millimeters
Repetition Time (TR)	100	milliseconds
Echo Time (TE)	10	milliseconds
Flip Angle α	25	degrees
Bandwidth settings per vendor:		
- Pixel bandwidth (SMS)	260	Hz per pixel
- Water-fat shift (PH)	1.67	pixels
- Bandwidth (GE)	(±) 31.25	kHz
Number of slices	1	…
Number of signals averaged (NSA/NEX)	1	…
Slice orientation / Scan plane	Transversal/Axial	…
Slice Position in xyz-direction	Isocenter	…
Corrections/Enhancements/Filters	None/Off	(see below)
Transmit coil(s) used	Body Coil (BC)	…
Receive coil(s) used	NHAC	…
Magnet room temperature	21±3	°C
Phantom temperature	21±3	°C

Corrections/Enhancements/Filters

Any additional settings option offered by the MR system should be disabled, i.e. set to “Off”, to “None” or – where neither is available – to “Auto”. This especially applies to every kind of “correction”, “enhancement” or “optimization” options.

For example: Siemens “Normalization filter” has to be turned off. GE “Intensity Correction” and “Filter” have to be set to “none”. Philips “Homogeneity correction” (legacy) has to be set to “none”. Philips “Uniformity” parameter (current) has to be set to “Classic”.

Image analysis

Almost every MRI scanner offers a software option to evaluate the acquired image data as described in the following. If your MRI system does not offer such an option, it should at least support the export of DICOM-images.

DICOM-images can then be evaluated using external software, e.g. the free “ImageJ” software, available on the internet at:
http://imagej.nih.gov/ij

Choose a gradient echo sequence suitable for the QA protocol settings on page 13. Then place a transversal slice in the center of the phantom. Make sure all image enhancements are switched off. The image quality check uses one single image acquisition for both signal and noise data collection.

Place a first circular region of interest (ROI) into the center of the bottle (signal). Note the “Mean”-value shown for this ROI in the table on the next page.

Place a second ROI into the image background (noise). Note the Standard Deviation (StdDev/SDev/S.D./sd) value shown for this ROI in the table on the next page.

Now calculate the signal-to-noise ratio (SNR) value.

$$\text{SNR} = \frac{\text{Mean-Value of the Signal-ROI}}{\text{StdDev-Value of the Background-ROI}}$$

The SNR value of the periodic QA test has then to be compared to the Initial SNR value. To do this calculate the SNR Index, using the following formula:

$$\text{SNR Index} = \frac{\text{Current SNR}}{\text{Initial SNR}} \times 100$$

If an SNR Index of 80 or more is reached, the NHAC is ready to be used for clinical imaging.

Should the calculated SNR Index be below 80, the coil must be taken out of service. Contact LMT for assistance. This coil is not ready for routine clinical imaging.

Note: The DICOM image files acquired in the initial QA measurement have to be stored in the local PACS and sent to LMT. This data must be provided for QA follow ups in the case of any potential malfunction of the NHAC.

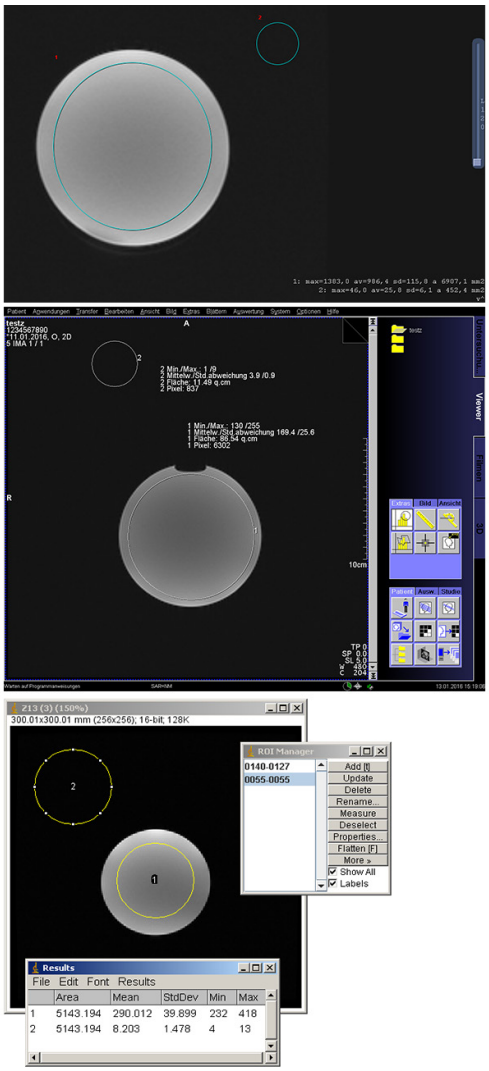


Figure 15: General Electric / Siemens / ImageJ

UTM NHAC,en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Data of the first QA measurement			
Phantom ID information (Model Name, Part/REF number, Manufacturing Date, Contents, ...)			
Date	Mean	StdDev	Initial SNR

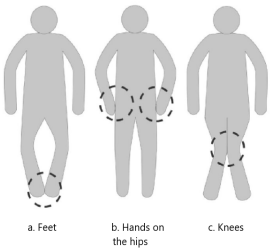
Data of the regular QA measurements				
Date	Mean	StdDev	Current SNR	SNR Index
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80
				> 80

Patient Preparation and Positioning

Prepare the patient and the Incubator as described in the User Manual of the nomag® IC Advanced.

⚠ **WARNING!** Always be especially careful and cautious when handling the patient. Closely watch patient connections and hoses when moving the coil or patient, to avoid patient injury.

⚠ **WARNING!** Always separate the legs from each other and the arms from the body with insulating material (e.g. cloth) to avoid eddy currents which can cause burns.



⚠ **WARNING!** No metal parts on or in the patient. Remove clothes with metal buttons. Take off all sensor probes (e.g. SpO2, ECG) and replace by MR-compatible sensor probes if required.

⚠ **WARNING!** The noise level during MR scans can be very high. Make sure hearing protection for the patient is in place and properly applied.

⚠ **WARNING!** Do not tighten the straps so far as to cause patient discomfort.

1. Insert the NHAC, as shown in Figure 15, into the open rear flap of the incubator.

Figure 16: Foam cushions on the right and left side of the patient's head.

2. Slide the NHAC freely, but cautiously over the patient's head, as shown in Figure 16. Pay attention to all lines and hoses leading to the patient, e.g. to the tube of intubated patients.

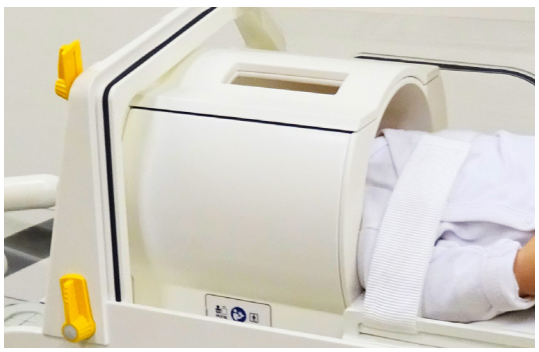


Figure 17: Foam cushions on the right and left side of the patient's head.

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

3. Close and lock the Incubator hood. Place the foam cushions between the patient's head and the inside of the coil in order to align the head in the left-right direction and restrict the patient's freedom of movement.

   Note: It is not necessary to center the head in the coil.

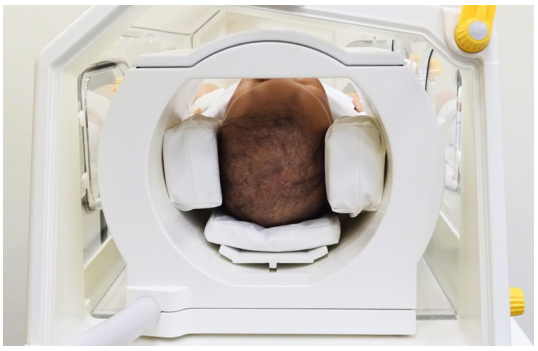


Figure 18: Foam cushions on the right and left side of the patient's head.

4. Place a large neo wedge pad between the back of the head coil and the flap rear. Feed the coil cables through the cable grommets while closing the rear flap. Lock the rear flap.

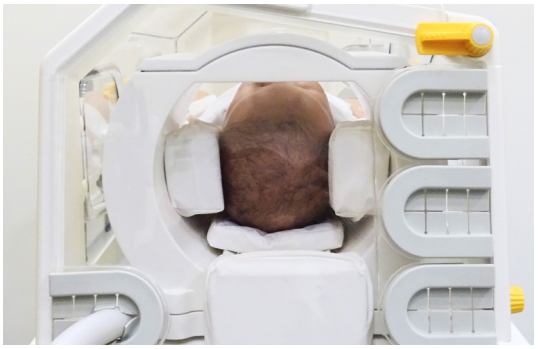


Figure 19: Foam cushions on the right and left side of the patient's head.

Positioning step-by-step
in the MR room - Siemens

- Take out the Siemens MR spine coil.
- Position cushions in the free space.
- Pace the incu plate on top of the cushions.
- Place the incubator on the incu plate.

Insert the coil connector in the MRI system's socket (see Figure). Ensure that the coil plug is well connected to the MRI system's interface socket.

Turn the MRI system's positioning laser ON and align the center of the coil to the light visor.
Follow the MRI manufacturer's instructions for advancing the incubator with coil to the isocenter.

⚠ **CAUTION!** Do not align laser light over the eyes of the patient. Exposing eyes to the laser light may result in eye injury.

TIM4G coil interface

Apply "Tim4G Coil Interface" adapters to sockets 2 of the MRI patient table (see Figure 4). Make sure to follow the adapters' and MRI system's Instructions for Use.

Connect the plug of Coil cable 1 to the adapter on socket 2.

NOTICE! Interruptions of power and signal transmission can cause damage to the coil and image artifacts. Make sure that the plug and socket are correctly connected.

Positioning step-by-step
in the MR room - GE

Place the incubator on the patient table.
Insert the coil connector into a socket of the MRI system that matches the coil's plug (see Figure 22 and 23). Ensure that the coil plug is well connected to the MRI system's interface socket.

Make sure that the rotary latch on the coil connector is in the unlocked position (red).

Connect the coil connector to the „P2" connector on the patient table of the MR system (see Figure 24).

Turn the MRI system's positioning laser ON and align the center of the coil to the light visor.
Follow the MRI manufacturer's instructions for advancing the incubator with coil to the isocenter.

⚠ **CAUTION!** Do not align laser light over the eyes of the patient. Exposing eyes to the laser light may result in eye injury.

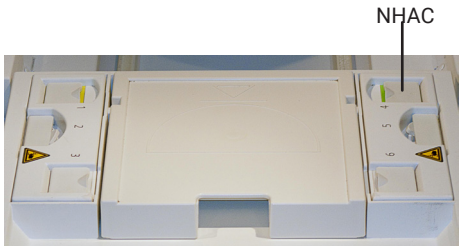


Figure 20: Siemens

Figure 21: Connection via Tim Coil Interface

Figure 22: GE

Figure 23: GE

Figure 24: Example for connector „P2"

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Positioning step-by-step
in the MR room - Philips Ingenia

Place the Philips dStream Interface on the patient table.

Place the incubator on the patient table of the MR system.

Connect the Interface PH Ingenia to the Philips dStream Interface as described on page 11.

Connect the coil cables to the local coil connectors on top of the Interface PH Ingenia (see Figure 25).

NHAC coil cable will be connected to the coil connector "II".

Make sure that the plug and socket are correctly connected.

Turn the MRI system's positioning laser ON and align the center of the coil to the light visor.
Follow the MRI manufacturer's instructions for advancing the incubator with coil to the isocenter.

⚠ **CAUTION!** Do not align laser light over the eyes of the patient. Exposing eyes to the laser light may result in eye injury.

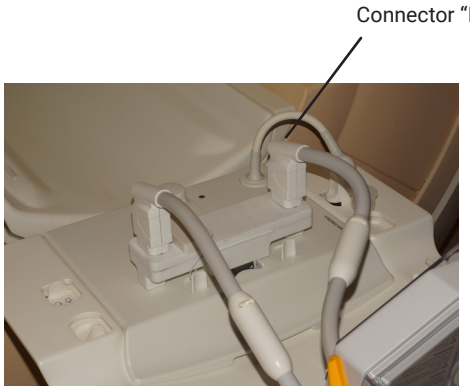


Figure 25: Interface Ingenia with connected local coils

MRI Protocols

Select a pediatric head protocol and modify as needed to suit the newborn imaging needs.

⚠ **WARNING!** When the coil is used in conjunction with MR Diagnostics Incubator System nomag® IC, there is a possibility of incubator proton signal backfolding onto patient images, thus creating misinterpretable artifacts.
Therefore any diagnosis shall be based on at least two different acquisitions, these acquisitions being different in orientation.

⚠ **WARNING!** When the coil is used in conjunction with MR Diagnostics Incubator System nomag® IC, the patient in the incubator has only limited ability to dissipate heat from inside the body. It is therefore advised to only perform MR scans in 'normal' mode (SAR << 2 W/kg) to avoid any dangerous increase in body temperature.

⚠ **WARNING!** In case of MR application with short spin echo time (TE < 4 ms), the material of the respiration tube system may become visible in MR imaging. This can lead to a possible misdiagnosis. Select a longer TE time to avoid these artifacts.

Troubleshooting

The following is a list of common problems and solutions for those problems. If you cannot solve a problem by following procedures in the manual, contact LMT.

⚠ **WARNING!** Do not open coil. Warranty voids if coil is opened. This coil contains no user serviceable parts. All repairs must be performed by LMT.

Receiving no signal

Problem:
You are scanning, but not receiving a signal.

Possible Solution:
Verify that the coil is correctly connected to the system.

Attempt to scan with the (built-in) system body coil. Before performing this quality check, please remove all imaging coils from the magnet bore.

If you continue to receive no signal the problem probably lies with your MRI system.

If the system body coil is working satisfactorily, there is a problem with the NHAC. Contact LMT for assistance.

Image quality

Problem:
The SNR obtained in the periodic quality assurance check is not greater than 80% of the value from the initial QA measurement, or the image quality is not what you expect it should be, given the parameters selected.

Possible Solution:
Review the selected protocol. If you are performing the Periodic Quality Assurance, be sure your protocol is identical to the protocol provided on page 13 of this manual.

Verify that there are no loops in the cables.

Verify that there are no metallic objects close to coil, patient or magnet (i.e. safety pin, hair pin).

Verify that the coil is properly positioned.

Verify that your center frequency is within the frequency adjustment range for your system.

If you have not done so already, perform a Quality Assurance phantom test, as outlined in section „Quality Assurance (QA)“ of this manual. If the values you obtain do not fall within normal operating parameters or the signal profile of the phantom is asymmetrical, then there may be a problem with the coil.
Contact LMT for further assistance.

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Artefacts

Problem:
There is a black line or signal void in the image (cancellation).

Possible Solution:
Verify that there is no metal in the scanned area.

If the above checks out, it is possible the coil has failed. Contact LMT for further assistance.

Interference

Problem:
EMI or other interference with other equipment in the MR room.

Possible Solution:
Use equipment that is classified as safe for use by the MRI OEM.

Identify the source of interference first. Close the magnet room door to avoid possible interference from equipment placed outside the magnet room. Also check that there are no cables or wires that bypass the shielding of the magnet room, e.g. going through conduits. Run scans with lights ON and OFF inside the MR room and look for interferences with the image.

Please turn equipment OFF inside the magnet room one-by-one and check whether the interference disappears by running MR scans with the NHAC. When the source is identified, please check to see if the equipment is approved for use by the MRI OEM. Only use equipment that is MRI compatible and approved safe for use by the MRI OEM.

⚠ **CAUTION!** Do not use unapproved equipment inside the magnet room.

If the interference persists, please use the MRI system's body coil. If the interference is also present when using the MRI system's body coil, please contact the MRI OEM. Otherwise, contact LMT for assistance.

Decommissioning and Cleaning

Decommissioning Coil

Remove the NHAC coil cable from the MRI system.

Decommissioning Interface Ingenia

First remove the coil cables from the Interface Ingenia. Then turn the ejector of the Philips dStream interface until the Interface Ingenia is lifted up, out of its slot. You can now remove the Interface Ingenia.

Note: In the event of signs of material wear which could lead to restrictions on use, do not reuse the product.

NOTICE! Hold the Interface Ingenia firmly in place with one hand while unplugging coil cables to avoid damages to the interfaces.

Cleaning

Coil and pads must be cleaned after every use to avoid patient contamination.

Observe national and international standards regarding procedures for cleaning and disinfection.

Always observe instructions of the cleaning/disinfection agent's manufacturer. Do not exceed specified concentrations and residence times.

⚠ **CAUTION!** Only use the cleaning and disinfecting agents and methods described! Certain components of the NHAC consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., alcohols, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately recognized. Sterilization of the coil or components with ethylene oxide (EtO) or disinfection with formaldehyde is also not recommended.

Wipe disinfection

For wipe disinfection, use the disinfectant "Dismozon® plus" made by PAUL HARTMANN AG in Germany.

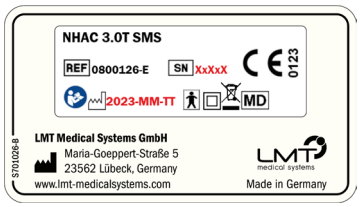
Spray or pour the cleaning liquid onto a soft cotton cloth, squeeze this cloth to remove excess solution and start to clean. Use only a damp cloth to clean.

⚠ **CAUTION!** Do not use a cloth that is dripping wet with cleaning solution.

⚠ **CAUTION!** Do not spray or pour cleaning liquid directly onto the coil or cables.

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

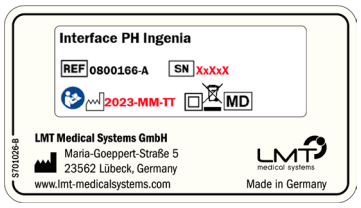
Labeling



Nameplate of the NHAC

Exemplary representation: NHAC, compatible with Siemens 3-Tesla MRI systems.

UDI of the NHAC, exemplary representation



Nameplate of Interface

Exemplary representation: Interface PH Ingenia

Indication of manufacturer and type of system on the cable connector of the coil

Exemplary representation: SMS 1.5T

Additional information on the GE coil on the cable connector

Label applyed part

Symbol	Definition
	Do not use if packaging is damaged or opened
	Do not exceed temperature limits stated to the left and right of this symbol during transport and storage
	Do not exceed air humidity limits stated to the left and right of this symbol during transport and storage
	Do not exceed air pressure limits stated to the left and right of this symbol during transport and storage
	Keep dry
	Obligatory task: “Observe instructions for use!”
	Type BF
	Electrical protection class II
	Manufacturer
	Manufacturing date
REF	Catalogue number
SN	Serial number
MD	Medical Device
CH REP	Indicates the authorised representative in Switzerland
UK REP	Indicates the authorised representative in United Kingdom
	Device contains electrical or electronic parts and must not be disposed of with household waste
	Registered NRTL certification mark of TÜV SÜD America, Inc. (TUVAM) - product tested and certified

UTM NHAC,en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Technical Data

Neonatal Head Array Coil

Classification

(EU) 2017/745 class:	IIa
Electrical protection class (IEC 60601-1):	II
Applied Part (IEC 60601-1):	Type BF
Mode of operation:	Continuous operation

The device includes application parts that are suitable for use with oxygen-enriched environment according to IEC 60601-1.

AP/APG: Equipment is not suitable for use in the presence of flamable anaesthetics.

Physical characteristics

Dimensions:	Approx. 20 cm × 24 cm × 22 cm / 8” × 9.5” × 8.5” (L×W×H, without cable)
	Approx. 10 cm × 27 cm × 10 cm / 4” × 10.5” × 4”, Interface PH Ingenia/ Prodiva (Philips MRI systems only)
Weight:	Approx. 2.5 to 3.5 kg / 5.5 to 7.7 lbs, NHAC (depending on the compatible MRI)
	Approx. 0.7 kg / 1.5 lbs, Interface PH Ingenia/Prodiva (Philips MRI systems only)

Compatible with:

- nomag® IC Advanced
- MR tomograph listed as compatible on page 2

Receiving frequencies

MRI-OEM	*Field strength 1.5 T*	*Field strength 3.0 T*
GE	63.8 MHz	127.7 MHz
Philips	63.8 MHz	127.7 MHz
Siemens	63.6 MHz	123.2 MHz

Compliance with standards

IEC 60601-2-33

Installation

Installation of the NHAC as well as its optional accessories is to be performed by the user in accordance with the instructions contained in chapter „Quality Assurance (QA)“ of this manual. There are no tools required for installation.

Disposal

The coil contains plastic and electrical parts. Please dispose of the coil per local laws and regulations.

Ambient conditions during operation

Temperature	10 °C to 40 °C (50 °F to 104 °F)
Air pressure	70 to 110 kPa
Relative humidity	20 to 80 %rH (without condensation)

Ambient conditions during transport/storage

Temperature	-25 °C to 70 °C (-13 °F to 158 °F)
Air pressure	70 to 110 kPa
Relative humidity	5 to 95 %rH (without condensation)

Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions

The NHAC - and optionally the Interface Ingenia - is intended for use in the electromagnetic environment specified below. The customer or the user of these NHAC devices has to assure that it is used in such environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions (CISPR 11)	Group 1	The NHAC devices use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The NHAC devices must be used only in a shielded location. Minimum RF shielding effectiveness and minimum RF filter attenuation of the location must meet the requirements specified by the manufacturer of the MR scanner that is listed as compatible on page 2 of this manual. The NHAC devices, when installed in such a shielded location, are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Not applicable	
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Not applicable	

Information on electromagnetic emissions in accordance with IEC 60601-1-2: 2007

Guidance and manufacturer's declaration — electromagnetic immunity

The NHAC - and optionally the Interface Ingenia - is intended for use in the electromagnetic environment specified below. The customer or the user of these NHAC devices has to assure that it is used in such environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge, ESD (IEC 61000-4-2)	Contact discharge: ±6 kV Air discharge: ±8 kV	±6 kV ±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

(...Continued on next page...)

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

(...continuing from last page...)

Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrical fast transient/burst (IEC 61000-4-4)	Longer input/ output lines: ±1 kV	±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges (IEC 61000-4-5)	Common mode: ±2 kV Differential mode: ±1 kV	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	>95 % dip, 0.5 cycles 60 % dip, 5 cycles 30 % dip, 25 cycles >95 % dip, 5 seconds	>95 %, 0.5 cycles 60 %, 5 cycles 30 %, 25 cycles >95 %, 5 seconds	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF interference (IEC 61000-4-6)	3V 150 kHz to 80 MHz	3V	The NHAC devices must be used only in a shielded location. Minimum RF shielding effectiveness and minimum RF filter attenuation of the location must meet the requirements specified by the manufacturer of the MR scanner that is listed as compatible on page 2 of this manual.
Radiated RF interference (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Information on electromagnetic immunity in accordance with IEC 60601-1-2: 2007

Room for notes

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

Room for notes

UTM NHAC, en
REF: 9000182
Ed.: 2024-03-19
Ver.: 03.10

LMT Medical Systems GmbH
Maria-Goeppert-Str. 5
23562 Lübeck, Germany
www.lmt-medicalsystems.com
info@lmt-medicalsystems.com

Tel: +49 (0)451/5 80 98-0
Fax: +49 (0)451/5 80 98-29

CE 0123

CH REP

Freyr Life Sciences GmbH
Bahnhofplatz
CH-6300 Zug

UK REP

Freyr Life Sciences GmbH
1 Bell Street
Maidenhead SL6 1BU
United Kingdom