

Operator's Manual



16ch T/R Hand Wrist Coil for GE 1.5T and 3.0T MRI Systems



Model Number:

GE	QED
5768098-2 (1.5T) / 5561531-2 (3.0T)	Q7000180 (1.5T) / Q7000152 (3.0T)

Warranty and Liability

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product. The warranty does not cover the following items, even during the warranty period:

- Damage or loss due to misuse or abuse.
- Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
- Damage or loss caused by failure to meet the specified conditions for this equipment, such as inadequate power supply, improper installation, or unacceptable environmental conditions.
- Damage due to changes or modifications made to the product.

In no event shall QED be liable for the following:

- Damage loss or problems caused by relocation, modification, or repair performed by personnel not explicitly authorized by QED.
- Damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operation manual.

Transportation and Storage Conditions

NOTICE: THIS EQUIPMENT SHALL BE TRANSPORTED AND STORED UNDER THE FOLLOWING CONDITIONS:

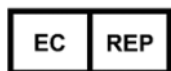
1. Ambient temperature range of -40°C to +70°C
2. Relative humidity range of 10% to 100%
3. Atmospheric pressure range of 50 kPa to 106 kPa

Medical Device Directive

This product conforms to the requirements of council directive 93/42/EEC concerning medical devices when it bears the following CE mark of conformity:



Authorized Representative in Europe:



Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

United States Federal Law

Caution: Federal law restricts this device to sale, distribution, and use by or on the order of a physician. The device is limited by Federal Law to investigational use for indications not in the Indications Statement.

Issue Date: January 2018

Introduction

This manual contains detailed information on the safety precautions, use and care of the 1.5T 16ch T/R Hand Wrist Coil (5768098-2) and 3.0T 16ch T/R Hand Wrist Coil (5561531-2). For safety and accuracy in using the product, read this manual as well as the MRI system operation manual carefully prior to operation of the product. This manual does not include instructions or safety information on equipment not provided by QED. Please consult the original equipment manufacturer for information regarding non-QED equipment.

Compatibility

The 1.5T 16ch T/R Hand Wrist Coil is compatible with GE 1.5T MRI Systems and 3T 16ch T/R Hand Wrist Coil is compatible with GE 3.0T MRI Systems.

User Profile

Operator – Radiological technologists, laboratory technologists, physicians (note, however, that all applicable laws in the relevant country must be followed).

User training – No special training is required to use this coil (however, GE provides a comprehensive training course for MRI systems in order to instruct operators on the correct use of MRI systems).

Patient Information

Age, health, condition – No special limitations

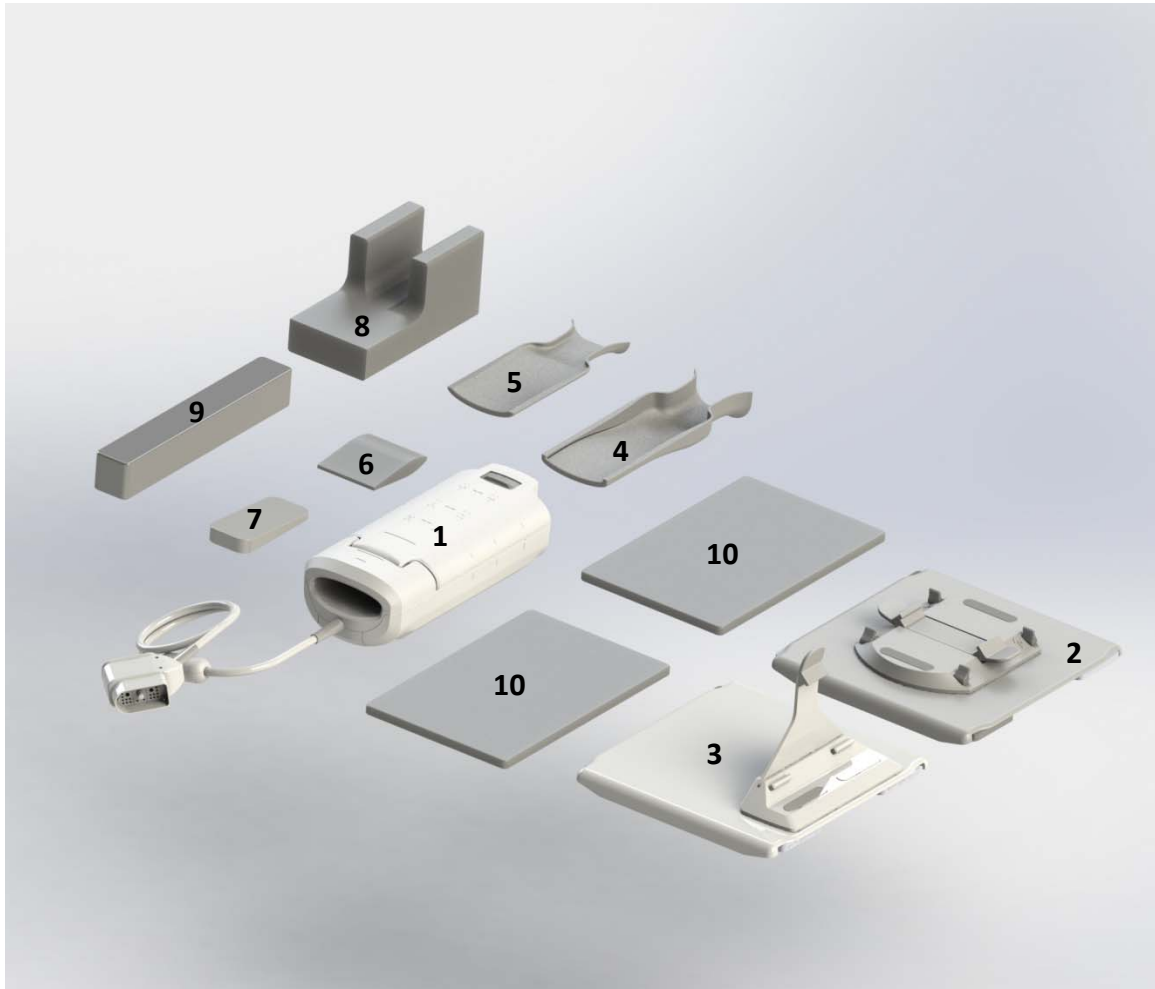
Weight – 550 lbs. or less (consult the operation manual for the MRI system, and if the maximum allowable patient's weight for the system is lower than that for this coil, priority must be given to the maximum weight for the system).

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Chapter 1 – 16ch T/R Hand Wrist Coil Components

The 16ch T/R Hand Wrist Coil is shipped with the parts shown below. Upon receipt, please ensure that all parts are included in the shipment.



Item #	Description	Qty	GE Part #	QED Part #
1	16ch T/R Hand Wrist Coil	1	5768098-2 (1.5T) / 5561531-2 (3.0T)	Q7000180 (1.5T) / Q7000152 (3.0T)
2	16ch T/R Hand Wrist Coil – Horizontal Baseplate	1	5561531-4	2001768
3	16ch T/R Hand Wrist Coil – Side-mount Baseplate	1	5561531-5	2001769
4	16ch T/R Hand Wrist Coil – Posterior Liner Pad	1	5561531-6	3004567
5	16ch T/R Hand Wrist Coil – Anterior Liner/Phantom Position Pad	1	5561531-7	3004566
6	16ch T/R Hand Wrist Coil – Palm Pad	1	5561531-15	3004964
7	16ch T/R Hand Wrist Coil – Wedge Pad	1	5561531-8	3004751
8	16ch T/R Hand Wrist Coil – Elbow/Arm Pad	1	5561531-9	3004607
9	16ch T/R Hand Wrist Coil – Wrist Coil Filler Pad	1	5561531-10	3004716
10	16ch T/R Hand Wrist Coil – Side-mount Base Pad	2	5561531-11	3004612

Coil weight: 3.9kg (8.5lb)














Chapter 2 – Safety





This section describes the general precautions and safety information that must be observed when this coil is used.



When using the MRI system, also refer to the contraindications, precautions, and other safety information described in the operation manual for the MRI system.

Symbols

Symbol	Number	Standard	Title, Meaning
	0434A	ISO 7000 IEC 60417	Caution, caution is necessary when operating the device and/or the situation described needs operator awareness or operator action in order to avoid undesirable consequences
	1641	ISO 7000 IEC 60417	Operator's manual, Consult operating instructions before operating the device
 eIFU indicator	5.4.3	ISO 15223-1	Operator's manual, Consult electronic operating instructions before operating the device
	5172	ISO 7000 IEC 60417	Class II equipment
	5333	ISO 7000 IEC 60417	Type BF applied part
	3082	ISO 7000 IEC 60417	Manufacturer
	2497	ISO 7000 IEC 60417	Date of Manufacture
	6192	ISO 7000 IEC 60417	RF Coil, Transmit and Receive
	5.1.2	ISO 15223-1	Authorized Representative in EU
	2493	ISO 7000 IEC 60417	Catalog Number
	2498	ISO 7000 IEC 60417	Serial Number
	N/A	N/A	ETL Listed (Canada & USA)
	0632	ISO 7000 IEC 60417	Temperature limit

Symbol	Number	Standard	Title, Meaning
	2620	ISO 7000 IEC 60417	Humidity limitation
	2621	ISO 7000 IEC 60417	Atmospheric pressure limitation
	W017	ISO 24409-2 ISO 8528-13	Warning; Hot surface
	N/A	EN50419 EU2012/18/EU	The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information concerning the return and recycling of this product, please consult the supplier from whom you purchased the product.

Indications

The 1.5T 16ch T/R Hand Wrist Coil is intended for use with GE 1.5T MR systems and 3.0T 16ch T/R Hand Wrist Coil is intended for use with GE 3.0T MR systems, to produce diagnostic images of the hand and or wrist that can be interpreted by a trained physician.

Contraindications

None.

Precautions



Patients with increased likelihood of seizures or claustrophobia



Patients who are unconscious, heavily sedated, or in a confused mental state



Patients with an inability to maintain reliable communications (for example, infants or young children)










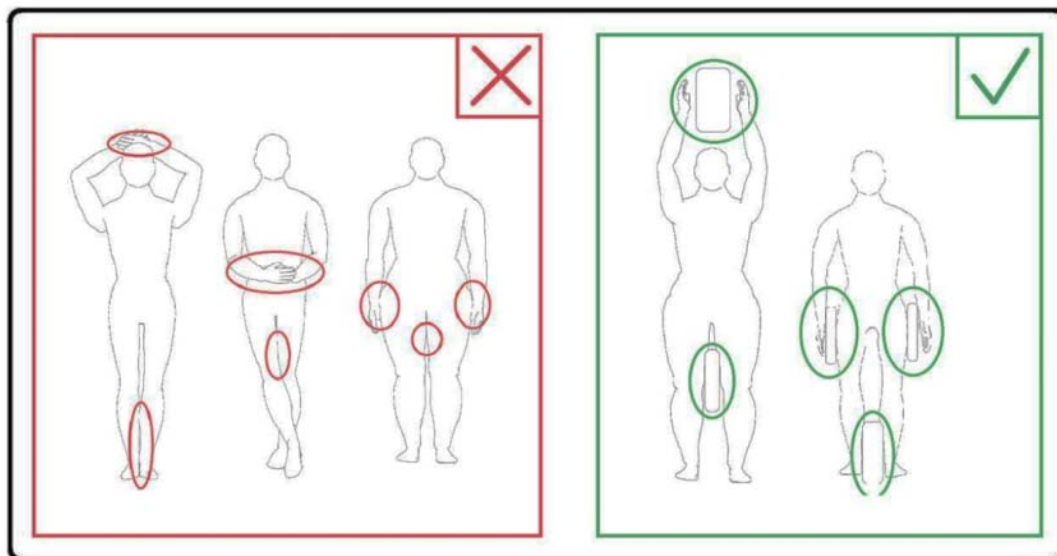
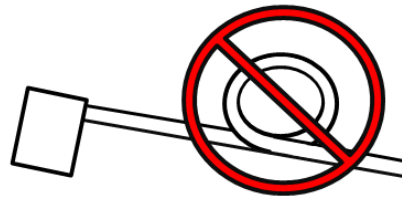
Patients with loss of feeling in any body part






Patients who have difficulty regulating their body temperature or who are particularly sensitive to increases in body temperature (for example, patients with fever, cardiac failure, or impaired perspiration)

Cautions – RF Coil

-  Do not place any disconnected devices (RF coils, cables, etc.) in the gantry during scanning.
-  Connect only the designated RF coils to the RF coil connection port.
-  Do not use a defective RF coil, especially if the outer covering has been damaged or if metal parts are exposed.
-  Do not attempt to change or modify the coil.
-  Do not cross or loop coil cables.
-  Ensure that the patient does not come into direct contact with the coil cables.
-  Do not allow the patient to form a loop with any body parts. Use pads to ensure that the patient's hands and legs do not touch the coil, MRI system, patient table, or another body part that may form a loop.



-  Do not allow the patient or RF coil to touch any part of the MRI system. Use pads to separate the patient from the bore, if necessary.
-  Stop the scan immediately if the patient complains of warming, tingling, stinging, or similar sensations. Contact a physician before continuing with the scan.
-  Ensure that the coil does not come into contact with liquids, such as water or medications.



If a coil is found to be defective, stop using the coil immediately and contact your GE representative.



Use only the accessories described in this manual with the coil.

Emergency Procedures

In case of an emergency during the scan, stop the scan immediately, remove the patient from the room, and obtain medical assistance, if necessary.

Chapter 3 – TR Port Location

TR Port Location

The 16ch T/R Hand Wrist Coil is a Transmit and Receive coil. To properly use the coil, ensure the system interface connector is connected to P-port on the system. Consult the system user manual to locate the port that supports both transmit and receive (P1 on 60 cm or 70 cm curved or detachable tables and P2 on 70cm fixed table systems).

Chapter 4 – Quality Assurance

Scanner Verification

Perform system level Signal to Noise (SNR) Test. Refer to Service Methods CD; System Level Procedures; Functional Checks; Signal to Noise (SNR) Test.

Signal to Noise Ratio (SNR) Test

Tools/Fixtures Required

Description	GE Part #	QED Part #	Qty
1.5T Unified Cubical Phantom	5342681	N/A	1
16ch T/R Hand Wrist Coil –Horizontal Baseplate	5561531-4	2001768	1
16ch T/R Hand Wrist Coil – Anterior Liner/Phantom Position Pad	5561531-7	3004566	1

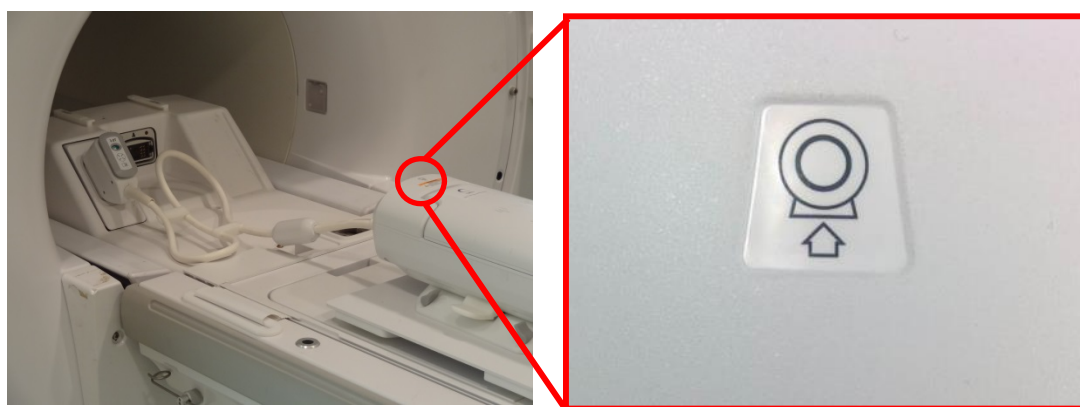
Coil and Phantom Setup

1. Record the serial number of the coil(s) being used, as well as software build version (from testrecord or getver).
2. Remove any other surface coils (if present) from the cradle.

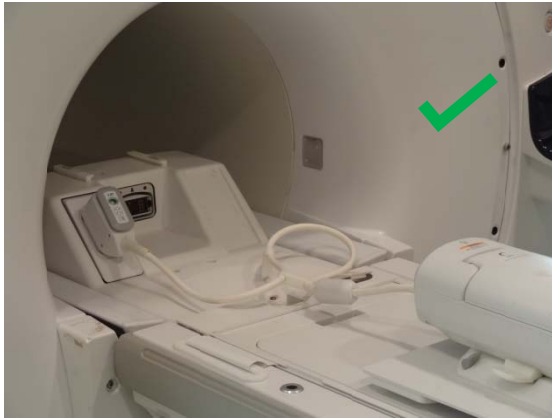
3. Transport the coil to the patient cradle. Be sure to carry the coil with both hands by the handle on the base.



4. Place the coil onto the patient cradle. Note that the bore direction arrow pictured below should be pointing **towards** the bore.



5. To avoid loops, route any excess cable using the cable routing clips attached to the system cable as shown below.

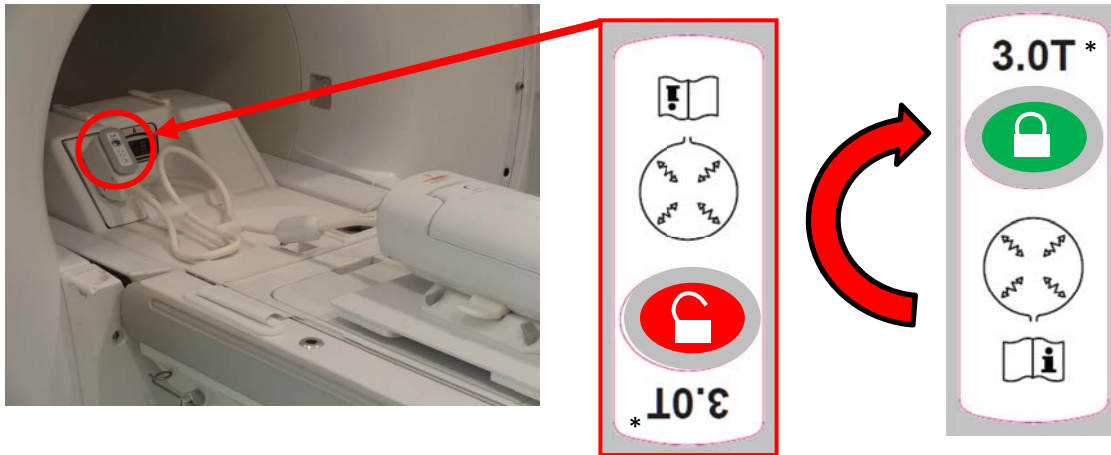


Do not cross or loop coil cables.



Ensure that patient does not come into direct contact with the coil cables.

6. Connect the coil connector to the appropriate Transmit Port of the system (P1 on 60 cm or 70 cm curved or detachable tables and P2 on 70cm fixed table systems). Turn the end of the P-Port connector around such that it exhibits the LOCKED position, see picture on right.

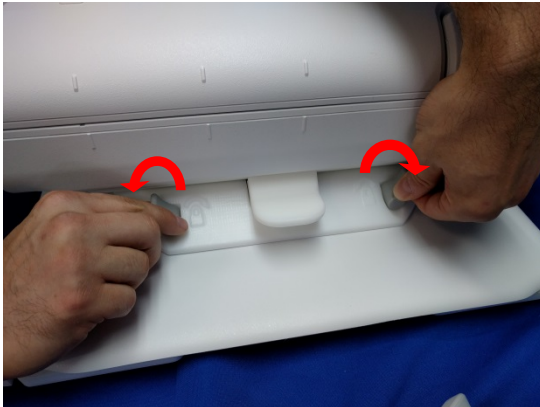


*: For reference only, applies to both 1.5T and 3.0T

7. Landmark the coil at the center landmark (hand/wrist mode) as shown below. If coil adjustment is required, rotate knobs into unlocked position, as shown below, to achieve desired alignment. Turn the knob again to the lock position to secure the coil in place once the coil has reached the desired position.



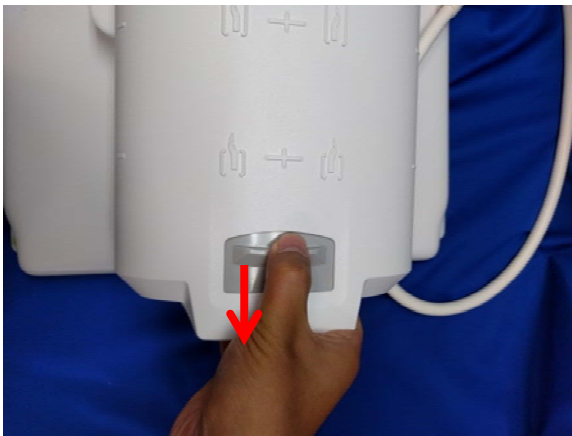
Unlock



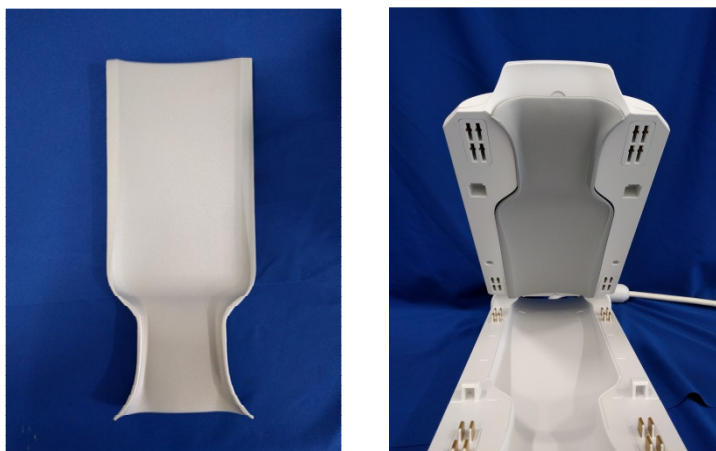
Lock



8. Open the coil by sliding the latch forward and pulling up on the anterior.



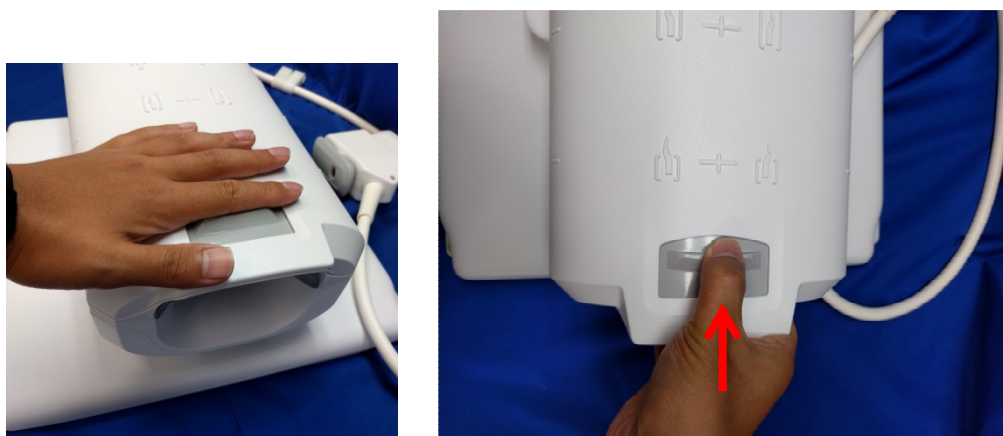
9. Place Anterior Liner Pad (3004566) on anterior of coil.



10. Place the Unified Cubical Phantom (5342681) into the coil as shown below. **Ensure the bottom edge of phantom aligns with FOV markings on the coil.**

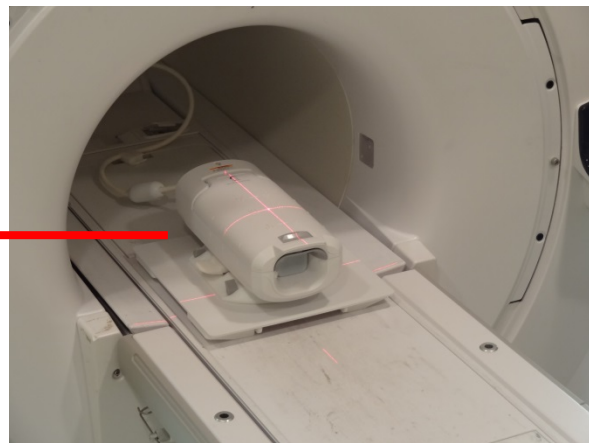
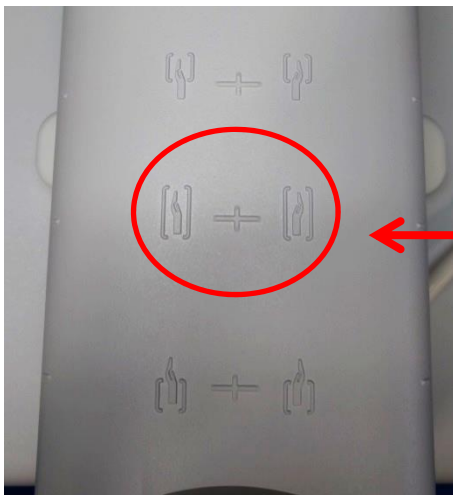


11. Close the coil, ensuring that the anterior latch release clicks into place.





12. Re-confirm the landmark the coil at the center-most landmarks shown below and move coil to isocenter.



Multi-Coil Quality Assurance (MCQA) Tool

All RF coil related tests must be run on a system that is well calibrated. EPIWP (White Pixel from install in spec) shall pass.

Test ID	Parameter Description	Expected Result
1	EPIWP in spec	PASS

To initiate MCQA:

1. From Common Service Desktop (CSD), go to Service Browser and select [Image Quality] “Multi-Coil QA Tool” and then “Click here to start this tool” as shown in Figure 1.

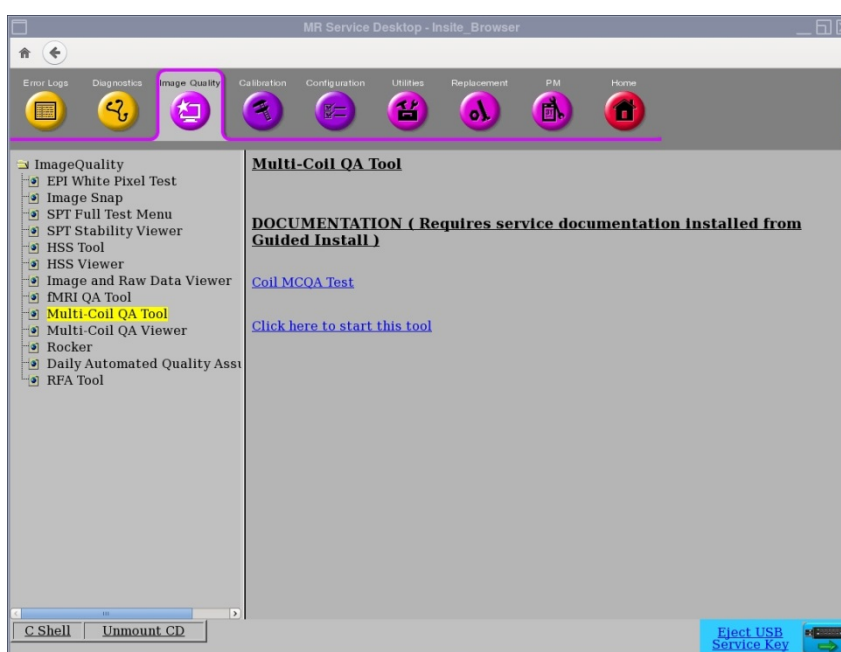


Figure 1

Note: If a “No valid MCR-V (or MCR2/3)” warning (Figure 2) pops up select [Yes] and proceed with test. MCR-V diagnostics must be run before turning over system to customer.

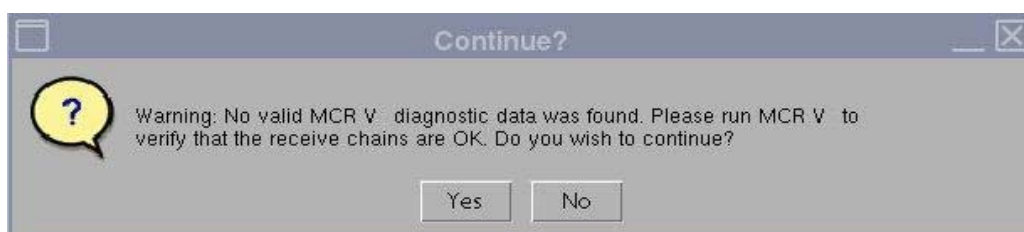


Figure 2

The current coil field will be automatically filled in (Figure 3), based on the CoiID of the coil connected to the LPCA. Enter the serial number of the coil being tested in the Coil Serial number field.

2. Click on **[Start]** to begin the automated test as shown in Figure 3. Depending on the number of test locations (complexity of the coil) the test may take from 3 to 5 minutes.

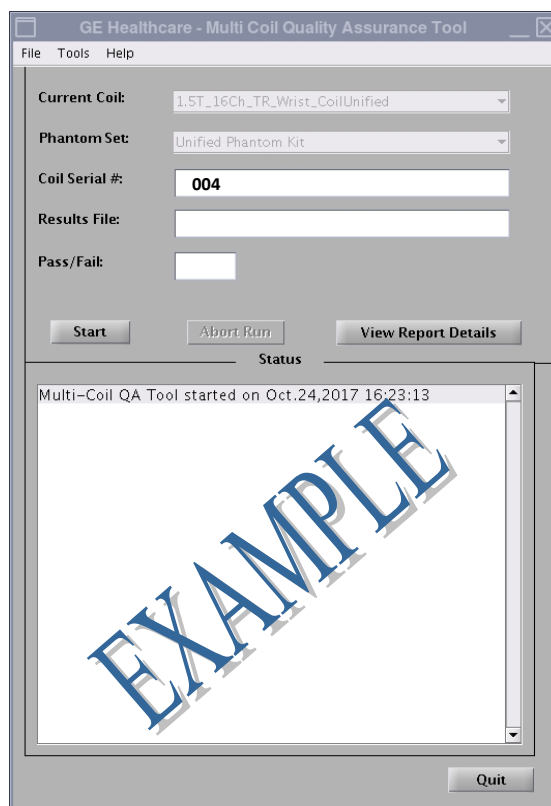


Figure 3

3. Upon start-up, a Note stating, “Phantom placement and coil landmarking are critical for repeatable results” will appear. If the landmark has been set correctly and there are no air bubbles in the phantom, click **[Yes]** to continue. (Figure 4).

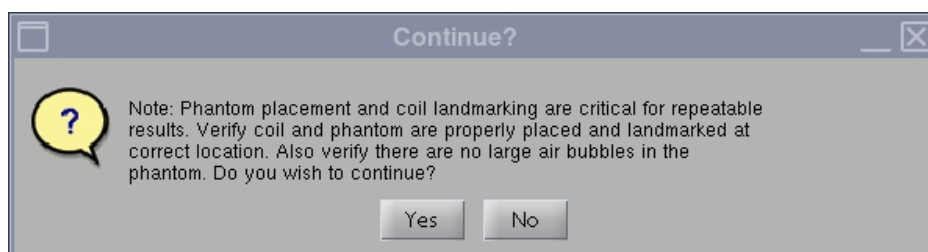


Figure 4

Note: The Status window of the MCQA Tool GUI will continuously update to give information on what the tool is doing at any point in time. A time bar (Figure 5) will appear, showing approximate total test time, elapsed time and percent complete.

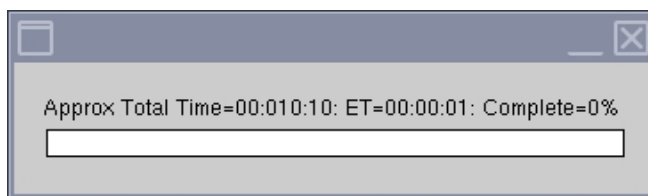


Figure 5

When the test is complete, test results display on the screen (Figure 6). The PASS/FAIL status shows PASS if all coil elements are functioning properly. The MCQA Tool GUI displays “Fail” for one of the following possible reasons but not limited to:

- Bad Coil Element
- Incorrect phantom used for the test (Unified Cubical Phantom 5342681 should be used)
- Incorrect positioning/placement of the phantom

More information on the MCQA test can be found on the MR service methods DVD or website via the path: Troubleshooting -> System -> Multi-Coil Quality Assurance Tool

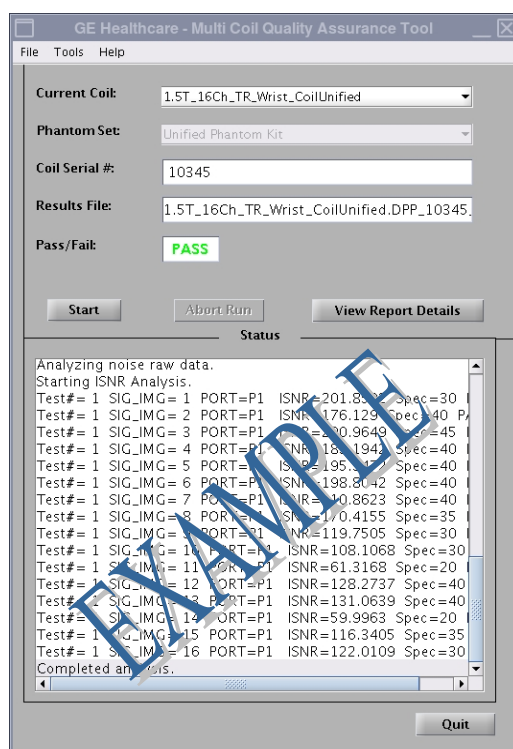


Figure 6

4. Click on **[Quit]** button to exit MCQA Tool.

Using MCQA Viewer

In case if the results are to be viewed at a later stage follow the below steps:

1. In the MCQA Tool window select File, Open Results File and select the desired coil results file select [View Report Details] to review the results.

Note: The Results Viewer will open as shown in Figure 7. The Results file name and Pass/Fail Results shown on the tool GUI will also be listed across the top of the viewer.

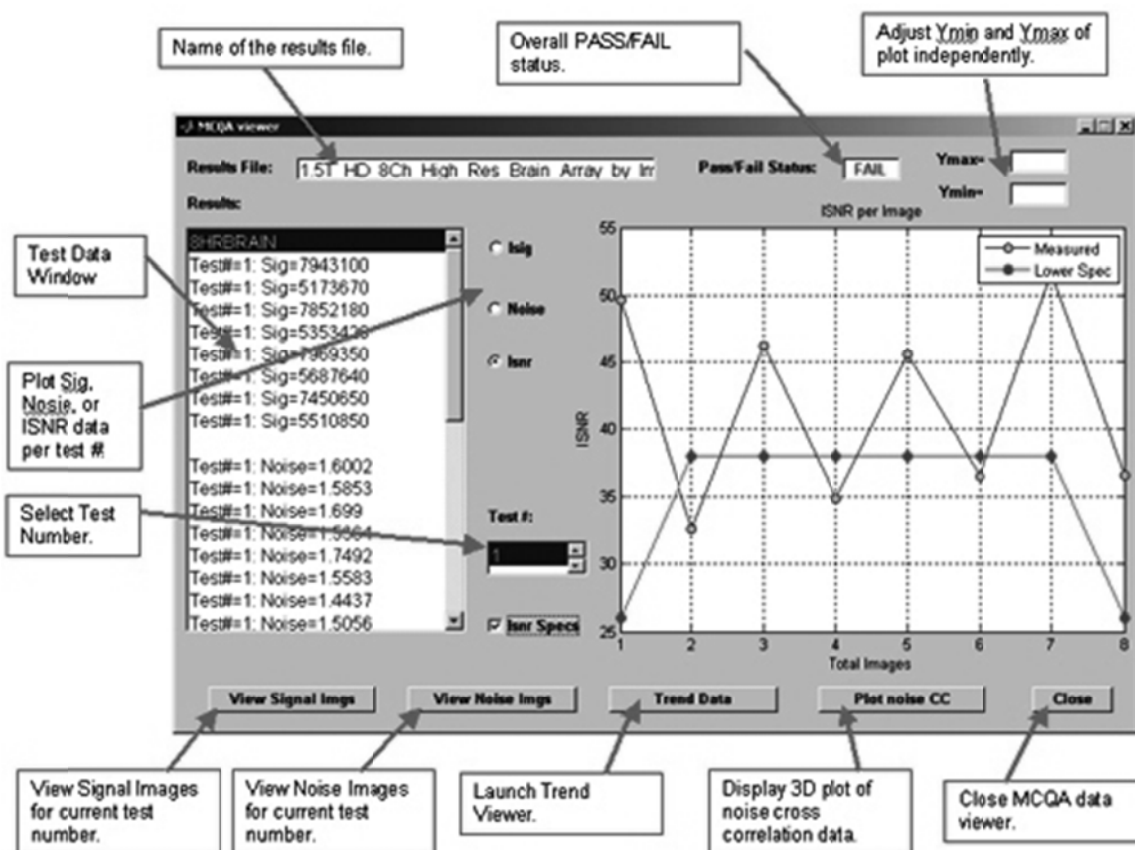


Figure 7

2. Select the ISNR option and the ISNR Specs check box in the middle portion of the Results Viewer to view the results.

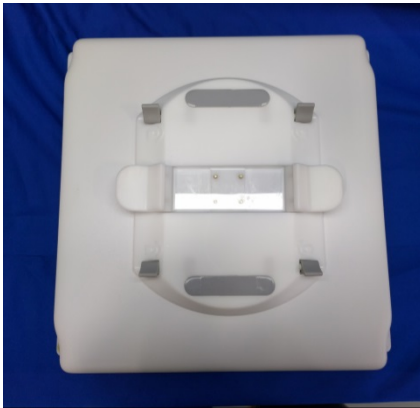
Test ID	Parameter Description	Expected Result
1	EPIWP in spec	PASS

Chapter 5 – Coil Setup and Use

Determine Scan Position

The 16ch T/R Hand Wrist Coil is equipped with two bases, designed to image the patient either at the patient's side (vertical base) or over the patient's head (horizontal base). Determine optimal scan position based on patient size, comfort, and scan preference.

Horizontal Base



Vertical Base



To switch bases, while holding the coil, firmly push on the coil release lever, shown on the respective bases below:

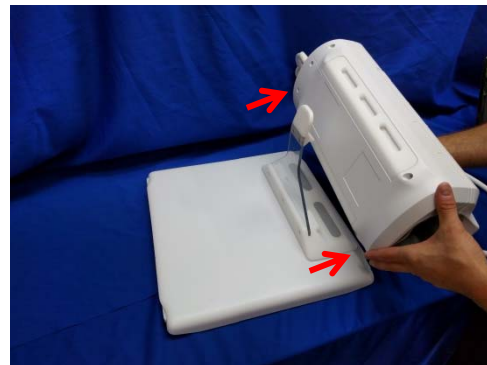


Note: Do not switch bases while the patient is in the coil.

Horizontal Base



Vertical Base

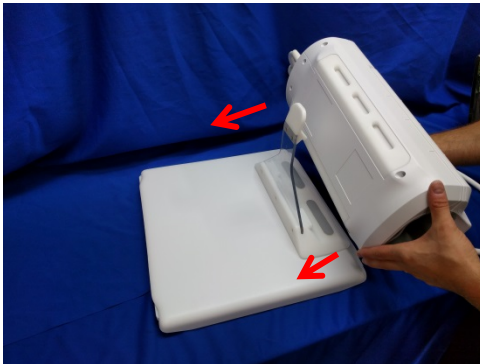


Then, install on desired base by aligning and locking coil into base, as shown below.

Horizontal Base



Vertical Base

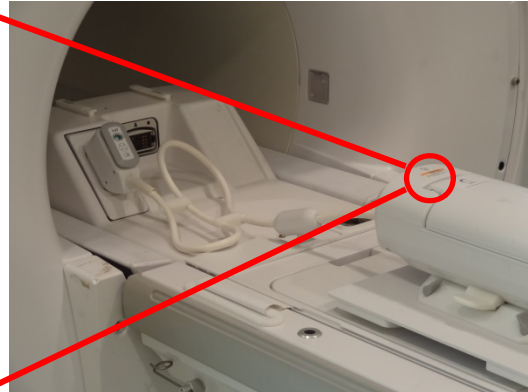


Positioning the 16ch T/R Hand Wrist Coil: Horizontal Base







1. Remove any other surface coils (if present) from the patient cradle.
2. Transport the coil to the patient cradle. Be sure to carry the coil with both hands by the handles on the base.



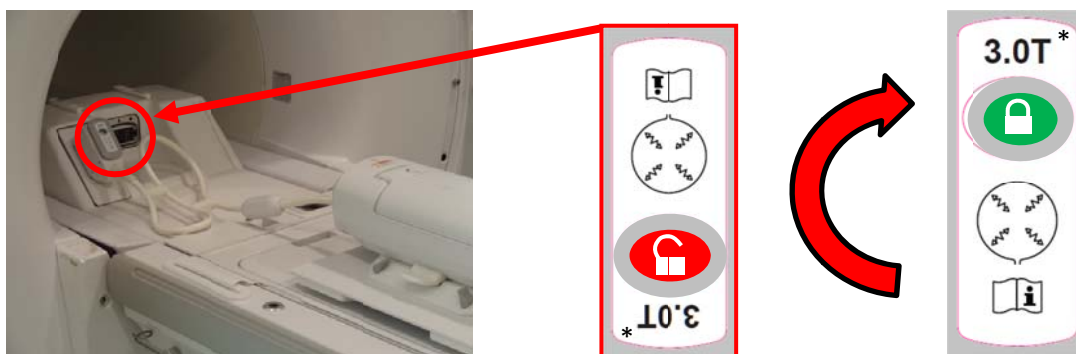
3. Place the coil onto the patient cradle. Note that the bore direction arrow pictured below should be pointing **towards** the bore.



4. To avoid loops and patient contact, route any excess cable using the cable routing clips attached to the system cable as shown below.

	
	
	Do not cross or loop coil cables.
	Ensure that patient does not come into direct contact with the coil cables.

5. Connect the coil connector to the appropriate Transmit Port of the system. (Refer to system user manual for TR Port Location) Turn the end of the P-Port connector around such that it exhibits the LOCKED position, see picture on right.



*: For reference only, applies to both 1.5T and 3.0T

Positioning the 16ch T/R Hand Wrist Coil: Vertical Base

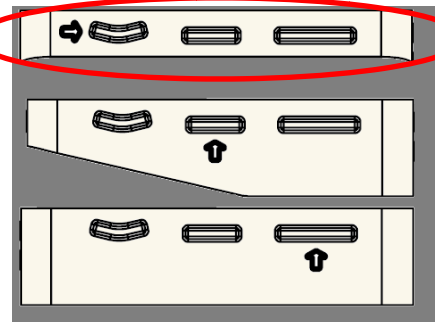


The 16ch T/R Hand Wrist Coil supports cross-platform compatibility across multiple systems. In order to provide optimized coil and patient position, the Vertical Base must be set accordingly.

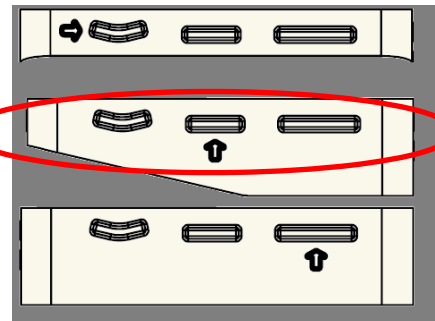
1. Set the vertical base feet to the position required for the system being used. The markings on the feet indicate what side should be facing out for the appropriate patient table. To change the setting, firmly grasp the feet shown below, and rotate to desired position.



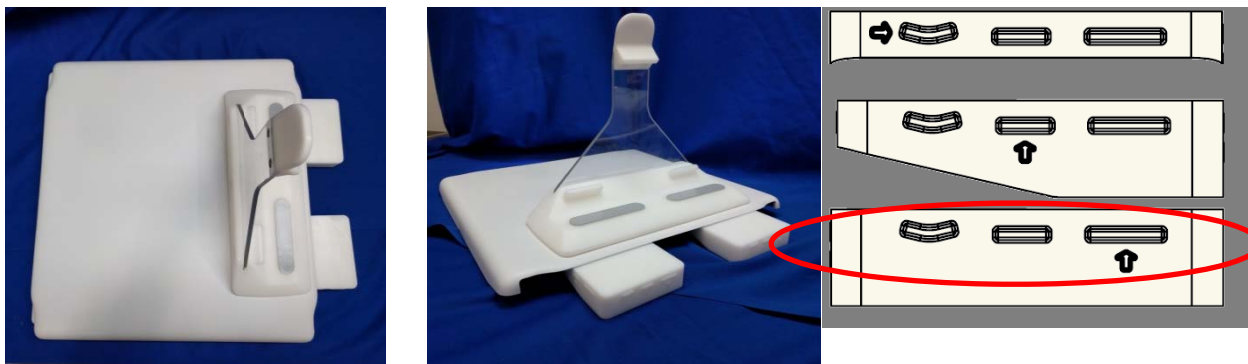
Curved Table – 60cm bore



Standard Flat Table – 70cm bore with removable table

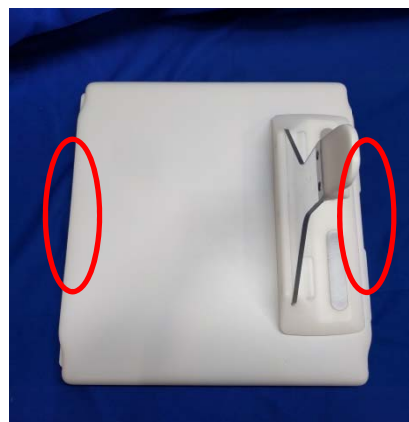


Extended Flat Table- 70cm bore with fixed table

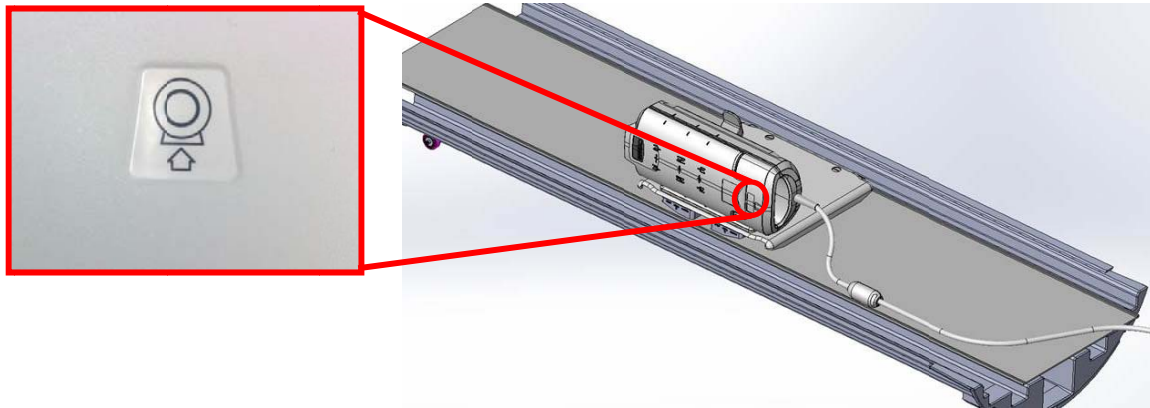


Note: Incorrect system base setup could result in poor image quality. Ensure the vertical base is set up correctly for the corresponding system.

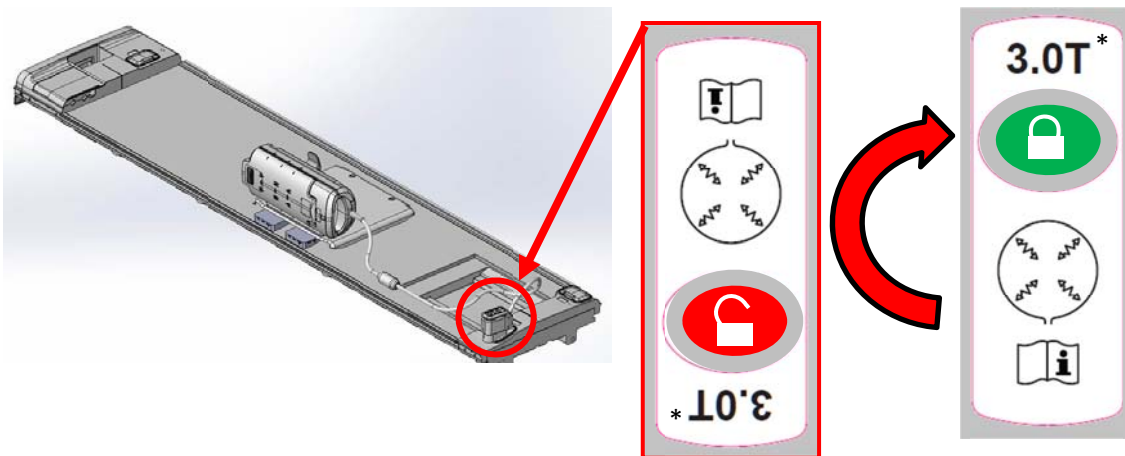
2. Remove any other surface coils (if present) from the patient cradle.
3. Transport the coil to the patient cradle. Be sure to carry the coil with both hands by the handles on the base.



4. Place the coil onto the patient cradle. Note that the bore direction arrow pictured below should be pointing **towards** the bore.

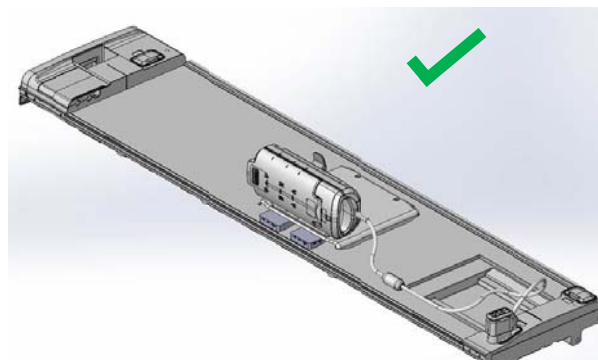
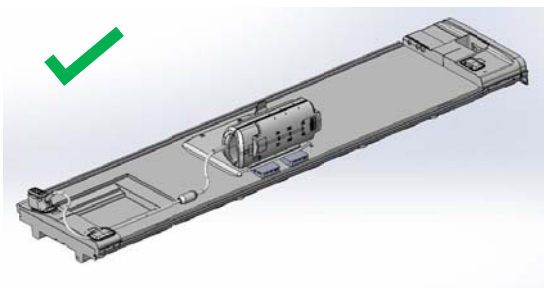


5. Connect the coil connector to the appropriate Transmit Port of the system. (Refer to system user manual for TR Port Location) Turn the end of the P-Port connector around such that it exhibits the LOCKED position, see picture on right.





*: For reference only, applies to both 1.5T and 3.0T

6. To avoid loops and patient contact, route any excess cable using the cable routing clips attached to the system cable as shown below.

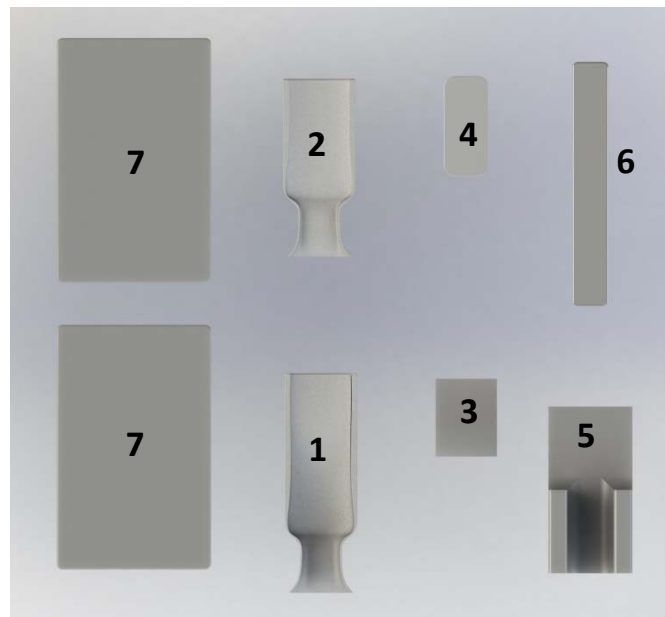




	Do not cross or loop coil cables.
	Ensure that patient does not come into direct contact with the coil cables.

Pad Configuration

1. Various pads are supplied with the 16ch T/R Hand Wrist Coil to minimize motion artifact and to provide patient comfort.



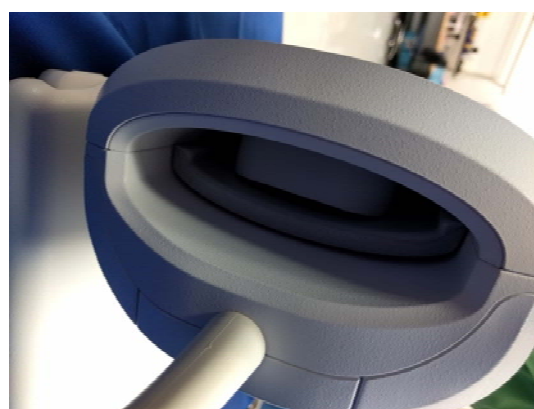
Number	Description	Qty	GE Part Number	QED Part Number
1	16ch T/R Hand Wrist Coil – Posterior Liner Pad	1	5561531-6	3004567
2	16ch T/R Hand Wrist Coil – Anterior Liner/Phantom Position Pad	1	5561531-7	3004566
3	16ch T/R Hand Wrist Coil – Palm Pad	1	5561531-15	3004964
4	16ch T/R Hand Wrist Coil – Wedge Pad	1	5561531-8	3004751
5	16ch T/R Hand Wrist Coil – Elbow/Arm Pad	1	5561531-9	3004607
6	16ch T/R Hand Wrist Coil – Wrist Coil Filler Pad	1	5561531-10	3004716
7	16ch T/R Hand Wrist Coil – Side-mount Base Pad	2	5561531-11	3004612

Position the Patient: Horizontal Base

1. The 16ch T/R Hand Wrist Coil comes with a variety of pads to facilitate patient comfort. Below is an example of the recommended layout for the horizontal orientation:

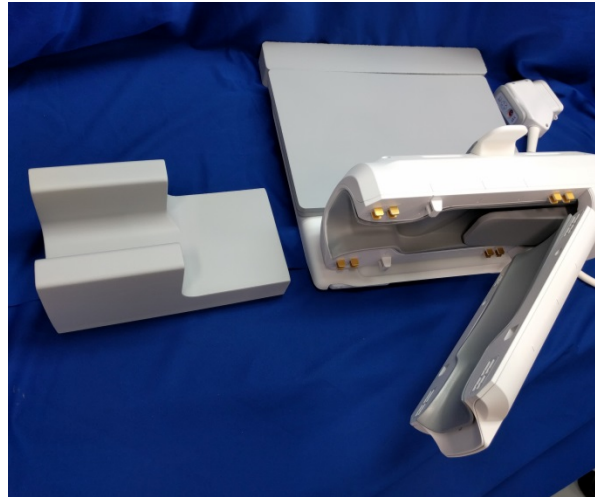


2. Position the patient's hand into the coil. Use marks on coil to aid in positioning as shown below. If necessary, use Wedge and/or Palm Pads to immobilize the patient's hand/wrist and to ensure patient comfort.



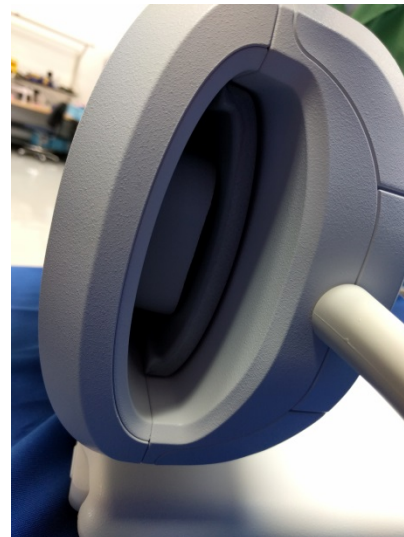
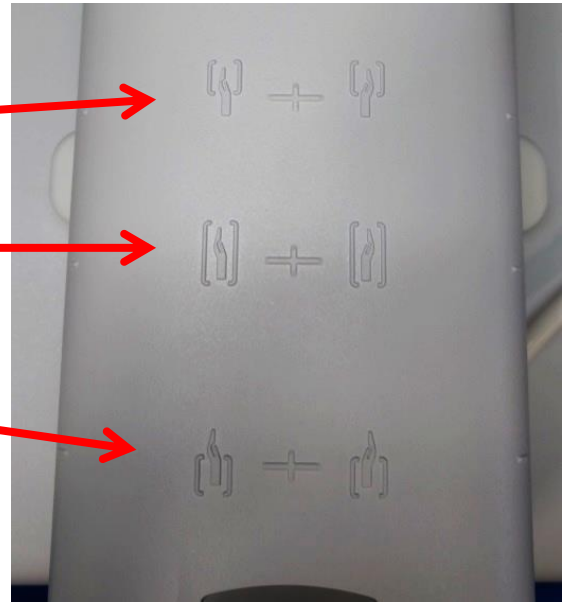
Position the Patient: Vertical Base

1. The 16ch T/R Hand Wrist Coil comes with a variety of pads to facilitate patient comfort. Below is an example of the recommended layout for the vertical orientation:



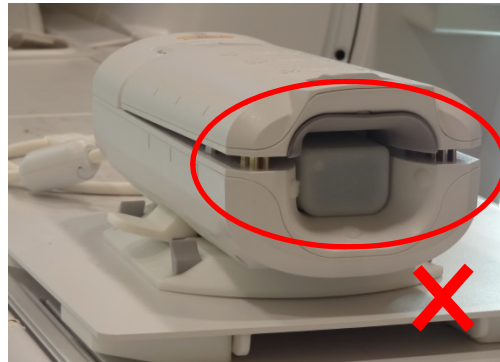
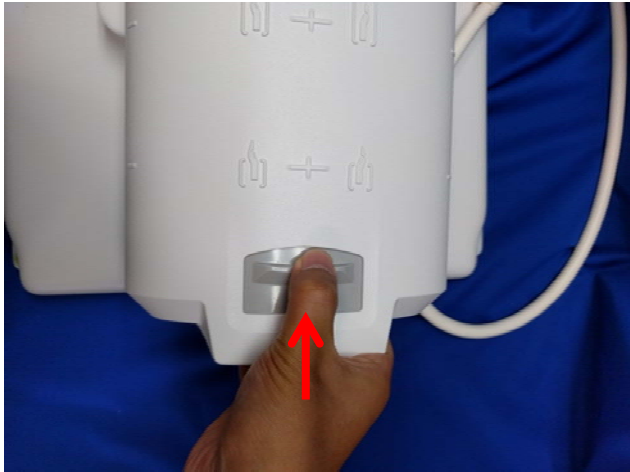
2. Position the patient's hand into the coil. Use marks on coil to aid in positioning the patient in the coil as shown below. If necessary, use Wedge and/or Palm Pads to immobilize the patient's hand/wrist and to ensure patient comfort.





Lock the Coil

1. Close the coil, making sure not to pinch the patient, gown, or bedding material between the coil halves. This could cause patient injury, poor image quality, or possibly result in damage to the coil. Push the anterior half of the coil down until it “clicks” into place.



Landmark

1. The 16ch T/R Hand Wrist Coil has 3 landmarks as shown below. These correspond to three different coil modes: Hand Only (8-channel mode), Hand/Wrist (16-channel mode), and Wrist Only (8-channel mode). Select landmark based on desired target anatomy.



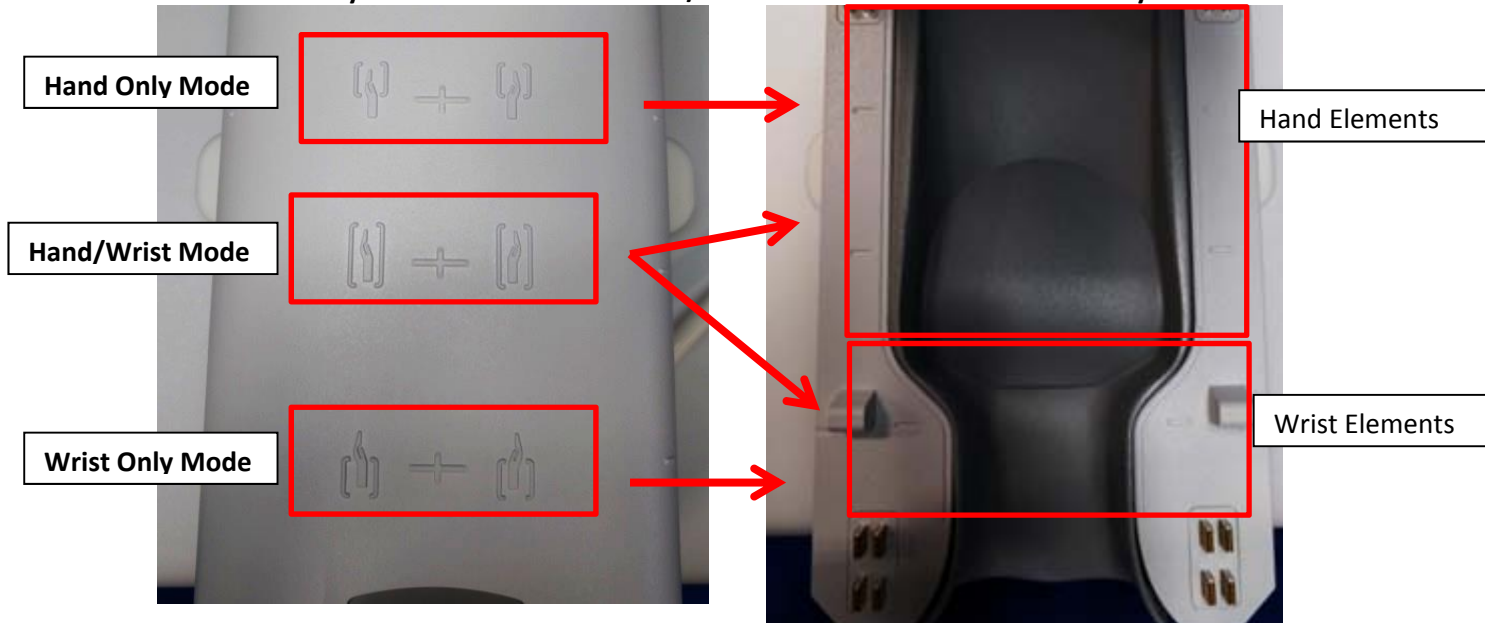
Hand Only Mode



Hand/Wrist Mode

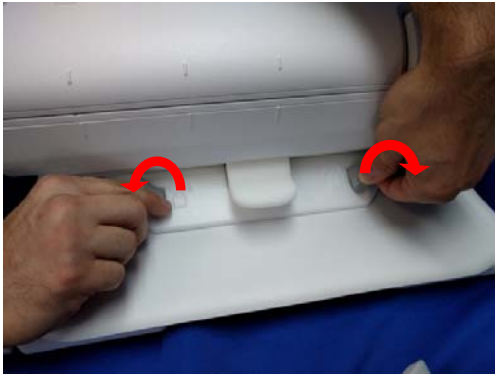


Wrist Only Mode

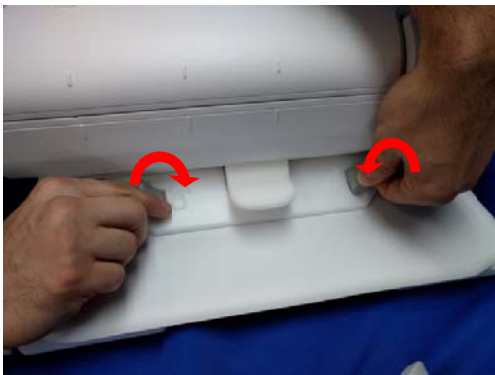


2. If coil adjustment is required for horizontal base configuration, rotate knobs into unlocked position, as shown below, to achieve desired alignment. Turn the knob again to the lock position to secure the coil in place once the coil has reached the desired position.

Unlock



Lock



Note: Ensure the horizontal base is locked after any adjustment during landmark setup. The coil may shift during scanning, which could result in poor image quality.

3. Advance the patient into the magnet and landmark the coil using the reference marks on the top of the 16ch T/R Hand Wrist Coil for the desired imaging mode.



Chapter 6 – Cleaning, Maintenance, Service, and Disposal

Cleaning the RF Coil



Caution: Do not pour cleaning solution directly onto the coil or accessories.



Caution: Do not sterilize the coil or accessories.



Caution: Do not apply cleaning solution to electrical contacts.

The RF Coil and patient comfort pads must be cleaned after each use using the following procedure:

1. Disconnect RF coil from the MRI scanner before coil cleaning.
2. Wipe off any dirt on the coil surface using a dry cloth. If dirt is difficult to remove, clean it according to the procedures described below.
3. Wipe with a cloth that has been dampened in a solution of 10% bleach and 90% tap water, or 70% ethanol and 30% tap water.
4. Should the coil need to be returned to GE Healthcare for service, wipe it down with a 10% bleach solution (as described above) to minimize risk of exposure to potentially infectious agents.
5. Dispose of any materials used to clean the coil and the pads according to all federal, state, and local regulations.

Disinfection

If disinfection of the RF coil or patient comfort pads is necessary, clean as described above then use the following procedure:

Pre-Disinfection Steps:

1. Wet all surfaces with CaviCide (using spray applicator or using towelettes for certain surfaces such as those close to electrical contacts; do not apply cleaning solution to electrical contacts). Ensure all surfaces are visibly wet and remain wetted for a minimum of 30 seconds.
2. Use a soft nylon bristle brush and/or additional cleaner/disinfectant towelettes to loosen hardened or difficult to remove debris or bioburden. Apply additional cleaner/disinfectant (using spray applicator or using towelettes for certain surfaces such as those close to electrical contacts) to areas subjected to any previous brushing or wiping. Ensure these previously brushed or wiped areas remain visibly wetted with cleaner/disinfectant for a minimum of 30 seconds.
3. Wipe surfaces with clean paper towels to remove debris.

4. Discard used brushes, used cleaner/disinfectant towelettes and used paper towels.
5. Repeat steps 1 through 4.
6. If debris remains on the surfaces, repeat pre-disinfection steps.

Disinfection Steps:

1. Apply CaviCide (using spray applicator or using towelettes for certain surfaces such as those close to electrical contacts) directly to pre-cleaned surfaces and ensure all surfaces are wet and remain wetted for a minimum of two (2) minutes. Do not apply cleaning solution to electrical contacts.
2. Wipe with clean paper towels to remove residual cleaner/disinfectant.
3. Discard used cleaner/disinfectant towelettes and used paper towels.

Allow coil and accessories to dry before use.

Maintenance

No regularly scheduled maintenance is required for the RF coil.

Service

Please contact your GE representative with questions regarding service of the RF coil.

Disposal

Please contact your GE representative with questions regarding the return or disposal of the RF coil.

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