Operator's Manual

16ch Tx/Rx Knee SPEEDER

For Canon 1.5T and 3.0T MRI Systems

www.qualityelectrodynamics.com

	Canon Model #	QED REF
1.5T	MJAJ-237A	Q7000160
3.0T	MJAJ-232A	Q7000147

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

Shock indicators for monitoring transport are affixed to the packaging. If the shock indicator is activated as shown by a red color inside the glass tube, the coil was not handled with the required care. However, an activated shock indicator does not necessarily indicate damage to the coil.


CAUTION

If the coil packaging is exposed to environmental conditions outside of the transportation and storage conditions, the packaging is damaged, the packaging is opened prior to delivery, or the shock indicator is activated, 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 and understand this manual as well as the MRI system user manual and safety manual 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.

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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 16ch Tx/Rx Knee SPEEDER is used to examine the knee, wrist, hand, and forefoot.

1.2 Operating Environment and Compatibility

The 16ch Tx/Rx Knee SPEEDER is intended to be used in conjunction with the following Canon MRI Systems in a specialized healthcare facility:

- Vantage Titan 1.5T
- Vantage Orian 1.5T
- Vantage Fortian 1.5T
- Vantage Titan 3T
- Vantage Galan 3T

1.3 User Profile

Operator – Radiologic technologists, laboratory technologists, physicians.

User training – No special training is required to use this coil. However, Canon Medical Systems provides a comprehensive training course for MRI systems in order to instruct operators on the correct use of MRI systems.

1.4 Patient Information

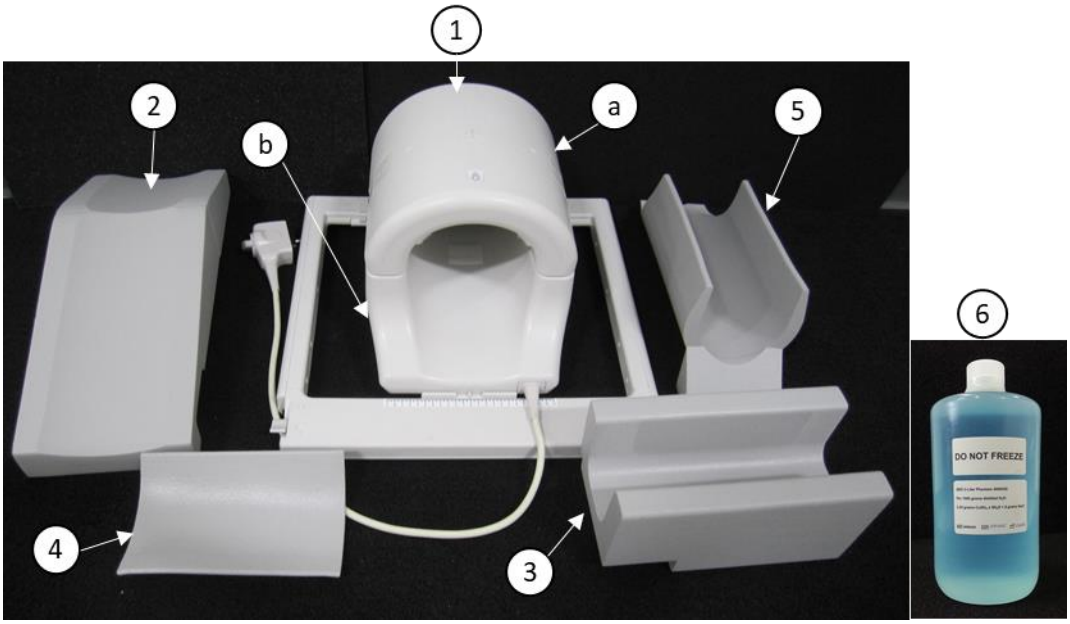
Age, health, condition – No special limitations. Do not use the coil for newborns or infants.

Weight – 255kg 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 Tx/Rx Knee SPEEDER Components

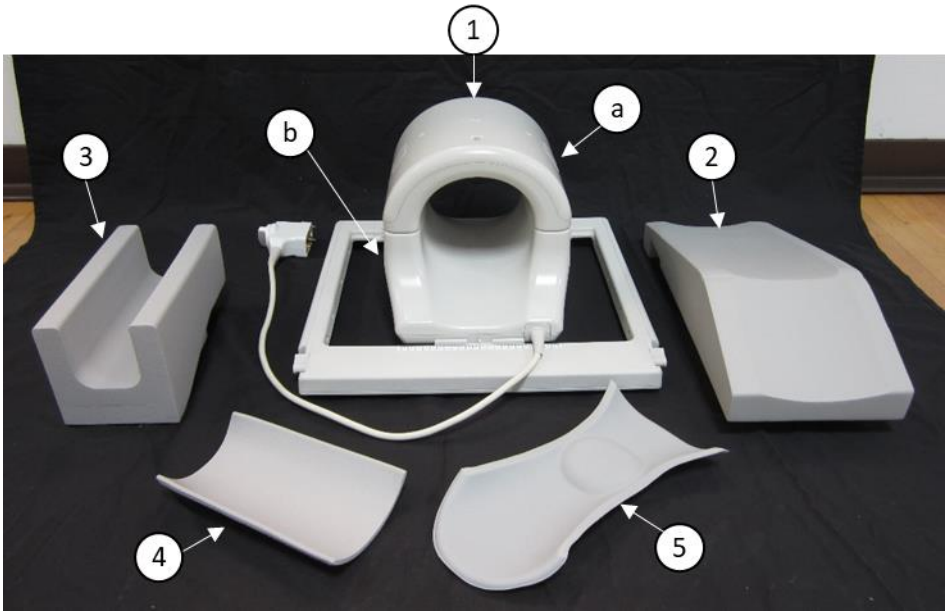
The 16ch Tx/Rx Knee SPEEDER is shipped with the parts shown below. Upon receipt, please ensure that all parts are included in the shipment. Please contact your Canon Medical Systems representative for replacement or replenishment of any accessories listed here.

1.5T 16ch TxRx Knee SPEEDER [MJAJ-237A, Q7000160] Components



Item #	Description	Quantity	Canon Part #	QED Part #
1	16ch TxRx Knee SPEEDER (1.5T) a. Anterior Section b. Posterior Section	1	MJAJ-237A	Q7000160
2	Free-Leg Pad	1	BSM41-6813	3003866
3	Inferior Leg Pad	1	BSM41-6814	3003865
4	Anterior Knee Pads - With hook-and-loop fasteners - Without Hook-and-Loop Fasteners	 1 2	 BSM41-7233 BSM41-7312	 3004872 3005043
5	Bottom Pad	1	BSM41-7232	3004871
6	$CuSO_4$ Phantom	1	BSM41-5604	4000420

3T 16ch TxRx Knee SPEEDER [MJAJ-232A, Q7000147] Components



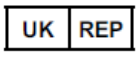
Item #	Description	Quantity	Canon Part #	QED Part #
1	16ch TxRx Knee SPEEDER (3T) a. Anterior Section b. Posterior Section	1	MJAJ-232A	Q7000147
2	Free-Leg Pad	1	BSM41-6813	3003866
3	Inferior Leg Pad	1	BSM41-6814	3003865
4	Anterior Knee Pad	1	BSM41-6812	3003890
5	Posterior Knee Support Pad	1	BSM41-6811	3003864

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 Symbol Glossary

Symbol	Number	Standard	Title, Meaning
	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 and Date of Manufacture
	6192	ISO 7000 IEC 60417	RF Coil, Transmit and Receive
	5.1.2	ISO 15223-1	Indicates the Authorized Representative in EU
	5.1.2	ISO 15223-1 ISO 20417	Indicates the UK Responsible Person
	5.1.2	ISO 15223-1 SwissMedic	Indicates the authorized representative in Switzerland
	2493	ISO 7000 IEC 60417	Catalog Number
	2498	ISO 7000 IEC 60417	Serial Number
	0632	ISO 7000 IEC 60417	Temperature limit
	2620	ISO 7000 IEC 60417	Humidity limitation
	2621	ISO 7000 IEC 60417	Atmospheric pressure limitation
	5.7.7	ISO 15223-1	Medical Device

Symbol	Number	Standard	Title, Meaning
	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.
	5.1.8	ISO 15223-1	Importer
	5.1.9	ISO 15223-1	Distributor

3.2 Indications

The 16ch Tx/Rx Knee SPEEDER is intended for use with Canon 1.5T or 3.0T MR systems to produce diagnostic images of the knee, wrist, hand, and forefoot that can be interpreted by a trained physician.

3.3 Contraindications

None.

3.4 Precautions

⚠ Patients with increased likelihood of seizures or claustrophobia may require special care. Consult the MRI system operation manual.

⚠ Patients who are unconscious, heavily sedated, or in a confused mental state are at increased risk of burn injury because they may not be able to notify the operator of heat or pain due to excessive heating and tissue damage.

⚠ Patients with an inability to maintain reliable communications (for example, young children) are at increased risk of burn injury because they may not be able to notify the operator of heat or pain due to excessive heating and tissue damage.

Patients with loss of feeling in any body part are at increased risk of burn injury because they may not be able to notify the operator of heat or pain due to excessive heating and tissue damage.

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) are at increased risk of burn injury or their body temperature may increase.

Ensure that the patient does not wear clothing that is wet or dampened by perspiration. The presence of moisture increases the risk of burn injury.

3.5 Cautions – RF Coil

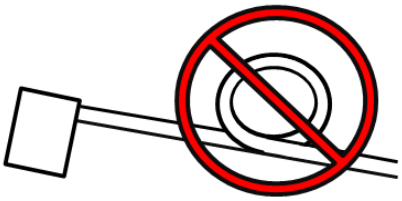
Do not place any disconnected devices (RF coils, cables, etc.) in the gantry during scanning. Remove unneeded RF coils from the couchtop and confirm that RF coils in use are connected to the connector port before scanning.

Disconnected RF coils present during scanning can cause a high-frequency induction current loop to form, resulting in burn injury to the patient. In addition, devices may be damaged.

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. There is a risk of electric shock.

Do not attempt to change or modify the coil. Unauthorized modifications could result in burn injury, electric shock, or decreased image quality.

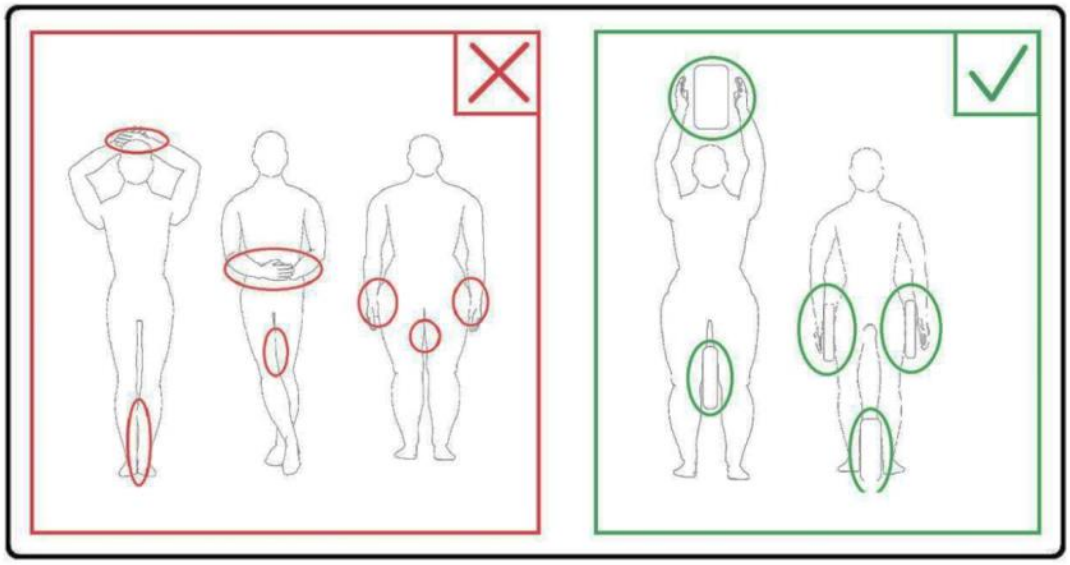


Do not cross or loop coil cables. A high-frequency current may form and burns may occur.

Ensure that the patient does not come into direct contact with the coil cables. Burn injuries may result due to the electric field that is generated in the RF coil when a high-frequency magnetic field is transmitted.

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. A high-frequency current may form and burns may occur.



Do not allow the patient or RF coil to contact the gantry inner wall. Separate the patient from the gantry inner wall by at least 10 mm using foam pads. Separate the patient from the RF coil cable using foam pads. Burn injuries may result due to the electric field that is generated in the RF coil etc. when a high-frequency magnetic field is transmitted.

Confirm that the cable of the coil is on the couchtop before sending the patient into the gantry. If the couchtop is moved with the cable protruding, the cable may interfere with the MRI system main unit, which could result in shifting of the coil position or in the patient being caught and injured by the system.

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.

The enclosure of the coil and the parts inside the coil may appear in the images under certain imaging conditions (for example, when a sequence with a short echo time (TE) is used or when the pixels are large).

If a coil is found to be defective, stop using the coil immediately and contact your Canon 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 in the EU, it should be reported to the manufacturer and the Competent Authority of the Member State in which the user facility is established.

Chapter 4 – Quality Assurance

4.1 Image Test Using the Automatic SNR Measurement Tool

The automatic SNR measurement tool may be available in system software V3.1 or later. If a description of the automatic SNR measurement tool is included in the system operation manual, perform the image test using the automatic SNR measurement tool.

The scan sequences to be used differ between systems with V4.5 or earlier and those with V6.0 or later. Keep this point in mind. However, there are no differences in coil setting or coil section selection.

4.2 Selecting the Sequences for V6.0 or Later (Image Test without Using the Automatic SNR Measurement Tool)

(1) Register a patient (set the system in SFT mode) and set the patient height to 160 cm and the patient weight to 60 kg.

(2) Select [Typical PAS] → [Coil QA] and click the [Other] button. Select the required sequences of the "Other" PAS.

The sequence names for V4.5 or earlier and the corresponding sequence names for V6.0 or later are shown below.

V6.0 or later	V4.5 or earlier	Required/Not required
Locator	locator	Required
Map	Map	Required
SNR	SE15	Required

* For V6.0 or later, it is not necessary to select the reconstruction conditions.

(3) Perform SNR measurement as described in the following subsections using the sequences selected in step (2). The parameters should be changed according to the SNR measurement procedures.

Use an intermediate image for SNR measurement.

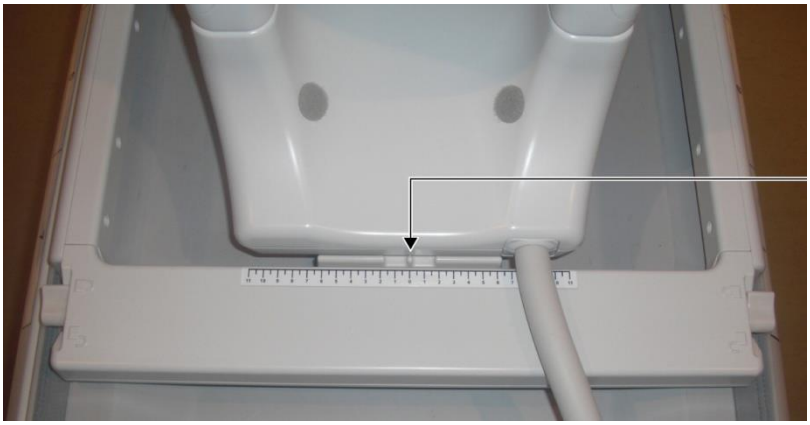
4.3 Scanning Procedure

Read the shield room temperature and confirm that it is in the range from 16°C to 24°C. Record the temperature in the datasheet (numbers after the decimal point are rounded down).

Remove all coils and pads from the couchtop and then place 16ch Tx/Rx Knee SPEEDER on the couchtop as indicated on the pictogram label.

(1) Position the coil at the center of the coil base using the following instructions.

Align the Center of the Coil with the Center of the Coil Base



a. Move the levers on the two sides to the unlocked position. (The levers are connected – moving the lever on one side causes the lever on the other side to move in the same manner.)

Unlock the levers

b. Adjust the coil position by sliding the coil to the left or right.

Slide Coil Left or Right to Desired Position

c. Return the levers to the locked position. When the coil is set at the desired position, move the levers on the two sides back to the locked position. Confirm that the coil is locked in position by trying to move it in the left/right direction.

Move Levers to Locked Position Once Desired Position is Reached

⚠ CAUTION	Be careful not to pinch a finger when locking the coil.

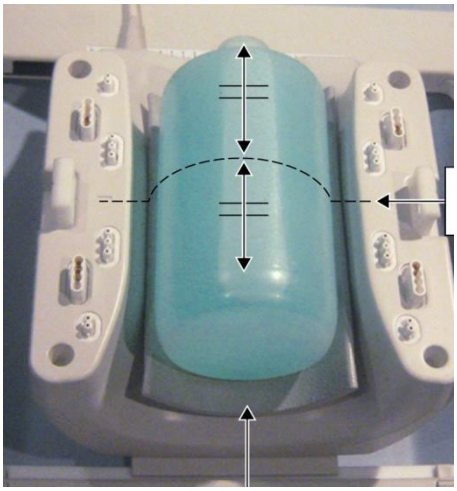
(2) Open the latches on both sides to remove the anterior coil.

Remove Anterior Coil

(3) Place the one of anterior knee pads without hook-and-loop fasteners and the 2-L copper sulfate bottle phantom horizontally in the posterior coil.

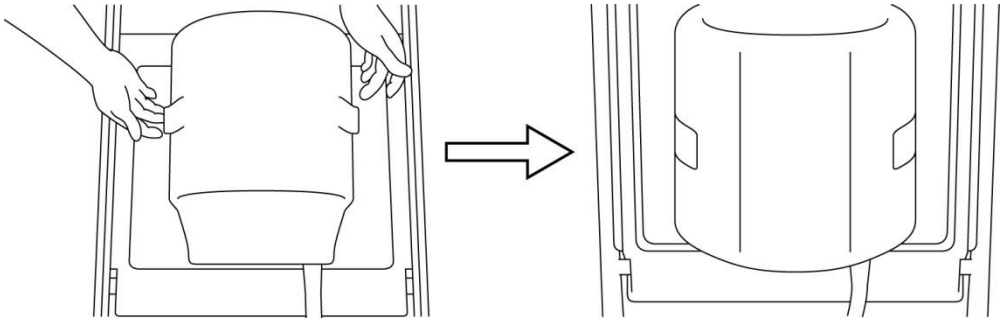
(4) Position the phantom center of HF direction to the center line of the coil.

Position Phantom



(5) Connect the anterior coil to the posterior coil and secure the anterior coil using the latches.

Connect the Anterior Coil



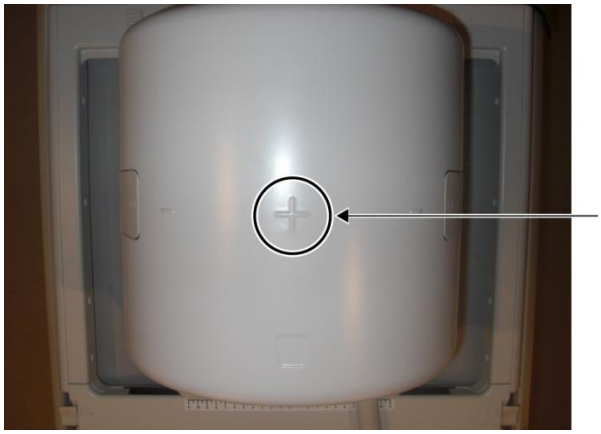
⚠ CAUTION	1. Be careful not to pinch a finger when locking the coil. 2. Do not scan the patient without the anterior coil attached. 3. Confirm that the anterior coil is securely attached to the posterior coil before starting scanning.

(4) Confirm that no parts of the coil or mats extend out from the couchtop and then raise the couch.

(5) Connect the connector to port A2 and lock the connector.

(6) Align the coil-center mark with the positioning projector beam and move the coil into the gantry.

Align Coil-Center Mark with Projector Beam



(7) Register a patient (be sure to set the system in SFT mode). Enter 160 cm for patient height and 60 kg for patient weight.

4.3.1 Image Test in Array Mode

1. Before starting image tests, be sure to set the system to SFT mode and set the reconstruction filter and intensity correction to OFF.
2. When the phantom is moved, wait approximately 1 minute to allow the liquid in the phantom to stabilize before starting the image test.
3. If scanning is started before the liquid in the phantom stabilizes, the resulting sensitivity nonuniformity in the image causes incorrect measurement.

(1) Select "FE_slt" from the FE PASs in the SEQ folder. For Windows 10 or later, select "Typical PAS" → "Coil QA" and select "FE_slt" from Other PAS in the Other folder. For Windows version details, refer to "Agreement for Microsoft Software" in the operation manual for the system.

(2) Select KNEE as SAR body region. Set the coil type to 16ch Knee.

(3) Confirm each parameter as follows.

FE_slt, Special Plan (Axial: 1, Sagital: 1, coronal: 1), TR 50 ms, NS3, ST 8 mm, FA 25 deg., FOV 40 cm × 40 cm, MTX 256 × 256 and NoWrap RO1.0/PE1.0

(4) Scan the sequence.

Record the TGC ratio (TGC_RFOut_ratio:x.xxxxxx (the value displayed before the RF level)) and RF level that are displayed in the Acquisition window on the installation quality check sheet.

When recording the TGC ratio and RF level, select the values displayed with a decimal point and round them to two digits after the decimal point.

(5) Select "FFE_map" from the FFE PASs in the SEQ folder. For Windows 10 or later, select "Typical PAS" → "Coil QA" and select "FFE_map" from Other PAS in the Other folder.

(6) Confirm each parameter as follows.

FFE_map, AX, TR6, NS 20, ST 8mm, Gap 0, FA20 deg, FOV38cm, MTX64*64, NoWrap PE1.0/RO2.0

Regarding positioning, be sure to set to the center of Slice positioning image in H-F direction, and set that Phantom is positioned to the center in A-P & R-L direction.

(7) Scan the sequence after pushing [Queue&Exit].

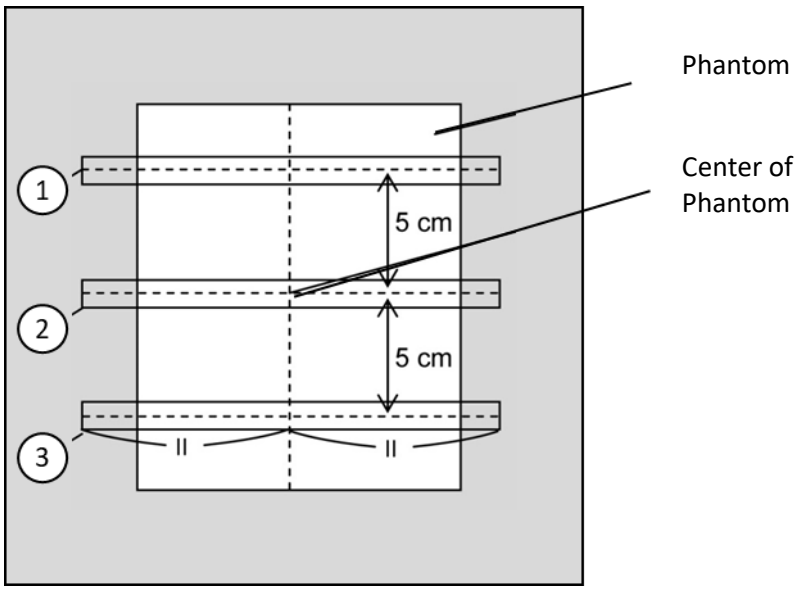
(8) Select "SE15" from the SE PASs in the SEQ folder. For Windows 10 or later, select "Typical PAS" → "Coil QA" and select "SNR" from Other PAS in the Other folder. Set the scan parameters as specified below.

SE15 or QA_SE: SNR, TR:200ms, TE:15ms, FA:90/180deg, NS:3, Gap: 2mm ST:5mm, FOV:25.6cm*25.6cm, Matrix:256*256, No Wrap(PE/RO):1/2, Axial plane, PE=RL

Right-click in the sequence parameter setting window, select "Reconstruction" in the menu, and then select "NONE: No filter" in the reconstruction filter selection menu.

(9) Arrange the Slices as Specified Below

Arrange the Slices as Specified Below



(CO Image)

(10) Start scanning.

(11) Record the receiver gain displayed in the Acquisition window on the installation quality check sheet.

(12) When scanning is completed, reconstruct the acquired images.

(13) Measure the SNR of each center slice of each slice.

Referring to the following section entitled "SNR Measurement Procedure", obtain the signal mean value and noise SD, and calculate SNR.

Standard value of SNR:

Slice 1 : _____≥ 250

Slice 2 : _____≥ 265

Slice 3 : _____≥ 250

Record the result on the installation quality check sheet.

4.3.2 Image Test in QD Mode

(1) Select "locator" sequence in "8ch Knee" PAS in the "QA" folder.

(2) Select KNEE as SAR body region. Set the coil type to 16ch Knee--1ch--.

(3) Confirm each parameter as follows.

FE_slt, Special Plan (Axial: 1, Sagital: 1, coronal: 1), TR 50 ms, NS3, ST 8 mm, FA 25 deg., FOV 40 cm × 40 cm, MTX 256 × 256 and NoWrap RO1.0/PE1.0

(4) Scan the sequence.

Record the TGC ratio (TGC_RFOut_ratio:x.xxxxxx (the value displayed before the RF level)) and RF level that are displayed in the Acquisition window on the installation quality check sheet.

When recording the TGC ratio and RF level, select the values displayed with a decimal point and round them to two digits after the decimal point.

(5) Select "Map" sequence in "8ch Knee" PAS in the "QA" folder.

(6) Confirm each parameter as follows.

Map, AX:RL, TR 160 ms, NS 20, ST 8 mm, FA20 deg, FOV 36 cm × 36 cm, MTX 64 × 64, NoWrap RO2.0/PE1.0

Regarding positioning, be sure to set to the center of Slice positioning image in H-F direction, and set that Phantom is positioned to the center in A-P & R-L direction.

(7) Scan the sequence after pushing [Queue&Exit].

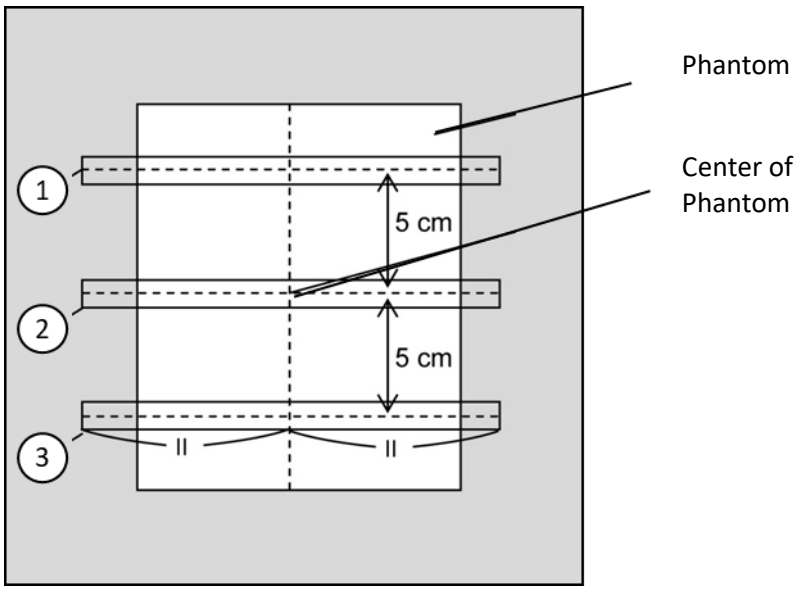
(8) Select "SNR" sequence in "8ch Knee" PAS in the "QA" folder.

Set each parameter to below.

<Sequence name SE15>

TR	:	200
Slice thickness	:	5 mm
Slice gap	:	2 mm
Number of slabs	:	3 with 3 slices each, at 5 cm apart from center to center of slabs
Number of slices	:	9 (total slice number of 3 slabs)
Matrix size	:	256 × 256
FOV	:	25.6 × 25.6
NAQ	:	1
No Wrap	:	RO2.0/PE1.0
Plane	:	AX
PE	:	RL

Arrange the Slices as Specified Below



(CO Image)

(9) Start scanning.

(10) Record the receiver gain displayed in the Acquisition window on the installation quality check sheet.

(11) When scanning is completed, reconstruct the acquired images.

(12) Measure the SNR of each center slice of each slab.

Referring to subsection 6.6.4 "SNR measurement procedure", obtain the signal mean value and noise SD, and calculate SNR.

Standard value of SNR:

Slice 1 : _____≥ 105

Slice 2 : _____≥ 115

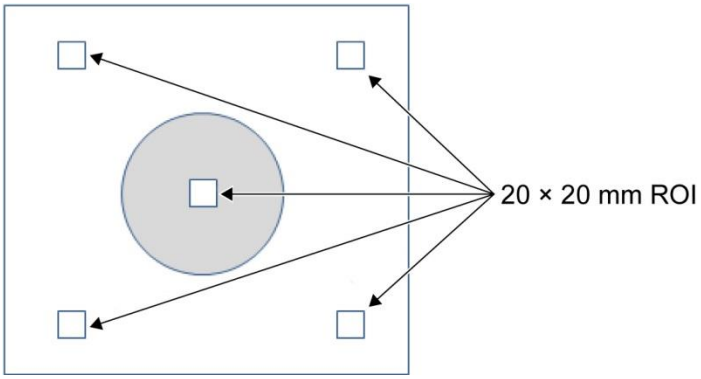
Slice 3 : _____≥ 105

Record the result on the installation quality check sheet.

4.4 SNR Measurement Procedure

(1) Display the center slice of the acquired image. Set a circular ROI for measuring the signal value at the center of the phantom image, and set a rectangular ROI for measuring the background noise, as shown in the figure below.

The noise ROI should be set in an area free from ghosting.



(2) Measure the signal value (signal mean) and background noise value (noise SD).

(3) Calculate the SNR using the equation below and record the result on the installation quality check sheet.

SNR calculation equation

SNR = S/N

Where

S : Measured signal mean value (value in the signal ROI in each image)

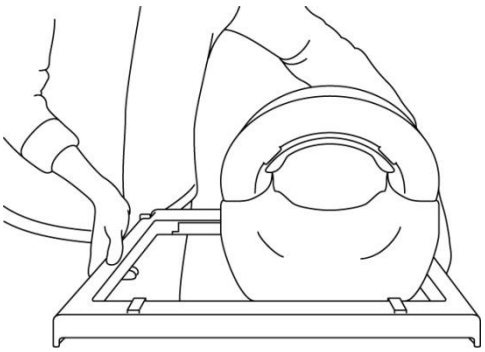
N : Average value of the four background noise values measured (NoiseSD values)

Chapter 5 – Coil Setup and Use

5.1 Carrying the Coil

When moving the coil, use the handles provided on the right and left sides of the base frame.

Carry Using the Handles on the Sides of the Base Frame



1. Do not subject the coil to physical shock (for example, by dropping it on the floor).
2. Be sure to use the handles on the base frame when lifting the coil. If the coil is lifted by holding only the anterior section, the posterior section may come loose and fall.
3. Do not lift the coil by holding the cable. Doing so will subject the coil to excessive stress, possibly resulting in damage.
4. Do not allow the cable to hang freely when carrying the coil. This could cause damage to the cable or connector.

Do Not Lift Using Anterior Section of Coil

5.2 Coil Setup

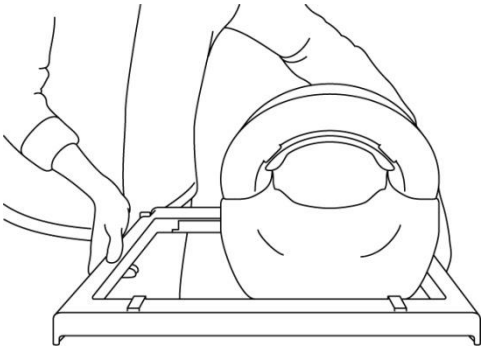
(1) Lower the patient couch to the lowest position.

(2) Remove all RF coils that are connected to the connector ports on the gantry and RF coils that are not connected to the connector ports on the couch top.

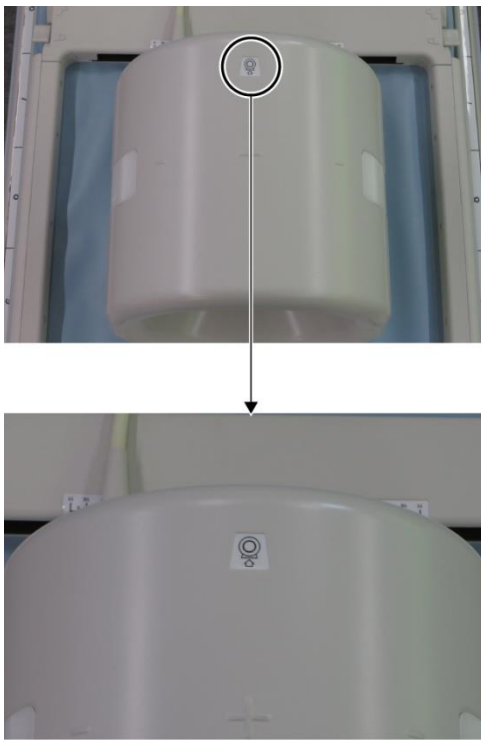
⚠ CAUTION	Ensure all other coils are removed from the couchtop. If an unplugged RF coil is left on the couchtop during scanning, burn injury, abnormal images, or coil failure may result.

(3) Place the coil on the couch. If the coil is transported by hand, be sure to carry the coil with both hands, using the handles on the left and right sides of the base frame. The coil should be placed on a couch pad or on the spine coil. (This coil can be used on Atlas SPEEDER Spine.)

Place the Coil on the Couch



Position the RF coil so that the arrow on the pictogram label shown below points toward the gantry.



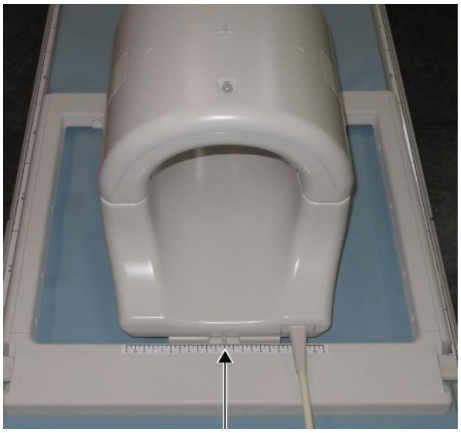
(4) Slide the posterior section to the desired position. To do this:

a. Move the levers on the two sides to the unlocked position. (The levers are connected – moving the lever on one side causes the lever on the other side to move in the same manner.)

Unlock the levers

b. Adjust the coil position by sliding the coil to the left or right.

Slide Coil Left or Right to Desired Position

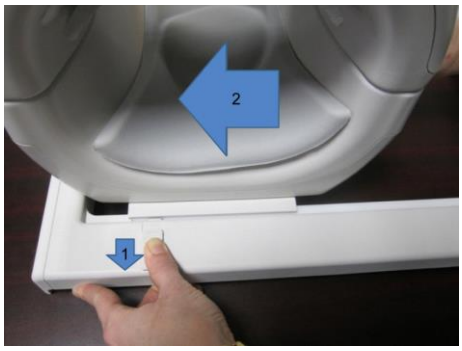


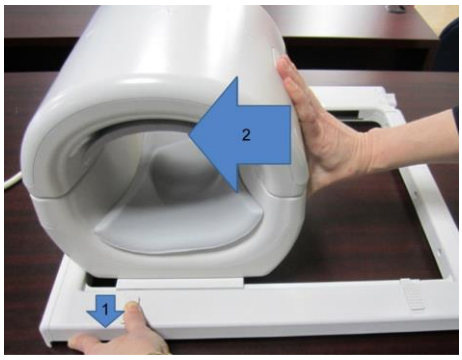
When the coil is positioned more than 8 cm from the isocenter, the coil must be moved as described below. Some deterioration in image quality may be observed if the coil is more than 8 cm from isocenter during imaging.

Step 1: Move the coil in the lateral direction until it reaches the stop.

Step 2: Retract the stop using the stop grip.

Step 3: Move the coil past the stop to the desired position.





c. Return the levers to the locked position. When the coil is set at the desired position, move the levers on the two sides back to the locked position. Confirm that the coil is locked in position by trying to move it in the left/right direction.

Move Levers to Locked Position Once Desired Position is Reached

5.3 Patient Positioning and Scanning

This RF coil is intended to be used for imaging of the knee, wrist, hand, and forefoot. Instructions for use with each anatomy are provided in this section.

⚠ CAUTION	Be sure to read this manual and the safety manual supplied with the MRI system before operating the system.

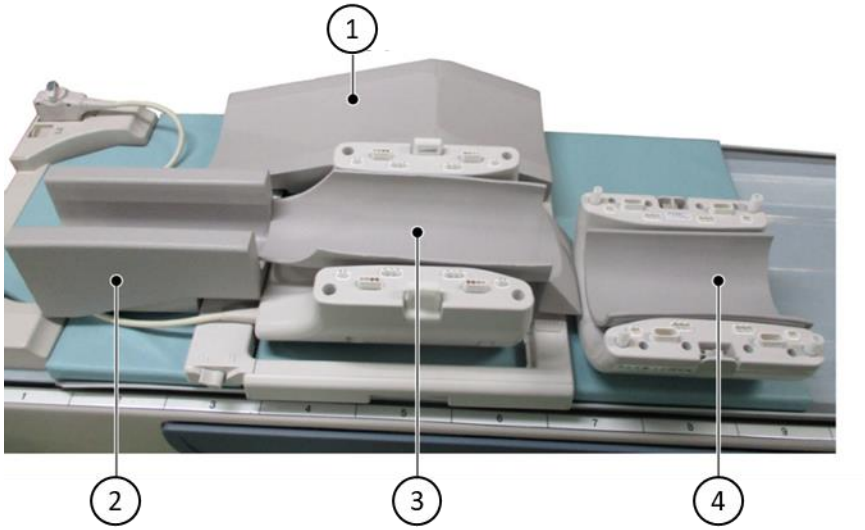
5.3.1 Patient Positioning for Knee Imaging

(1) Open the latches on both sides by pulling the latch flaps as shown in the figure below and remove the anterior section.

Open Latches and Remove Anterior Section

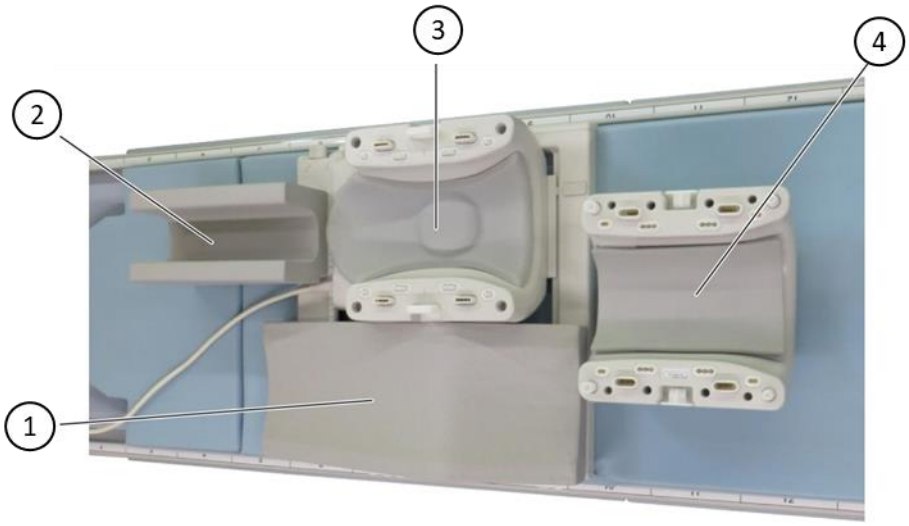
(2) Position the pads supplied with the coil on the couchtop as shown in the figure below.

Pad Positioning for 1.5T Knee Imaging [MJAJ-237A, Q7000160]



Number	Pad
1	Free-Leg Pad
2	Inferior Leg Pad
3	Bottom Pad
4	Anterior Knee Pad with Hook-and-Loop Fasteners

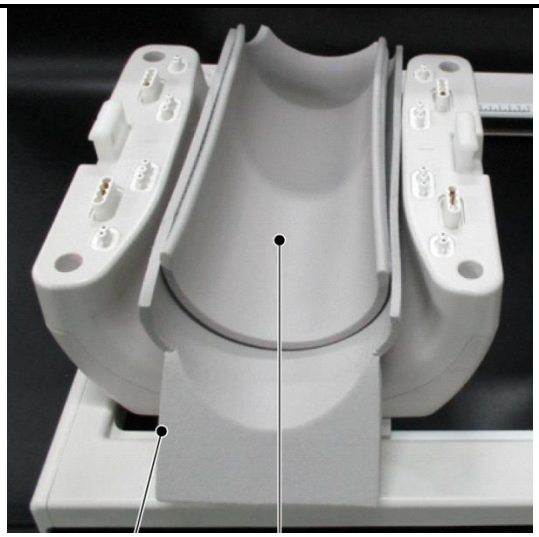
Pad Positioning for 3T Knee Imaging [MJAJ-232A, Q7000147]



Number	Pad
1	Free-Leg Pad
2	Inferior Leg Pad
3	Posterior Knee Support Pad
4	Anterior Knee Pad

1. The anterior knee pad is secured to the anterior coil using hook-and-loop fasteners. The inferior leg pad provides insulation between the patient and the coil cable.

2. Optionally, it is possible to adjust the knee height to coil center by adding the anterior knee pad without hook-and-loop fastener.

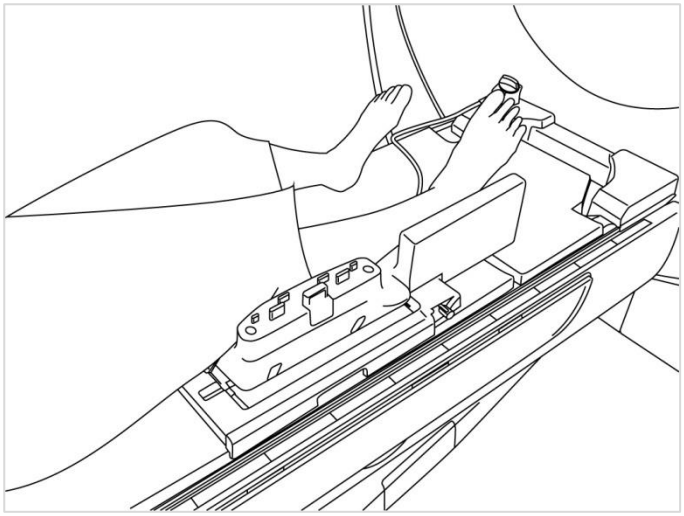


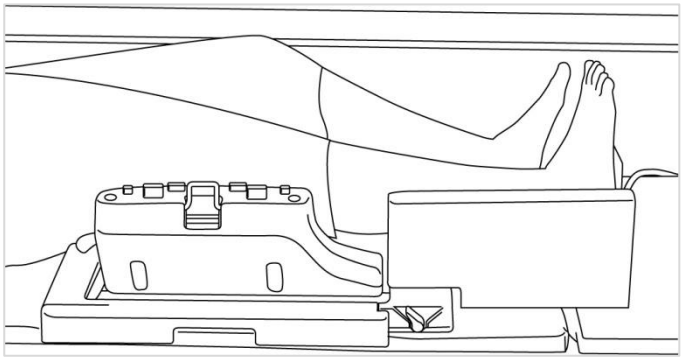
Bottom Pad

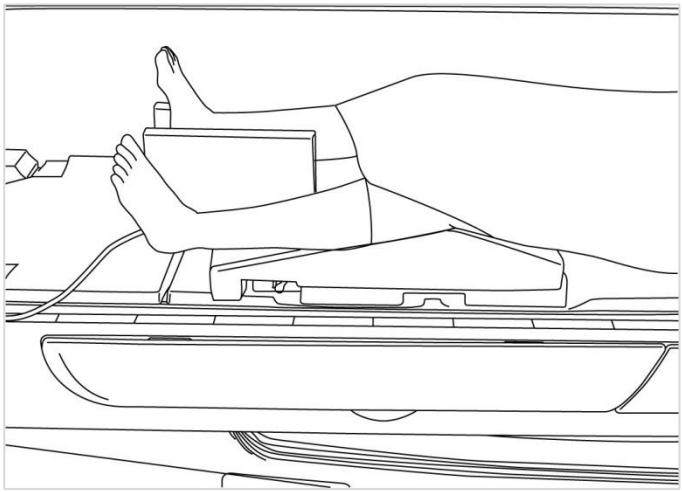
1 or 2 Anterior Knee Pads without Hook-and-Loop Fasteners

(3) Position the patient as shown below.

Position the Patient

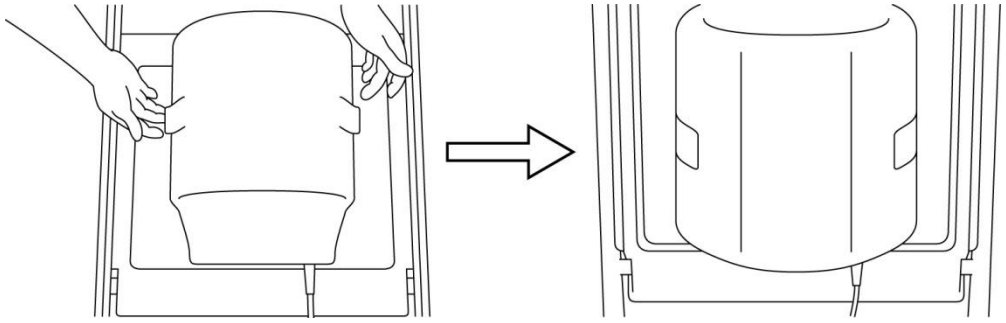






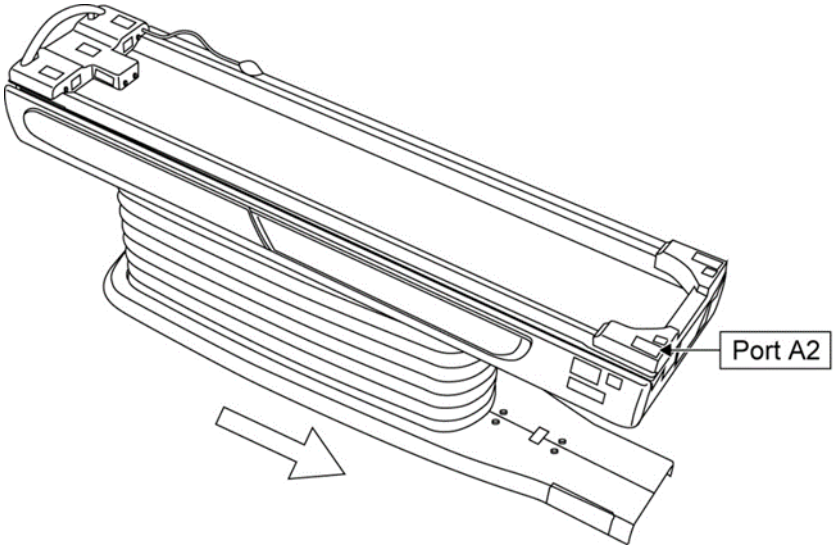
(4) Connect the anterior section to the posterior section and secure the sections together using the latches. Confirm that the anterior and posterior sections are fully connected and that the latch flaps are pushed in.

Connect and Secure Anterior Section to Posterior Section

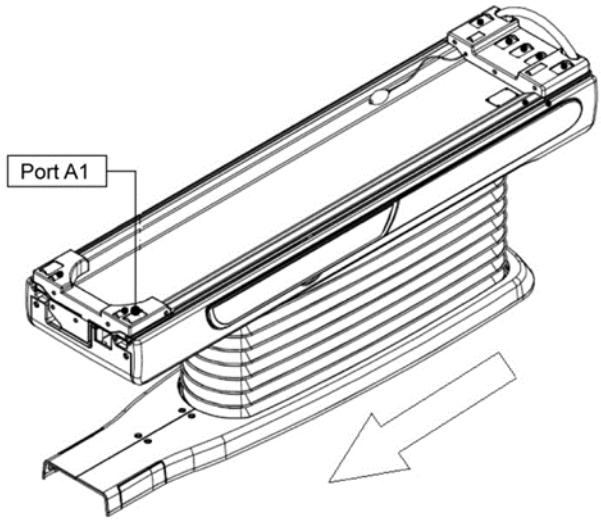


(5) Confirm that the coil cable is not in direct contact with the patient. Then, for 1.5T systems, connect the connector to port A2 on the couchtop or, for 3T systems, connect the connector to port A1. Lock the connector.

1.5T Systems: Connect the Connector to Port A2

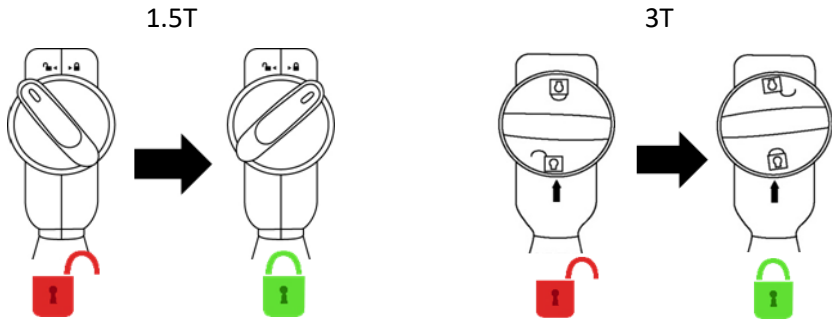


3T Systems: Connect the Connector to Port A1



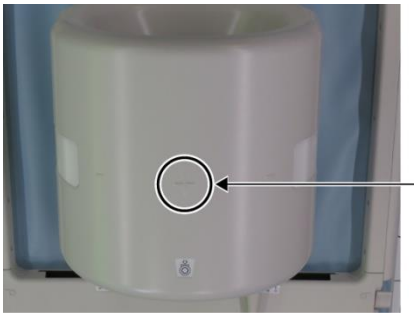
CAUTION

Confirm that the connector of the coil is securely attached and locked to the connector port before starting scanning. If scanning is performed with the coil connector not connected to the connector port, the coil may be damaged or abnormal heating may result.



(6) Align the coil-center mark with the positioning projector beam.

Align Coil-Center Mark with Projector Beam



CAUTION

Instruct the patient to close his or her eyes to prevent exposure of the eyes to the projector beam.

(7) Confirm that no parts of the coil, cable, or mats extend out from the couchtop, and then move the patient into the gantry.

(8) Register the patient.

(9) Set the scanning conditions.

Set the RF coil type to 16ch Knee.

Select Extremities for the SAR region.

(10) Start scanning per the instructions in the MRI system manual.

When removing the coil from couchtop, rotate the coil to facilitate access to the handles and then lift the coil using the handles.

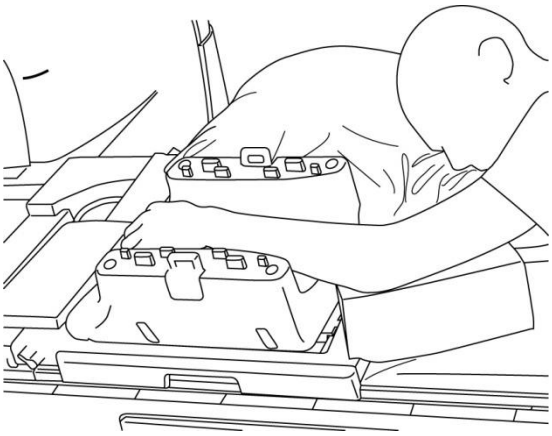
5.3.2 Patient Positioning and Scanning – Hand or Wrist

(1) Open the latches on both sides by pulling the latch flaps as shown in the figure below and remove the anterior section.

Open Latches and Remove Anterior Section

(2) Position the patient using the pads as shown below.

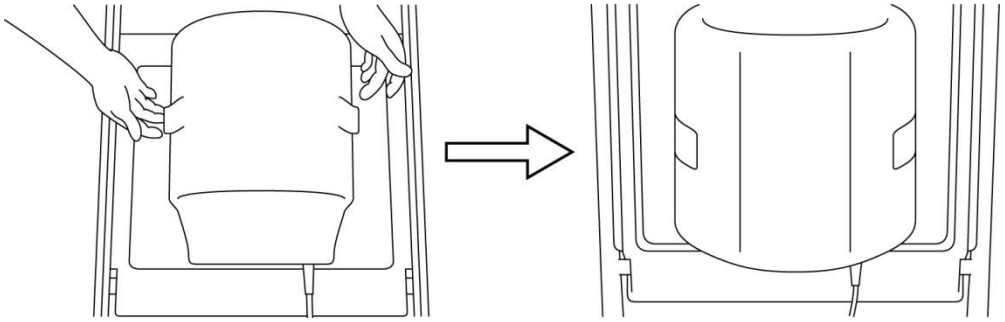
Position the Patient



(3) Secure wrist with pads or straps on anterior side to prevent movement.

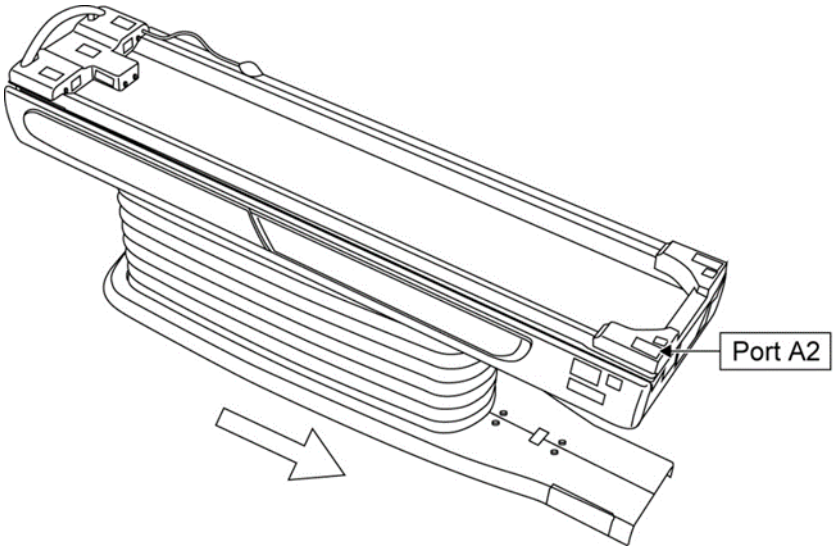
(4) Connect the anterior section to the posterior section and secure the sections together using the latches. Confirm that the anterior and posterior sections are fully connected and that the latch flaps are pushed in.

Connect and Secure Anterior Section to Posterior Section

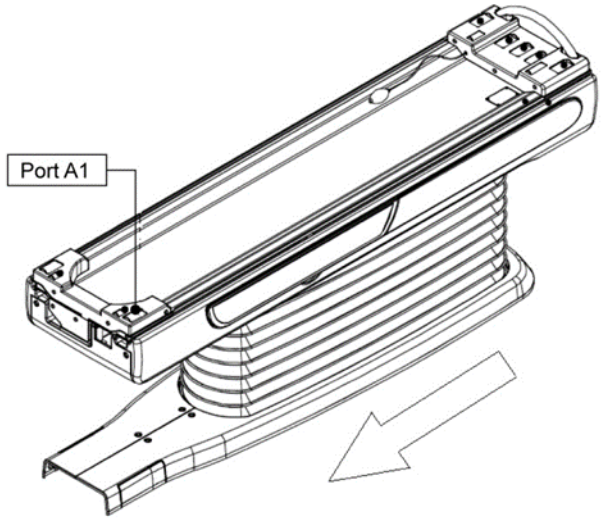


(5) Confirm that the coil cable is not in direct contact with the patient. Then, for 1.5T systems, connect the connector to port A2 on the couchtop or, for 3T systems, connect the connector to port A1. Lock the connector.

1.5T Systems: Connect the Connector to Port A2

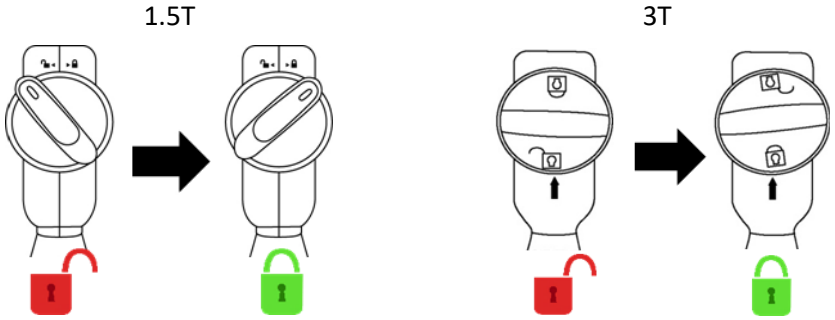


3T Systems: Connect the Connector to Port A1



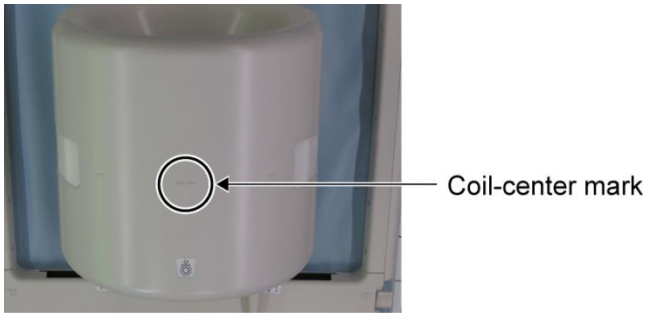
CAUTION

Confirm that the connector of the coil is securely attached and locked to the connector port before starting scanning. If scanning is performed with the coil connector not connected to the connector port, the coil may be damaged or abnormal heating may result.



(6) Align the coil-center mark with the positioning projector beam.

Align Coil Center with Projector Beam



CAUTION

Instruct the patient to close his or her eyes to prevent exposure of the eyes to the projector beam.

(7) Confirm that no parts of the coil, cable, or mats extend out from the couchtop, and then move the patient into the gantry.

(8) Register the patient.

(9) Set the scanning conditions.

Set the RF coil type to 16ch Knee.

Select Extremities for the SAR region.

(10) Start scanning per the instructions in the MRI system manual.

When removing the coil from couchtop, rotate the coil to facilitate access to the handles and then lift the coil using the handles.

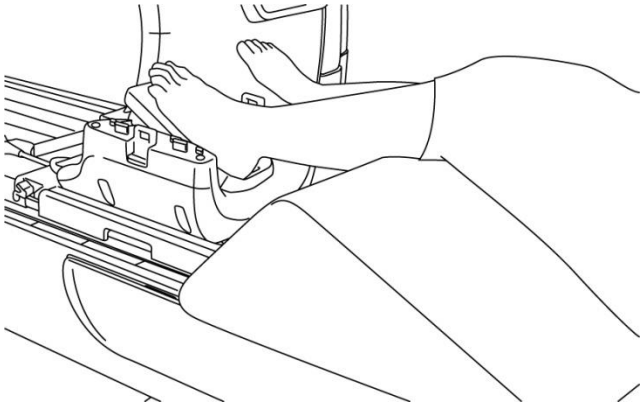
5.3.3 Patient Positioning and Scanning - Forefoot

(1) Open the latches on both sides by pulling the latch flaps as shown in the figure below and remove the anterior section.

Open Latches and Remove Anterior Section

(2) Position the patient using the pads as shown below.

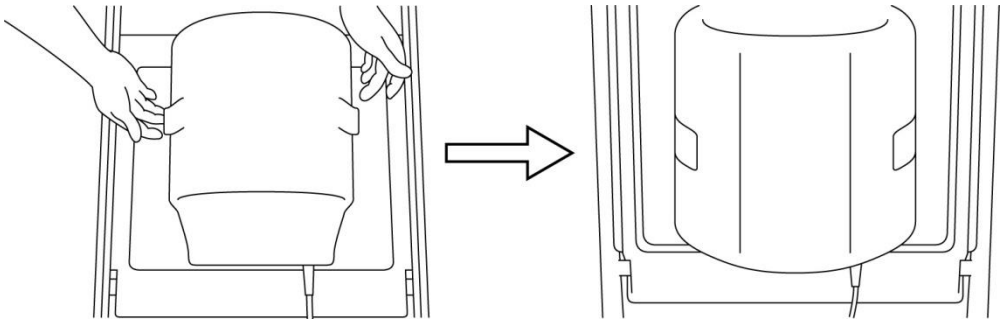
Position the Patient



(3) Secure foot with anterior pads or straps to prevent movement.

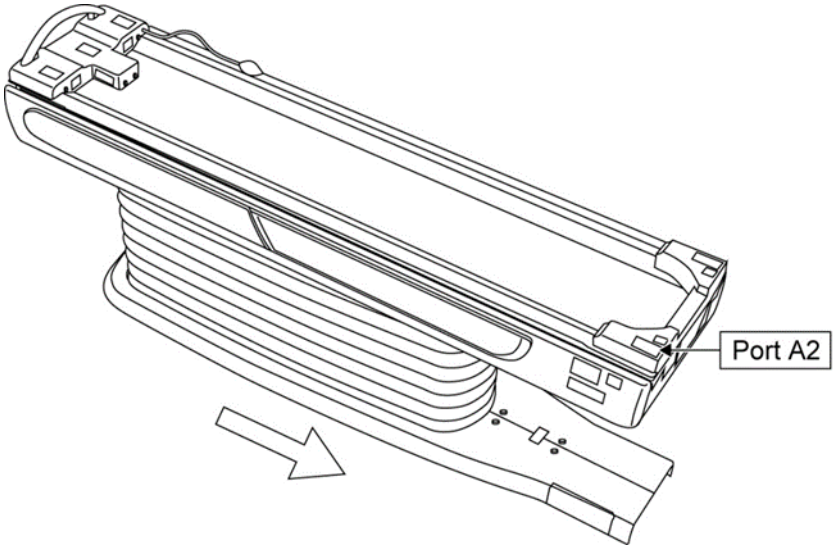
(4) Connect the anterior section to the posterior section and secure the sections together using the latches. Confirm that the anterior and posterior sections are fully connected and that the latch flaps are pushed in.

Connect and Secure Anterior Section to Posterior Section

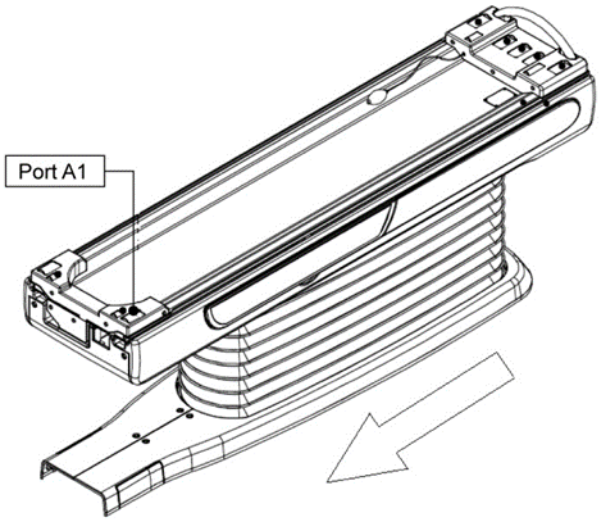


(5) Confirm that the coil cable is not in direct contact with the patient. Then, for 1.5T systems, connect the connector to port A2 on the couchtop or, for 3T systems, connect the connector to port A1. Lock the connector.

1.5T Systems: Connect the Connector to Port A2

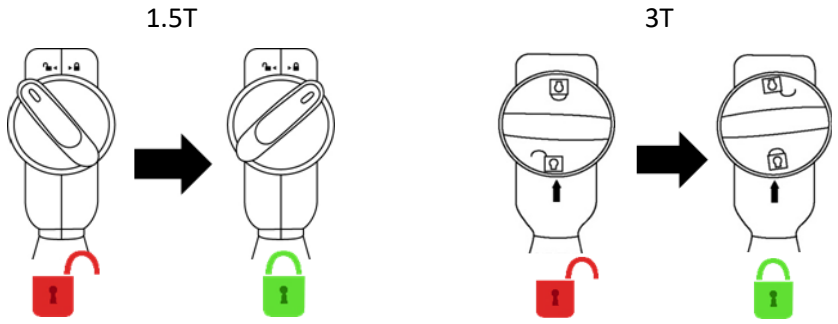


3T Systems: Connect the Connector to Port A1



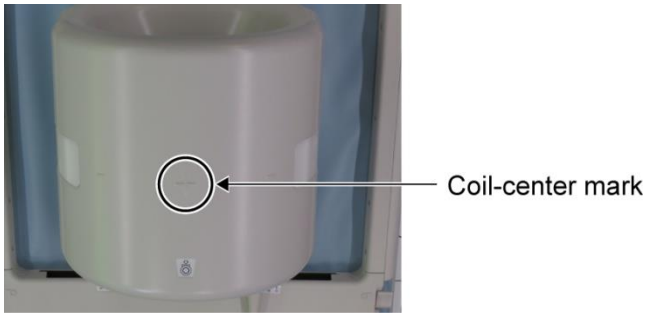
CAUTION

Confirm that the connector of the coil is securely attached and locked to the connector port before starting scanning. If scanning is performed with the coil connector not connected to the connector port, the coil may be damaged or abnormal heating may result.



(6) Align the coil-center mark with the positioning projector beam.

Align Coil Center with Projector Beam



CAUTION

Instruct the patient to close his or her eyes to prevent exposure of the eyes to the projector beam.

(7) Confirm that no parts of the coil, cable, or mats extend out from the couchtop, and then move the patient into the gantry.

(8) Register the patient.

(9) Set the scanning conditions.

Set the RF coil type to 16ch Knee.

Select Extremities for the SAR region.

(10) Start scanning per the instructions in the MRI system manual.

When removing the coil from couchtop, rotate the coil to facilitate access to the handles and then lift the coil using the handles.

Chapter 6 – Cleaning, Maintenance, Service, and Disposal

6.1 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.
4. Do not use benzine to clean the product. This may result in discoloration, distortion, deterioration, or damage.

The RF Coil and accessories 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 or gauze that has been dampened with 70-99% isopropanol, 70% ethanol, mild detergent diluted with water, or water.
4. Allow the coil to dry completely, preferably for a full day.
5. Dispose of any materials used to clean the coil and the pads according to all federal, state, and local regulations.
6. Commonly available cleaning agents can also be used on the surface of the coils without compromising the safety of the device. Refer to the cleaning agent manufacturer's instructions for use and clean the coil according to the procedures specified by the healthcare facility.

Some cleaning agents may cause discoloration. This does not affect proper functioning.

6.2 Maintenance

No regularly scheduled maintenance is required for the RF coil.

6.3 Service

Please contact your Canon Medical Systems representative with questions regarding service of the RF coil.

6.4 Disposal

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

6.5 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 7 – 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.

7.1 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.

7.2 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.

7.3 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.

7.4 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 ±8 kV
Electrostatic discharge (ESD), air discharge	IEC 61000-4-2 ±2kV, ±4kV, ±8kV, ±15kV

CE 2797

UK CA 0086

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Mayfield Village, OH 44143
U.S.A.

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The Netherlands

Importer - EU:
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After 2023-07-30: Bovenkerkerweg 59, 1185 XB Amstelveen, The Netherlands

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After 2023-06-30: Bovenkerkerweg 59, 1185 XB Amstelveen, The Netherlands

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