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PRODUCT GUIDE & USER MANUAL

119781 (RT-5200-01)

Encompass™ 15 Channel MRI Head Coil, 3T

NORAS MRI products

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Patents Pending

TABLE OF CONTENTS

GENERAL INFORMATION 4
- GENERAL INFORMATION 4
- MR COMPATIBILITY CHART 4
- WARNING STATEMENTS 5
- AUTHORIZED OPERATING PERSONNEL 6
- NOTICE 6
- SAFETY INFORMATION 6
- MRI SAFETY INFORMATION 7
- CARRYING THE ENCOMPASS™ 15 CHANNEL MRI HEAD COIL 7
- WARNING LABELS & DESCRIPTIONS 8

INTENDED USE 9
PATIENT POPULATION 10
INDICATIONS 11
CONTRAINDICATIONS 12
DESCRIPTION 13
FEATURES 14
- COMPONENTS 14
- COMPONENTS IDENTIFICATION 15
- PRODUCT LABELS 16

SYSTEM COMPONENTS 20
- ENCOMPASS™ 15 CHANNEL MRI HEAD COIL, 3T 20

OPERATING INSTRUCTIONS 21
- SET UP 21
- REMOVAL 31

CLEANING, DISINFECTING, STORAGE, AND DISPOSAL 34
- CLEANING THE SYSTEM 34
- DISINFECTING THE SYSTEM 34
- STORAGE 35
- DISPOSAL 35

SPECIFICATIONS 36
- DEVICE DATA 36
- PERFORMANCE DATA 36
- ELECTROMAGNETIC COMPATIBILITY INFORMATION 37

PARTS LIST 38
FUNCTIONAL TESTING 39
INCIDENT REPORTING 47
- WHAT IS AN INCIDENT 47
- WHEN TO REPORT 47
- TO WHOM TO REPORT 47

GENERAL INFORMATION

GENERAL INFORMATION

To ensure safe and failure-free operation of the Encompass™ 15 Channel MRI Head Coil, carefully read and follow the instructions of this Product Guide & User Manual.

The Encompass™ 15 Channel MRI Head Coil can be used with the following Siemens® MRI systems:

Distributor Part Number	Manufacturer Part Number	Encompass™ 15 Channel MRI Head Coil
RT-5200-01	119781	Compatible with 3T*

*Refer to MR Compatibility Chart below.

To receive up-to-date information about the further development or new accessories for the Encompass™ 15 Channel Head Coil or to request translated instructions for use, send an e-mail with the serial number of the Encompass™ 15 Channel MRI Head Coil to sales@Qfix.com.

This device is intended to be used in accordance with its defined intended use with consideration of all stated warnings and measures specified in the product labeling. Visual inspection of all components prior to each use is recommended.

MR COMPATIBILITY CHART

MRI Scanners	Encompass 15 Channel MRI Head Coil
MAGNETOM® Skyra	✓
MAGNETOM® Prisma	✓
MAGNETOM® Prisma Fit	✓
MAGNETOM® Skyra Fit (4G)	✓
MAGNETOM® Verio	✓
MAGNETOM® Trio	✓
MAGNETOM® Skyra pTx	✓
MAGNETOM® Vida	✓
MAGNETOM® Vida Fit	✓
MAGNETOM® Lumina	✓
Other MRs	*

* Not compatible with other MRI Scanners

To connect to TIM 4G systems, ensure the appropriate TIM Coil Interface is used.

! CAUTION ! MAKE SURE THE DEVICE IS APPROPRIATE FOR THE FIELD STRENGTH (B_0) OF YOUR MRI SYSTEM.

GENERAL PRECAUTIONS

WARNING STATEMENTS

⚠ **! WARNING ! DEVICE IS FRAGILE! HANDLE WITH CARE. DO NOT DROP DEVICE. DO NOT PLACE OBJECTS ON TOP OF DEVICE. DO NOT LEAN ON DEVICE. KEEP DEVICE IN UPRIGHT, RIGHT SIDE UP ORIENTATION AT ALL TIMES.**

⚠ **! WARNING ! ARTIFACTS COULD LEAD TO WRONG DIAGNOSIS. MAKE SURE THE STAFF OPERATING THE DEVICE IS SUFFICIENTLY TRAINED. DO NOT USE THE DEVICE IF YOU OBSERVE OBVIOUS IMAGING ARTIFACTS (FOR EXAMPLE: INCREASED NOISE OR ZIPPER ARTIFACTS).**

⚠ **! CAUTION ! KEEP FINGERS AND PATIENT HAIR AWAY FROM THE GAP FORMED WHEN THE TOP COIL IS LIFTED OR LOWERED TO AVOID USER AND PATIENT DISCOMFORT.**

⚠ **WHEN USING THE ENCOMPASS™ 15 CHANNEL MRI HEAD COIL AND ACCESSORIES, ALWAYS OBSERVE THE OPERATING INSTRUCTIONS OF THE MANUFACTURER! THE ENCOMPASS™ 15 CHANNEL MRI HEAD COIL MAY ONLY BE USED IN COMBINATION WITH INDICATED DEVICES AS WELL AS THE ACCESSORIES SUPPLIED BY NORAS MRI PRODUCTS GMBH. THE USE OF OTHER ACCESSORIES IS ONLY PERMITTED WITH THE WRITTEN PERMISSION OF NORAS MRI PRODUCTS GMBH.**

⚠ **DO NOT STACK MULTIPLE RECEIVE COILS ON TO THE PATIENT.**

⚠ **DO NOT LET RECEIVE COILS OVERLAP WITH THIS DEVICE.**

⚠ **! CAUTION ! THE FIRST CONTACT OF THE DEVICE, AT THE BEGINNING OF THERAPY, IS INTENDED ONLY ON INTACT SKIN. DO NOT USE THE DEVICE ON WOUNDS THAT ARE ALREADY OPEN. THE DEVICE OR PARTS OF THE DEVICE MUST NOT BE PENETRATED, EVEN PARTIALLY, INTO THE BODY.**

⚠ **DO NOT PERFORM SERVICE AND MAINTENANCE ACTIVITIES WHILE DEVICE IS IN USE.**

AUTHORIZED OPERATING PERSONNEL

The Encompass™ 15 Channel MRI Head Coil must be operated according to the intended use and only by qualified persons with the necessary knowledge in accordance with country-specific regulations, e.g. physicians, radiological technicians, or technologists.

GENERAL PRECAUTIONS

NOTICE

- **Follow the safety instructions of the MRI manufacturer for operators, patients and third parties.**
- **Refer to the MRI manufacturer's instructions for use as well as the technical specifications for your MRI system.**
- **Special precautions must be taken when scanning sedated or unconscious patients or patients with impaired feeling e.g. paralysis of arms or legs. These patients would not be able to alert the operator to sensory feedback.**
- **Monitor patient at all times during scanning.**
- **MRI examinations might cause patient anxiety (e.g. Claustrophobia)**
- **The product is limited for use at altitudes below 2000 meters (6500 feet).**

SAFETY INFORMATION

Prior to each patient examination, visually inspect all system components. Do not use the Encompass™ 15 Channel Head Coil if housing or connection cables appear damaged. Damaged parts may cause injuries to patients and/or users. If system is damaged, discontinue use. Do not produce images with a defective device.

- The Encompass™ 15 Channel MRI Head Coil Device is not suited for operation in areas subject to explosive hazards or in the presence of flammable anesthetics or combustible gases, such as anesthetics.
- The Encompass™ 15 Channel MRI Head Coil Device has been designed for use with a MRI device in a climately controlled, electrically shielded examination room.
- The external housing of the Encompass™ 15 Channel MRI Head Coil Device must not be opened by the user. Functionality cannot be guaranteed if the housing is opened or damaged.

MRI SAFETY INFORMATION

Consider and evaluate possible distortions of the MR images acquired. Establish a quality process in order to assess remaining distortions independent of system type, size of Field of View, and MR measurement parameters.

MR Non-clinical testing has demonstrated the **Encompass™ 15 Channel MRI Head Coil Device Mirror Holder** is MR Safe. This component may be used in an MR system.

CARRYING THE ENCOMPASS™ 15 CHANNEL MRI HEAD COIL

⚠ **! CAUTION ! USE TWO HANDS WHEN CARRYING DEVICE TO AVOID DROPPING OR DAMAGING THE DEVICE.**

- **THE TOP COIL SHOULD BE INSTALLED PROPERLY ON TOP OF THE BOTTOM COIL.**
- **THE TWO COIL CONNECTORS SHOULD BE PLUGGED INTO THE STORAGE RECEPTACLES ON THE BOTTOM COIL.**
- **CARRY DEVICE BY GRIPPING THE HANDLE ON THE BOTTOM COIL WITH ONE HAND. PLACE THE OTHER HAND UNDERNEATH THE BOTTOM COIL.**
- **DEVICE MAY BE DAMAGED IF NOT CARRIED PROPERLY.**

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.1
	Authorized representative in the European community	Indicates the Authorized Representative in the European Community.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.2
	Conformité Européene (European Conformity)	CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.	Directive 93/68/EEC.	N/A
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.7
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read.	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-M002
	General mandatory action sign	To signify a mandatory action	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-M001
	MR Safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.	ASTM F2503–13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.1
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.	ASTM F2503–13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.2
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503–13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.3
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.4.4

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	General warning sign	To signify a general warning	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-W001
	Protective Insulation: Devices of Protection Class II	To identify equipment meeting the safety requirements specified for Class II equipment.	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	IEC 60417-5172
	Waste Electrical and Electronic Equipment Directive (WEEE)	Waste products should not be disposed of with household waste. e.g. at a local authority collection point.	Waste Electrical and Electronic Equipment Directive (WEEE)	RoHS Directive 2002/96/EC
	Type BF Applied Part	On medical equipment. To identify a type BF applied part complying with IEC 60601-1.	IEC 60417–Graphical Symbols for Use on Equipment	IEC 60417-5333
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.4
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.1
	This Way Up	To indicate correct upright position of the transport package.	ISO 7000—Graphical symbols for use on equipment — Registered symbols	ISO 7000-6023
	Temperature Limit	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.	ISO 7000—Graphical symbols for use on equipment—Registered symbols	ISO 7000-6032
	Rx	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A	N/A
 Medical Device	Medical Device	Indicates the product is a medical device.	N/A	N/A

INTENDED USE

The Encompass™ 15 Channel Head Coil is intended to be used in conjunction with a Magnetic Resonance Scanner for the MR examination of the human brain just before, during, and at the end of brain surgery. The Encompass™ 15 Channel Head Coil can also be used as a standard diagnostic head coil for diagnostic examinations and fMRI (Functional Magnetic Resonance Imaging). When used with magnetic resonance imaging systems, it is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

! NOTE ! 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 they practice to use or order the use of the device.

PATIENT POPULATION

Patients are of any gender, age, and ethnicity except patients with unclear medical history. Each patient's medical history should be screened for risks that might arise by a magnetic resonance imaging (MRI) examination (such as unclear status of implants) prior to the examination. The Encompass 15 Channel Head Coil is intended to be used with patients undergoing MRI examination of the head. One such population are patients undergoing MR-guided radiation therapy or stereotactic radiosurgery for lesions or other abnormalities in the brain or head.

Patients that have MRI contraindicated implants such as breast implants, heart pacemakers, surgical metallic implants, or similar objects are contraindicated for use with this coil.

INDICATIONS

MRI procedures that include the evaluated device will be conducted for clinical purposes at the discretion of the ordering physician.

(Generally, MRI is particularly, but not exclusively, suited to image non-bony parts or soft tissues of the body. MRI differs from computed tomography in that no ionizing radiation is involved.)

CONTRAINDICATIONS

Patients that have MRI contraindicated implants such as breast implants, heart pacemakers, surgical metallic implants, or similar objects are contraindicated for use with this coil. Refer to the Instructions for Use for the MRI for more information regarding contraindications.

⚠ ! WARNING ! USE OF UNAPPROVED MR ACCESSORIES MAY RESULT IN:

- **INJURY TO PATIENT**
- **PATIENT BURNS**
- **DAMAGE TO EQUIPMENT**

⚠ ! WARNING ! DO NOT USE DEVICE WITH OTHER DEVICES THAT ARE MAGNETIC OR EXPERIENCE FORCE, TORQUE, OR HEATING IN A MR ENVIRONMENT.

Use only proven MR Safe or MR Conditional accessories, tested and approved for your MR system.

Consider the MR compatibility of accessories prior to use on your MR system.

The responsibility lies with the examining physician to determine if images are of diagnostic quality prior to making diagnostic determinations.

Follow the safety instructions of the MRI manufacturer for operators, patients and third parties.

DESCRIPTION

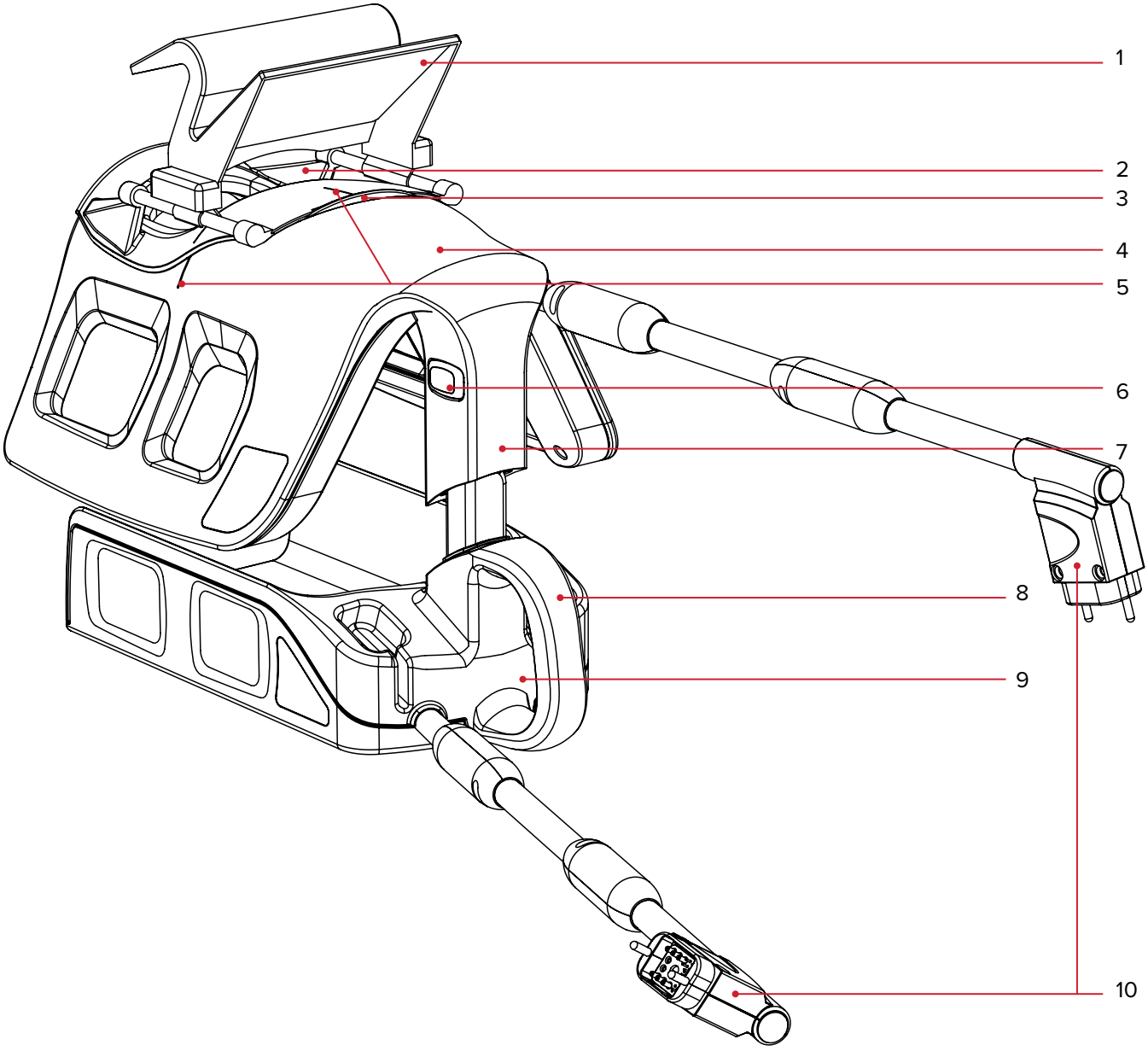
The Encompass™ 15 Channel MRI Head Coil described in this document has been designed, depending upon model type, for use with an MRI system with field strength of 3T.

The coil system consists of pure receiving coils for the reception of high frequency signals from the hydrogen-(^{1}H)-nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRI device.

The Encompass™ 3T Head Coil consists of a rigid Coil Frame System. Imaging is performed with a 15-Channel “phased array” Coil developed and manufactured by the NORAS company. The coils are mounted in the rigid Coil Frame. Interconnection is handled by the software of the MRI.

FEATURES

COMPONENTS



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FEATURES

COMPONENTS IDENTIFICATION

1. Detachable Double Mirror*
2. Patient Viewing Window
3. Mirror Holder
4. Top Coil
5. Laser Alignment Lines
6. Height Adjustment Push Button
7. Height Adjustment Post
8. Handle
9. Bottom Coil
10. Coil Connectors

For components of the Encompass™ SRS Immobilization Device, consult the Encompass Devices Product Guide and User Manual (IFU) (P/N 2005445).

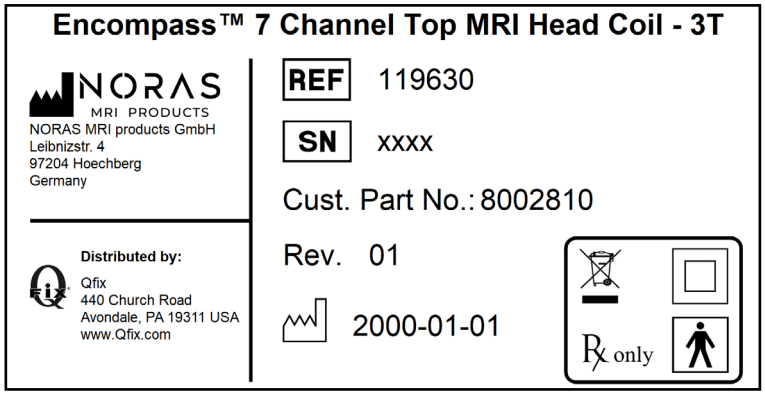
**Mirror_20: Optional component produced by Siemens (P/N 10496700). Contact Siemens for pricing and availability.*

FEATURES

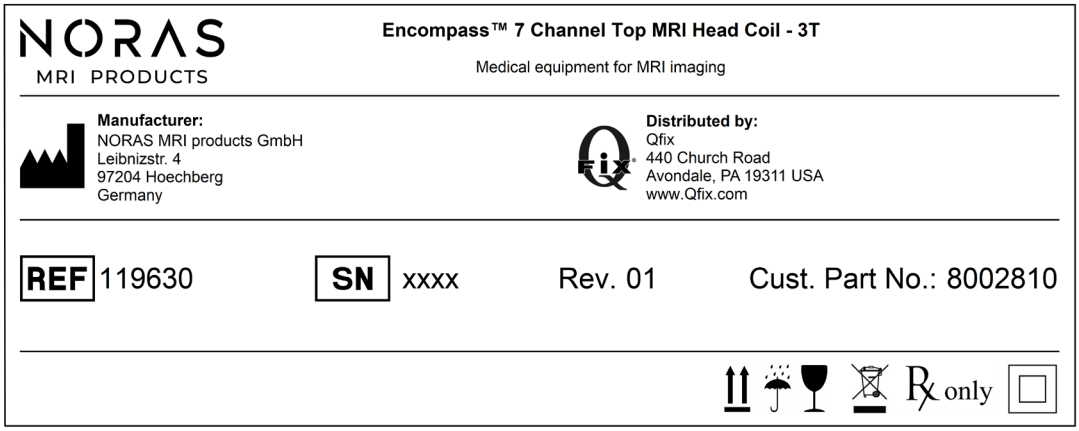
PRODUCT LABELS

A product label is located on the underside of the Bottom Coil and on the underside of the Top Coil. The term “15 Channel” on the labeling refers to the 15 channels that are included between the top and bottom coils. See sample labels below.

Top Coil Product Label



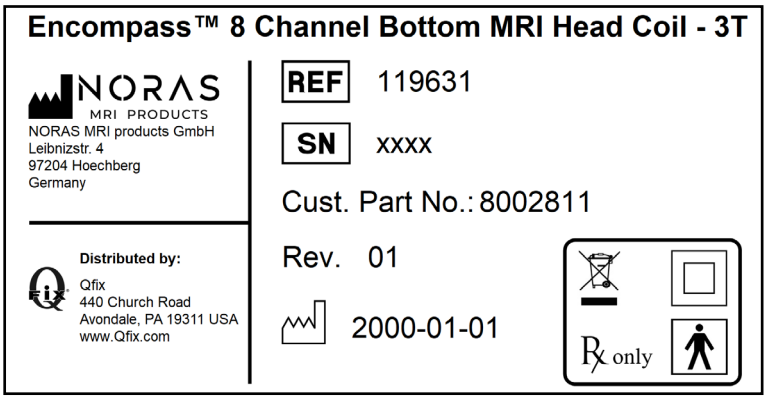
Top Coil Carton Label



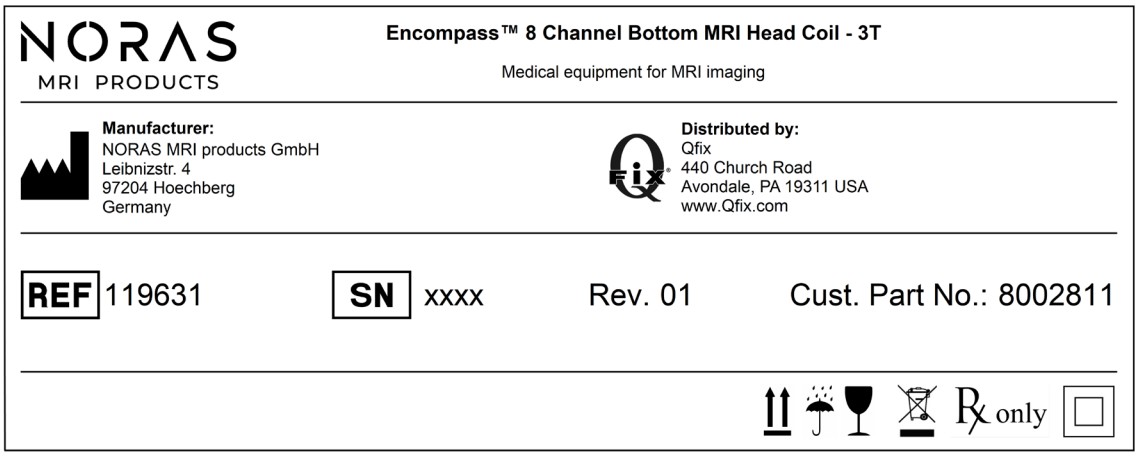
FEATURES

PRODUCT LABELS

Bottom Product Label



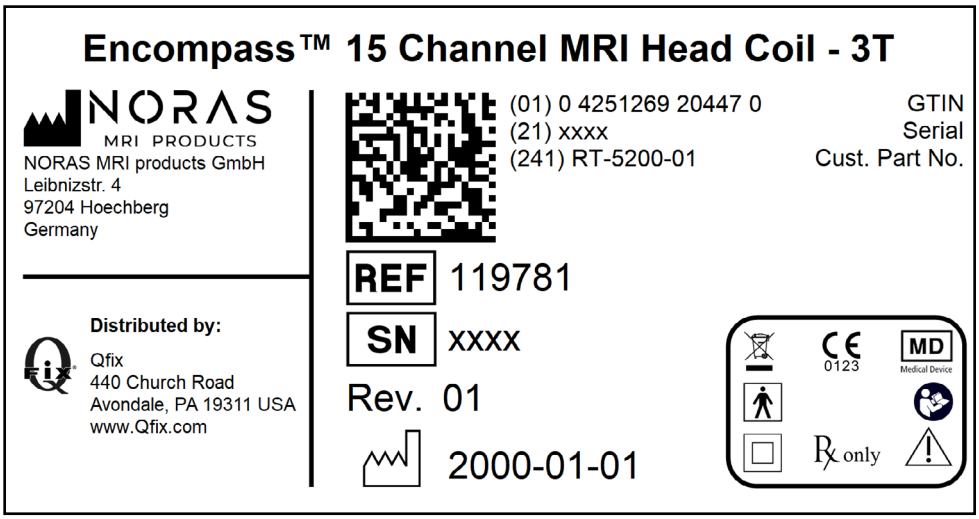
Bottom Carton Label



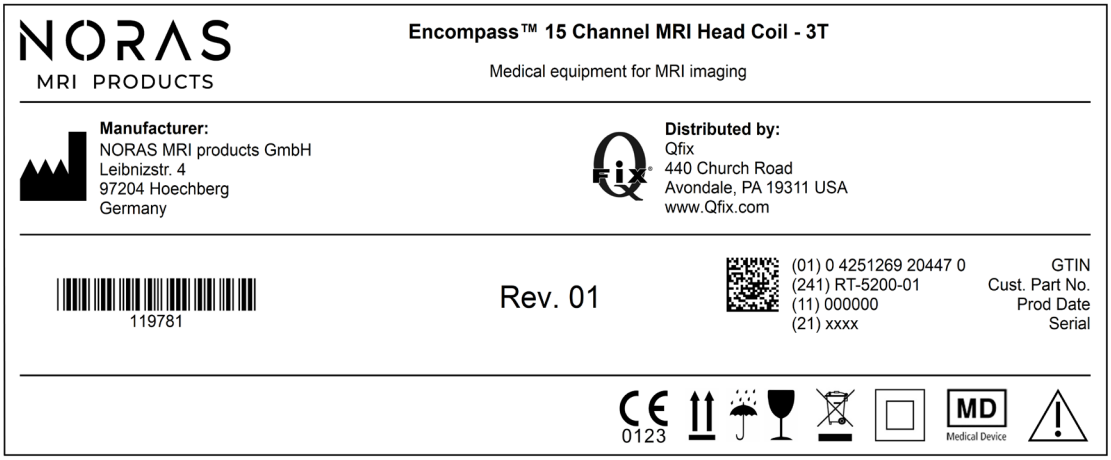
FEATURES

PRODUCT LABELS

Product Label



MRI Head Coil Carton Label



FEATURES

PRODUCT LABELS

Mirror Holder Product Label

Encompass™ MRI Head Coil, Mirror Holder

NORAS MRI PRODUCTS

NORAS MRI products GmbH
Leibnizstr. 4
97204 Hoechberg
Germany

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440 Church Road
Avondale, PA 19311 USA
www.Qfix.com

REF 119878

Cust. Part No.: 8002812

Rev. 01

℞ only

MRI Mirror Holder Carton Label

NORAS MRI PRODUCTS

Encompass™ MRI Head Coil, Mirror Holder

Medical equipment for MRI imaging

Manufacturer:
NORAS MRI products GmbH
Leibnizstr. 4
97204 Hoechberg
Germany

Distributed by:
Qfix
440 Church Road
Avondale, PA 19311 USA
www.Qfix.com

REF 119878 Rev. 01 Cust. Part No.: 8002812

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SYSTEM COMPONENTS

ENCOMPASS™ 15 CHANNEL MRI HEAD COIL, 3T

Distributor Part Number: RT-5200-01 / Manufacturer Part Number: 119781

Devices	Distributor Part Number	Manufacturer Part Number
Encompass™ 7 Channel Top MRI Head Coil – 3T	8002810	119630
Encompass™ 8 Channel Bottom MRI Head Coil – 3T	8002811	119631
Encompass™ MRI Head Coil, Mirror Holder	8002812	119878

OPERATING INSTRUCTIONS

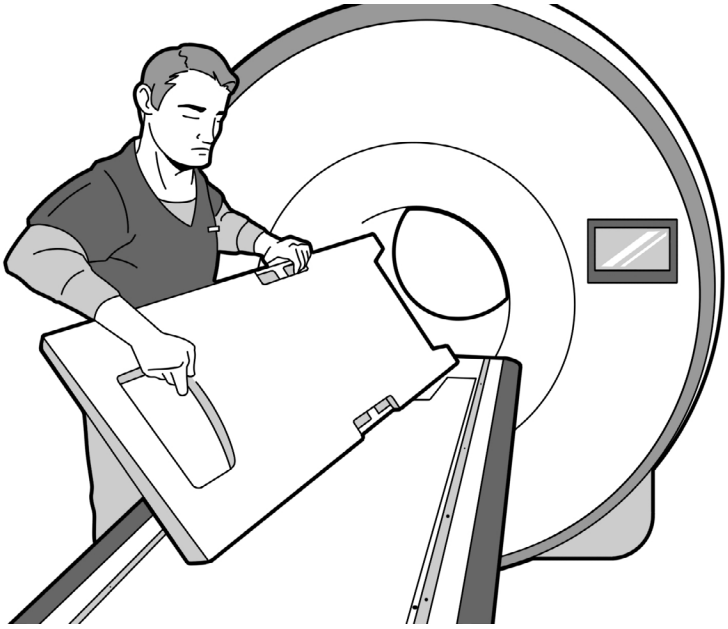
SET UP

⚠ **! WARNING ! PERFORM VISUAL INSPECTION PRIOR EACH USE.**

⚠ **! WARNING ! NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED. IF ANY PART OF THIS DEVICE EXPERIENCES A CATASTROPHIC LOAD, APPEARS DAMAGED OR FUNCTIONS IMPROPERLY, DISCONTINUE USE IMMEDIATELY AND CONTACT QFIX AT +1 800-526-5247 OR SALES@QFIX.COM.**

⚠ **! WARNING ! DO NOT USE THE ENCOMPASS™ 15 CHANNEL HEAD COIL IF HOUSING OR CONNECTION CABLES APPEAR DAMAGED. DAMAGED PARTS MAY CAUSE INJURIES TO PATIENTS AND/OR USERS IF SYSTEM IS DAMAGED, DISCONTINUE USE. DO NOT PRODUCE IMAGES WITH A DEFECTIVE DEVICE.**

1. Remove the spine coil per MRI system manufacturer instructions.



Removing the spine coil

OPERATING INSTRUCTIONS

SET UP, CONTINUED

2. Replace the spine coil with spine coil spacers per MRI system manufacturer instructions, or other appropriate support surfaces such as the Qfix Insight™ MRI Overlay.

Replace the spine coil with a support surface such as the Qfix Insight™ MRI Overlay.

3. Place Encompass™ MRI SRS Immobilization Device (RT-4600-01-MRI) on the MR Table (Fig. 1).

It is recommended that patients, especially those suffering from claustrophobia, are positioned with their feet toward the magnet bore.

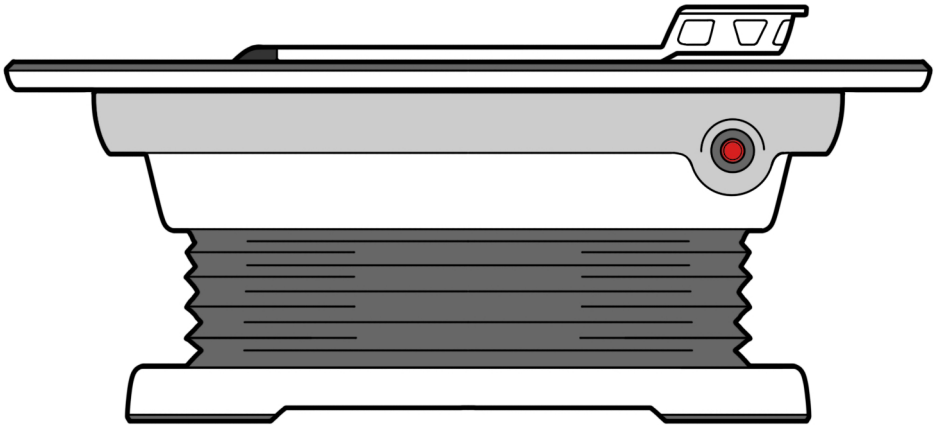


Figure 1

OPERATING INSTRUCTIONS

SET UP, CONTINUED

4. Place Bottom Coil on the MR Table. Using the handle on the device, slide the device in place under the Encompass™ MRI SRS Immobilization Device (RT-4600-01-MRI) (Fig. 2).

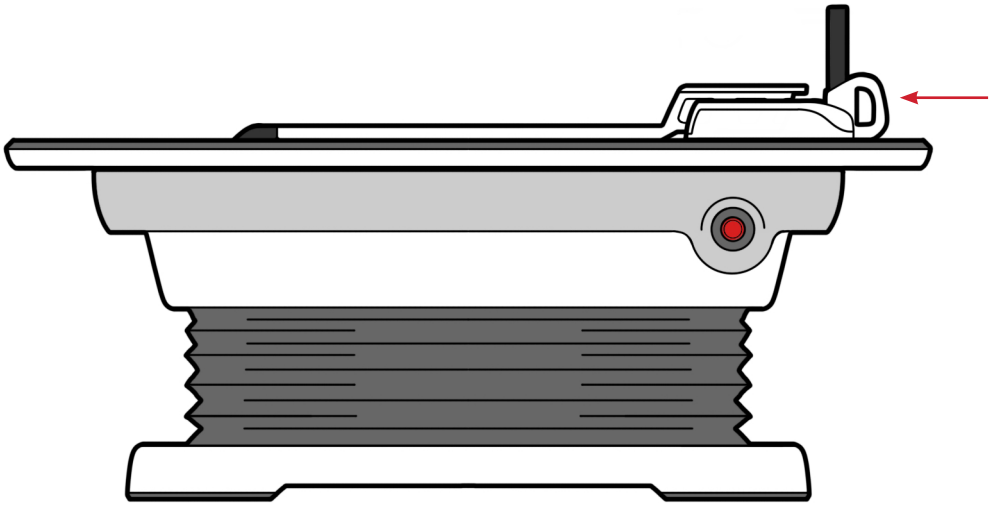


Figure 2

OPERATING INSTRUCTIONS

SET UP, CONTINUED

5. Set up patient on the Encompass™ MRI SRS Immobilization Device and Bottom Coil on the MR Table (Fig. 3). Position mask over the patient and attach to the Encompass™ MRI SRS Immobilization Device (if applicable).

! NOTE ! Refer to the Product Guide and User Manuals for Encompass Devices (P/N 2005445) and Aquaplast™ & Fibreplast® (P/N 2002890) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Encompass™ SRS Immobilization System and the use of Aquaplast™ and Fibreplast® Masks.

⚠ PATIENT BURNS

- **NEVER RUN COIL CABLES OVER THE PATIENT'S HEAD.**
- **AVOID DIRECT CONTACT BETWEEN THE COIL CABLES AND THE PATIENT.**
- **USE ONLY OPERATIONALLY SATISFACTORY RF COILS/COIL CABLES.**
- **ENSURE THAT THE PATIENT, IN THE MR SCANNER, DOES NOT TOUCH THE SURFACE OF THE HF TRANSMITTING COIL (BORE WALL). IF NECESSARY, USE CUSHIONS, SANDBAGS, OR DRY CLOTHS AS A BARRIER.**
- **AVOID THE FORMATION OF LOOPS WITH RF RECEIVING COIL CABLES AND ECG LEADS. LOOPS COULD LEAD TO WARMING. IN CASE OF DAMAGE, CONTACT QFIX.**

⚠ THE FOLLOWING SITUATIONS MAY FORM A CONDUCTIVE LOOP THROUGH PARTS OF THE BODY, E.G., INNER THIGH-TO-THIGH, CALF-TO-CALF, HAND-TO-HAND, HAND-TO-BODY, ANKLE-TO-ANKLE CONTACT

- **THE PRESENCE OF DAMP CLOTHING**
- **THE PLACEMENT OF THE BODY OR EXTREMITIES AGAINST THE RF TRANSMIT COIL SURFACE**
- **THE FORMATION OF LOOPS WITH RF RECEIVE COIL CABLES AND ECG LEADS**
- **THE PRESENCE OF UNCONNECTED RECEIVE COILS OR ELECTRIC CABLES THAT REMAIN IN THE RF TRANSMIT COIL DURING THE EXAMINATION**

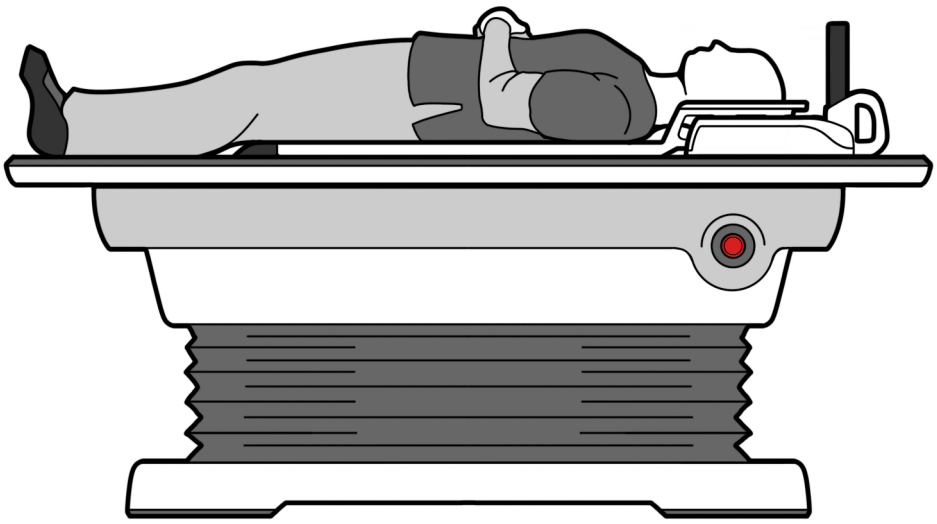


Figure 3

SET UP, CONTINUED

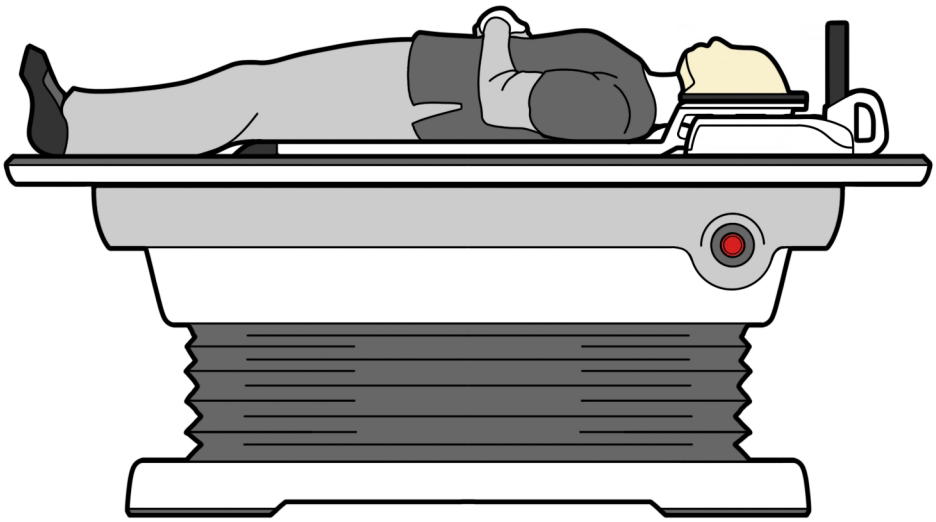


Figure 4

OPERATING INSTRUCTIONS

SET UP, CONTINUED

6. Install Top Coil over Patient and lower to appropriate height (Fig. 5 and Fig. 6). Use Height Adjustment Button to achieve appropriate height.

! NOTE ! Carefully lower the Top Coil avoiding patient contact.

⚠ ! WARNING ! DO NOT DROP TOP COIL ONTO PATIENT.

⚠ ! CAUTION ! KEEP FINGERS AND PATIENT HAIR AWAY FROM THE GAP FORMED WHEN THE TOP COIL IS LIFTED OR LOWERED TO AVOID USER AND PATIENT DISCOMFORT.

⚠ ! WARNING ! CAREFULLY LOWER THE TOP COIL COMPONENT AVOIDING PATIENT CONTACT. DO NOT DROP TOP COIL COMPONENT ONTO PATIENT.

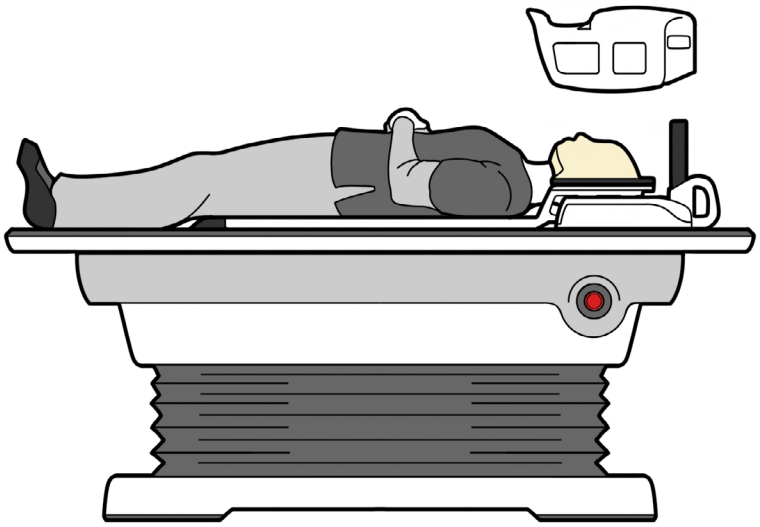


Figure 5

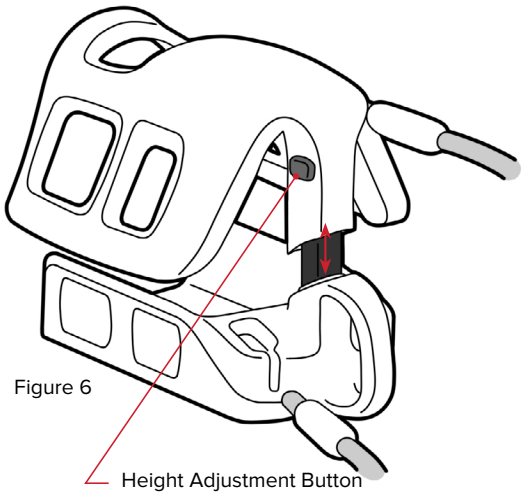


Figure 6

OPERATING INSTRUCTIONS

SET UP, CONTINUED

7. Attach Detachable Double Mirror to Top Coil using the Mirror Holder (Fig. 7) (optional):

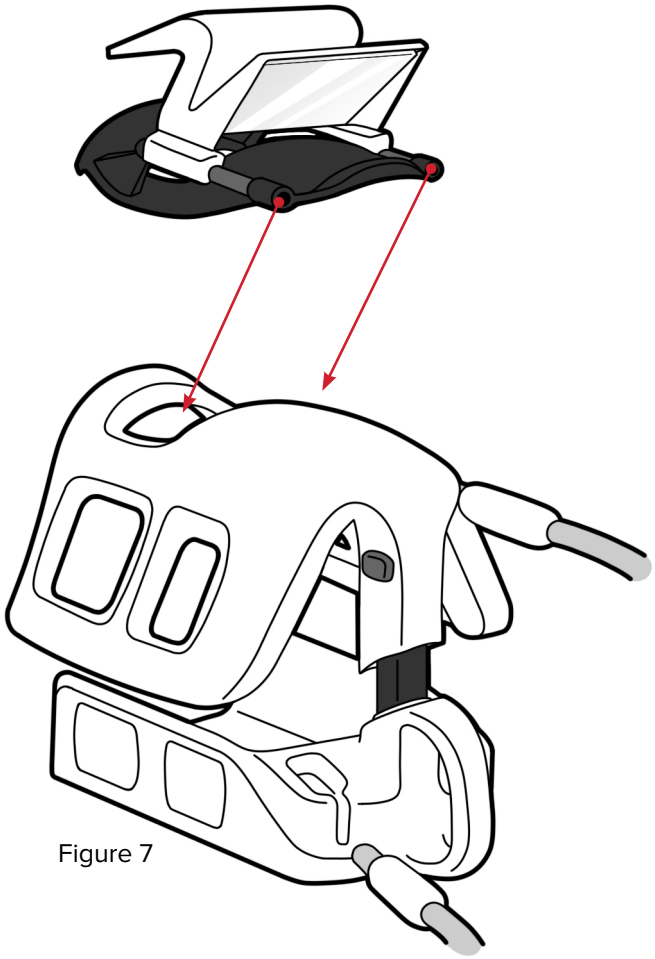


Figure 7

8. Align top of Patient Viewing Window with top of orbital ridge. If the area of interest is superior, slide coil superiorly. If the area of interest is inferior, slide the coil inferiorly (Fig. 8).

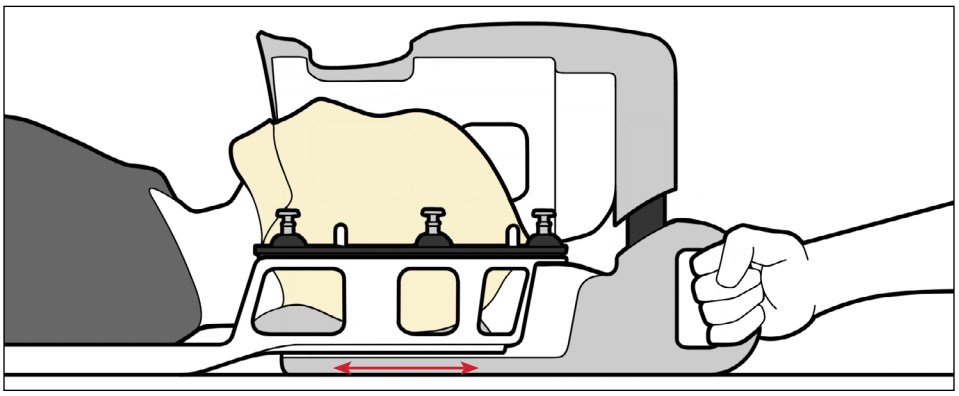


Figure 8

OPERATING INSTRUCTIONS

SET UP, CONTINUED

9. When using the Detachable Double Mirror, slide the mirror along mirror guide rails independent of the Encompass MRI Coil allowing patient to see out of the MR Bore.

10. Plug the two Coil Connectors into the Coil Slot on the MRI.

To connect to TIM 4G systems, ensure the appropriate TIM Coil Interface is used.

NOTE: If there is a connection error, check to see if the device has been properly plugged in.

NOTE: Ensure the cables are securely connected to the scanner.

! CAUTION ! VERIFY PROPER CONTACT OF THE COILS HAS BEEN MADE PRIOR TO SCANNING IF THE COIL PAIR IS NOT PROPERLY PLUGGED IN, NO IMAGES CAN BE PRODUCED.

11. Using the MR laser system, align the coils to the laser alignment marks on the Encompass MRI Coil using MR table adjustments. Refer to MR Scanner manual. (Fig. 9, 10, and 11).

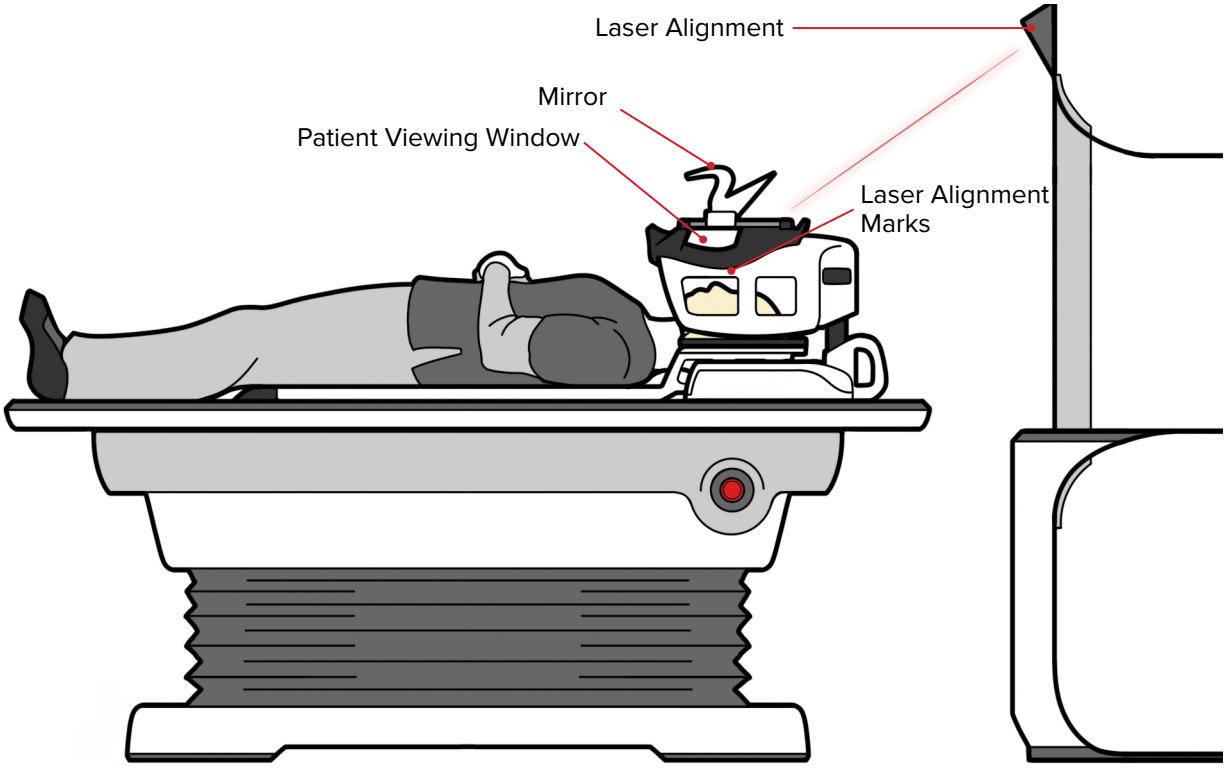


Figure 9

OPERATING INSTRUCTIONS

SET UP, CONTINUED

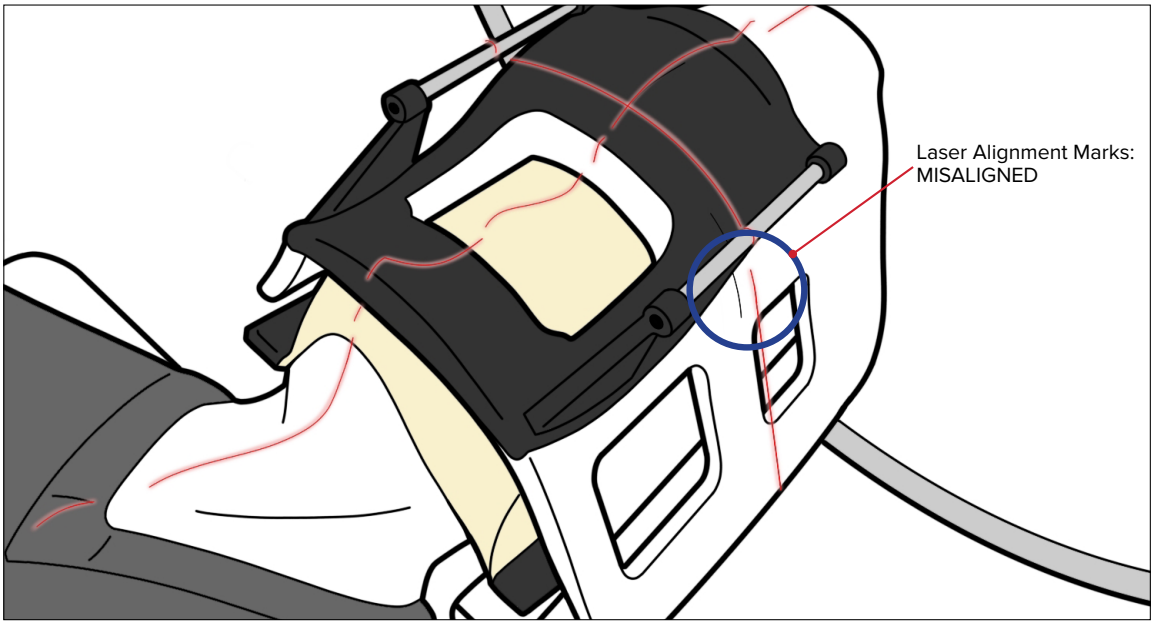


Figure 10

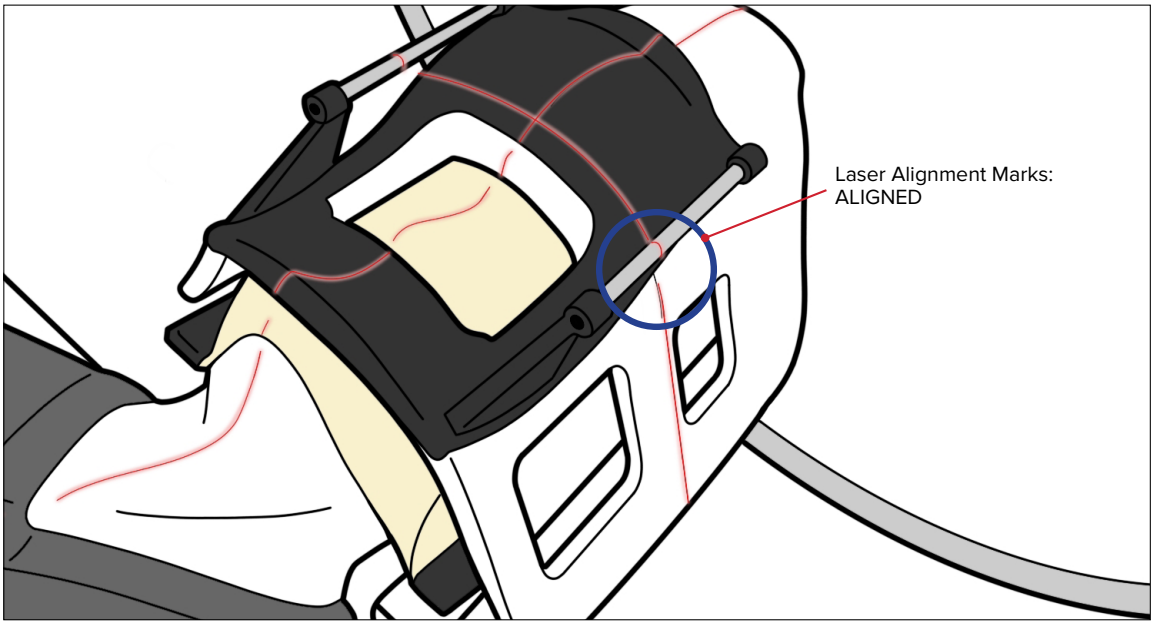


Figure 11

SET UP, CONTINUED

12. Advance patient into MR Bore for imaging (Fig. 12).

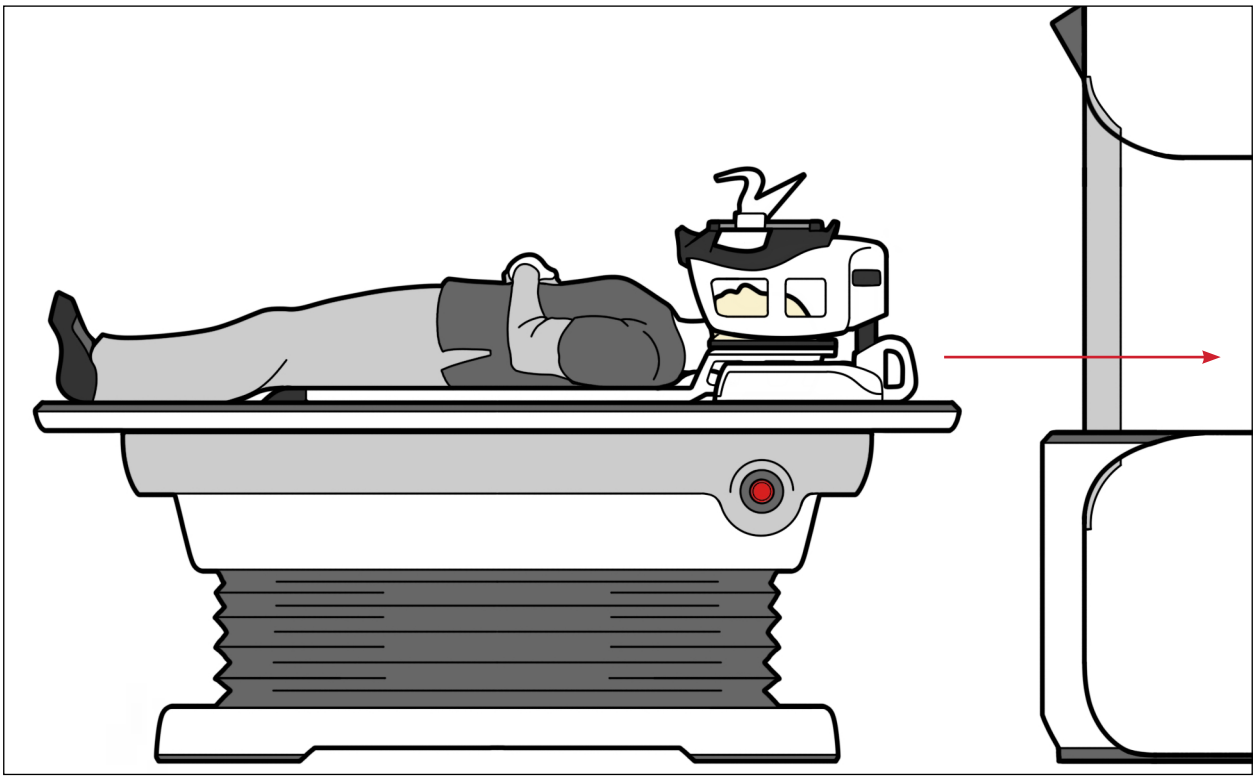


Figure 12

OPERATING INSTRUCTIONS

REMOVAL

1. After imaging is complete, remove the patient from the MR Bore (Fig. 13).

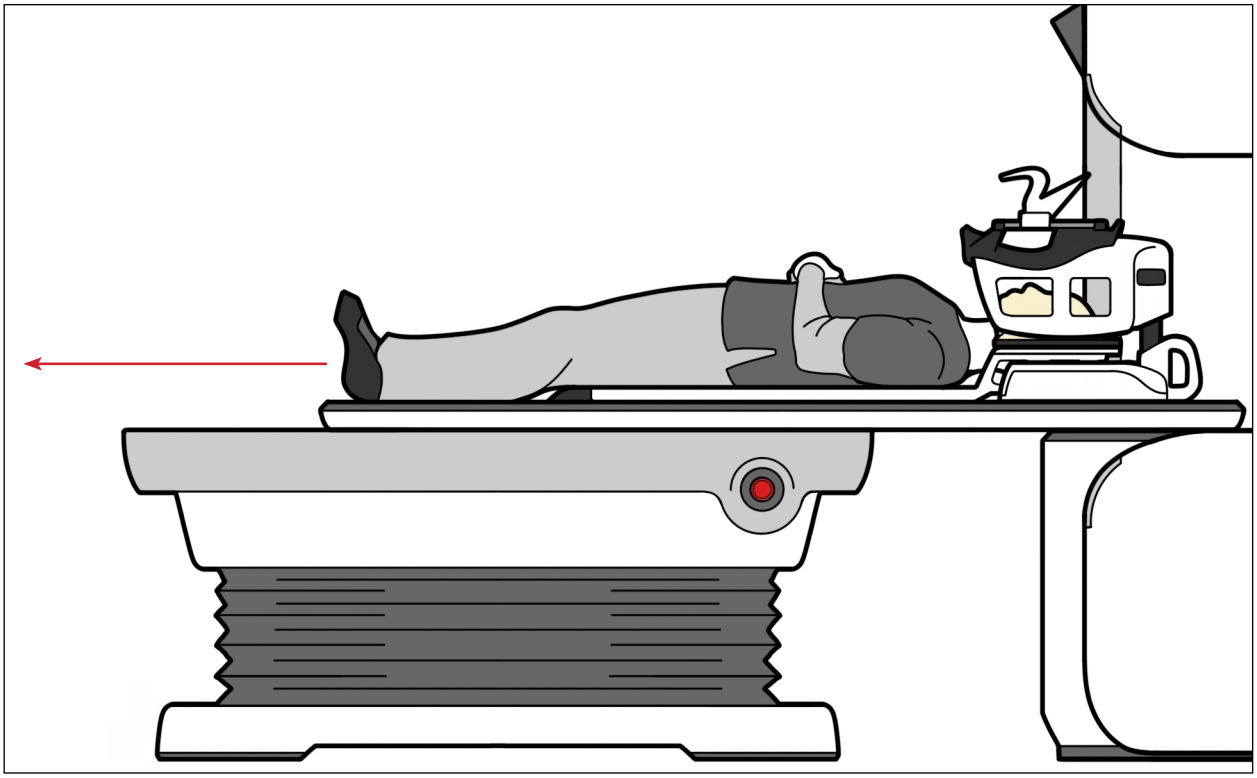


Figure 13

OPERATING INSTRUCTIONS

REMOVAL, CONTINUED

2. Press the Height Adjustment Button to lift the Top Coil away from the patient leaving the Top Coil attached to the Bottom Coil (Fig. 14 & 15).

Carefully raise the Top Coil avoiding patient contact.

! WARNING ! DO NOT DROP TOP COIL ONTO PATIENT.

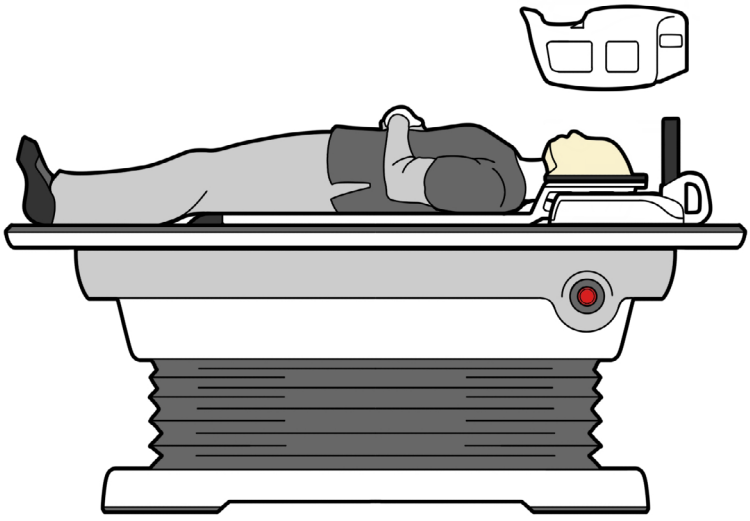


Figure 14

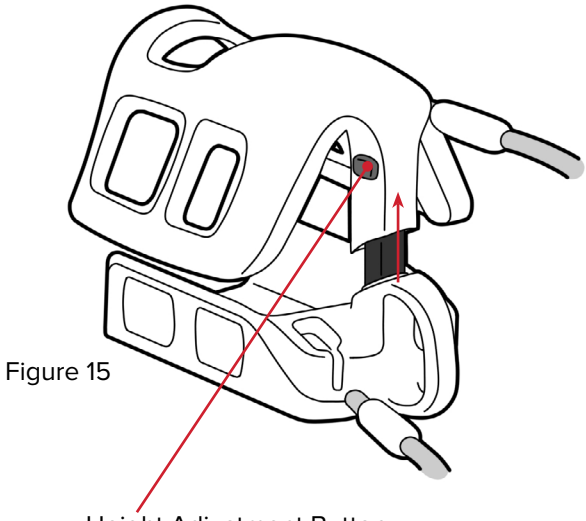


Figure 15

3. Remove thermoplastic mask from the patient (if applicable).
4. Remove patient from the Encompass™ Device.
5. Remove Encompass™ Device from the MR Table.
6. Install Top Coil onto Bottom Coil.

OPERATING INSTRUCTIONS

REMOVAL, CONTINUED

7. Unplug the two Coil Connectors from the MRI table Coil Slot and plug them into the storage receptacles on the bottom coil (Fig. 16). Remove the Encompass 15 Channel MRI Head Coil Device from the MR Table.

! NOTE ! DO NOT UNPLUG THE DEVICE BY PULLING ON THE CABLE. PULL OUT THE PLUG BY PULLING FROM THE RIGID PART OF THE CONNECTOR.

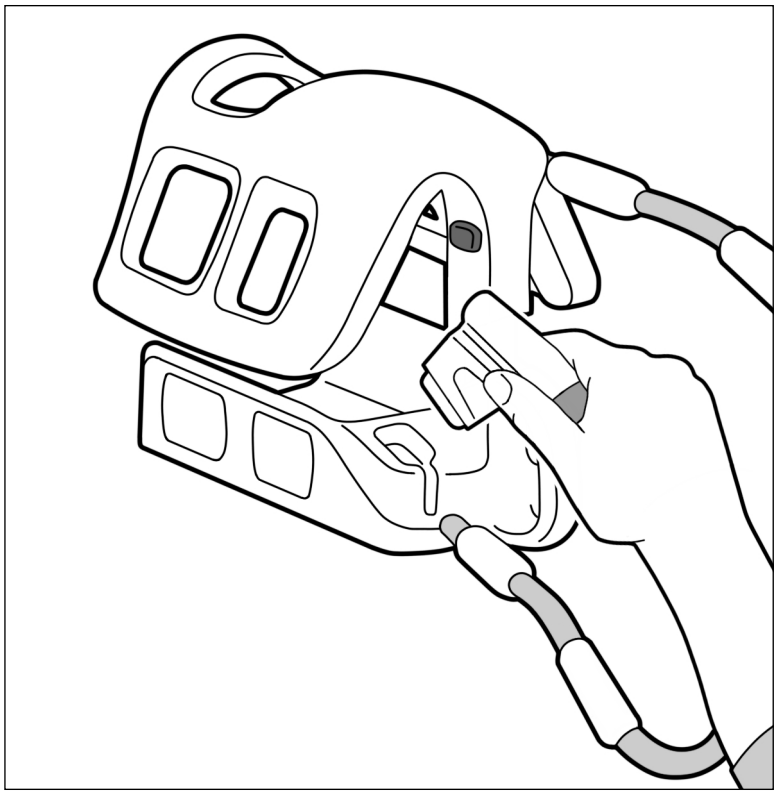


Figure 16

CLEANING, DISINFECTING, STORAGE, AND DISPOSAL

CLEANING THE SYSTEM

The Encompass 15 Channel MRI Head Coil Device can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. Coil must be cleaned in the normal operating orientation to avoid potential ingress of liquids and damage to coil. To clean, apply solution to clean cloth and wipe the surface.

! NOTE ! DO NOT SPILL OR SPRAY FLUIDS ON THE DEVICE, CLEAN ONLY WITH DAMP CLOTH, DO NOT USE RUNNING WATER FOR CLEANING.

DISINFECTING THE SYSTEM

In order to clean the Encompass 15-Channel Head Coil, follow the following steps at temperatures lower than 25°C.

Wet the surface of the device using a cloth moistened with Bacillol™ 30 Foam, wiping until visible soiling has been removed. Allow the Bacillol 30 foam to remain on the device for at least 30 seconds. Dry the device by wiping with a lint free cloth. Repeat until all visible soiling has been removed.

The following cleaning materials have also been tested and found to be appropriate for cleaning the device surface. Refer to specific instructions from the cleaning or disinfecting agent manufacturer.

- Water
- A 10% Clorox® Bleach Solution
- Isopropyl Alcohol
- Cidex® 2.4% Activated Dialdehyde Solution
- Soap and Water

⚠ **! WARNING ! REFER TO CENTER PROTOCOLS FOR REQUIRED DISINFECTION PROCEDURES WITH SOLUTIONS DESCRIBED ABOVE.**

⚠ **! WARNING ! TO PREVENT DESTRUCTION OF THE COILS, THE DEVICE MUST NOT BE CLEANED IN IMMERSION BATHS OR HELD UNDER RUNNING WATER.**

⚠ **DO NOT IMMERSE THE COIL IN WATER!**

⚠ **OBSERVE DISINFECTION INSTRUCTIONS!**

! NOTE ! IT IS RECOMMENDED TO DISINFECT THE SYSTEM AFTER EACH USE.

! NOTE ! ENSURE NO RESIDUE OF CLEANING OR DISINFECTING AGENTS ARE LEFT ON THE DEVICE AFTER CLEANING OR DISINFECTION.

CLEANING, DISINFECTING, STORAGE, AND DISPOSAL

STORAGE

After each use, the system must be disinfected as described above to eliminate any risk of infection.

The Encompass™ 15 Channel MRI Head Coil Device should be stored upright at all times with the top coil installed properly on top of the bottom coil. The two Coil Connectors should be plugged into the storage receptacles on the bottom coil.

Ensure storage location is stable with no risk of falling. Do not place other objects on top of device during storage. Do not lean other objects against device. Ensure device is safely stored to minimize any risk of jostling or impact during removal or placement of other objects or devices within the storage area.

It is recommended to store the device within the MR room.

⚠ **DEVICE SHOULD BE STORED UPRIGHT AT ALL TIMES WITH TOP COIL INSTALLED PROPERLY IN PLACE ON TOP OF BOTTOM COIL.**

DISPOSAL

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

The Encompass™ 15 Channel MRI Head Coil Device should be disposed of by returning the device to the manufacturer.

⚠ **! CAUTION ! DISPOSE OF DEVICE PROPERLY. FAILING TO DO SO COULD LEAD TO DAMAGE TO THE ENVIRONMENT.**

SPECIFICATIONS

DEVICE DATA

Manufacturer: NORAS MRI products GmbH Leibnizstrasse 4 97204 Hoechberg Germany	**Exclusive Distributor:** Qfix 440 Church Road Avondale, PA 19311 USA
Designation (Model/Type) Encompass 15 Channel MRI Head Coil Device	**Product Type / Device Type (according to UMDNS / DIMDI)** 17542
Product Class / Device Class IIa according the rule 10 section 6, part 6.2 to the Regulation MDR (EU) 2017/745 chapter III "classification rules" of annex VIII.	**Identification Number of Notified Body (CE-Marking)** 0123
Operator Type ☒ Active ☐ Non-Active	

PERFORMANCE DATA

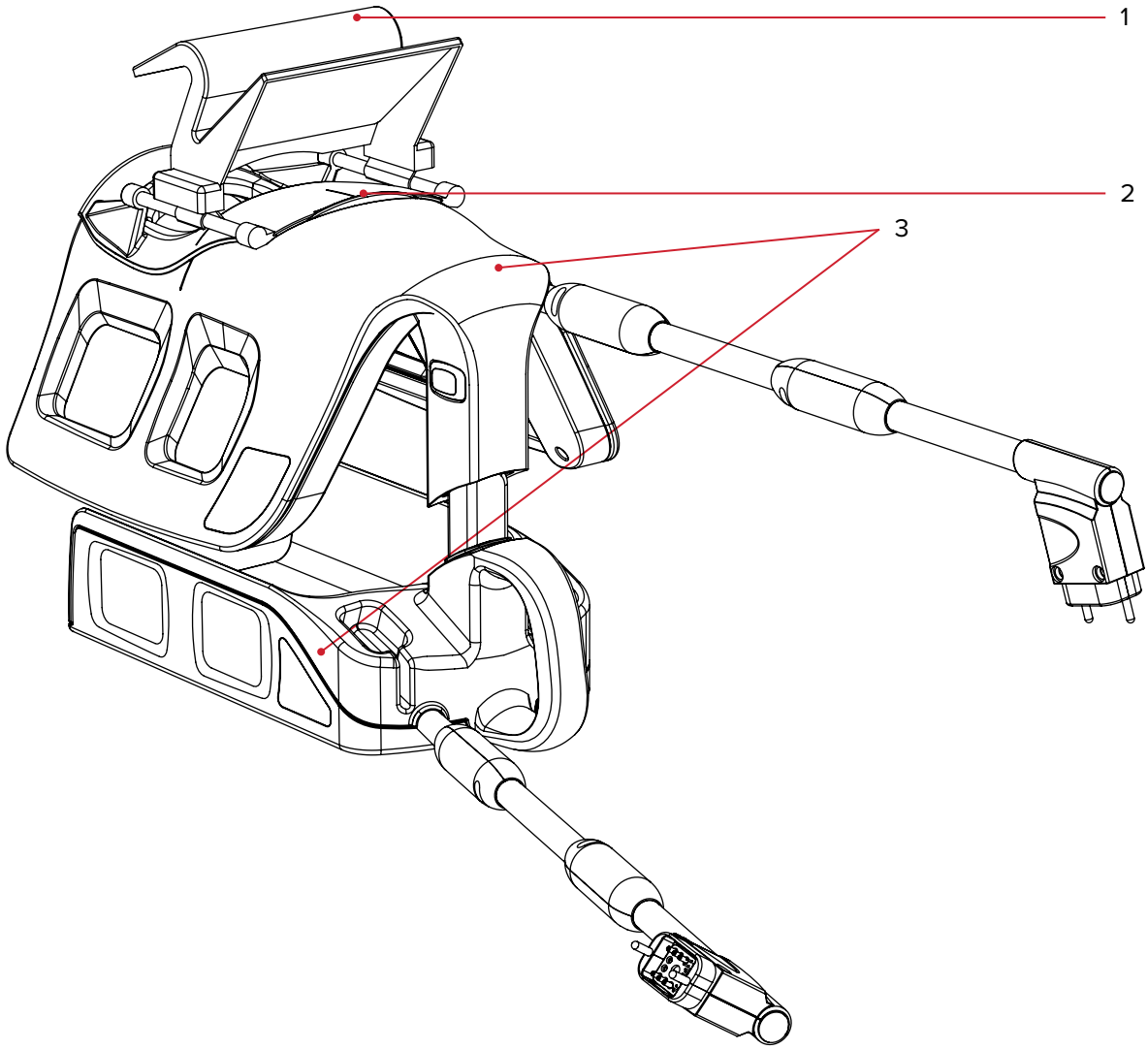
Operating Conditions	*Temperature* between +10°C (50°F) and 50°C (122°F) *Humidity* between 10% and 95% *Air pressure* between 500 hPa and 1060 hPa
Storage Conditions	*Temperature* between -20°C (-4°F) and 60°C (140°F) *Humidity* between 10% and 95% *Air pressure* between 500 hPa and 1060 hPa
IEC Protection Class	II type BF
Service Life	5 years I NOTE: Repeated use of operating elements (e.g. Plugging/ Unplugging the coil) will decrease the lifetime of the device.
Weight	4.7 kg (10.5 lbs)
Dimensions	*Width:* 350 mm *Height with Mirror attached:* 420 mm (Collapsed) *Height with Mirror attached:* 470 mm (Extended) *Depth:* 485 mm
Resonance Frequency	3T: 123.2 MHz I ± 500kHz
Interfaces	Electrical: SIEMENS® MRI with two TIM 3G or 4G receptacles available Mechanical: Qfix Encompass™ SRS Immobilization System
Maximum Operating Time of Coils	Continuous operation
Field of View (Maximal)	*Width:* approx. 310 mm *Height:* approx. 310 mm *Depth:* approx. 310 mm

SPECIFICATIONS

ELECTROMAGNETIC COMPATIBILITY INFORMATION

The MRI Coil is intended for use in the electromagnetic environment specified below. The customer or the user of the MRI Coil should assure that it is used in such an environment.			
Immunity Test	**Compliance Level**	**Electromagnetic Environment-Guidance**	**Results/Remarks**
Electrostatic Discharge (ESD) IEC 61000-4-2 Direct Contact	Contact ±8 kV Air ±15 kV	Use only within the shielded MRI cabinet.	pass
Electrostatic Discharge (ESD) IEC 61000-4-2 Indirect Contact	Contact ±8 kV Air ±15 kV	Use only within the shielded MRI cabinet.	pass
The MRI Coil must not be used outside the shielded environment. If the shield of the MRI room is compromised for any reason (for example door left open) decreased imaging performance has to be expected.			
Do not stack coils onto the patient!			
Using other cables or cable lenghts other than those specified when connecting the device to the mri scanner could lead to increase electromagnetic interference and could lead to burns of the patient or user. Do not use cables or components different from those stated compatable by the manufacture.			
Keep at least 30 cm distance from mobile HF communication devices. Ignoring this will lead to device failure due to electronic interference.			
Device is not intended for home use.			
Keep doors of MRI room shut during examination. Do not compromise the shield of the MRI room.			
Warning: Device may only be used in shielded environment.			
See the manufacturer's specification of the MRI room for its shielding specifications.			
See the manufacturer's specification of the MRI room for appropriate test methods to measure the HF filter attenuation.			
See the manufacturer's specification of the MRI room for allowed emissions from other devices that are also to be operated in the MRI room.			
The receive frequency of the MRI Coil is dependent on the MRI system static magnetic field strength: for 3.0 Tesla systems 123.2 MHz, ± 500kHz			

PARTS LIST



1. 10496700—Mirror_20, Detachable Double Mirror
   Optional component produced by Siemens. Contact Siemens for pricing and availability.
2. 8002812—Encompass MRI Head Coil, Mirror Holder
3. RT-5200-01—Encompass 15 Channel MRI Head Coil Device, **3T** (Top & Bottom Coils)

FUNCTIONAL TESTING

Before each use, all components of the Encompass™ 15 Channel MRI Head Coil must be visually inspected.

⚠ **! WARNING ! NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED. IF ANY PART OF THIS DEVICE EXPERIENCES A CATASTROPHIC LOAD, APPEARS DAMAGED OR FUNCTIONS IMPROPERLY, DISCONTINUE USE IMMEDIATELY AND CONTACT QFIX AT +1 800-526-5247 OR SALES@QFIX.COM.**

It is recommended that a single-channel coil test be performed each month using the specified MRI test program.

! NOTE! If coil malfunctions are suspected, the operator may perform the qualitative functional test described below.

The Siemens 5300 mL phantom bottle (Fig. 17) and the Siemens Phantom Holder 29* (Fig. 18) is recommended for use during functional testing of the Encompass™ 15 Channel MRI Head Coil.

Figure 17: Siemens 5300 mL Phantom Bottle (P/N: 10606530 K2305)

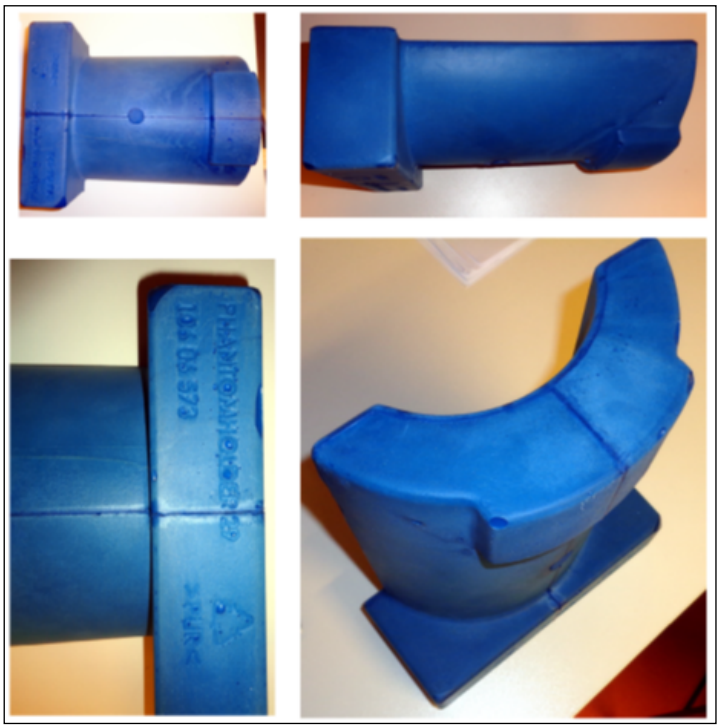


Figure 18: Siemens Phantomholder 29 (Siemens P/N: 106060573)

**For optimal positioning of the Phantom, the Siemens "Phantom Holder 29" should be used (Fig. 18).*

Refer to instructions for QA phantoms and take appropriate precautions during use.

FUNCTIONAL TESTING

Place the phantom holder into the bottom coil (Fig 19 & 20).

Place the Siemens 5300 mL bottle on top of the phantom holder and place it at the end of the coil until it mechanically touches the coil wall at the head-end.

Ensure the bottle is positioned in the center of the openings between Top and Bottom coils (Fig. 19 & 20).

Connect the coil to the MRI scanner (Fig. 21). The scanner display located directly above the bore will recognize the coil provided the coil files are installed and the spine coil is removed.

Figure 19: Phantom bottle positioning inside the coils

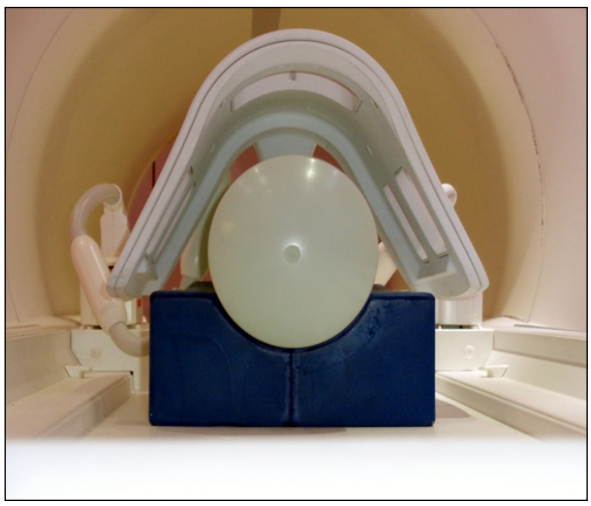


Figure 20: Phantom bottle positioning between the coils

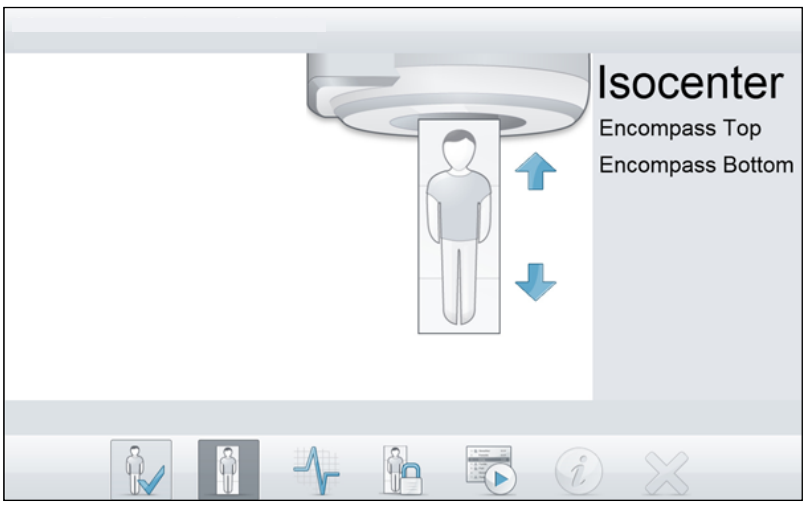


Figure 21: MRI Display located directly above the bore with plugged coils

FUNCTIONAL TESTING

To prepare for measurement, first align the laser sight on the lines and then move the coil into the Isocenter.

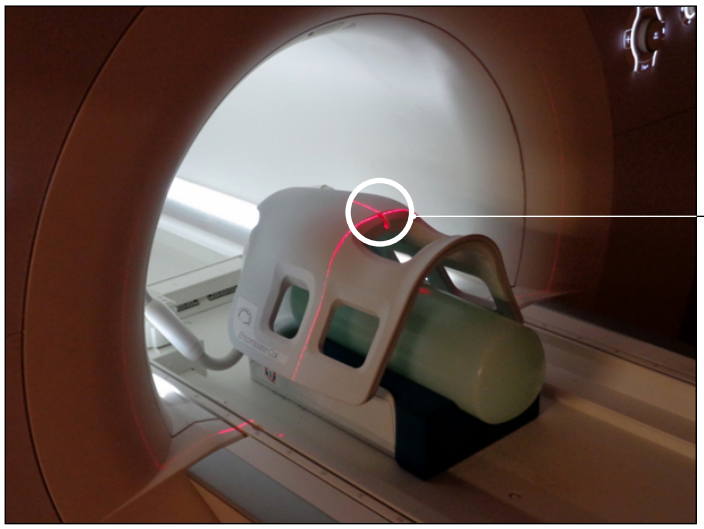


Figure 22: Aligning the laser sight on the coils

The following measurements may be performed for both coil halves simultaneously (top and bottom).

Take a normal localizer sequence measurement and then position the slice of a standard Siemens “sn“ sequence transversal centered through the bottle. This sequence may be found under:

\\Siemens\SequenceRegion\SiemensSequences\DefaultProtocols\sn

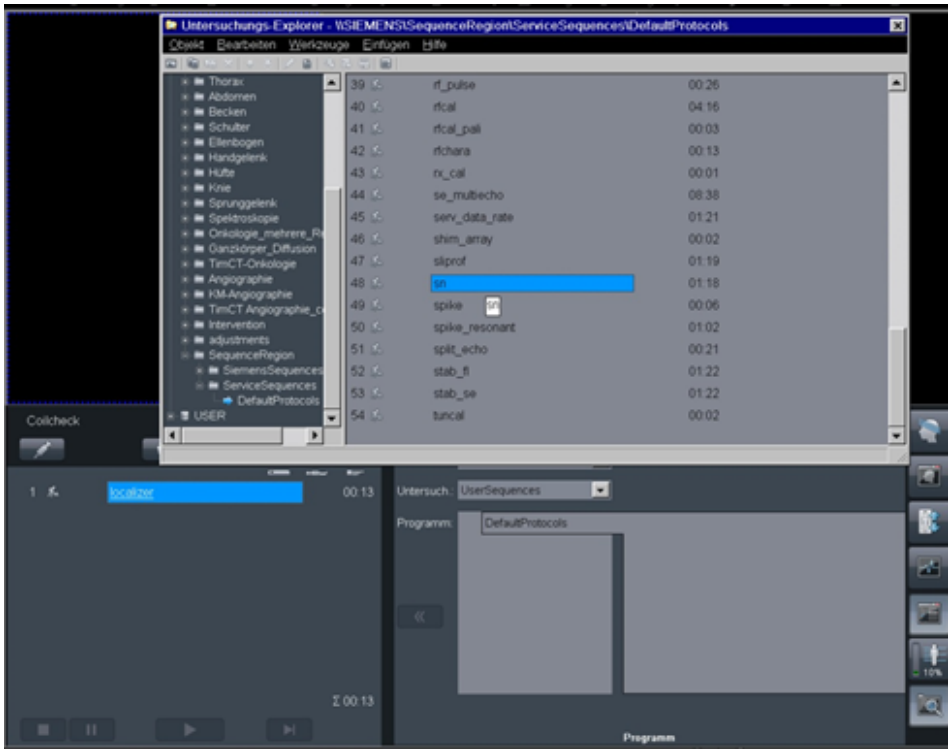


Figure 23

FUNCTIONAL TESTING

Select the function “save uncombined“.

Figure 24: Save uncombined to reconstruct single-channel images

FUNCTIONAL TESTING

Select the following Coil Options for the Coil Elements:

Then make the following final sequence adjustments:

- Field of view (FoV) = 200 mm
- Transversal slice through the middle of the bottles as shown above on the localizer scan. *H-F offset must remain on 0*.

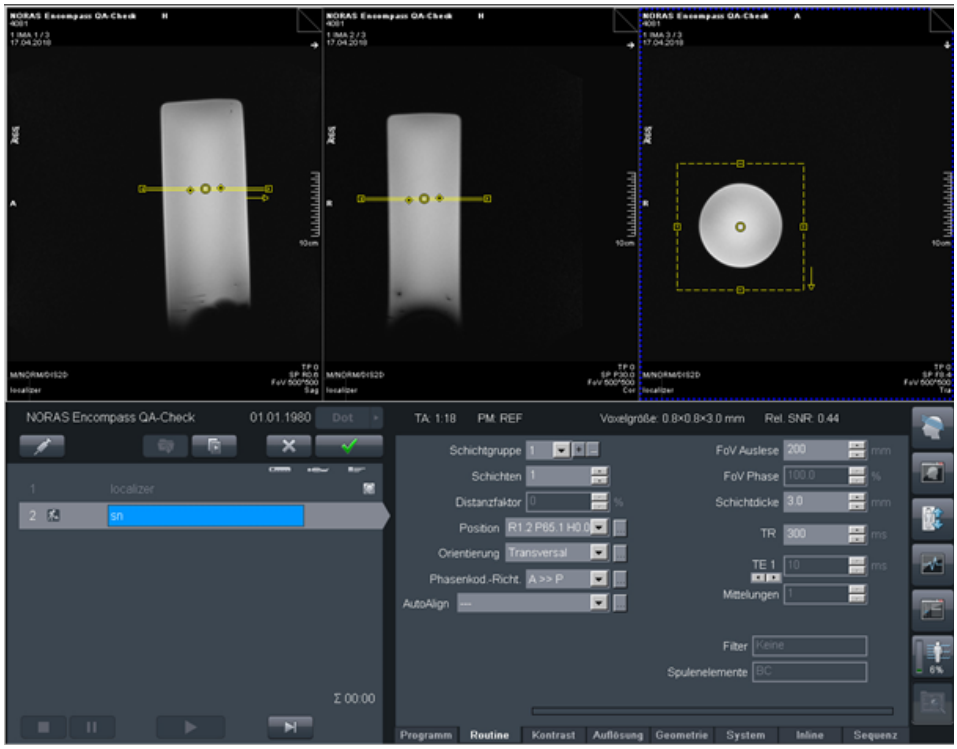


Figure 25

FUNCTIONAL TESTING

Select the coil elements in the coil options:

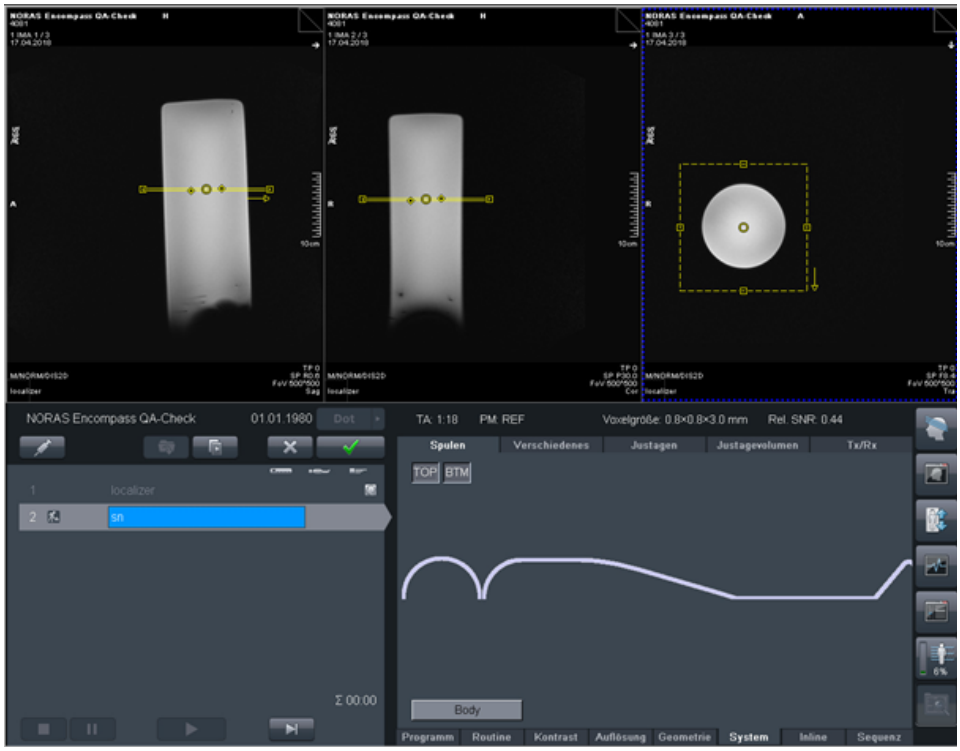


Figure 26

Coil selection: Select the “TOP” as well as the “BTM” button, activating both coil halves plus all 15 coil channels, per two receive groups (Menu: System, Subitem: Coils).

FUNCTIONAL TESTING

Select “save uncombined” in the “System” Menu > Miscellaneous thereby reconstructing single channel images of all 15 channels.

Begin the measurement.

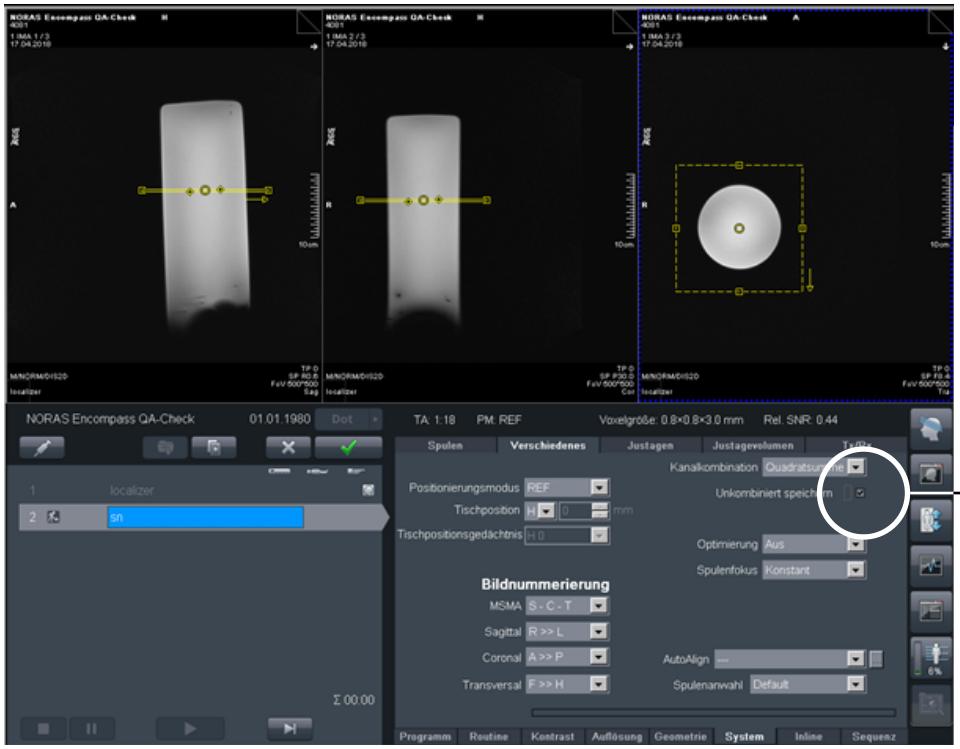


Figure 27

FUNCTIONAL TESTING

The single channel images should appear in the viewer similarly to the 4 x 4 window layout (Fig. 28):

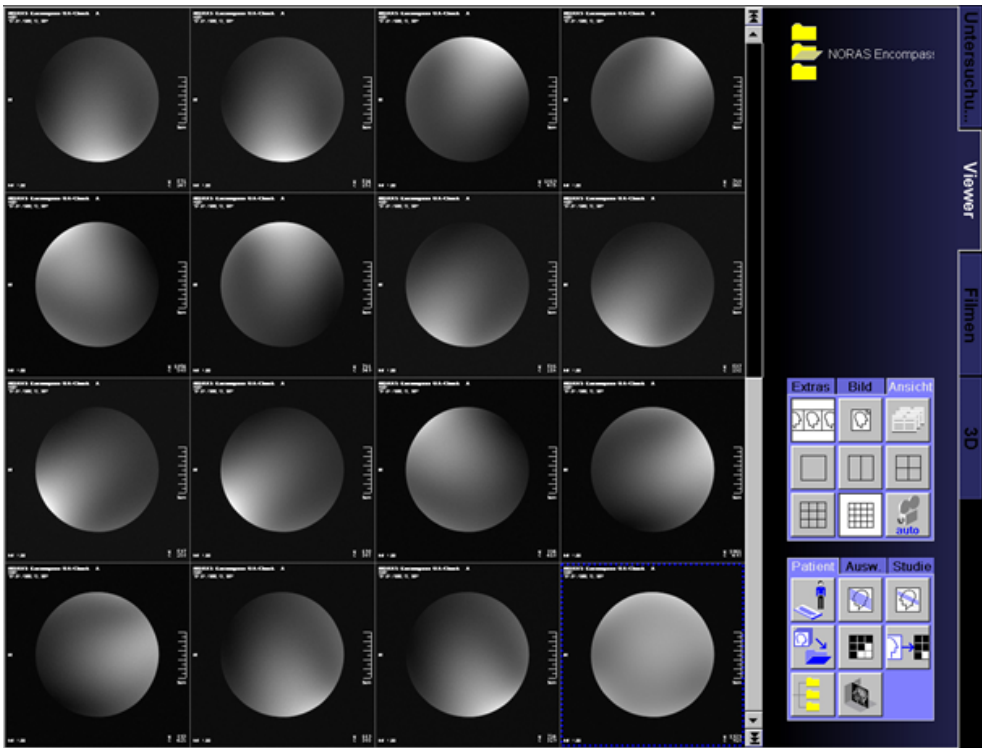


Figure 28

The illustration indicates all 15 channels are producing a good quality, artifact-free signal. The image on the bottom right is the combined signal from all 15 channels (standard diagnostic image typically displayed).

If the images produced during measurement appear significantly different from Figure 28 (e.g. the image contains banding or one channel indicates a weaker signal), a coil may be defective. Contact the manufacturer of the coil or the MRI if issues persist.

INCIDENT REPORTING

WHAT IS AN INCIDENT

Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to **the death of a patient, or USER or of other persons** or to a **serious deterioration in their state of health.**

WHEN TO REPORT

Upon becoming aware that an event has occurred with this device or the device may have caused or contributed to that event, the user should determine whether it is an INCIDENT.

TO WHOM TO REPORT

In general, the report should be made to the National Competent Authority in the country of occurrence of the INCIDENT and the manufacturer NORAS MRI products GmbH (contact details see page 2).

NORAS MRI products

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