8ch T/R Knee Coil Operator Manual - English Model 10-F31896



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Proper performance of this coil can be guaranteed only when the coil is used on the MR system (hardware/software level) specified at the time of purchase. Upgrades or any other modifications to the system software and/or hardware may affect compatibility. Prior to upgrading your MR system, please contact your GE Medical Systems, LLC representative to discuss coil compatibility issues. Failure to do so may void your warranty.

Medical Device Directive

Products with the following CE Mark of Conformity meet the requirements of European Union Directive EU 2017/745 MDR concerning medical devices:



The product is a Class II device that complies with the international safety standard IEC 60601-1, and can be operated continuously. As a type BF application part, it is used in the environment with ordinary waterproof function and without flammable anesthetic gases.

WARNING:

The equipment must be disposed of separately from unsorted municipal waste. Contact an authorized manufacturer representative for information concerning disposal.

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INTRODUCTION

This manual describes the safety precautions, features, use and care of 8ch T/R Knee Coil, for use with GE 1.5T MRI systems. 8ch T/R Knee Coil is a transmit/receive coil. Please read this manual thoroughly before using the device. If you have any questions or comments regarding this manual, or if you need any assistance with the use of this product, please contact an authorized manufacturer representative.

COMPATIBILITY

The connector for 8ch T/R Knee Coil is a P-Port Connector, which is connected to the specific port on the GE system that contains a T/R terminal. Please note the P-Port plug label. Compatibility of 8ch T/R Knee Coil with GE 1.5T SIGNA Victor & SIGNA Prime systems is controlled by coil ID and is documented in the system related documents.



Figure P-Port Connector

INTENDED USE

8ch T/R Knee Coil is a transmit/receive RF surface coil designed for use with GE 1.5T MRI systems. 8ch T/R Knee Coil is indicated for patients undergoing MRI examinations of the knee and limbs. The surface material of the coil has limited contact (< 24 hours) with the patient's skin.

INTENDED USER

GE MR coils are intended to be used by experienced healthcare professionals.

IMAGING PRINCIPLES AND CLINICAL BENEFITS

MRI represents the relative response of a particular nucleus to the absorbed RF energy. Most MRIs aim to observe hydrogen atom nuclei because they are relatively abundant in human body. MRI is therefore typically a tomogram for proton distribution in an imaged sample. Similar to other imaging techniques, MRI images are a function of density.

MRI is noninvasive and does not use ionizing radiation. The distribution of nuclei can be observed by MRI techniques. The contrast of the image is also affected by other physical factors, including differences in the ability to re-emit the absorbed RF signal (relaxation) and flow phenomena. This dependence on multiple parameters means that the information content of MRI differs greatly from that of X-ray or ultrasound images. The different physical and chemical characteristics of specific protons can be modified by changing specific elements of the acquisition protocol to highlight the relative appearance of normal versus pathological tissues, thereby ensuring excellent tissue comparison across various tissue types. The imaging sequences can even be modified to visualize blood flow and to compensate for the blurring effects of cardiac or respiratory motion.

MRI also offers a unique ability to acquire images in almost any direction without repositioning the patient. This not only brings greater convenience to healthcare professionals, but also minimizes patient discomfort. Furthermore, magnetic resonance provides chemical information that cannot be measured with conventional X-ray or ultrasound. It is the combination of versatility, sensitivity, and specificity as a diagnostic modality that has accelerated the acceptance of MRI.

No undesirable side effects have been identified with the use of MRI coils. Refer to the MR System Instructions for Use/Operator's Manual for any undesirable side effects related to the use of MRI.

EXPLANATION OF SYMBOLS

| S/N | Symbol | Description |
|-----|---------|------------------------------|
| 1 | | Manufacturer |
| 2 | ₩ CN | Date of Manufacture |
| 3 | REF | Catalogue number |
| 4 | SN | Serial number |
| 5 | FIELD | High magnetic field |
| 6 | | Follow instructions for use |
| 7 | (i) | Consult instructions for use |

| r | Version. Nz.u | | | |
|-----|---------------|---|--|--|
| S/N | Symbol | Description | | |
| 8 | * | Type BF applied part | | |
| 9 | | Class II equipment | | |
| 10 | | Transmit/receive integration | | |
| 11 | | This symbol indicates that the waste of electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Contact the authorized representative of the manufacturer for information concerning the decommissioning of your equipment. | | |
| 12 | CE | CE Mark of Conformity or "CE Mark" indicates the mark that the manufacturer shows that the device complies with the applicable requirements set out in this regulation and other applicable EU harmonized regulations. | | |
| 13 | MD | Medical device | | |
| 14 | UDI | Unique device identifier | | |
| 15 | | Temperature limit | | |
| 16 | <u>%</u> | Humidity limitation | | |
| 17 | \$•• | Atmospheric pressure limitation | | |

| S/N | Symbol | Description |
|------|--|--|
| O/IN | Symbol | Description |
| 18 | Ť | Keep dry |
| 19 | Ī | Fragile, handle with care |
| 20 | 类 | Keep away from sunlight |
| 21 | 11 | This side up |
| 22 | <u>3</u> | Stacking limit by 3 |
| 23 | CH REP | Authorized representative |
| 24 | CA | UK product certification mark |
| 25 | $R_{\!X}$ only | Prescription device Note: US Federal law restricts this device to sale by or on the order of a clinician. |
| 26 | RECOGNIZED COMPONENT C Intertek 5002975 | The ETL Listed Mark indicates that the product has been tested by Intertek and found to be in compliance with accepted national standards. |
| 27 | | Warning: Crush hazard/Mind your hand |

| | version: R2.0 | | |
|-----|---------------|---|--|
| S/N | Symbol | Description | |
| 28 | | General warning sign | |
| 29 | | Warning High temperature | |
| 30 | 0-1 | Do not cross or wind the cable; failure to do so may cause ignition and burns to the patient. Pass the cable through the center of the magnet cavity. Place the cable under the pad whenever possible. Keeping the cable close to the sides of the magnet cavity increases the possibility of cable heating (caused by induced current) Minimize the length of cable within the magnet cavity. Avoid bending the cable to 180 degrees. Remove the cable from the magnet cavity in the most direct way without winding or coiling. | |
| 31 | MR MR | MR safe | |
| 32 | MR | MR unsafe | |
| 33 | MR MR | MR constraints Note: Items that are demonstrated to be safe in the MR environment under defined conditions. They determine the conditions for the static magnetic field, switched gradient magnetic field, and RF magnetic field at least. Accessory conditions may be required, including specific item configurations. | |
| 34 | (((-1)) | Non ionizing radiation mark | |

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CHAPTER 1: APPLICATION PARTS OF 8CH T/R KNEE COIL

Please check whether all application parts are complete and in good condition when receiving the goods. These application parts are supplied by Shenzhen RF Tech Co., Ltd. Refer to the following guidelines for the names of application parts in this manual.

Figure 1-1 Application Parts:

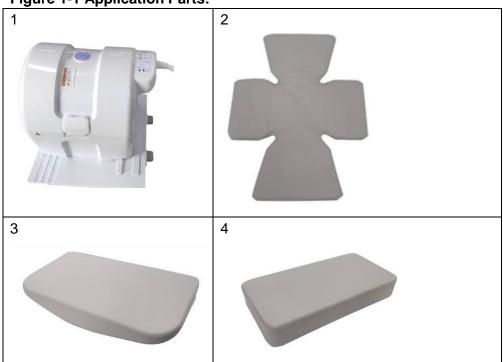


Table 1-1 Application Parts:

| | i abio i i Applicationi altoi | | | | | |
|------|---------------------------------------|-----------|-----------|--|--|--|
| | TABLE OF CONTENTS | | | | | |
| S/N | Description | RFT part | GE part | | | |
| S/IN | Description | number | number | | | |
| 1 | 8ch T/R Knee Coil | 10-F31896 | 5869241-2 | | | |
| 2 | 8ch T/R Knee Coil cavity pad (bottom) | 6-F32413 | 5869241-4 | | | |
| 3 | 8ch T/R Knee Coil ramp pad (2pcs) | 6-F32054 | 5869241-5 | | | |
| 4 | 8ch T/R Knee Coil side pad | 6-F32055 | 5869241-6 | | | |

For instructions on the replacement of accessories, please contact your local GE engineer.

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CHAPTER 2: SAFETY

2-1 Prerequisite Skills

This manual contains detailed information regarding the installation, positioning and use of 8ch T/R Knee Coil. Users must read the instructions carefully and thoroughly before attempting to scan patients with this coil.

This manual is not intended to teach MR imaging. Users must have sufficient knowledge to perform various diagnostic imaging procedures on their devices. You may gain the knowledge through a variety of learning approaches, including clinical working experience, hospital based programs, and as part of many college and university radiological technology programs.

2-2 Importance



MRI system is very complex and precision equipment, the receiving coil is an important part of this system, and improper use and operation of the equipment may cause serious damage, and even endanger the patient and operator.



Patient safety is critical; the primary prerequisite during operations and maintenance is to protect patients from electrical and mechanical damage.



Make sure your operator manual is available at any time, and regularly review operating procedures and safety precautions.

2-3 Quality Assurance

The procedure described in the chapter "Quality Assurance" of this manual should be performed upon receipt of the coil to establish a baseline of coil performance.

2-4 Cautions

The following general warning statements apply to scanning with an MR system. For further details, consult the warnings in your MR System Operator Manual.



Do not cross or loop the cable. Failure to do so may result in arcing and burns to the patient. Cables from the magnet should be routed appropriately to avoid touching the patient.



Remove the coil from the MR system when the coil cable is not connected to the system. Failure to do so may cause burns to the patient.



Make sure that the patient does not touch the jack hole. If necessary, a pad should be placed between the patient and the surface of the jack hole.

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Please keep electronic equipment (e.g. mobile phones), magnet cards, and damp clothing outside the magnetic shielded room. Metal wire or metal components and other metal articles in clothes, such as watch and coins should be removed from the patient. Do not take them into the scanning room, otherwise electronic devices may be damaged, and magnet cards may be demagnetized.



Make sure that the patient does not touch the magnetic cavity. If necessary, a guard should be placed between the patient and the surface of the magnetic cavity.



Do not use the coil in the environment with flammable anesthetic gases and flammable air mixture, oxygen, or nitrous oxide gas mixture.



Remove the unconnected receive coil and cable from the RF transmit coil during inspection. Failure to do so may cause burns to the patient.



If the patient feels fever, tingling, stinging, or similar sensations, immediately stop the scan procedure, examine the patient, and contact the responsible physician before continuing the procedure. Pay special attention to very young, sedated, or other compromised patients who may not be able to communicate effectively.



Physiological monitors, ECG, respiratory gating, and auxiliary equipment including receiver coil may cause burns and other injuries to patients. Use only auxiliary equipment approved for MRI system.



Patients with implantable magnetic metal devices should not be scanned, because the magnetic field may interact with the implantable surgical clips or other magnetic materials.



Persons with cardiac pacemakers or other implantable electronic devices should not enter the magnetic field zone delineated by the MR system manufacturer.



There is a risk of scanning patients with fever or cardiac metabolic disorder.



Patients with a surgery history of surgery must clearly inform the presence of metal or electronic devices and other materials in their bodies.



Use thermal resistance materials or liner to prevent direct contact between patients and the cable connection, failure to do so may cause burns to patients.

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Facial makeup should be removed before scanning because it may contain small amounts of metallic substances that cause irritation to skin and eyes. Permanent eyeliner tattoos may cause eye irritation due to ferromagnetic particles.



Patients who work in environments in which there is a risk of having embedded metallic fragments in or near the eye should be carefully screened before undergoing an MR examination.



Some transdermal patches may cause burns to the subcutaneous skin due to absorption of RF energy. The supplier of the patches should be consulted or the patch should be removed to avoid burns. A new patch should be applied after the examination.



Before each use, visually inspect the cable insulation, stress relief and junction box. If the insulation is broken, or if the cable is worn, stop using the equipment immediately.



In fact, a conductive ring may also be formed by contact with body parts, such as the inner thigh, inner calf, palm and palm, palm and body, ankle and ankle. Such contacts should be avoided, because they may cause burns to the patient.



Advise the patient to keep still throughout the scanning to avoid nausea. Patients should be supervised at all times during the scanning.



Avoid wearing damp clothes, which may cause burns to the patient.



Patients should always be taken care of during system scanning.



Use only approved accessories.

2-5 Contraindications



MR system has a very strong magnetic field that may be hazardous to persons entering the environment or the system room if they have some medical conditions or implantable devices.

When using this coil, please refer to the "Contraindication of Use" statement of your compatible MR system.

2-6 Precautions

Precautions should be taken during the scanning of patients with the following conditions:

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Risk of cardiac arrest exceeding the general level.



Increased likelihood of seizures or claustrophobia.



Unconscious, heavily sedated, or confused mental state.



Inability to maintain effective communications

Please refer to Chapter 2 "Safety" in your MR System Operator Manual or your *MR* Safety Guide for more and comprehensive MR safety information.

2-7 Emergency Procedures

If the coil creates smoke, sparks, or makes an unusually loud noise, or if the patient requires emergency assistance, perform the following steps:

- 1. Stop the scanning in case any of the above occurs.
- 2. Pull the cable assembly and unplug coil from MR system.
- 3. Release the scanning table by turning the handle at the end of the scanning table assembly.
- 4. Evacuate the patient from the scanning room. Provide medical treatment, if necessary.

2-8 Technical Considerations



Special conditions should be met in terms of electromagnetic compatibility of coil and accessories. The coil must be installed and used in a shielded scanning room provided for the MR system.



The user must ensure that the scanning room door is closed during system scanning. Failure to do so may cause mutual interference with portable and mobile RF communication equipment, affecting the performance of the MR coil and/or such equipment.



The coil should be used with the accessories specified in this manual.



The use of accessories other than those specified in this manual may result in decreased ESD (electrostatic discharge) immunity of the MR system, causing damage to the coil and/or system.



The coil should not be used with other coils or equipment present in the MR scanner except as specified in this manual.



The coil should be placed out of reach of the patient when not in use.



The coil should not be left unplugged in the system during body scanning in the coil.



Users must be trained in the safe and effective use of the MRI scanner before attempting to operate the coil.



Tampering with the cable pins and connector may damage connector and affect coil or system performance. Please verify that the connector and pins are not damaged before use.



For split coils, the user/patient should avoid touching any exposed connector pins.



After unpacking the coil, allow it to remain under stable atmospheric conditions for several hours prior to use. Extreme temperature and/or humidity during storage and/or transportation may cause condensation inside the coil.



At the end of its service life, dispose of the coil in accordance with local regulations.



Do not modify this equipment without authorization from the manufacturer.

2-9 Electrical and Mechanical Safety



The coil contains electrical and mechanical components. The electrical and mechanical assemblies and parts of the coil must be used with care and should be regularly inspected.



Service personnel must have received special training to ensure the safe operating condition of the coil. Therefore, only properly trained and qualified personnel should be authorized to repair the coil.



Any changes or modifications to the coil must be approved and performed by GE Medical Systems prior to installation.



Before using the coil, visually inspect it for any external damage. Do not use the coil if the housing or cable is broken.

2-10 Accident Reporting

In the event of an accident or injury to the patient, operator, or maintenance personnel while operating the coil, the user should immediately report the situation to <u>GE Healthcare</u> and <u>Shenzhen RF Tech Co., Ltd.</u> as well as to the user and the patient's member state.

If an accident occurs as a result of coil operation, do not operate the equipment until an authorized investigation is conducted. For more information, please contact:

| GE Healthcare Americas (North America) | | | |
|---|--------------------|--|--|
| USA | 800-558-5102 | | |
| Canada | 800-668-0732 | | |
| GE Healthcare Asia/Australia (Asia/Austra | lia) | | |
| China | 86-21-62192228 | | |
| Taiwan Province of China | 886-2-2505-7900 | | |
| Singapore | 65-291-8528 | | |
| Australia | 61-2-9975-5501 | | |
| Japan | 81-120-48-2630 | | |
| South Korea | 82-31-740-6119 | | |
| India | 91-80-845-2923 | | |
| GE Healthcare SCS Europe | | | |
| Europe | (33) 1-41-19-76-76 | | |

CHAPTER 3: INSTALLATION AND MAINTENANCE

3-1 Installation and Configuration

The coil must be installed and configured by the GE Service Representative.

3-2 Cleaning and Disinfection

Your MRI coils and accessories must be cleaned and disinfected in accordance with the regulations of your affiliation and your local, state, and federal regulations, and the following cleaning and disinfection instructions have been tested and verified.

To prevent accidents, pay special attention to:



Caution: No magnetic disinfection equipment should be brought into the magnet room (including the magnet UV device). The movable accessories between coil and magnet are recommended to be cleaned and disinfected outside the magnet room.



Cleaning and disinfection personnel entering the magnet room must be aware of the working practices under a strong magnetic field environment before they can perform cleaning and disinfection of equipment in the magnet room. After cleaning and disinfection are done in the magnet room, it is necessary to open the ventilation system for ventilation.



Remove the coil connector from the scanner before attempting to clean the coil. An electrical shock accident may occur if the system is connected during the process of cleaning the coils, the coils are not dry, or the system becomes damp.

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Do not touch the connector by hand, nor wipe the connector with a corrosive cleaning substance, such as alcohol or isopropyl alcohol and bleach.



Do not continue to use the coil if it is found to be cracked or broken.



Check the pads for flaking or cracking. To prevent biological hazards, replace the cracked or flaked pads before use.



Dispose of the used cleaning, sanitizing, and drying materials according to the contamination procedures.



Do not gather detergents after cleaning. Accessories such as coils and pads must be completely dry before use.

To avoid possible damage to equipment, avoid these practices:



Do not use flammable or explosive sprays as the vapors generated may result in detonation, causing injury or damage to the equipment.



Sprays are not recommended for disinfecting medical devices as this may allow disinfectant vapors to penetrate the device, causing a short circuit or corrosion.



Do not pour any cleaning solution directly on the coil.



Do not use solutions containing amines, strong bases, esters, iodine, aromatic hydrocarbons, or chlorinated hydrocarbons or ketones.



In no case should the coil be placed in any type of sterilizer. Disinfection or contact with liquids may damage the electrical parts of the device. Do not autoclave any components of the coil.



Harsh chemically degradable plastics may compromise device safety. It is known that some sterilizing and other harsh cleaning compounds may damage some plastics by weakening structural integrity and compromising electrical insulation.



Cavicide, Virex, Virex 256, PDI Sani-Cloth Bleach Plus, Super Sani-Cloth, and Sani-Cloth AF3 are commonly used quaternary ammonium salt disinfectants. Manufacturers advertise that these disinfectants can be safely applied on hard, non-porous surfaces such as linoleum floors, Bakelite tables, and stainless steel. Manufacturers discourage the use of these disinfectants on data cables, patient cables, and power cables because these cables are classified as porous materials.



Do not spray or pour cleaning solution directly on the coil as the coil contains sensitive electronics which are prone to damage.



Do not immerse the coil in any solution. Under no circumstances should the coil be placed into any type of sterilizer. Soaking in liquid may cause equipment failure and will void the warranty.

3-2-1 Cleaning

- 1. Cleaning refers to physical removal of foreign matter, such as dust, soil, blood, secretions, excretions, microorganisms, and other organic matters.
- 2. Cleaning refers to removing microorganisms rather than killing them.
- 3. Cleaning is done with water, detergents, and wiping.
- 4. Cleaning is an essential prerequisite for effective disinfection.

3-2-2 Disinfection

- 1. Disinfection is the process of eliminating or reducing harmful microorganisms from inanimate objects and surfaces.
- 2. According to the Spaulding classification, the MRI coils and accessories are considered non-critical. Non-critical equipment refers to the instruments and devices with surface only contacting intact skin but not penetrating the skin. Medium or low level disinfection is required.



Non-critical equipment does not come into direct contact with the patient, but may become contaminated with microorganisms and organic soil (e.g., blood fluids) during patient care.

3-2-3 Recommended Detergent

Use a mild household detergent (such as neutral soap or liquid soap), dilute with water, and wipe with a soft, damp lint-free cloth.



Do not use plenty of water.

3-2-4 Recommended Disinfectant

| Disinfectant | Level of disinfection | Exposure duration | Temperature | Drying duration |
|--|-----------------------|-------------------|---|--------------------|
| Isopropyl alcohol 70% | Intermediate | At least 1 min | Room temperature (15°C–25°C or 59°F–77°F) | 1 min |
| 1:200 bleach water (containing 250 ppm chlorine) (5 mL household bleach water plus 1 L water) | Low | At least 5 min | Room temperature (15°C–25°C or 59°F–77°F) | 1 min |



Use of a non-recommended disinfectant, use of an incorrect solution strength, or exposure of the coil to a detergent or disinfectant for longer than recommended duration may damage or discolor the coil and its accessories.



If using disinfectant wipes, make sure that they contain the active ingredient at the same concentration as above and no other ingredients.



Do not use bleach solutions above 250 ppm.



Do not use bleach wipes.

3-2-5 Prevent Residual Stain or Virus on MR Coil



Every effort should be made to cover the patient contact surfaces with coils and accessories with a test strip or MR-compatible working paper prior to patient positioning.



The use of bed sheet or paper sheet cannot prevent the spread of infectious diseases without actual cleaning and disinfection.

Risk of cross infection



Always clean and disinfect the bed, mattress, physiological sensor, positioning aid, coils, and cables after each examination of the (injured or infected) patient site.



Appropriate personal protective and preventive measures should be taken when removing blood or residual contrast media.

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3-2-6 Cleaning and Disinfection Frequency

| Equipment and accessories | | Cleaning | Disinfection | Frequency | | |
|---------------------------|---------------|-----------------|--------------|----------------------|-----|----------------------|
| | Rigid coil | Yes | Yes | Clean before use for | | |
| | | | | each patient | | |
| | Flexible coil | Yes | Yes | Clean before use for | | |
| Non-critical | | | | each patient | | |
| diagnostic coil | Coil base | Coil base Yes Y | Voo | Voc | Yes | Clean before use for |
| | | | 165 | each patient | | |
| | Coil cable | Yes | Yes | Clean before use for | | |
| | | | | each patient | | |
| Pad/mattress | Pad/mattress | | Yes | Clean before use for | | |
| | | | | each patient | | |
| Coil pad | | Yes | Yes | Clean before use for | | |
| | | | | each patient | | |

3-2-7 Cleaning and Disinfection Steps

General Steps:

1 Check

1.1 Check the coil and cable for any damage such as cracks, fractures, and wear.



If the coil or cable is damaged, contact your GE service representative.

1.2 Regularly check the surface of positioning tools such as a mattress, pad, sandbag regularly for damages, tears, or wear. Remove and place the damaged mattress or sandbag, if any.



Internal sponge structures cannot be adequately cleaned and disinfected.



Do not repair tears or holes with patches or adhesive tapes.

2 Cleaning

- 2.1 Prepare a mild soap or detergent solution (see "Recommended Detergent" above).
- 2.2 Wipe all surfaces with a soft, lint-free cloth dampened with detergent.
- 2.3 Use a cotton swab or toothpick to remove the stain from the coil gap and corner of the housing.
- 2.4 Wipe all surfaces until all visible signs of surface contamination are removed.
- 2.5 Wipe off any residual detergent by applying a soft, lint-free cloth dampened with tap water.
- 2.6 Air dry for 2 minutes or wipe all surfaces dry with a lint-free cloth.

3 Disinfection

- 3.1 Check all surfaces for cleanliness. Repeat the above steps for surface cleaning if necessary.
- 3.2 Dampen a soft, lint-free cloth with a recommended disinfectant (see "Recommended Disinfectant" above), and wipe the surface with a lint-free cloth dampened with clean tap water to remove the disinfectant solution.
- 3.3 Allow the surface to air dry when using alcohol.
- 3.4 When using bleach solution, contact with bleach for at least 5 minutes. Then wipe the surface with a lint-free cloth dampened with clean tap water to remove the bleach solution.
- 3.5 Dry with a clean lint-free cloth or allow to air dry.



Residual detergent or disinfectant on the coil may damage the coil surface and cause surface cracks.

3.6 Dispose of any used sterilization materials according to your disposal policy.

3-3 Product Life

The function, lifetime, and normal performance of the coil can be guaranteed only if the coil is used on the MR system (hardware/software level) specified at the time of purchase. Upgrades or other modifications to the system software and/or hardware may affect compatibility.

Stop using the equipment immediately in case of the following conditions when using the coil continuously:



Cracked coil housing: Cracked coil housing may expose electrical components and may cause an electrical shock.



Broken cable: If the cable is worn, insulation or housing is damaged, please stop using the equipment immediately.



Damaged connectors and pins: Damaged cable pins and connectors may damage the MR system connector and affect compromise coil or system performance.

3-4 Replaceable Accessories

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| S/N | Description | RFT part | GE part | |
| 3/19 | Description | number | number | |
| 1 | 8ch T/R Knee Coil cavity pad (bottom) | 6-F32413 | 5869241-4 | |
| 2 | 8ch T/R Knee Coil ramp pad | 6-F32054 | 5869241-5 | |

| 3 | 8ch T/R Knee Coil side pad | 6-F32055 | 5869241-6 |
|---|----------------------------|-----------|-----------|
| 0 | oon the tales oon side pad | 0 1 02000 | 00002110 |

3-5 Storage

Store the coil in a well-ventilated scanning room or equipment room.

To store the coil and base plate, a storage space of greater than 41 cm \times 36 cm \times 33 cm (D \times W \times H) is required.

3-6 Environmental Requirements

This equipment should be transported, stored and operated under the following conditions:

| Item | Transport/Storage | Operating conditions | | |
|----------------------|-------------------|----------------------|--|--|
| Atmospheric pressure | 500 hPa-1,060 hPa | 500 hPa-1,060 hPa | | |
| Relative humidity | 5% to 95% | 30% to 75% | | |
| | Non-condensing | 30% to 75% | | |
| Temperature | -30°C to +70°C | 15°C to 21°C | | |

3-7 Weight and Dimensions

| Item | Package | Coil (including base) |
|------------|-----------------------------|-----------------------------|
| Weight | 11 kg | 6.1 kg |
| Dimensions | 61.0 cm x 56.0 cm x 41.0 cm | 40.4 cm x 35.8 cm x 32.6 cm |

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CHAPTER 4: QUALITY ASSURANCE

4-1 Purpose

To check the system single-noise ratio (SNR). This procedure allows the user to check the coil elements for proper functioning.

The quality assurance test should be performed upon receipt of the coil to establish a baseline of coil performance. To check the system-level signals and noise. For the specific frequency of quality assurance tests, please refer to the system service frequency.

The following steps detail the instructions for performing this assessment.

4-2 Tools Required

| Table 4-1 Tools Required | | | | |
|--|----------------|----------|--|--|
| Description | GE part number | Quantity | | |
| Large, homogeneous cylindrical phantom | 5342679 | 1 | | |

4-3 Coil Base Positioning

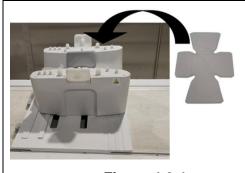


Figure 4-3-1

The lower portion of 1.5T 8ch T/R Knee Coil is designed with a base plate on which the coil slides left and right. The base is placed directly on the patient table to achieve stability. The coil cable should be let out from the foot of the patient.

1. Place the coil pad on the lower portion of the coil.

4-4 Phantom Fixation



Figure 4-4-1

2. Place the large, homogeneous cylindrical phantom on the lower portion of the coil.



3. Align the connectors of both upper and lower portions of the coil for connection; Lock the buckles on both sides.

Note: If the upper and lower portions of the coil are not correctly locked, the scanner will not work.

Figure 4-4-2

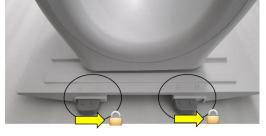


Figure 4-4-3

4. Slide the knee coil to the desired position. Then slide the base switch to where the coil is locked to the base.

Pay attention to the slot during movement to prevent pinching.

4-5 Cable Connection

Connect 8ch T/R Knee Coil cable to the system P-Port port.



The 8ch T/R Knee Coil connector can only be connected to a specific port on the GE system that contains a T/R terminal. Please note the P-Port plug label. Connecting the wrong port will make it impossible to scan.

4-6 Coil Positioning

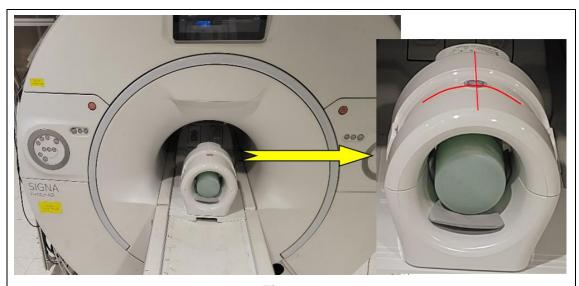


Figure 4-6-1

As shown in Figure 4-6-1, feed the coil into the magnet for positioning on the positioning marker.

4-7 Multi-Coil Quality Assurance (MCQA) Tool



WARNING: All RF coil related tests must be run on a system that is well-calibrated and passes all system tests (the system should have passed "Install In Specification" (IIS)), especially white pixel, correlated noise, and MCR (Multi-Coil-Receive) tool.

From the Common Service Desktop (CSD), select [Image Quality], Multi-Coil QA Tool, and Click here to start this tool. The MCQA Tool window will open, as shown in Figure 4-7-1.

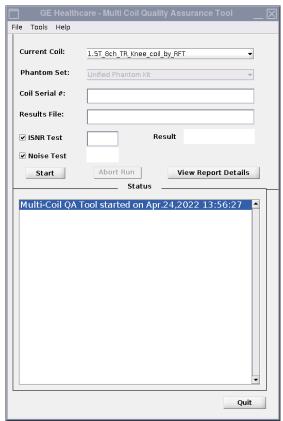


Figure 4-7-1: Multi-Coil QA Tool

A warning (Figure 4-7-2) will pop up, requiring the user to verify the coil/phantom set-up and position and verify that there are no large air bubbles in the phantom. Ensure the phantom and coil are set up properly and select [Yes] to continue.

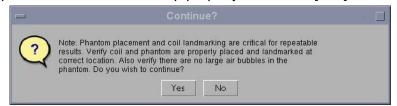


Figure 4-7-2: Phantom/Coil Setup Warning Pop-Up

When the test is complete, test results are displayed on the screen (Figure 4-7-3). The PASS/FAIL status shows PASS if all coil elements are functioning properly. If any coil element displays FAIL, call the GE Service Representative for coil repair.

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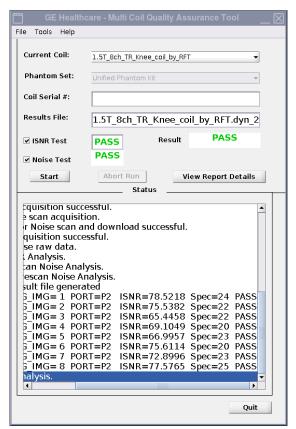


Figure 4-7-3: Test Results

The MCQA Tool GUI displays Fail for reasons including, but not limited to:

- Failure of coil element
- Incorrect phantom used for the test
- Incorrect positioning/placement of the phantom

Click [Quit] button to exit MCQA Tool.

Remove coil and phantoms from the system cavity.

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CHAPTER 5: USE OF 8CH T/R KNEE COIL

5-1 Base Positioning



Figure 5-1-1

The 8ch T/R Knee Coil is equipped with a fixed base. The base is directly placed on the patient's scanning table to ensure that the coil is stable.

For knee imaging, orient the coil bore toward the magnet end of the patient table to image the patient's knee in the supine position.

5-2 Left and Right Positioning of Coil



Figure 5-2-1

Instructions for base switch:

means that the base switch is unlocked, and the knee coil can be slided:

means that the base switch is locked, the knee coil is fixed, and cannot be slided:

The operation process is as follows in actual use:

Slide the base switch to , so that the knee coil slides left and right on the base to adapt to the knee examination on the left or right.

The coil in the figure is located on the left knee.

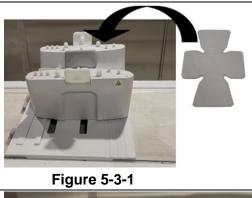
Slide the knee coil to the desired position. Then slide the base switch to where the coil is locked to the base.

Pay attention to the slot during movement to prevent pinching.

5-3 Pad Configuration



8ch T/R Knee Coil is equipped with 4 pads.

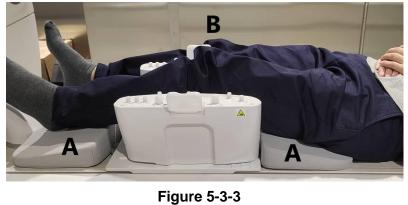


Center the cavity pad in the lower portion of the coil. It also ensures patient comfort.



Ramp pad [A] supports the scanned calf or ankle to ensure patient comfort.

Figure 5-3-2



Side pad [B] ensures patient comfort and balances the other knee to reduce its motion during scanning.

5-4 Patient Knee Positioning



Figure 5-4-1

Knee scanning:

Let the patient lie flat on the table with one knee imaged in the lower portion of the knee coil, so that the apex of the patella is centered in the coil and aligned with the positioning line.

5-5 Patient Elbow/Wrist Positioning



Figure 5-5-1

Elbow scanning:

The patient extends the arms forward in a prone position, with head first entering the scanning environment, then the patient lies on the bed with the face down, and centers the elbow to be scanned in the coil, aligned with the positioning line.

Wrist scanning:

The patient extends the arms forward in a prone position, with head first entering the scanning environment, then the patient lies on the bed with the face down, and centers the wrist to be scanned in the coil, aligned with the positioning line.

5-6 Coil Locking

Align the connector with care, place the upper portion of the knee coil on the lower portion of the knee coil, and make sure that no foreign material obstructs the connection of the connector. Lock the upper and lower parts of the knee coil by locking the buttons on both sides of the upper portion of the knee coil. To open the coil, just open the buckles on both sides of the coil and lift the upper portion of the knee coil.



The scanner will not operate if connectors of the upper and lower parts of the knee coil are not properly locked.



Be sure not to pinch the patient when locking the upper portion of the knee coil to the lower portion of the knee coil.

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Open the coil: Open the buckle on both sides and lift the upper portion.



Lock the coil: Lock the buckle on both sides.

5-7 Patient's Hearing



Provide ear plugs for the patient after the patient is informed of all instructions.



Hearing protection is required for all personnel in the scanning room during scanning, to prevent hearing impairment.



Acoustic levels may exceed 99 dB(A). Hearing protection must have a Noise Reduction Rating (NRR) of 28 dB or better (e.g., 30 dB, 32 dB.)

5-8 Connect Coil to System



The connector for 8ch T/R Knee Coil is a P-Port Connector, which is connected to the specific port on the GE system that contains a T/R terminal. Please note the P-Port plug label. Connecting the wrong port will make it impossible to scan.



Do not cross or loop the cable. Failure to do so may result in arcing and burns to the patient.



The coil must be removed before lowering the patient table.



Lead the cable from the direction toward the magnet to avoid contacting with the patient.



Figure 5-8-1 P-Port

5-9 Coil Positioning

The patient is fed into the magnet for positioning on the positioning line, as shown in the figure below.

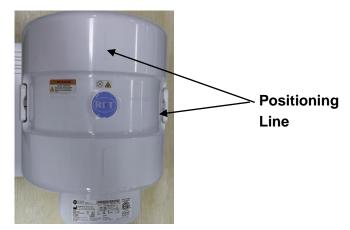


Figure 5-9-1 Coil Positioning

5-10 Coil Removal

After scanning, remove the bed, disconnect the coil cable and the MR system, separate the upper and lower portions of the coil, and ask the patient to leave the coil.

CHAPTER 6: SCANNING

6-1 Autoshim

Generally, the image quality can be improved by enabling autoshim. AUTOSHIM is a feature of the GE MRI System to improve image quality. It does this by improving the magnetic field homogeneity within the FOV selected. When the selected FOV is far from the center, autoshim can improve the quality significantly.

6-2 Positioning

The 8ch T/R Knee Coil is designed in such a manner that the body coil is not allowed to be used when the coil is connected to the scanner.

6-3 Fat Saturation Techniques

Off-center FOV imaging is a more complex and difficult technique since it is dependent upon the homogeneity of the magnetic field and the determined fat peak signal. Imaging at the edge of the magnet may produce poor fat saturation. For best fat saturation results, position the patient as close to isocenter as possible, while ensuring that the non-imaged foot is away from the coil to avoid phase overlapping.

For axial imaging, use an axial positioner, but before specifying the slices, use the same FOV you intend to use in your study for positioning or use explicit positioning. Use of graphic indication from a large FOV positioner sometimes results in software error, thus producing blank slices, shifted slices, or both.

6-4 Scanning Protocols

GE Corporation recommends that you select imaging protocols that have been created by your radiologist. In addition, you may refer to the GE protocols acting on the system.