**Operator's Manual** 



# 16ch T/R Hand Wrist Coil

# For GE 1.5T and 3.0T MRI Systems





GE	QED
5768098-2 (1.5T) /	Q7000180 (1.5T) /
5948697-2 (1.5T) /	Q7000238 (1.5T) /
5561531-2 (3.0T)	Q7000152 (3.0T)



www.qualityelectrodynamics.com



#### 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**

This equipment shall be transported and stored under the following conditions:

	Temperature	-10°C to +50°C
Ŵ	Relative humidity	20% to 95%
) See	Atmospheric pressure	700 hPa to 1060 hPa



If the coil packaging is exposed to environmental conditions outside of the transportation and storage conditions, the packaging is damaged, or the packaging is opened prior to delivery, complete Quality Assurance testing prior to actual use. If the coil passes QA testing, it may be used normally.

#### 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.



## About This Manual

This manual contains detailed information on the safety precautions, use and care of the RF Coil.

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, such as the MRI system. Please consult the MRI system manufacturer for information regarding non-QED equipment.

The operator's manual is available online as a PDF file at <u>www.qualityelectrodynamics.com</u>. To request a paper copy of the operator's manual, please email <u>info@qualedyn.com or</u> complete the contact form at <u>www.qualityelectrodynamics.com</u>.



www.qualityelectrodynamics.com

## Legend

In this manual, the following symbols are used to indicate safety and other important instructions. The signal words and their meanings are defined below.



#### CAUTION

Caution is necessary to avoid a hazardous situation, which, if not avoided, could result in minor or moderate injury.



#### INFORMATION

Emphasizes important details or provides information on how to avoid operating errors or other potentially hazardous situation, which, if not observed, may result in property damage.



# Table of Contents

About	This Manual	R
	of Contents	
	er 1 – Introduction	
1.1	Description	
1.2	Operating Environment and Compatibility	6
1.3	User Profile	
1.4	Patient Information	
Chapte	er 2 – 16ch T/R Hand Wrist Coil Components	
Chapte	er 3 – Safety	9
3.1	Symbols	
3.2	Indications	
3.3	Contraindications	. 10
3.4	Precautions	. 11
3.5	Cautions – RF Coil	. 11
3.6	Emergency Procedures	. 12
Chapte	er 4 – TR Port Location	. 13
Chapte	er 5 – Baseplate Configuration	. 13
5.1	Universal Baseplate	. 13
5.2	Dual Baseplates	. 14
5.2.1	Horizontal Baseplate	. 14
5.2.2	Vertical Baseplate	. 15
Chapte	er 6 – Quality Assurance	. 17
6.1	Scanner Verification	. 17
6.2	Signal to Noise Ratio (SNR) Test	. 17
6.3	Multi-Coil Quality Assurance (MCQA) Tool	. 25
6.4	Using MCQA Viewer	. 28
Chapte	er 7 – Coil Setup and Use with Universal Baseplate	. 29
7.1	Determine Scan Position and Set Universal Baseplate Orientation	. 29
7.1.1	Changing Universal Baseplate from Vertical to Horizontal Orientation	. 30
7.1.2	Changing Universal Baseplate from Horizontal to Vertical Orientation	
7.1.3	Adjusting Coil Position on the Universal Baseplate	. 33
7.2	Connect 16ch T/R Hand Wrist Coil to System – Universal Baseplate	. 34
7.3	Position the Patient	
7.3.1	Positioning the Patient in the Horizontal Orientation	. 37
7.3.2	Positioning the Patient in the Vertical Orientation	. 39
7.4	Lock the Coil	. 41
7.5	Landmark the Coil	. 42
Chapte	er 8 – Coil Setup and Use with Dual Baseplates	
8.1	Determine Scan Position and Connect Coil to Horizontal or Vertical Baseplate	
8.2	Connect 16ch T/R Hand Wrist Coil to System - Horizontal Baseplate	
8.3	Connect 16ch T/R Hand Wrist Coil to System - Vertical Baseplate	
8.4	Position the Patient - Horizontal Baseplate	
8.5	Position the Patient - Vertical Baseplate	
8.6	Lock the Coil	
8.7	Landmark the Coil	. 58



Chapte	r 9 – Cleaning, Maintenance, Service, and Disposal	61
9.1	Cleaning the RF Coil	61
9.2	Maintenance	62
9.3	Service	62
9.4	Disposal	62
9.5	Expected Service Life	62
Chapte	r 10 – Guidance and Manufacturer's Declaration – Electromagnetic Compatibility (EM	$\sim$
	10 – Guidance and Manufacturer's Declaration – Electromagnetic Compatibility (EM	C)
•	10 – Guidance and Manufacturer's Declaration – Electromagnetic Compatibility (Elvi	•
•		63
·····		63 63
 10.1	Classification	63 63 63



## Chapter 1 – Introduction

## 1.1 Description

Transmit/receive RF coils transmit an RF pulse and then receive magnetic resonance signals generated in hydrogen nuclei (protons) in the human body. The received signals are amplified and transmitted to the MRI system, where they are processed into tomographic images by the computer.

The 16ch T/R Hand Wrist Coil is used to examine the hand and wrist.

## **1.2** Operating Environment and Compatibility

The 16ch T/R Hand Wrist Coils are intended to be used in conjunction with GE 1.5T and 3T MRI systems, respectively, in a specialized healthcare.

### 1.3 User Profile

Operator – Radiological technologists, laboratory technologists, physicians (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).

## **1.4** 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).



## Chapter 2 – 16ch T/R Hand Wrist Coil Components

The 16ch T/R Hand Wrist Coil shipment contains the 16ch T/R Hand Wrist Coil, a variety of pads used to minimize movement and provide patient comfort during imaging, and either the universal baseplate (Figure 1) or dual baseplates (Figure 2). The contents of the universal baseplate and dual baseplate configurations are shown below. Upon receipt, please ensure that all parts are included in the shipment.

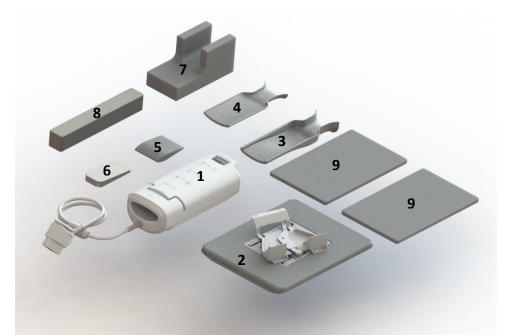


Figure 1: 16ch T/R Hand Wrist Coil with Universal Baseplate Configuration

Item #	Description	Qty	GE Part #	QED Part #
			5768098-2 (1.5T) /	Q7000180 (1.5T) /
1	16ch T/R Hand Wrist Coil	1	5948697-2 (1.5T) /	Q7000238 (1.5T) /
			5561531-2 (3.0T)	Q7000152 (3.0T)
2	16ch T/R Hand Wrist Coil – Universal Baseplate	1	5561531-16	2002864
3	16ch T/R Hand Wrist Coil – Posterior Liner Pad	1	5561531-6	3004567
4	16ch T/R Hand Wrist Coil – Anterior	1	5561531-7	3004566
4	Liner/Phantom Position Pad		5201221-7	5004500
5	16ch T/R Hand Wrist Coil – Palm Pad	1	5561531-15	3004964
6	16ch T/R Hand Wrist Coil – Wedge Pad	1	5561531-8	3004751
7	16ch T/R Hand Wrist Coil – Elbow/Arm Pad	1	5561531-9	3004607
8	16ch T/R Hand Wrist Coil – Wrist Coil Filler Pad	1	5561531-10	3004716
9	16ch T/R Hand Wrist Coil – Side-mount Base Pad	2	5561531-11	3004612



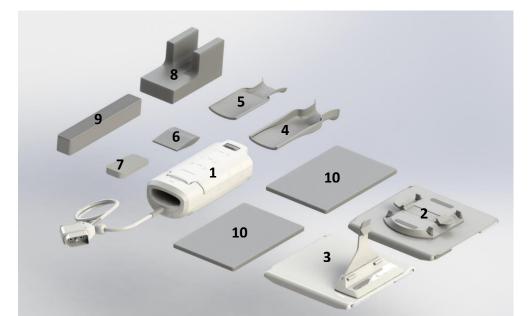


Figure 2: 16ch T/R Hand Wrist Coil with Dual Baseplate Configuration

Item #	Description	Qty	GE Part #	QED Part #
1	16ch T/R Hand Wrist Coil	1	5768098-2 (1.5T) / 5948697-2 (1.5T) / 5561531-2 (3.0T)	Q7000180 (1.5T) / Q7000238 (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 – Vertical 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 – Vertical Base Pad	2	5561531-11	3004612

Coil weight: 3.9kg (8.5lb)



## Chapter 3 – Safety

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



Before using the coil, review the safety information in the MRI system operation manual for a full list of safety considerations.

## 3.1 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	
Ĩ	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	
Ŕ	5333	ISO 7000 IEC 60417	Type BF applied part	
	3082	ISO 7000 IEC 60417	Manufacturer	
$\sim$	2497	ISO 7000 IEC 60417	Date of Manufacture	
And	6192	ISO 7000 IEC 60417	RF Coil, Transmit and Receive	
EC REP	5.1.2	ISO 15223-1	Authorized Representative in EU	
UK REP	5.1.2	ISO 20417 ISO 15223-1	Indicates the UK Responsible Person	
CH REP	5.1.2	SwissMedic ISO 15223-1	Indicates the authorized representative in Switzerland	
REF	2493	ISO 7000 IEC 60417	Catalog Number	
SN	2498	ISO 7000 IEC 60417	Serial Number	



Symbol	Number	Standard	Title, Meaning
eccontent content Intertek 5000606	N/A	N/A	ETL Listed (Canada & USA)
X	0632	ISO 7000 IEC 60417	Temperature limit
Ì	2620	ISO 7000 IEC 60417	Humidity limitation
<b>6</b>	2621	ISO 7000 IEC 60417	Atmospheric pressure limitation
	W017	ISO 24409-2 ISO 8528-13	Warning; Hot surface
MD	5.7.7	ISO 15223-1	Medical Device
UDI	5.7.10	ISO 15223-1	Unique Device Identifier
<u></u>	6049 5.1.11	IEC 60417 ISO 15223-1	Country of Manufacture – US
	5.1.8	ISO 15223-1	Importer
	5.1.9	ISO 15223-1	Distributor
	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.

## 3.2 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.

## **3.3** Contraindications

None.



## 3.4 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)

Ensure that the patient does not wear clothing that is wet or dampened by perspiration.

## 3.5 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.

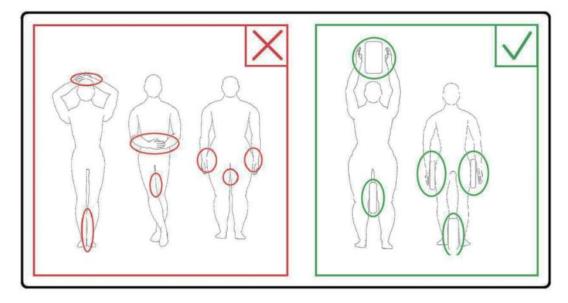
Ensure that the patient does not come into direct contact with the coil cables.







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.

## 3.6 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.

If a serious incident occurs, it should be reported to the manufacturer and the Competent Authority of the Member State in which the user facility is established.



## Chapter 4 – 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 5 – Baseplate Configuration

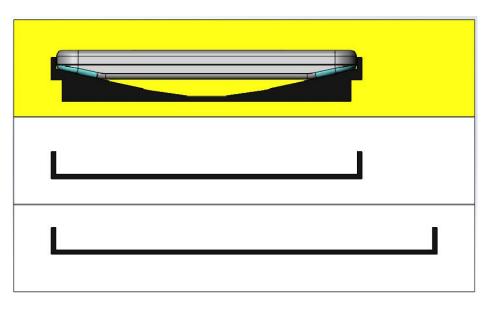
The Hand Wrist baseplates (universal and dual baseplates) are designed to accommodate multiple MRI systems and patient tables. This section describes how to configure the Hand Wrist baseplates for each of the three table styles.

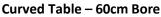
## 5.1 Universal Baseplate

CAUTION

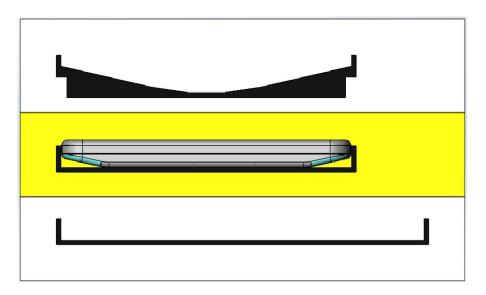
The 16ch T/R Hand Wrist Coil supports cross-platform compatibility across multiple systems. In order to provide optimized coil and patient position, the universal baseplate must be set accordingly, when used in the vertical orientation.

Set the universal baseplate into the required orientation for the system table being used. The universal baseplate can be flipped and rotated to fit each table so that the coil will be properly positioned for scanning. Determine which table and bore size your system has, and refer to the appropriate diagram below. Note that the edges of the base in the diagrams are highlighted to indicate orientation proper orientation. The actual universal baseplate will be uniform in color.



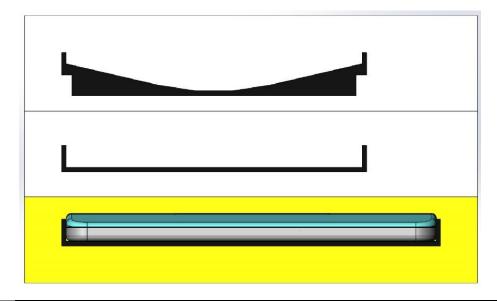






Standard Flat Table – 70cm Bore with Removable Table





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

## 5.2 Dual Baseplates

## 5.2.1 Horizontal Baseplate

The horizontal baseplate has a single configuration that is compatible with all the system tables; no preliminary set-up is required. Proceed to the next section.

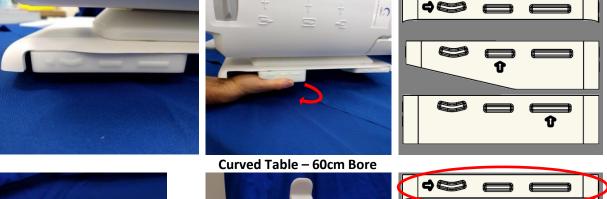


### 5.2.2 Vertical Baseplate

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 baseplate must be set accordingly.

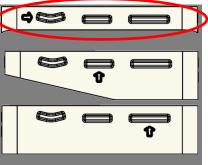
Set the vertical baseplate feet to the position required for the system being used. The markings on the feet indicate what side should be facing out for the appropriate patient table. To change the setting, firmly grasp the feet shown below, and rotate to desired position.

#### **Rotate Vertical Baseplate Feet for System in Use**





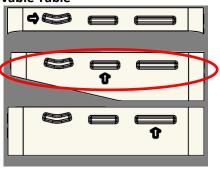




Standard Flat Table – 70cm Bore with Removable Table











#### Extended Flat Table- 70cm Bore with Fixed Table



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



# Chapter 6 – Quality Assurance

## 6.1 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.

## 6.2 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	
or	or	or	1
Universal 16ch TR Hand Wrist Universal Baseplate	5561531-16	2002864	
16ch T/R Hand Wrist Coil – Anterior	5561531-7	3004566	1
Liner/Phantom Position Pad	2201221-1	5004500	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 table.

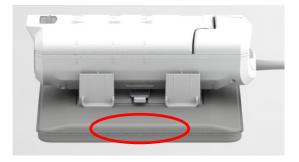


3. Transport the coil to the patient table. Be sure to carry the coil with both hands by the handle on the horizontal baseplate or the bottom edge of the universal baseplate.



#### Horizontal Baseplate Handles

**Universal Baseplate Handles** 





4. Place the coil onto the patient table. 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.





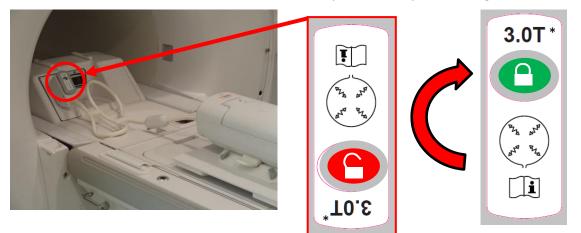
Do not cross or loop coil cables.

CAUTION Ensure that

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, unlock the baseplate and re-position the coil to achieve desired alignment.
    - a. If using the horizontal baseplate, 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.
    - b. If using the universal baseplate, rotate the latch and re-position the coil to achieve the desired alignment, and then rotate the latch back to its locked position to lock the coil in place.





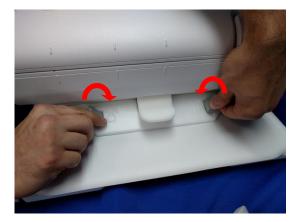


#### Unlock – Horizontal Baseplate



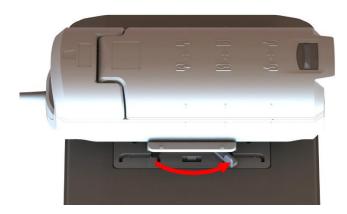


Lock – Horizontal Baseplate



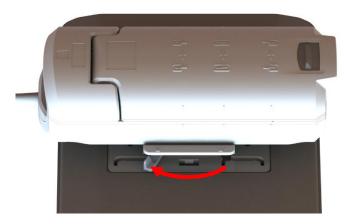


Unlock – Universal Baseplate





#### Lock – Universal Baseplate



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.

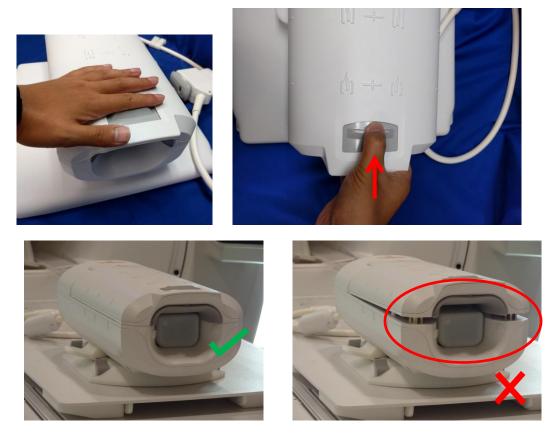




10. Place the Unified Cubical Phantom (5342681) into the coil as shown below. **Ensure the bottom** edge of phantom aligns with FOV markings on the coil.



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.





## 6.3 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

<u>Note</u>: 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 CoilID 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.

	care - Multi Coil Quality Assurance Tool 🛛 🔄 🔀
File Tools Help	
Current Coil:	1.5T_16Ch_TR_Wrist_CoilUnified
Phantom Set:	Unified Phantom Kit
Coil Serial #:	004
Results File:	
Pass/Fail:	
Start	Abort Run View Report Details
Multi-Coil QA To	ol started on Oct.24,2017 23:13

#### 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).

	Continue?	$ \boxtimes$
?	Note: Phantom placement and coil landmarking are critical for repeatable results. Verify coil and phantom are properly placed and landmarked at correct location. Also verify there are no large air bubbles in the phantom. Do you wish to continue? Yes No	





**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

GE Healtho	are - Multi Coil Qu	ality Assurance Tool	_ 🗵	
File Tools Help				
Current Coil:	1.5T_16Ch_TR_Write	st_CoilUnified	•	
Phantom Set:	Unified Phantom Kit			
Coil Serial #:	10345			
Results File:	1.5T_16Ch_TR_Wrist_CoilUnified.DPP_10345.			
Pass/Fail:	PASS			
Start	Abort Run	View Report Det	ails	
	Status			
Analyzing noise raw data.				
Starting ISNR Ana Test#= 1 SIG_IM		ISNR: 01.859. bec=	30	
Test#= 1 SIG_IM			0 P	
Test#= 1 SIG_IM		'SNK OC 549 Sp		
Test#= 1 SIG_IM		'R= '9.1 ? Speo		
Test#= 1 SIG_IM			40	
Test#= 1 SIG_IM Test#= 1 SIG_IM		SNI 98.8042ec= 'R= 0.8623 Spec=		
Test#= 1 SIG	G= 8 P1	'Si =1, 4155 Spec=		
Test#= 1 SIG_	9 PU T=	Nk 19.7505 Spec=		
Test#= 1 G_IM	PO PO H	NR=108.1068 Spec		
Test#= 1IM		R=61.3168 Spec=		
Teste S. IM		ISNR=128.2737 Spec		
<pre>&gt; = 1 M <t#= 1="" pre="" sig<=""></t#=></pre>	G= OK PI C= 1 PORT=P1	ISNR=131.0639 Spec= ISNR=59.9963 Spec=		
T = 1 SIG	= 1 PORT=P1			
Test siG_I	= PORT=P1			
Comp. d analy			-	
			•	
			Quit	

Figure 6

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

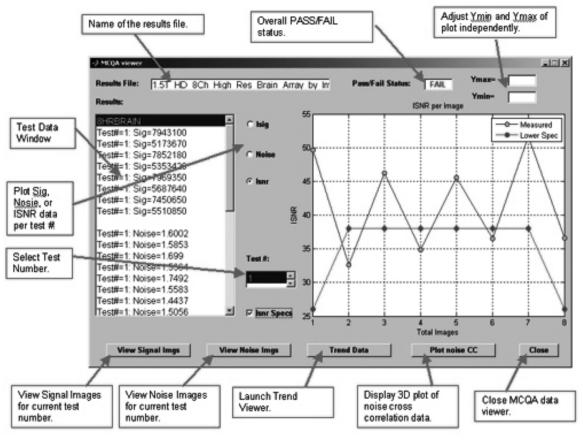


## 6.4 Using MCQA Viewer

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.





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 7 – Coil Setup and Use with Universal Baseplate

Chapter 77 contains instructions for setting up and using the coil with the universal baseplate. For instructions using the dual baseplate configuration, please see Chapter 8.

## 7.1 Determine Scan Position and Set Universal Baseplate Orientation

The 16ch T/R Hand Wrist Coil is designed to image the patient either at the patient's side (vertical orientation) or over the patient's head (horizontal orientation). The universal baseplate is comprised of two parts, the "baseplate" and the "coil support". The universal baseplate can be adjusted to accommodate either of these orientations by repositioning the coil support. Determine optimal scan position based on patient size, comfort, and scan preference. Then set the universal baseplate orientation based on desired patient scan position using the applicable instructions below.



Coil Support

**Universal Baseplate – Horizontal Orientation** 





**Universal Baseplate – Vertical Orientation** 

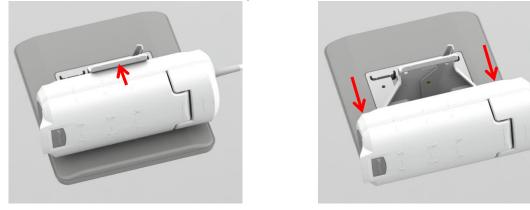


Do not switch orientation while the patient is in the coil.



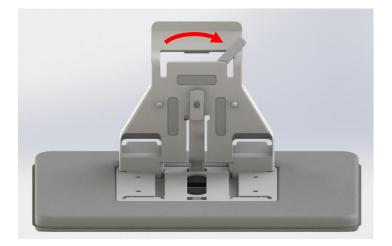
### 7.1.1 Changing Universal Baseplate from Vertical to Horizontal Orientation

1. Remove the 16ch T/R Hand Wrist coil from the baseplate by holding the coil and firmly pushing on the coil release lever, as shown below.



#### **Universal Baseplate, Vertical Orientation**

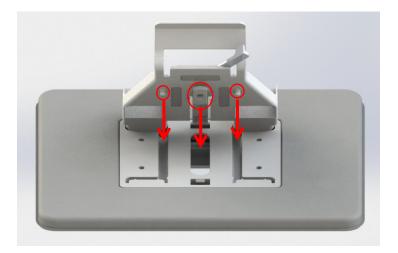
2. Remove the coil support from the baseplate by rotating the latch to the unlock position and lifting the coil support from the baseplate.



#### Unlock the Coil Support



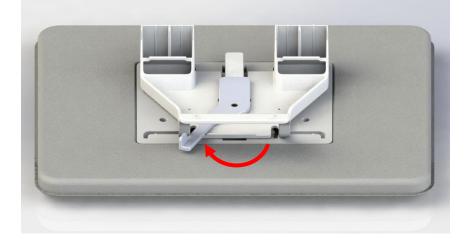
3. Rotate the coil support downward and align the catch and studs with the slots on the baseplate.



**Rotate and Align Coil Support** 

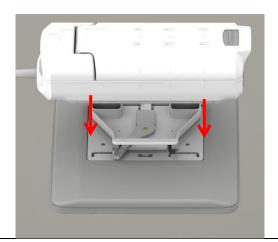
4. Lock the coil support to the baseplate by moving the locking lever from the unlocked to locked position.







5. Install coil in the horizontal orientation by aligning the coil with the coil support and pushing towards the support until the coil locks into the coil support.

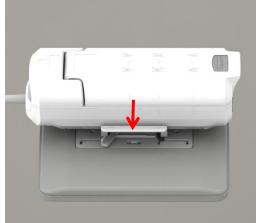


#### Install Coil onto Coil Support

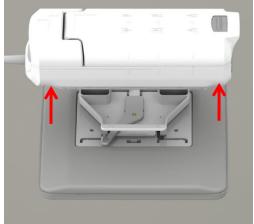
## 7.1.2 Changing Universal Baseplate from Horizontal to Vertical Orientation

The 16ch T/R Hand Wrist Coil supports cross-platform compatibility across multiple systems. In order to provide optimized coil and patient position, the universal baseplate must be set accordingly, when used in the vertical orientation. Incorrect system baseplate setup could result in poor image quality.

1. Remove the 16ch T/R Hand Wrist coil from the baseplate by holding the coil and firmly pushing on the coil release lever, as shown below.



#### Universal Baseplate, Horizontal Orientation



CAUTION



Rotate the coil support to the upright position. Determine the appropriate coil support placement on the baseplate for the system in use. Refer to Chapter 5.



Note: Ensure the vertical baseplate is set up correctly for the corresponding system.

- Place the coil support in the appropriate position based on the patient hand/wrist to be imaged. Lock the coil support to the baseplate by moving the locking lever from the unlocked to locked position. Refer to Chapter 5.
- 3. Install coil in the vertical orientation by aligning the coil with the coil support and pushing towards the support until the coil locks into the coil support.



## 7.1.3 Adjusting Coil Position on the Universal Baseplate

If coil position adjustment is required, move the locking lever into the unlocked position, as shown below, to achieve desired alignment. The coil is also capable of being adjusted 15 degrees in either direction. Move the locking lever again to the lock position to secure the coil in place once the coil has reached the desired position.











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

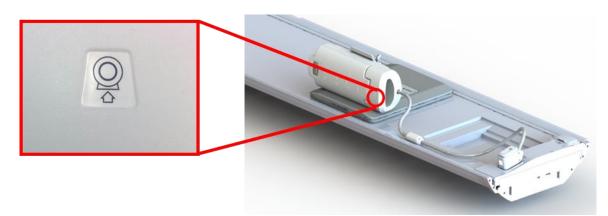
## 7.2 Connect 16ch T/R Hand Wrist Coil to System – Universal Baseplate

- **1.** Remove any other surface coils (if present) from the patient table.
- **2.** Transport the coil to the patient table. Be sure to carry the coil with both hands by the sides of the baseplate.



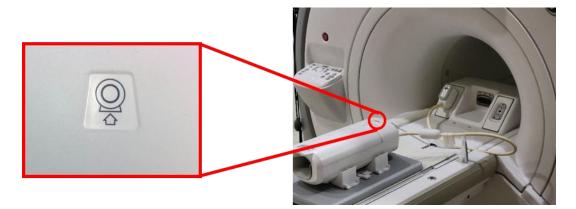


3. Place the coil onto the patient table. Note that the bore direction arrow pictured below should be pointing **towards** the bore.

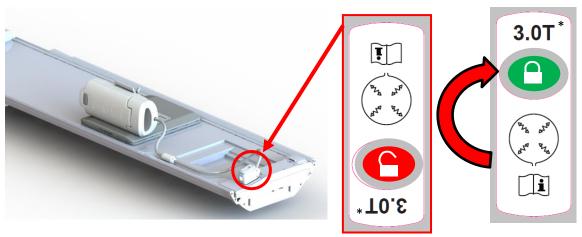


#### **Vertical Orientation**

**Horizonal Orientation** 



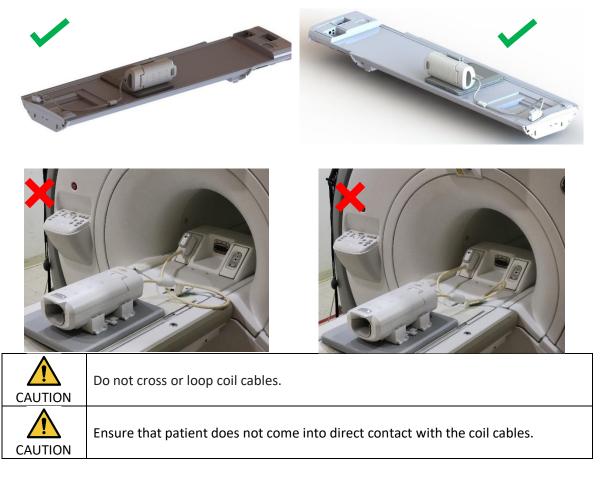
4. Connect the coil connector to the appropriate Transmit Port of the system. (Refer to system user manual for TR Port Location) Turn the end of the P-Port connector around such that it exhibits the LOCKED position, see picture on right.



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



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





## 7.3 Position the Patient

#### 7.3.1 Positioning the Patient in the Horizontal Orientation

1. The 16ch T/R Hand Wrist Coil comes with a variety of pads to minimize movement and facilitate patient comfort during imaging; see Chapter 2. 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.







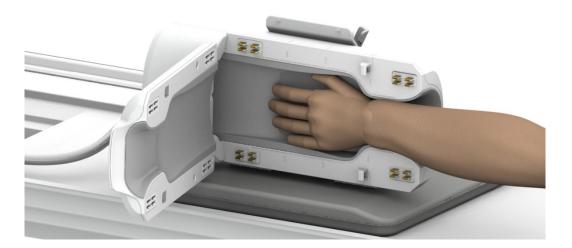


#### **7.3.2** Positioning the Patient in the Vertical Orientation

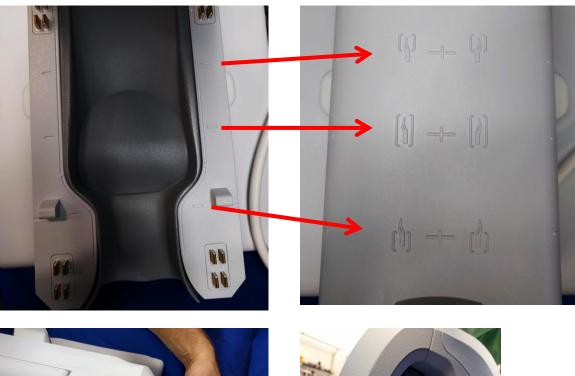
1. The 16ch T/R Hand Wrist Coil comes with a variety of pads to minimize movement and facilitate patient comfort during imaging; see Chapter 2. Below is an example of the recommended layout for the vertical orientation:



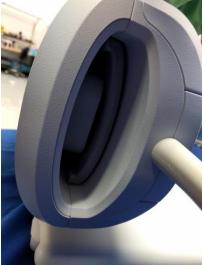
2. Position the patient's hand into the coil. Use marks on coil to aid in positioning the patient in the coil as shown below. If necessary, use Wedge and/or Palm Pads to immobilize the patient's hand/wrist and to ensure patient comfort.







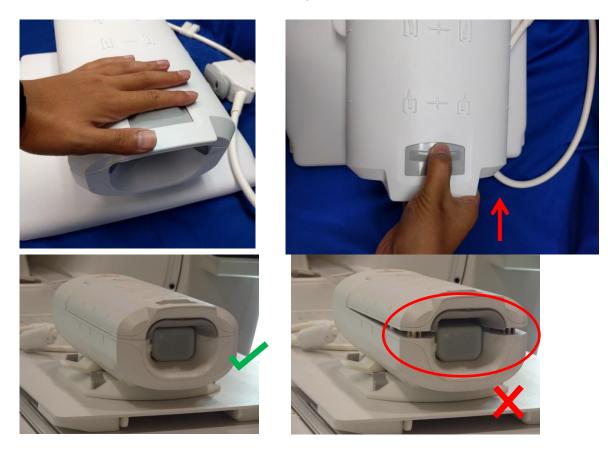






## 7.4 Lock the Coil

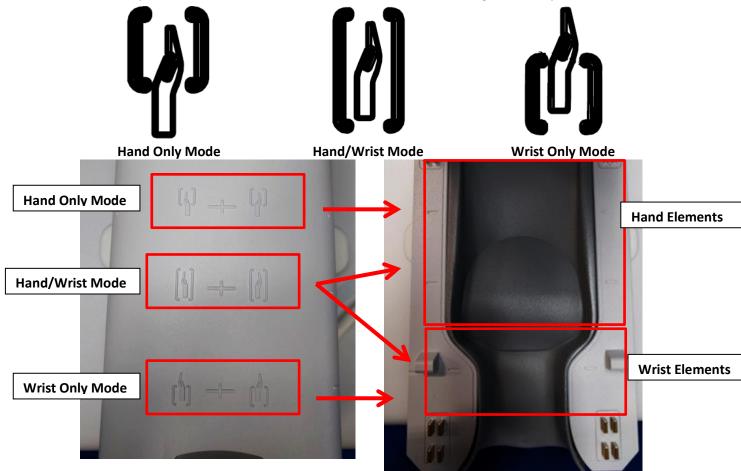
 Close the coil, making sure not to pinch the patient, gown, or bedding material between the coil halves. This could cause patient injury, poor image quality, or possibly result in damage to the coil. Push the anterior half of the coil down until it "clicks" into place.





## 7.5 Landmark the Coil

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.



2. If coil adjustment is required, follow instructions in section 7.1.

Note: Ensure the baseplate is locked after any adjustment during landmark setup.CAUTIONThe 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 8 – Coil Setup and Use with Dual Baseplates

Chapter 8 contains instructions for setting up and using the coil with the dual baseplate configuration. For instructions using the universal baseplate configuration, please see Chapter 7.

## 8.1 Determine Scan Position and Connect Coil to Horizontal or Vertical Baseplate

The 16ch T/R Hand Wrist Coil is designed to image the patient either at the patient's side (vertical orientation) or over the patient's head (horizontal orientation). The vertical baseplate is used to image the hand and wrist at the patient's side, and the horizontal baseplate is used to image the hand and wrist over the patient's head. Determine optimal scan position based on patient size, comfort, and scan preference.







**Vertical Baseplate** 





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





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



**Horizontal Baseplate** 





**Vertical Baseplate** 



Then, install in desired orientation by aligning the coil with the coil support and pushing towards the support until the coil locks into the coil support, as shown below.



#### Horizontal Baseplate







Vertical Baseplate







## 8.2 Connect 16ch T/R Hand Wrist Coil to System - Horizontal Baseplate

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



3. Place the coil onto the patient table. 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.



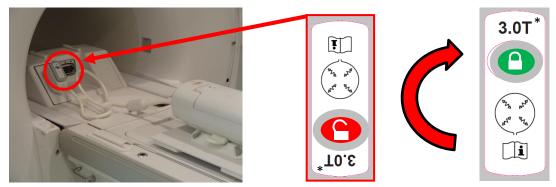


Do not cross or loop coil cables.

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

## 8.3 Connect 16ch T/R Hand Wrist Coil to System - Vertical Baseplate



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 baseplate must be set accordingly.

1. Set the vertical baseplate 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 position the feet correctly for the system see Chapter 5.



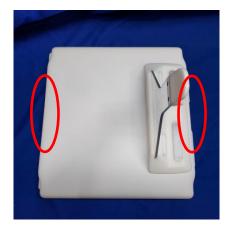
**Note:** Incorrect system baseplate setup could result in poor image quality. Ensure the vertical baseplate is set up correctly for the corresponding system.

2. Remove any other surface coils (if present) from the patient table.

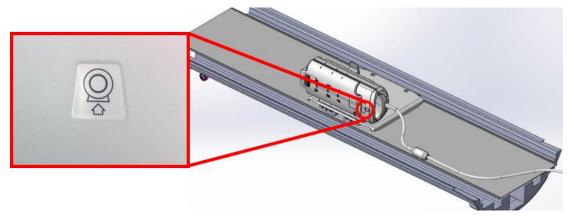


3. Transport the coil to the patient table. Be sure to carry the coil with both hands by the handles on the baseplate.



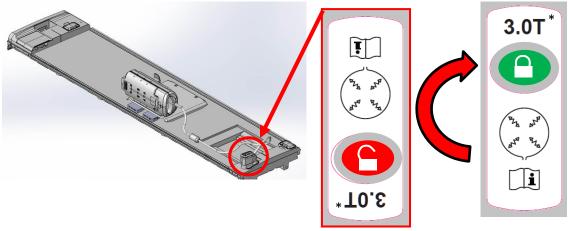


4. Place the coil onto the patient table. Note that the bore direction arrow pictured below should be pointing **towards** the bore.





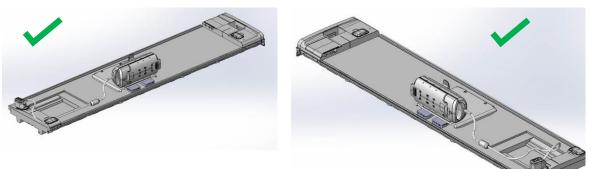
5. Connect the coil connector to the appropriate Transmit Port of the system. (Refer to system user manual for TR Port Location) Turn the end of the P-Port connector around such that it exhibits the LOCKED position, see picture on right.



\*: 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.



## 8.4 **Position the Patient - Horizontal Baseplate**

1. The 16ch T/R Hand Wrist Coil comes with a variety of pads to minimize movement and facilitate patient comfort during imaging; see Chapter 2. 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.



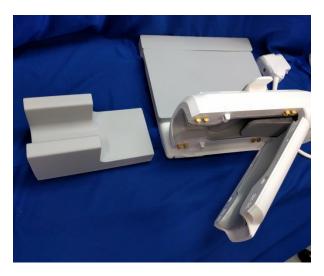






## 8.5 **Position the Patient - Vertical Baseplate**

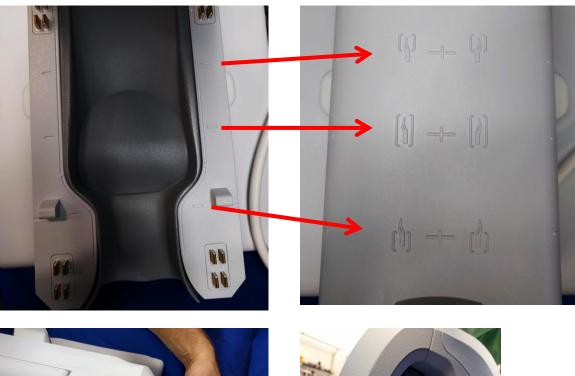
1. The 16ch T/R Hand Wrist Coil comes with a variety of pads to minimize movement and facilitate patient comfort during imaging; see Chapter 2. Below is an example of the recommended layout for the vertical orientation:



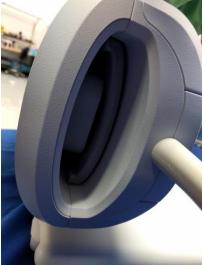
2. Position the patient's hand into the coil. Use marks on coil to aid in positioning the patient in the coil as shown below. If necessary, use Wedge and/or Palm Pads to immobilize the patient's hand/wrist and to ensure patient comfort.













## 8.6 Lock the Coil

 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.



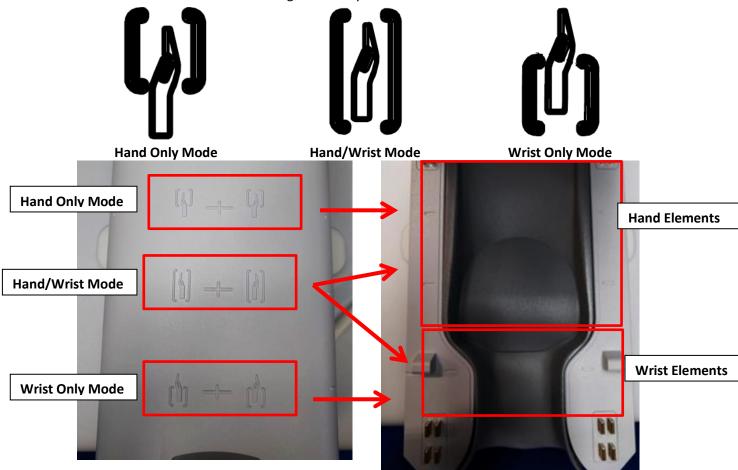






## 8.7 Landmark the Coil

 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.





2. If coil adjustment is required for horizontal baseplate configuration, rotate knobs into unlocked position, as shown below and in Section 5.1, 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.





Lock – Horizontal Baseplate





**Note:** Ensure the baseplate 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 9 – Cleaning, Maintenance, Service, and Disposal

## 9.1 Cleaning the RF Coil

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

- 2. Do not sterilize the coil or accessories.
- CAUTION 3. Do not apply cleaning solution to electrical contacts.

The RF Coil and patient comfort pads should 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, 70-99% isopropanol, or 70% ethanol.
- 4. Dispose of any materials used to clean the coil and the pads according to all federal, state, and local regulations.
- 5. Commonly available cleaning agents can also be used on the surface of the coils without any safety problems. Refer to the cleaning agent manufacturer's instructions for and clean the coil according to the procedures specified by the healthcare facility.

#### **Detailed Cleaning Steps**

#### **Pre-Cleaning Steps:**

- 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 towelettes to loosen hardened or difficult to remove debris or bioburden. Apply additional cleaner (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 for a minimum of 30 seconds.
- 3. Wipe surfaces with clean paper towels to remove debris.
- 4. Discard used brushes, used cleaner towelettes and used paper towels.
- 5. Repeat steps 1 through 4.



6. If debris remains on the surfaces, repeat pre-cleaning steps.

#### **Cleaning 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.
- 3. Discard used cleaner towelettes and used paper towels.

Allow coil and accessories to dry before use.

#### 9.2 Maintenance

No regularly scheduled maintenance is required for the RF coil.

#### 9.3 Service

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

#### 9.4 Disposal

Please follow local regulations for the disposal of electrical equipment. Do not dispose of the RF coil in unsorted waste bins. Contact your GE representative with questions regarding the return or disposal of the RF coil.

## 9.5 Expected Service Life

This RF coil is designed for an expected service life of at least 6 years under normal usage conditions. The coil is safe to use beyond the expected service life as long as information in the Safety section is followed and Quality Assurance tests pass.



# Chapter 10 – Guidance and Manufacturer's Declaration – Electromagnetic Compatibility (EMC)

This coil requires special attention regarding EMC and must be installed and used in accordance with the EMC guidelines provided in this manual. Only use the RF coil in the environment specified below; electromagnetic compatibility is not ensured in environments other than those specified.

## **10.1** Classification

This RF coil is classified as group 2, class A per CISPR 11 when it is used in combination with an MRI system.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

## **10.2** Environment and Compatibility

This RF coil is intended to be used in combination with an MRI system that resides in an RFshielded scan room within a specialized healthcare facility. All cables and accessories are part of the RF coil and cannot be removed or replaced by the user.



- 1. Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services.
- 2. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 3. Use of accessories and cables other than those specified or provided in this manual could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RF coil, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



## **10.3** Electromagnetic Emission

The RF coil can only function when connected to the MRI system, which is contained within an RF-shielded environment. Therefore, IEC 60601-1-2 clause 7 regarding electromagnetic emission does not apply.

## **10.4 Electromagnetic Immunity**

This RF coil complies with IEC 60601-1-2 clause 8 when used in the specified electromagnetic environment.

Immunity Test	Test and Compliance Level
Electrostatic discharge (ESD), contact discharge	IEC 61000-4-2 ±2kV, ±4kV, ±6kV, ±8 kV
Electrostatic discharge (ESD), air discharge	IEC 61000-4-2 ±2kV, ±4kV, ±8kV, ±15kV



# 



Manufacturer: Quality Electrodynamics, LLC. (QED) 6655 Beta Drive, Suite 100 Mayfield Village, OH 44143 U.S.A.

www.qualityelectrodynamics.com



#### Authorized Representative in Europe: EMERGO EUROPE Westervoortsedijk 60 6827 AT Arnhem The Netherlands



Swiss Authorized Representative: MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug



**Distributor:** GE Medical Systems, LLC

Date of First Issue: 2016-11 / Revision Date: 2024-02

Switzerland



#### UK Responsible Person:

Emergo Consulting (UK) Limited c/o Cr360 - UL International Compass House, Vision Park Histon Cambridge, CB24-9BZ United Kingdom

#### Importer - Turkey:

GE Medical Systems Turkey Ltd. Sti. Esentepe Mah. Harman Sok. No: 8 34394 Sisli – Istanbul Turkey