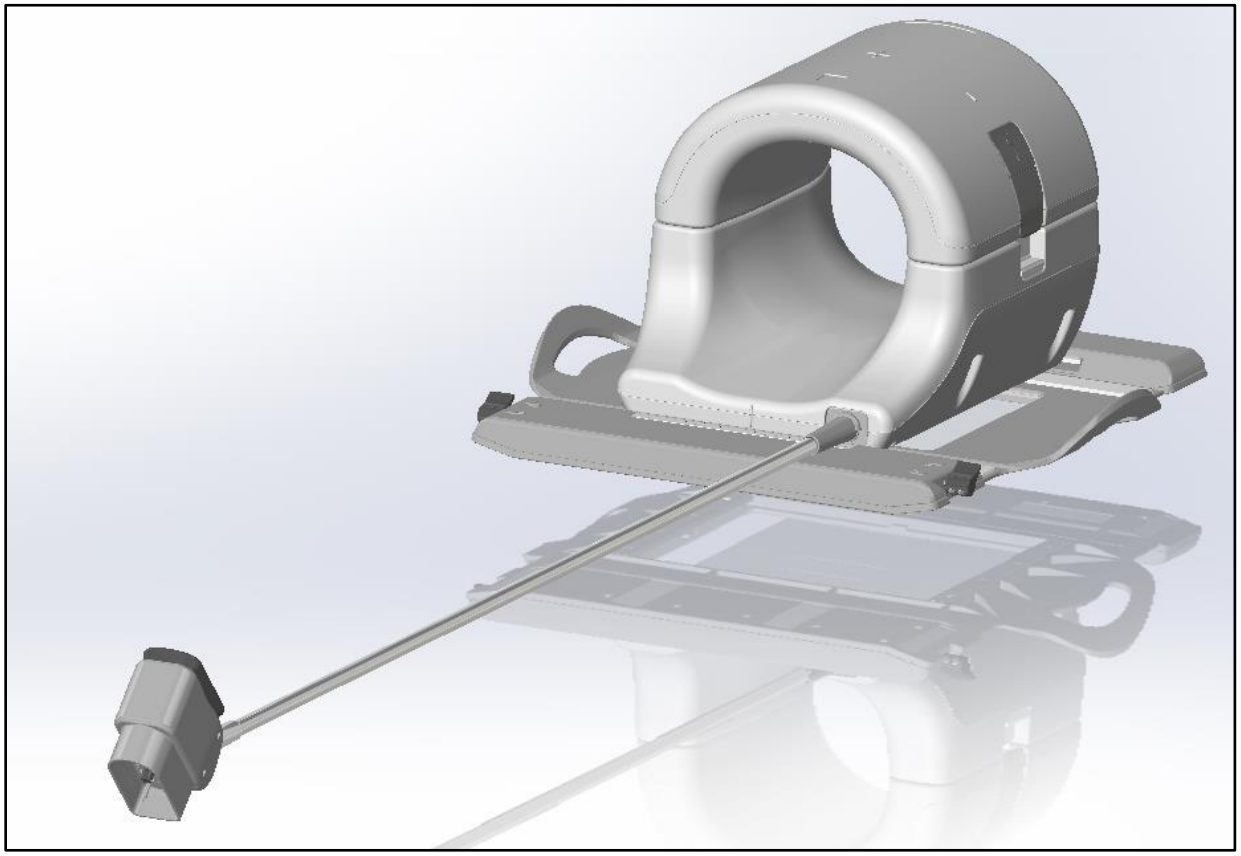
Operator's Manual

18ch T/R Knee Coil

for GE 3.0T MRI Systems



www.qualityelectrodynamics.com

REF Model Number:

GE	QED
5561409-2	Q7000074

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
	Relative humidity	20% to 95%
	Atmospheric pressure	700 hPa to 1060 hPa


CAUTION

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.

CAUTION	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 www.qualityelectrodynamics.com. To request a paper copy of the operator's manual, please email info@qualedyn.com or complete the contact form at 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

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

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 18ch T/R Knee Coil is used to examine the knee.

1.2 Operating Environment and Compatibility

This coil is intended to be used in conjunction with a GE 3.0T MRI System in a specialized healthcare facility.

1.3 User Profile

Operator – Radiologic 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).

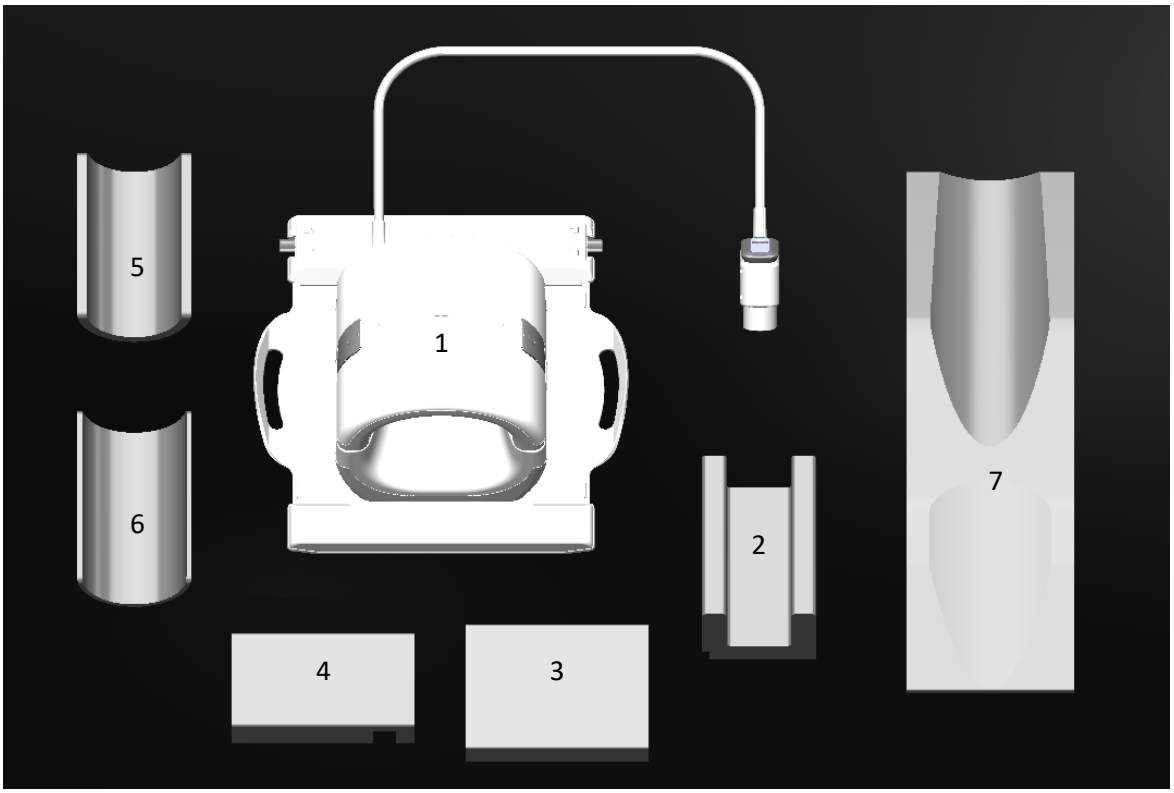
1.4 Patient Information

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 – 18ch T/R Knee Coil Components

The 18ch T/R Knee 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	18ch T/R Knee Coil	1	5561409-2	Q7000074
2	18ch T/R Knee Coil - Foot Pad	1	5561409-7	3003887
3	18ch T/R Knee Coil - Thigh Ramp Pad	1	5561409-10	3003863
4	18ch T/R Knee Coil - Calf Pad	1	5561409-11	3003896
5	18ch T/R Knee Coil - Bottom Pad, 0.5”	1	5561409-8	3003885
6	18ch T/R Knee Coil - Bottom Pad, 0.25”	1	5561409-9	3003884
7	18ch T/R Knee Coil - Pad, Non-Imaged Knee	1	5561409-6	3003888

Total product weight: 7.5kg (16.5lb)

Chapter 3 – Safety

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

CAUTION	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
	1641	ISO 7000 IEC 60417	Operator's manual, Consult 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
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
	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
	5.7.7	ISO 15223-1	Medical Device
	5.7.10	ISO 15223-1	Unique Device Identifier
	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 18ch T/R Knee Coil is intended for use with GE 3.0T MR systems to produce diagnostic images of the knee that can be interpreted by a trained physician.

3.3 Contraindications

None.

3.4 Precautions

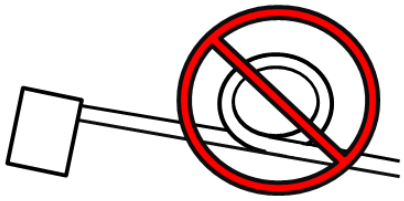
 Patients with increased likelihood of seizures or claustrophobia

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

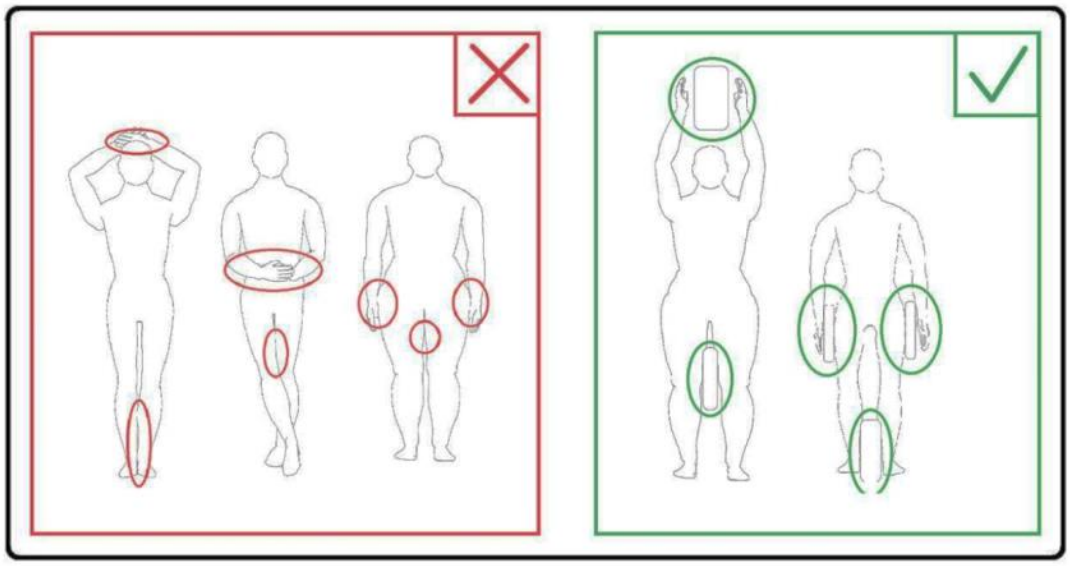
- Patients with an inability to maintain reliable communications (for example, infants or young children)
- Patients with loss of feeling in any body part
- Patients who have difficulty regulating their body temperature or who are particularly sensitive to increases in body temperature (for example, 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 18ch T/R Knee Coil is a Transmit and Receive coil. To properly use the coil, ensure the system interface connector is connected to the correct port. Consult the system user manual to identify the port that supports both transmit and receive.

Chapter 5 – Quality Assurance

5.1 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.

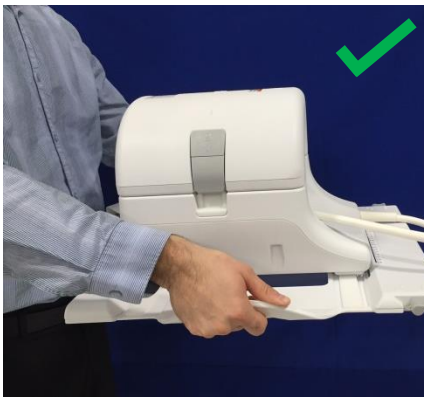
5.2 Signal to Noise Ratio (SNR) Test

Tools/Fixtures Required

Description	GE Part #	QED Part #	Qty
Large Cylindrical Unified Phantom, SiOil	5342679-2	N/A	1
T/R Knee Coil - Bottom Pad, 0.5"	5561409-8	3003885	1

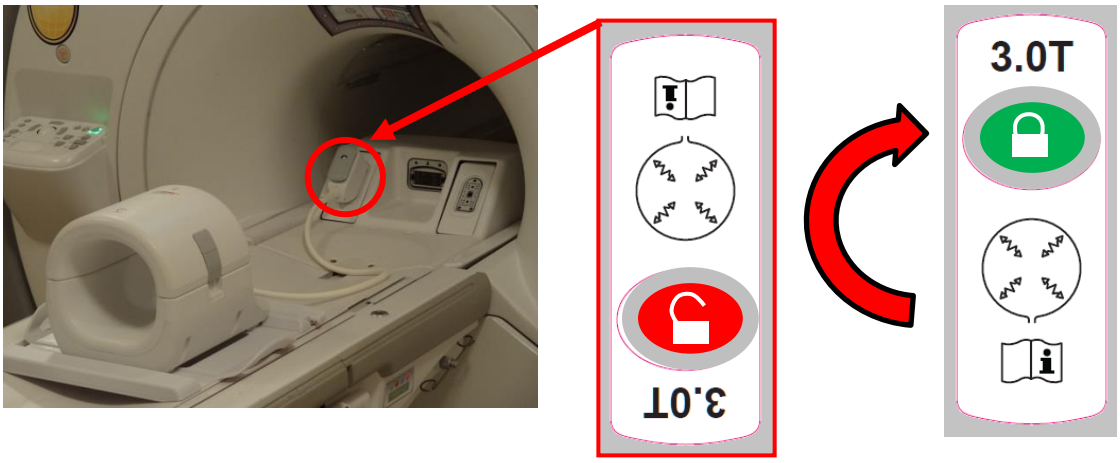
Coil and Phantom Setup

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 Knee coil to the patient table. Be sure to carry the coil with both hands by the handle on the frame.

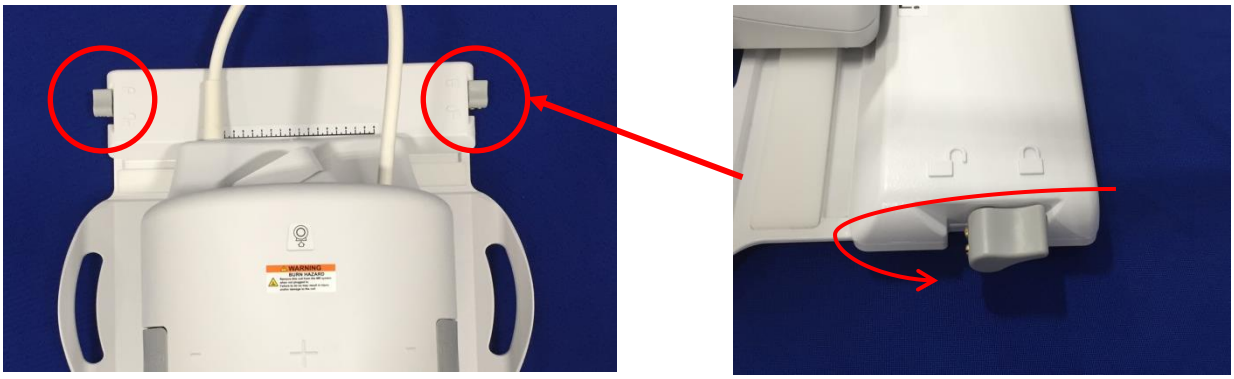


4. Place the coil onto the patient table. Note that the bore direction arrow pictured below should be pointing **towards** the bore.

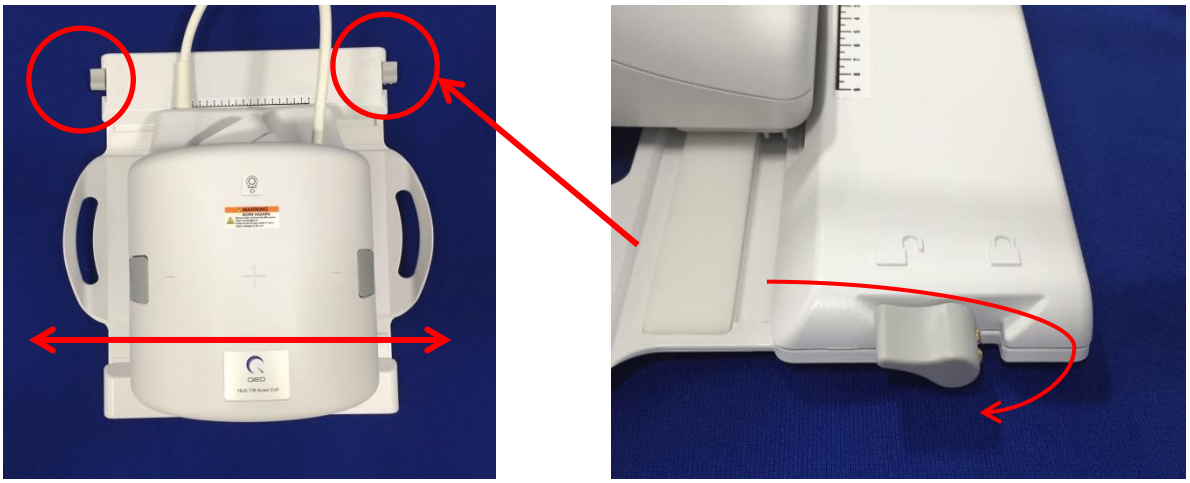
5. Connect the coil connector to the appropriate Transmit Port of the system. (Refer to system user manual for TR Port location) Turn the end of the P-Port connector around such that it exhibits the LOCKED position, see picture on right.



6. Ensure the Left-Right position of the coil is in the center of the frame. If adjustment is required, turn the knob on the coil frame to unlock the coil and slide it to its desired position.



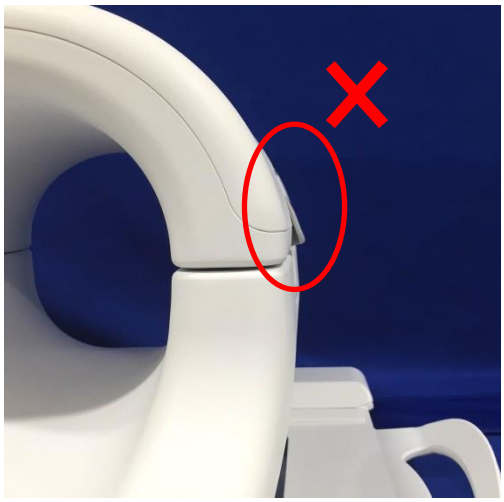
7. Once the coil has reached the desired position, turn the knob again to the lock position to secure the coil in place.



8. Separate the Anterior Coil by pulling both of the latch flaps simultaneously until the two halves are fully disengaged.

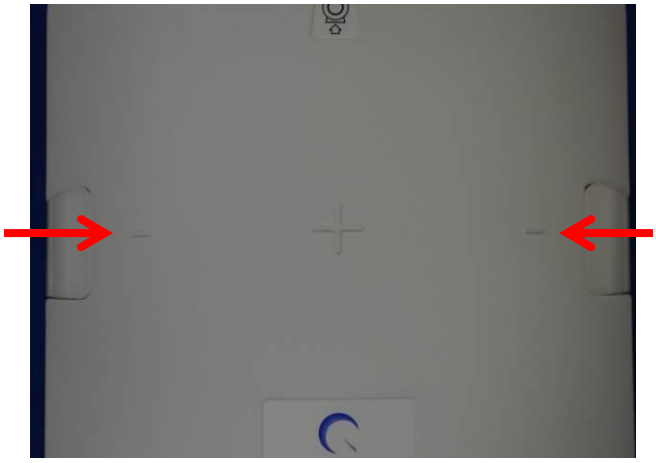
9. Place the 18ch T/R Knee CoilBottom Pad, 0.5" (5561409-8) and Large Cylindrical Unified Phantom, SiOil (5342679-2) onto the coil as shown below.

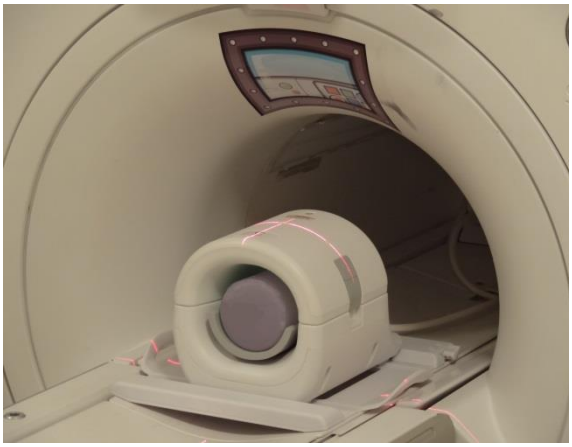
10. Reattach the Anterior Coil half**. Ensure the two halves are fully closed and the latch flaps are pushed in.**



CAUTION	Caution: Take care to not place fingers underneath the latch. Hold only the accessible flaps as shown in the picture above.

11. Landmark the coil at the marks shown below and move coil into the bore.





5.3 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.

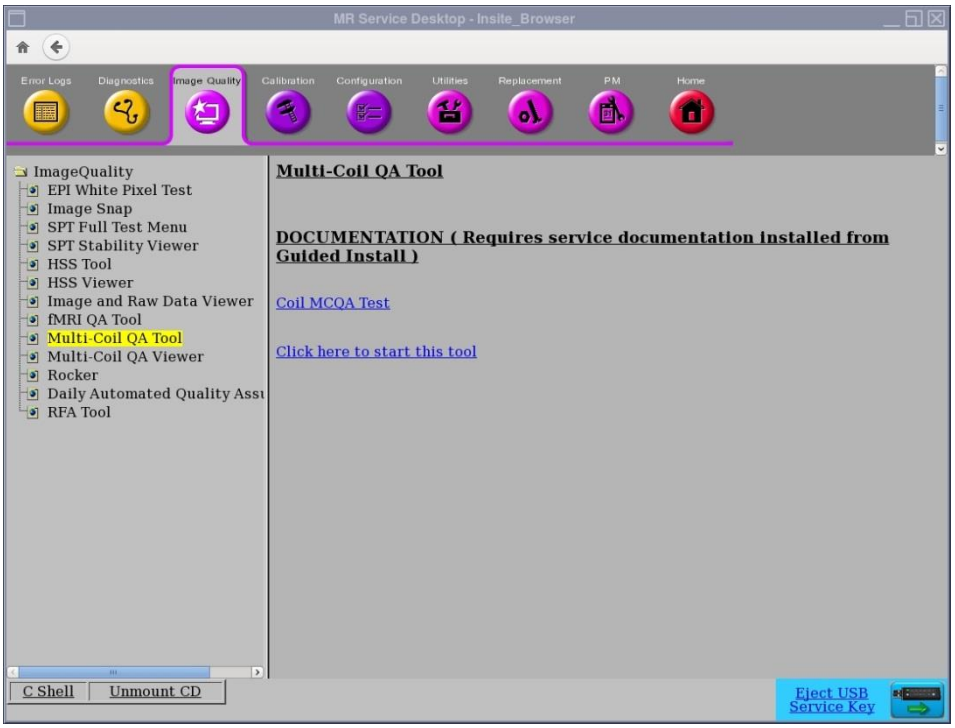


Figure 1

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.

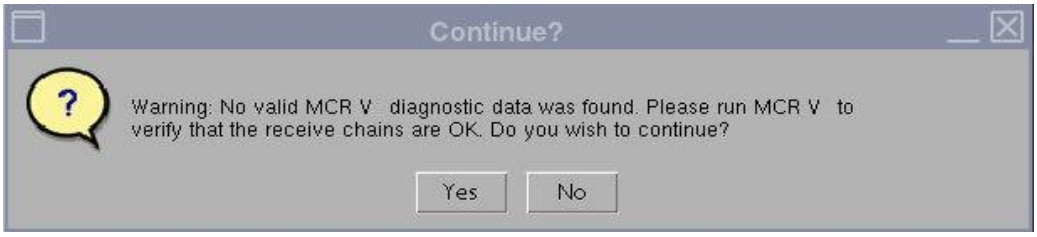


Figure 2

The current coil field will be automatically filled in (Figure 3), based on the 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.

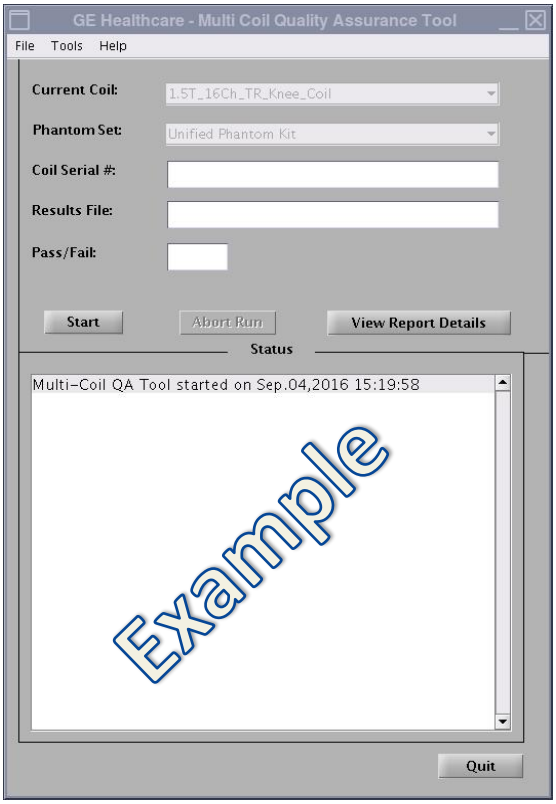


Figure 3

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).

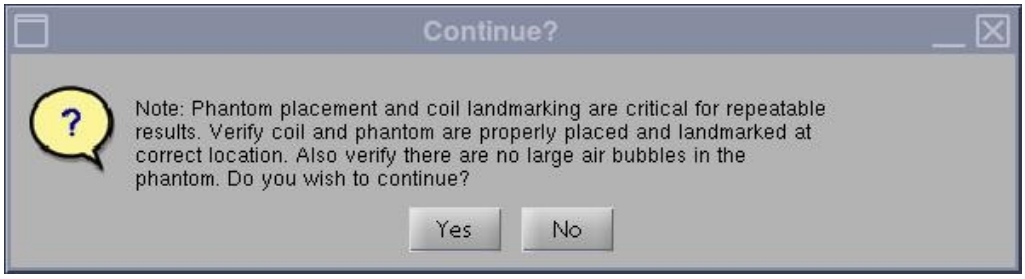


Figure 4

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
- 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

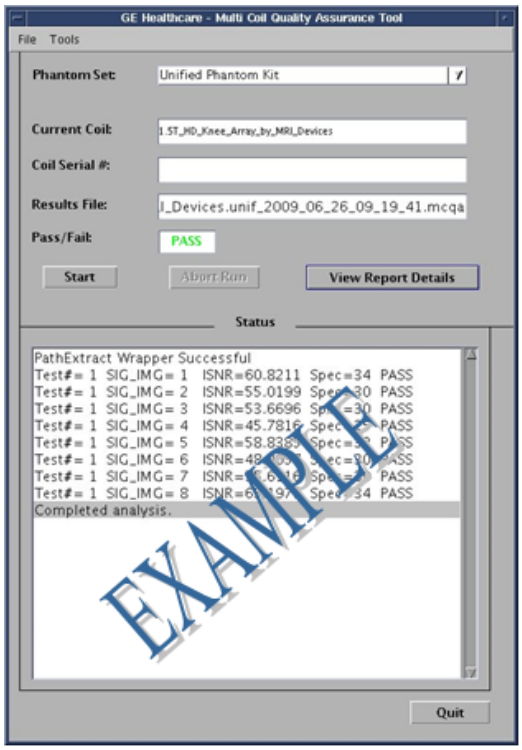


Figure 6

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

5.4 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.*

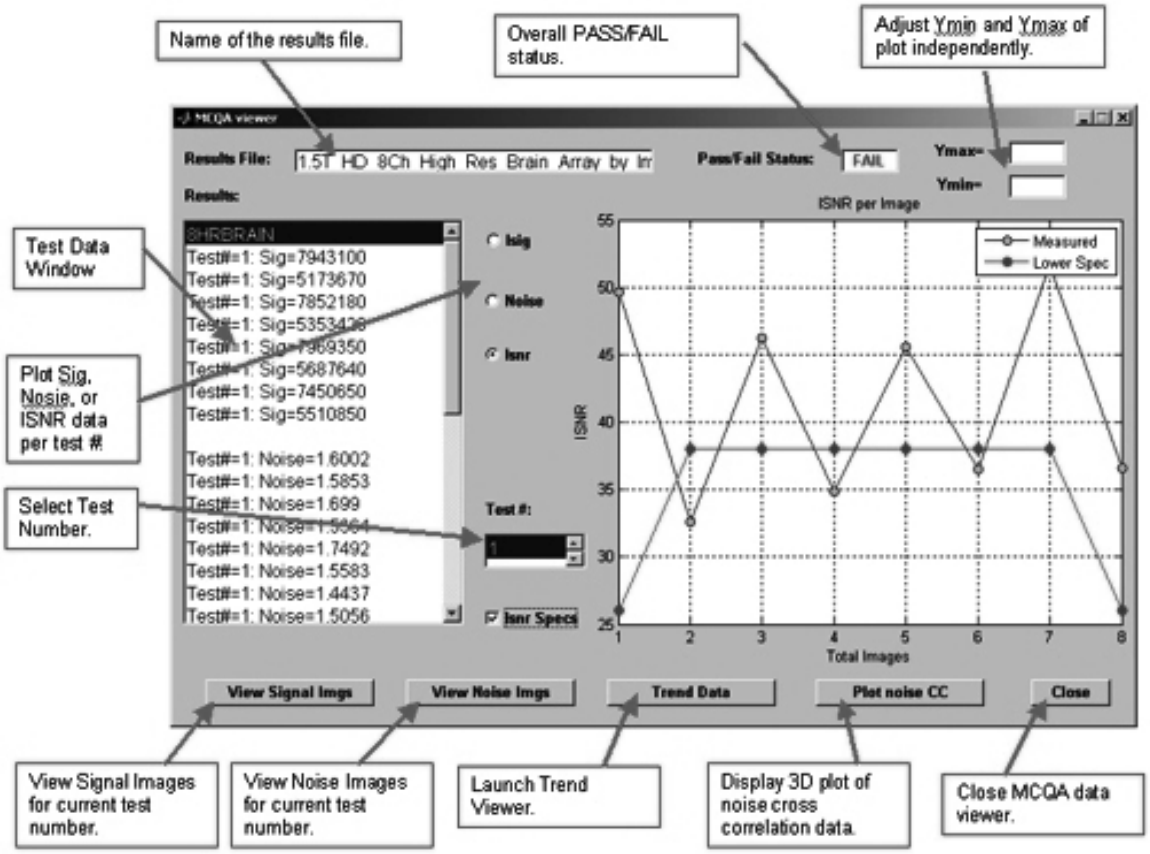


Figure 7

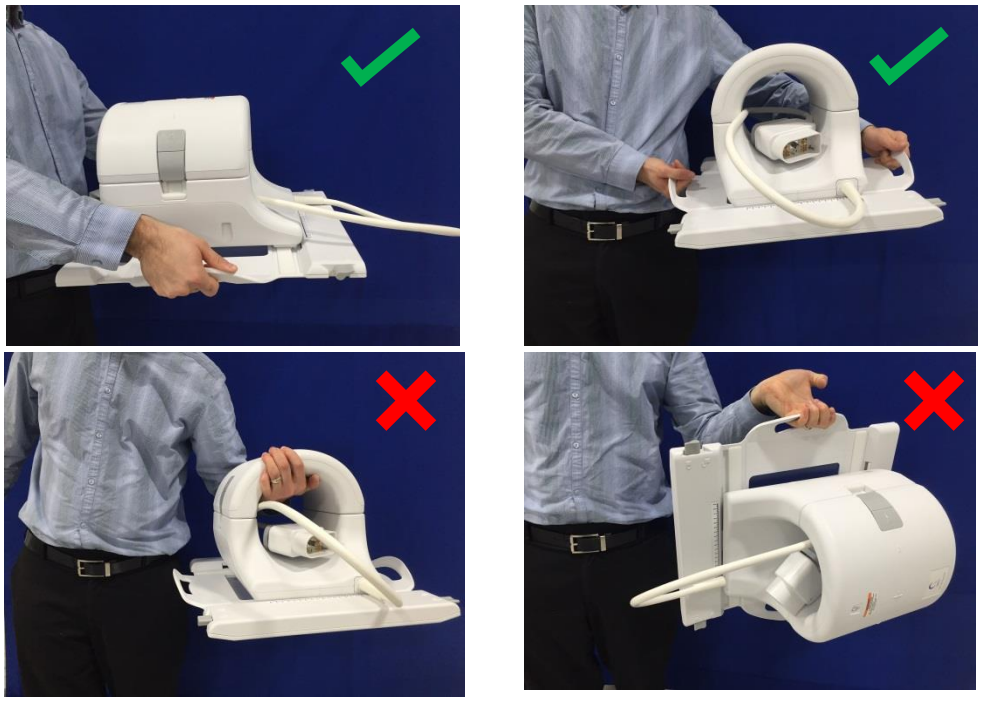
2. Select the ISNR option and the ISNR Specs check box in the middle portion of the Results Viewer to view the results.

Test ID	Parameter Description	Expected Result
1	EPIWP in spec	PASS

Chapter 6 – Coil Setup and Use

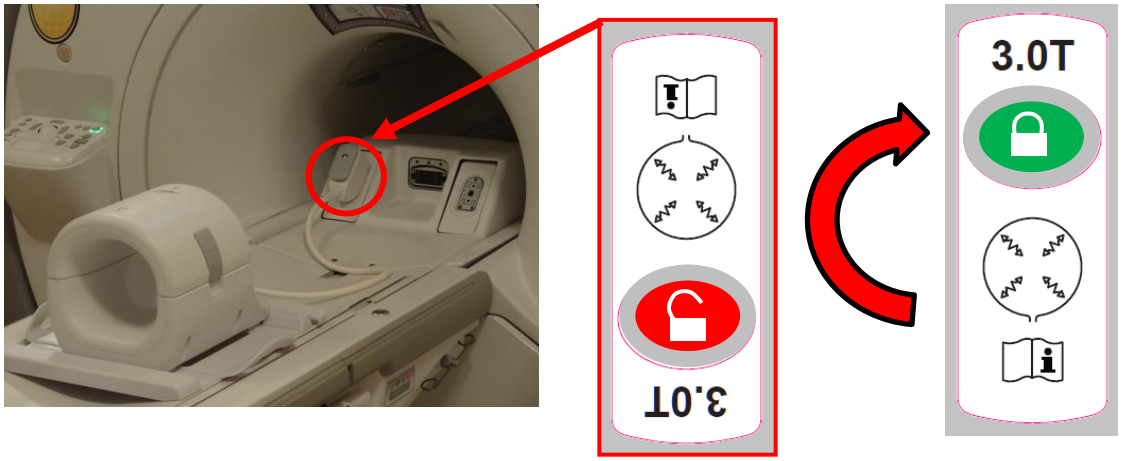
6.1 Positioning the 18ch T/R Knee Coil on the System Table

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

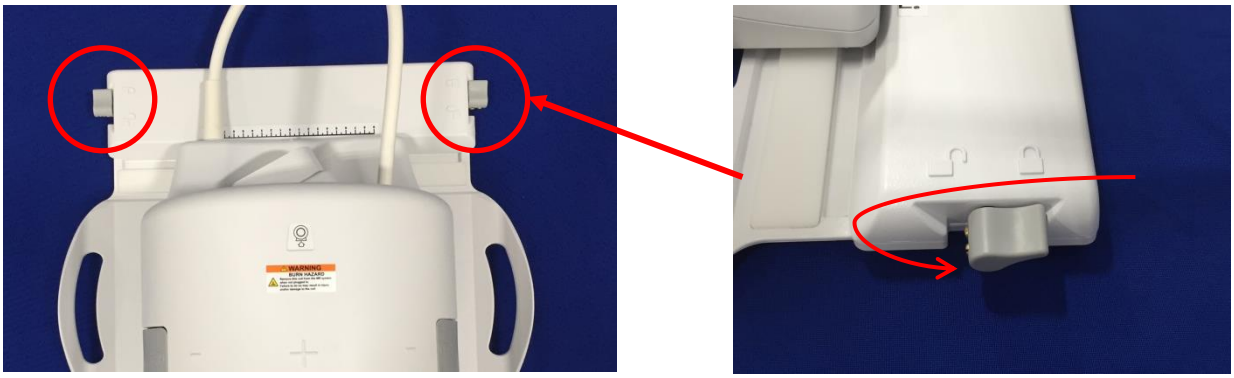


3. Place the coil onto the patient table. Note that the bore direction arrow pictured below should be pointing **towards** the bore.

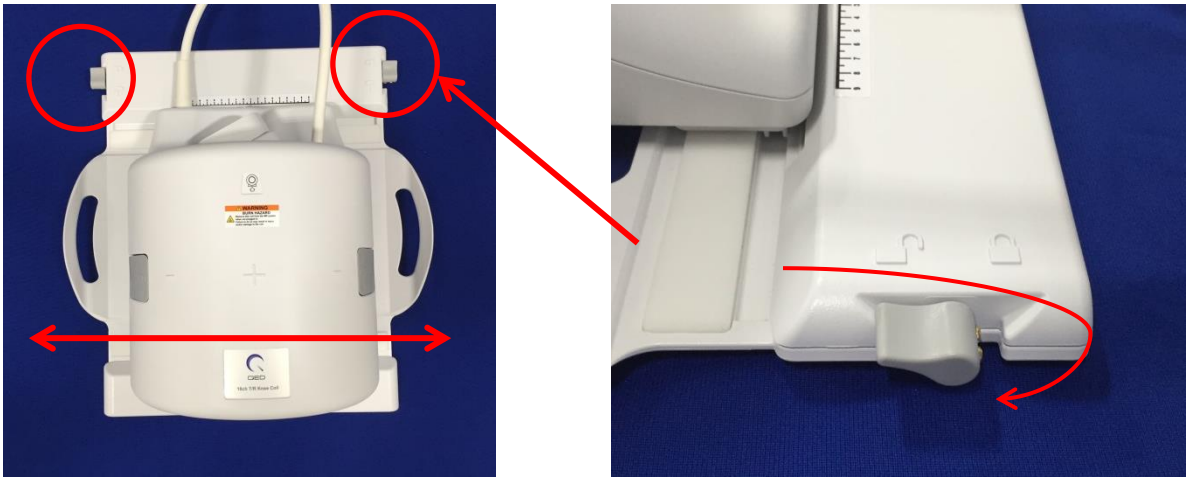
4. Connect the coil connector to the appropriate Transmit Port of the system. (Refer to system user manual for TR Port Location) Turn the end of the P-Port connector around such that it exhibits the LOCKED position, see picture on right.



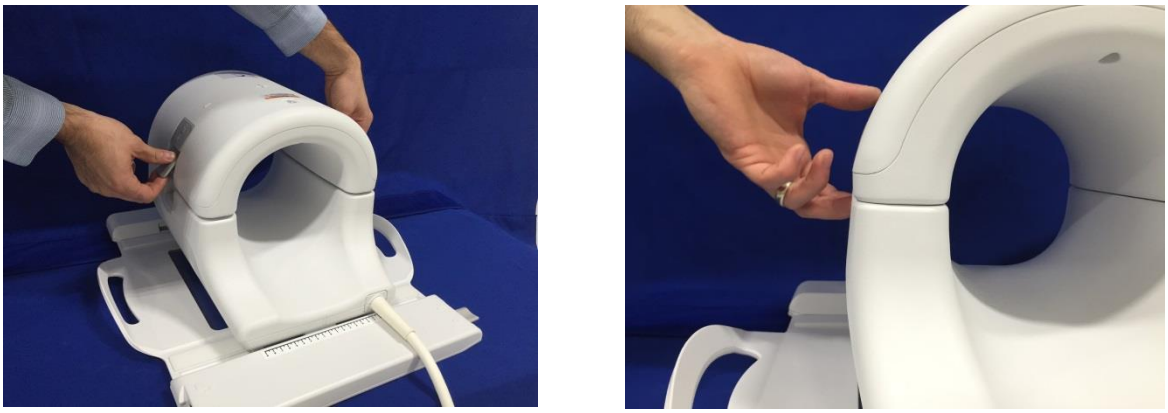
5. Ensure the Left-Right position of the coil is in the center of the frame. If adjustment is required, turn the knob on the coil frame to unlock the coil and slide it to its desired position.



6. Once the coil has reached the desired position, turn the knob again to the lock position to secure the coil in place.

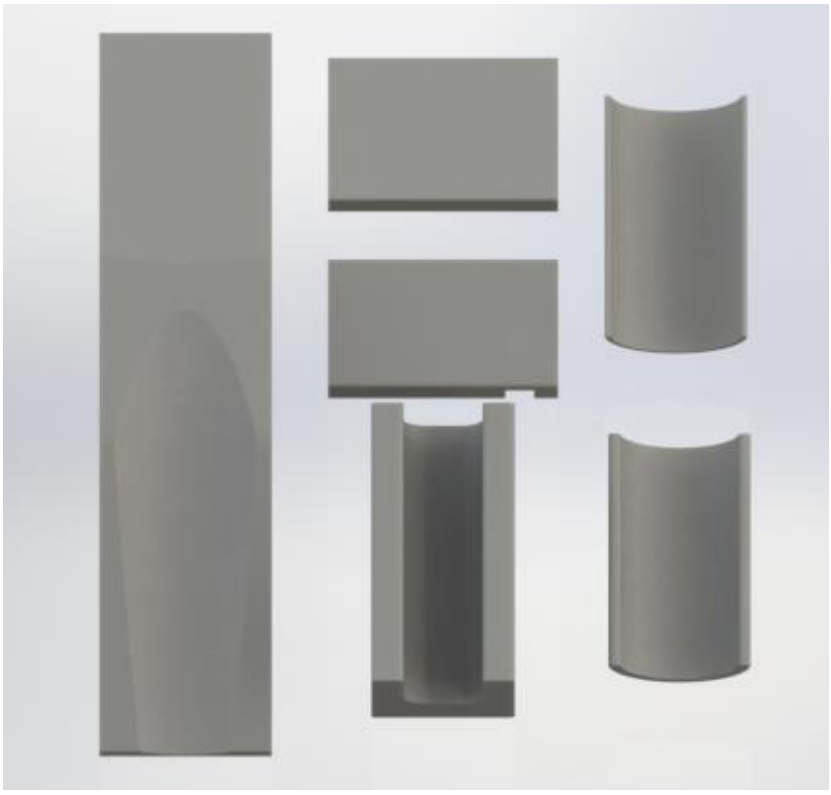


7. Separate the Anterior Coil by pulling both of the latch flaps simultaneously until the two halves are fully disengaged.



6.2 Pad Configuration

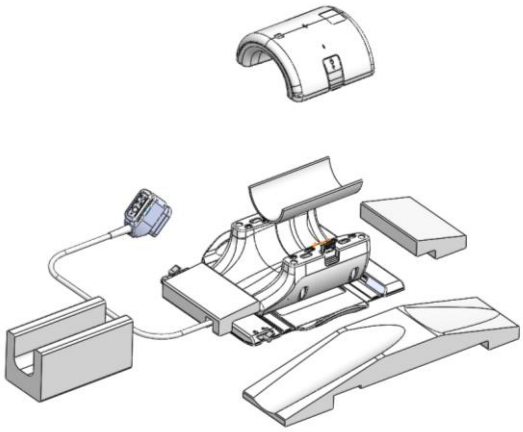
Various pads are supplied with the 18ch T/R Knee Coil to minimize motion artifact and to provide patient comfort. In addition, some pads provide insulation between the patient body and the cable to help prevent any potential hazards from cable contact and/or electrical burns.

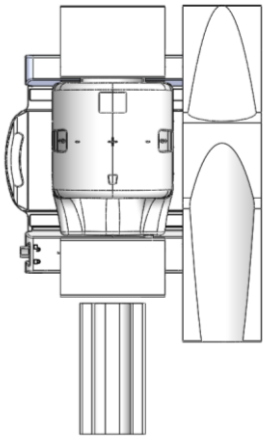


6.3 Position the Patient

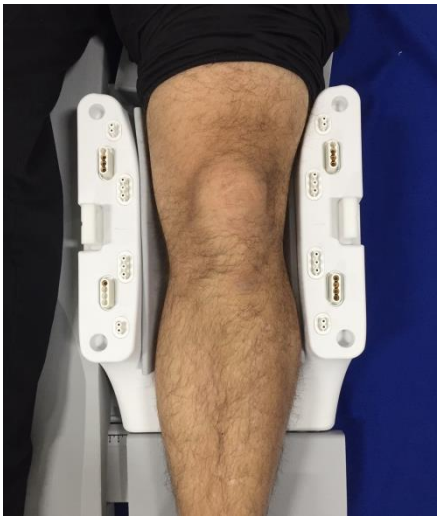
The 18ch T/R Knee Coil is designed to image either the left or right knee with the patient laying on his/her back, feet first into the magnet.

1. Place coil and pads prior to patient positioning. The 18ch T/R Knee Coil comes with a variety of pads to facilitate patient comfort. Below is an example of the recommended layout:





2. Position the patient's knee into the posterior half of the coil. Appropriate pads should be used to properly immobilize the patient's knee and to ensure patient comfort.



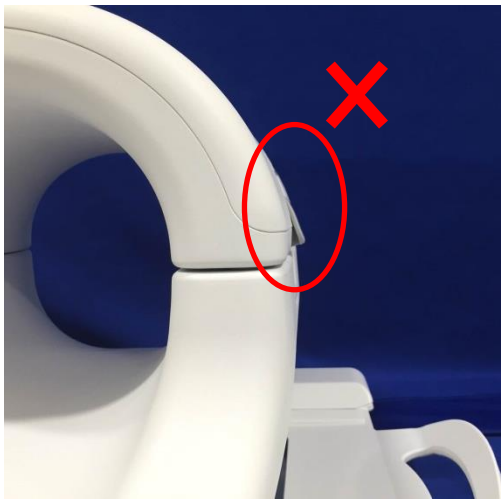
6.4 Lock the Coil

3. 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.

   The two coil halves are designed such that the coil can only be closed in the correct orientation.

4. Once the anterior half is closed completely, push the latch flaps down on both sides against the coil surface to fully engage the mechanical latches. In the case the latches are not fully engaged, the coil may disengage during the scan and cause a total loss of connection or intermittent

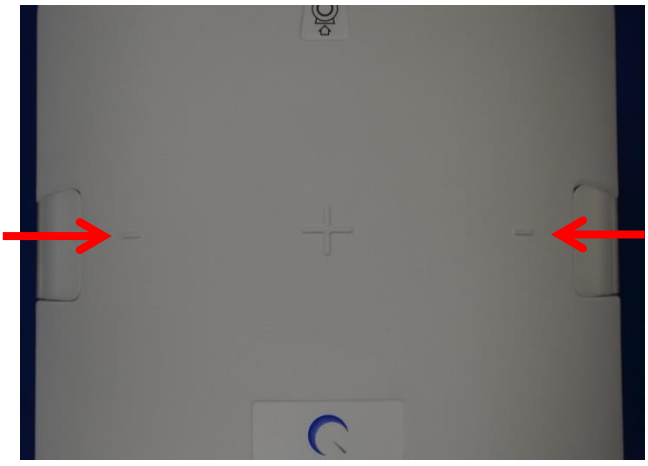
connection between the coil halves, which will result in poor image quality or damage to the coil.

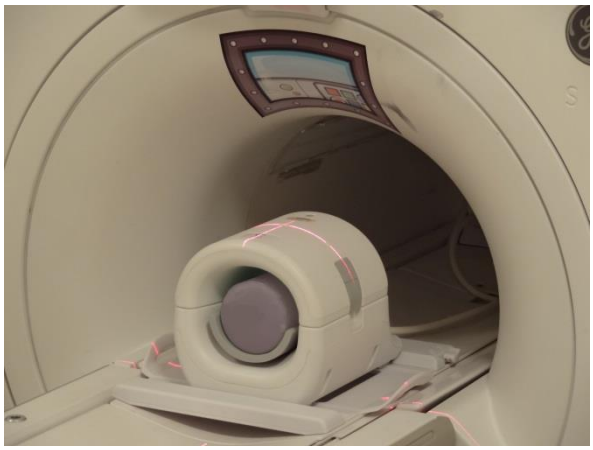


CAUTION	Caution: Take care to not place fingers underneath the latch. Hold only the accessible flaps as shown in the picture above.

6.5 Landmark

5. Advance the patient into the magnet and landmark the coil using the reference marks on the top of the 18ch T/R Knee Coil. Move coil into the bore and begin exam.





Chapter 7 – Cleaning, Maintenance, Service, and Disposal

7.1 Cleaning the RF Coil

CAUTION	1. Do not pour cleaning solution directly onto the coil or accessories. 2. Do not sterilize the coil or accessories. 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:

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 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.

7.2 Maintenance

No regularly scheduled maintenance is required for the RF coil.

7.3 Service

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

7.4 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.

7.5 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 8 – 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.

8.1 Classification

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

i	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 re-orienting the equipment.

8.2 Environment and Compatibility

This RF coil is intended to be used in combination with an MRI system that resides in an RF-shielded 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.

CAUTION

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.
4. 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.

8.3 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.

8.4 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

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Date of First Issue: 2015-04 / Revision Date: 2023-03