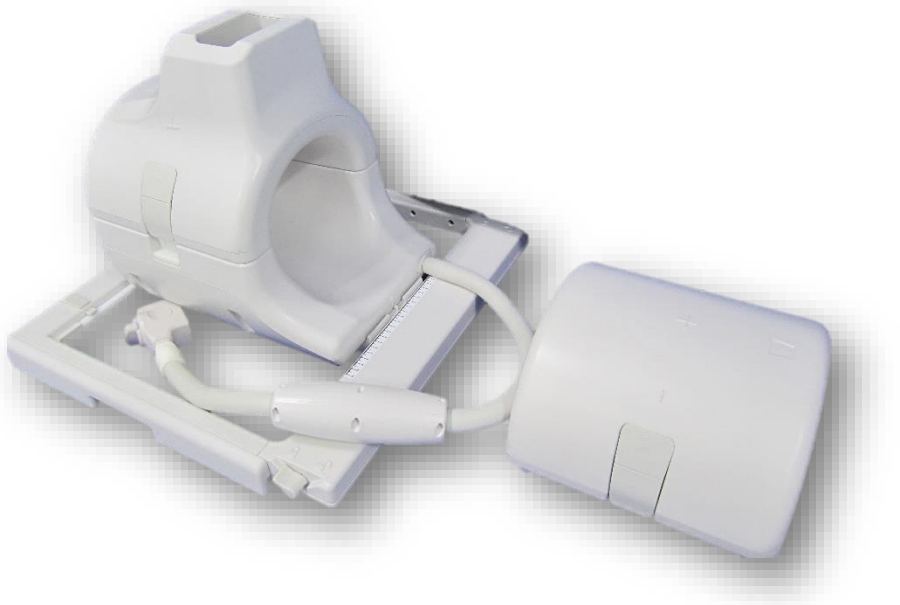
Operator's Manual

8ch Knee-Foot SPEEDER

For Canon 1.5T MRI Systems



www.qualityelectrodynamics.com

Canon Model #	QED REF
MJAJ-257A	Q7000172

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.

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

Receive-only RF coils 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 8ch Knee-Foot SPEEDER is used to examine the knee, wrist, hand, foot, and ankle.

1.2 Operating Environment and Compatibility

The 8ch Knee-Foot SPEEDER is intended to be used in conjunction with the following Canon MRI Systems in a specialized healthcare facility:

- Vantage Elan 1.5T
- Vantage Titan 1.5T
- Vantage Orian 1.5T
- Vantage Fortian 1.5T

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

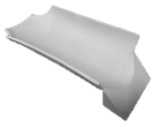
Age, health, condition – No special limitations.

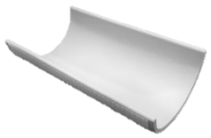
Weight – 255kg or less (consult the operation manual for the MRI system, and if the maximum allowable patient's weight for the system is lower than that for this coil, priority must be given to the maximum weight for the system).

Chapter 2 – 8ch Knee-Foot SPEEDER Components

2.1 Included Components

The 8ch Knee-Foot 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.

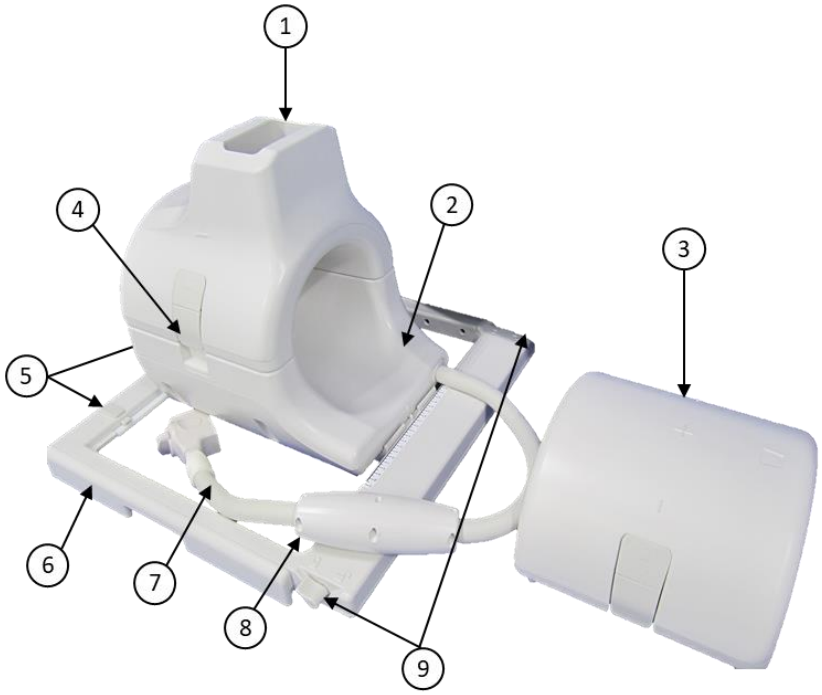
Picture	Description	Quantity	Canon PN	QED PN
	8ch Knee-Foot SPEEDER Coil	1	MJAJ-257A	Q7000172
	Foot Positioning pad	1	BSM41-7236	3004802
	Wedge Pad	1	BSM41-7237	3004823
	Bottom Pad	1	BSM41-7232	3003871
	Inferior Leg Pad	1	BSM41-6814	3003865
	Free-Leg Pad	1	BSM41-6813	3003866

Picture	Description	Quantity	Canon PN	QED PN
	Anterior Knee Pad With Hook-and-Loop Fasteners	1	BSM41-7233	3004872
	Anterior Knee Pad Without Hook-and-Loop Fasteners	2	BSM41-7312	3005043
	Phantom Alignment Pad	1	BSM41-7238	3004824
	Phantom	1	BSM41-5601	3000228
	2-L copper sulfate bottle phantom	1	BSM41-5604	4000420

2.2 Parts of the Coil

The figure below shows the appearance and name of each part of the coil.

Parts of the Coil



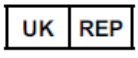
Number	Description	Number	Description
1	Anterior Section (Foot Attachment)	6	Coil Base
2	Posterior Section	7	Cable
3	Anterior Section (Knee Attachment)	8	Cable Case (Balun)
4	Latch	9	Lock/Unlock Levers
5	Stop Grips		

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, Receive
	N/A	IEC 60601-2-33 IEC 62570	MR Safe
	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	N/A	This symbol reminds the operator to ensure that the patient and coil do not come into contact with the gantry during patient couch movement.
	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 8ch Knee-Foot SPEEDER Coil is intended for use with Canon 1.5T MR systems to produce diagnostic images of the knee, wrist, hand, foot and ankle 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

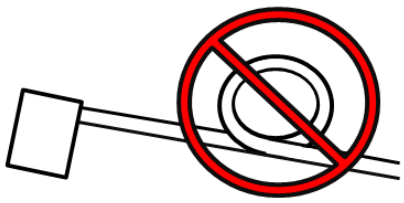
Do not place any disconnected devices (RF coils, cables, etc.) in the gantry during scanning. Remove unneeded RF coils from the couchtop and confirm that RF coils in use are connected to the connector port before scanning.

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.

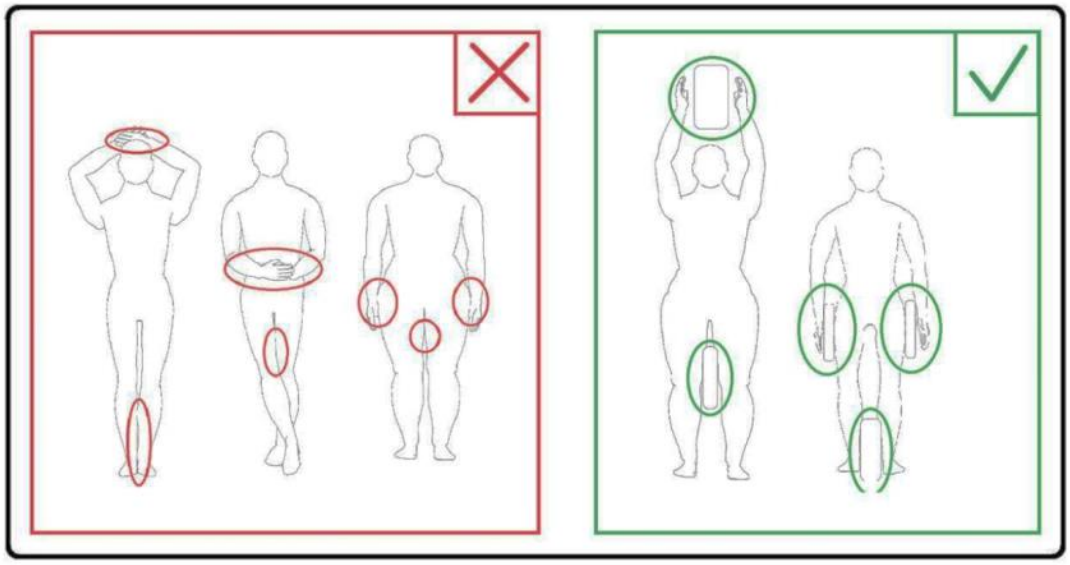


Do not cross or loop coil cables. A high-frequency current may form and burns may occur.

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

Perform the image quality check using the automatic SNR measurement tool and the phantoms specified below.

Coil	Phantom	Part number
Knee/Foot SPEEDER	2-L copper sulfate bottle phantom	BSM41-5604
	3000228 Phantom	BSM41-5601

Prepare the automatic SNR measurement tool and the phantoms in advance referring to the operation manual for the system.

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 180 cm and the patient weight to 60 kg.

(2) Select [Typical PAS] → [Coil QA] and click the [Other] button. Select the required sequence 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	SNR	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.

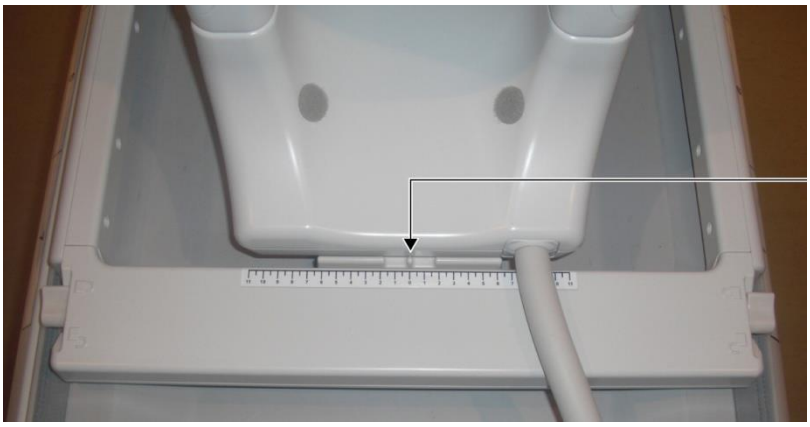
Use an intermediate image for SNR measurement.

4.3 Scanning Procedure When the Anterior Section (Knee Attachment) is Installed

Remove all coils from the couchtop and then place on the couchtop as indicated on the pictogram label. The coil should be placed on a couch pad.

(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

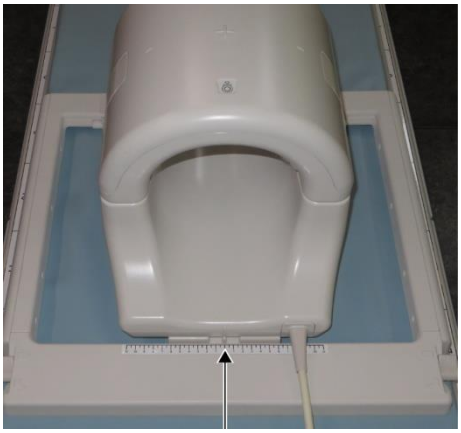


a. Move the levers on the two sides to the unlocked position. (The levers are connected – moving the lever on one side causes the lever on the other side to move in the same manner.)

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

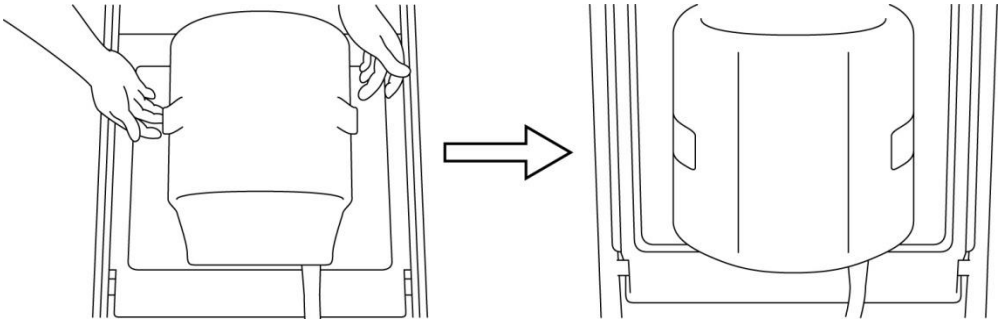
(3) Place the 2-L $CuSO_4$ bottle phantom horizontally in the posterior coil. Adjust the coil position so that the phantom is at the center of the coil.

Place the Phantom

i This coil consists of surface coils. If the phantom is not at the coil center, image testing cannot be performed correctly.

(4) Connect the anterior coil (Knee attachment) to the posterior coil and secure the anterior coil using the latches.

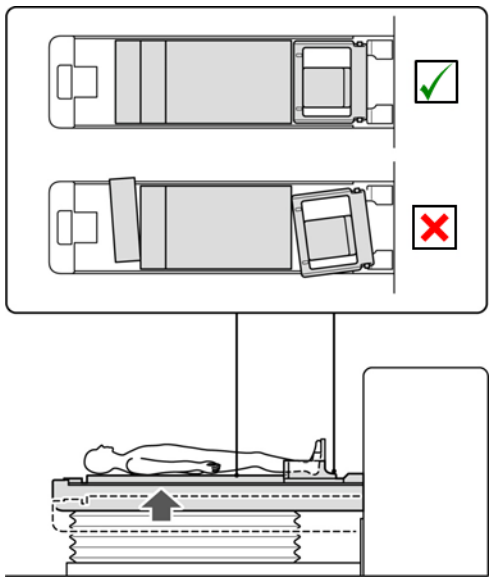
Connect the Anterior Coil



⚠ 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.

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

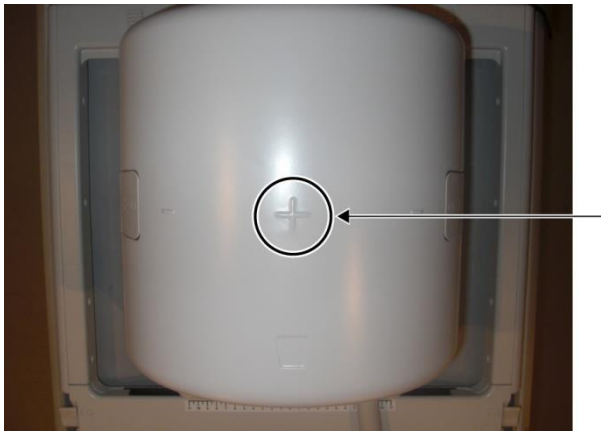
Confirm Coil and Mats are Not Protruding



(6) Connect the connector to ports A1 and A2 and lock the connector.

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

Align Coil-Center Mark with Projector Beam

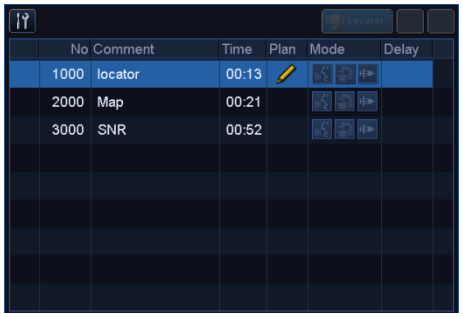


(8) Register a patient (be sure to set the system in SFT mode). Enter 180 cm for patient height and 60 kg for patient weight.

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.

(9) Select the "locator" sequence from the "8ch knee" PAS in the QA folder.

Select Locator Sequence



(10) Select "Knee" for the SAR region. In addition, confirm that the patient insertion direction is set to supine and head first.

(11) Confirm that the parameters are set as follows.

Confirm Parameters

FE_slt, Special Plan (Axial:1, Sagittal:1, coronal:1), TR50, NS3, ST 8 mm, Flip25, FOV 40 cm, MTX 256 × 256, NoWrap RO1.0/PE1.0

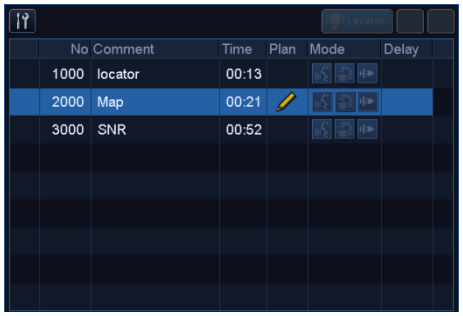
(12) Run the locator sequence.

Record the TGC value (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 value and RF level, select the values displayed with a decimal point and round them to two digits after the decimal point.

(13) Select the "Map" sequence.

Select Map Sequence



(14) Select "Knee" for the SAR region.

(15) Confirm that the parameters are set as follows.

Confirm Parameters

Map, AX:RL, TR160, NS20, ST 8 mm, FA20, FOV 36 cm, MTX 64 × 64, NoWrap RO2.0/PE1.0

Perform positioning so that the HF direction is set at the center of the locator image and the phantom is at the center of the locator image in both the AP and RL directions.

(16) Click [Queue & Exit] and run the map sequence.

(17) Select the "SNR" sequence.

Change the parameter settings as follows.

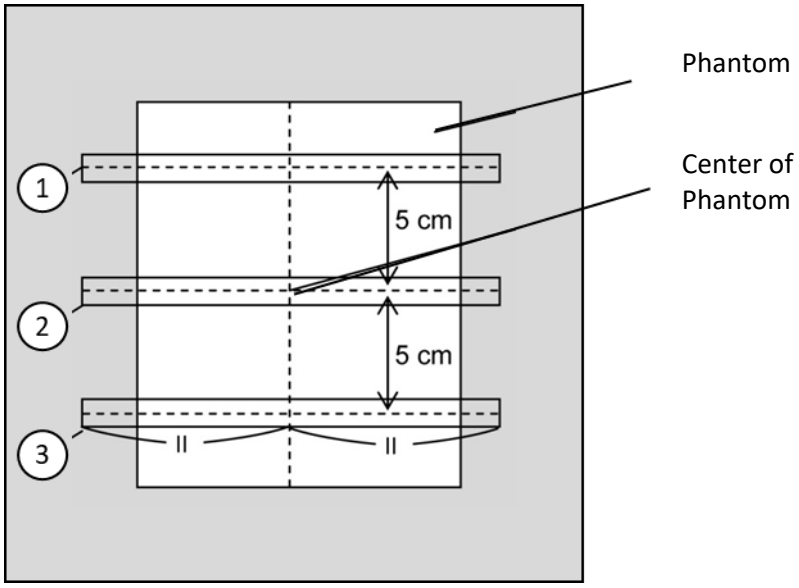
Change Parameter Settings

<Sequence name SE15>

TR	:	200
Slice thickness	:	5 mm
Slice gap	:	50 mm
Number of slices	:	3
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)

(18) Set the coil type to 8ch knee and set the SAR region to Knee.

(19) Start scanning.

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

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

(22) Measure the SNR of each slice.

(23) Referring to the following section entitled "SNR Measurement Procedure When the Anterior Section (Knee Attachment) Is Installed", obtain the signal mean value and noise SD, and calculate SNR.

Standard value of SNR:

Slice 1 : _____ > 210

Slice 2 : _____ > 230

Slice 3 : _____ > 210

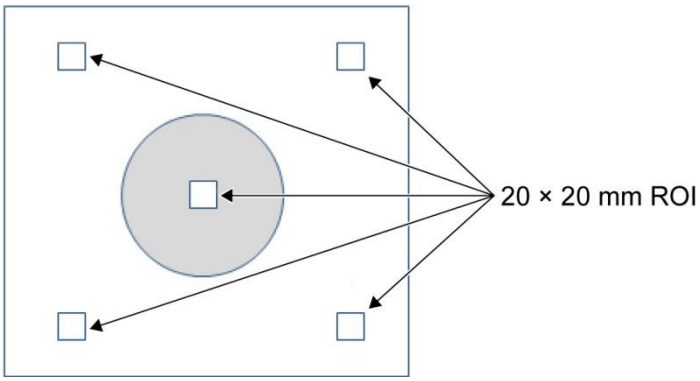
Record the result on the installation quality check sheet.

4.4 SNR Measurement Procedure When the Anterior Section (Knee Attachment) is Installed

(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.

Set ROI



(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)

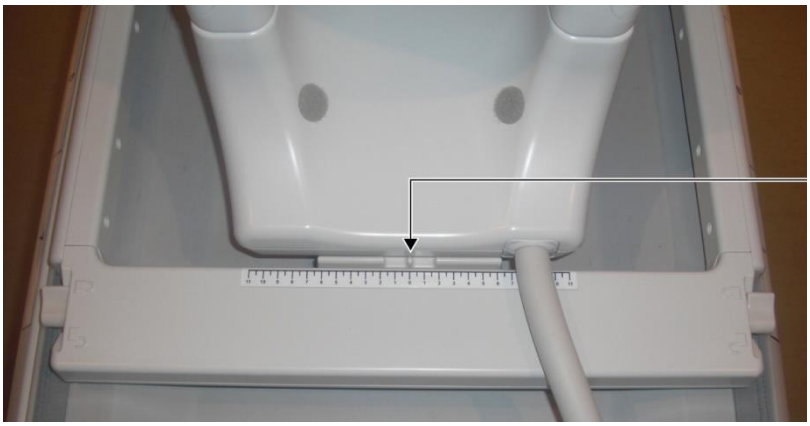
N : Average value of the four background noise values measured (noise SD values)

4.5 Scanning Procedure When the Anterior Section (Foot Attachment) is Installed

Remove all coils from the couchtop and then place the knee coil on the couchtop as indicated on the pictogram label. The coil should be placed on a couch pad.

(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

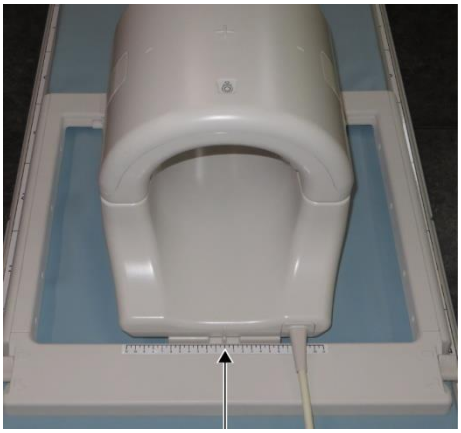


a. Move the levers on the two sides to the unlocked position. (The levers are connected – moving the lever on one side causes the lever on the other side to move in the same manner.)

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

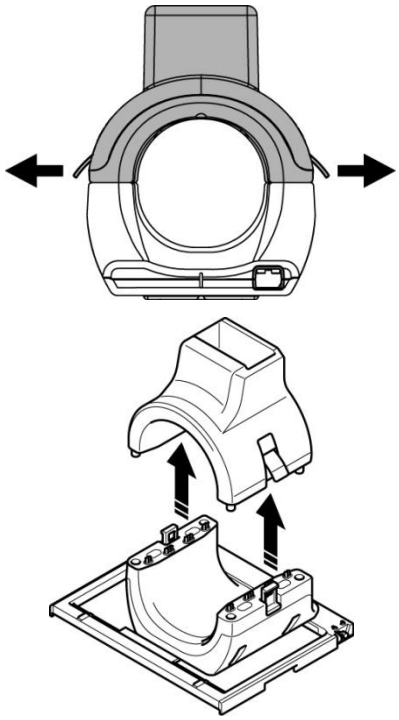


c. Return the levers to the locked position. When the coil is set at the desired position, move the levers on the two sides back to the locked position. Confirm that the coil is locked in position by trying to move it in the left/right direction.

Move Levers to Locked Position Once Desired Position is Reached

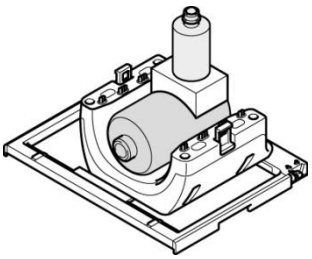
(2) Open the latches on both sides in the directions shown by the arrows to remove the foot attachment

Open Latches and Remove Foot Attachment



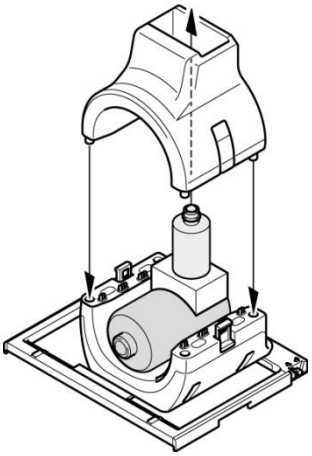
(3) Place the 2-L copper sulfate phantom (BSM41-5604) horizontally in the posterior section. Place the phantom supplied with the 8ch Knee/Foot SPEEDER (BSM41-5601) in the phantom alignment pad and position it above the 2-L copper sulfate phantom.

Position the Phantoms



(4) Place the foot attachment over the phantom bottle, ensuring that the vertical phantom is positioned in the center of the foot attachment opening. Connect the foot attachment to the posterior section.

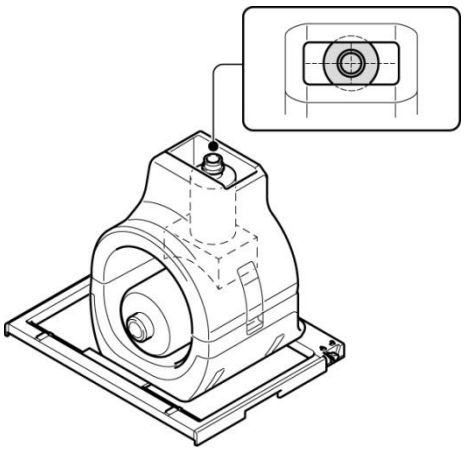
Connect Foot Attachment



⚠ CAUTION	This coil consists of surface coils. If the phantoms are not set at the correct positions, image testing cannot be performed correctly. Confirm that the 2-L copper sulfate phantom is placed straight and is in the center of the posterior section, and confirm that the bottle phantom is set vertically at the center of the foot attachment opening.

(5) Adjust the coil position so that the phantom is at the center of the coil.

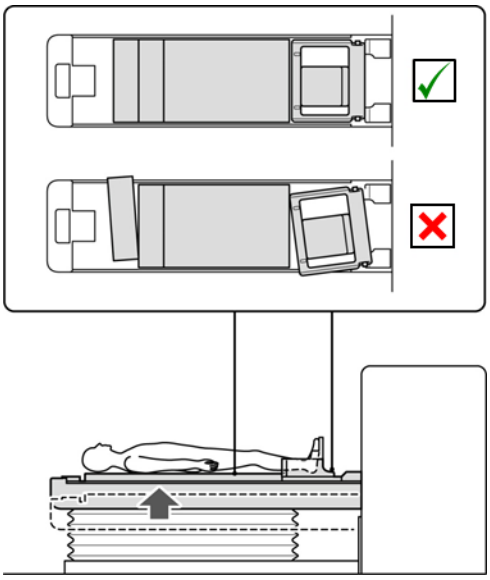
Center the Phantom



⚠ 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.

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

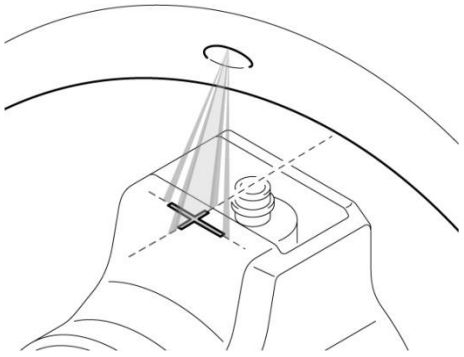
Confirm Coil and Mats are Not Protruding



(7) Connect the connector to ports A1 and A2 and lock the connector.

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

Align Coil-Center Mark with Projector Beam

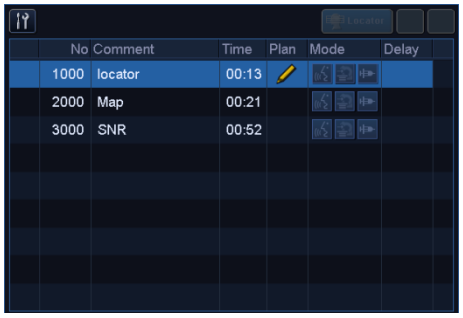


(9) Register a patient (be sure to set the system in SFT mode). Enter 180 cm for patient height and 60 kg for patient weight.

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.

(10) Select the "locator" sequence from the "8ch knee" PAS in the QA folder.

Select Locator Sequence



(11) Select "Knee foot" as the coil type and "ANKLE" as the SAR region. Confirm that the patient orientation is set to supine/head first.

(12) Confirm that the parameters are set as follows.

Confirm Parameters

FE_slt, Special Plan (Axial:1, Sagittal:1, coronal:1), TR50, NS3, ST8 mm, Flip25, FOV40 cm, MTX 256 × 256, NoWrap RO1.0/PE1.0

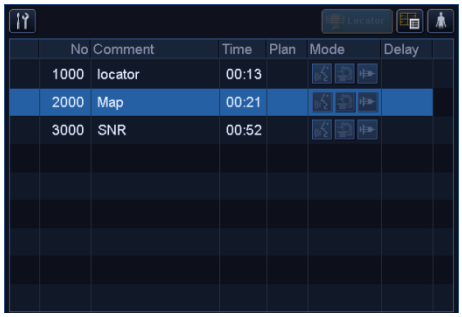
(13) Run the locator sequence.

Record the TGC value (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 value and RF level, select the values displayed with a decimal point and round them to two digits after the decimal point.

(14) Select the "Map" sequence.

Select Map Sequence



(15) Select "ANKLE" for the SAR region.

(16) Confirm that the parameters are set as follows.

Confirm Parameters

Map, AX:RL, TR160, NS20, ST 8 mm, FA20, FOV 36 cm, MTX 64 × 64, NoWrap RO2.0/PE1.0
Perform positioning so that the two phantoms are included in the displayed sagittal slice.

(17) Click [Queue & Exit] and run the map sequence.

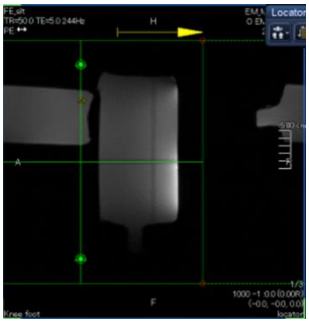
(18) Select the "SNR" sequence. Change the parameter settings as follows.

Change Parameter Settings

<Sequence name SE15>

TR	:	200
Slice thickness	:	5 mm
Slice interval	:	1 mm
Number of slices	:	1
Matrix size	:	320 × 320
FOV	:	32 × 32
NAQ	:	1
NoWrap	:	RO2.0/PE2.0
Plane	:	Sagittal
PE	:	AP

Perform positioning so that the two phantoms are included in the displayed sagittal slice.



(19) Set the coil type to “Knee Foot” and set the SAR region to ANKLE.

(20) Start scanning.

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

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

(23) Measure the SNR of each slice.

Referring to subsection 6.6.6 "SNR measurement procedure when the anterior section (Foot attachment) is installed", obtain the signal mean value and noise SD, and calculate SNR.

Standard value of SNR:

ROI 1 :_____> 250

ROI 2 :_____> 330

ROI 3 :_____> 390

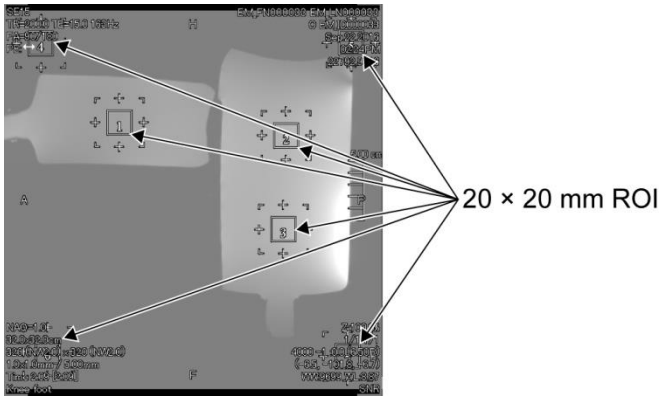
Record the result on the installation quality check sheet.

4.6 SNR Measurement Procedure When the Anterior Section (Foot Attachment) is Installed

(1) Display the center slice of the acquired image. Set a rectangular 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.

Set ROI



(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

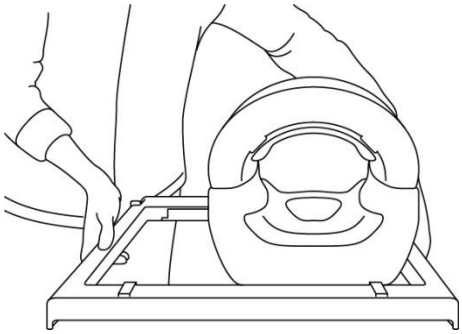
S : Measured signal mean value (value in the signal ROI in each image)

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, hold it by the handles on the sides of the base frame. Do not allow the cable to hang freely when moving the coil.



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

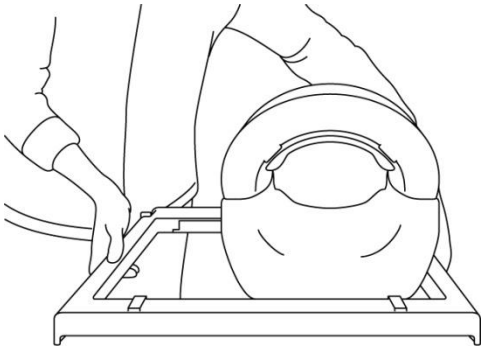
(24) Lower the patient couch to the lowest position.

(25) 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.

(26) 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.

Place the Coil on the Couch



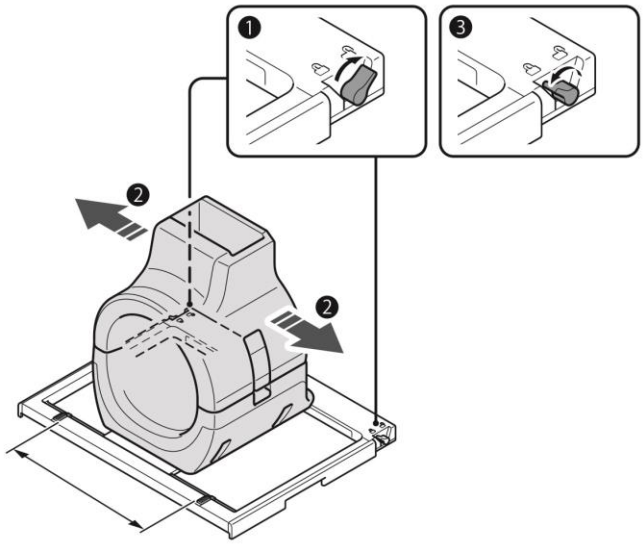
(27) Slide the posterior section to the desired position.

a. Move the levers on the left and right sides of the base frame to the unlocked position. (The left and right lock/unlock levers are linked together. When either one of the levers is moved to the unlocked position, the other lever is also moved to the unlocked position.)

Unlock the levers

b. Adjust the position of the coil.

Slide Coil Left or Right to Desired Position

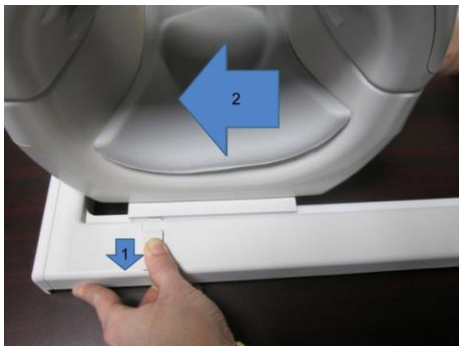


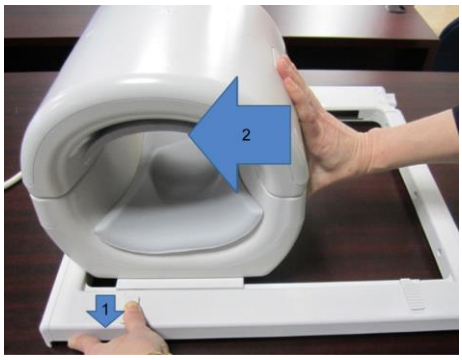
When the coil is positioned more than 8 cm from the isocenter, the coil must be moved as described below. Some deterioration in image quality may be observed if the coil is more than 8 cm from isocenter during imaging.

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

Step 2: Retract the stop using the stop grip.

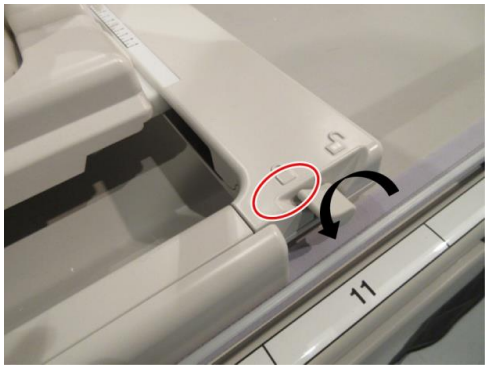
Step 3: Move the coil past the stop to the desired position.





c. Return both levers to the locked position. When the coil is set at the desired position, return both levers to the locked position. Confirm that the coil cannot be moved 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, foot, and ankle.

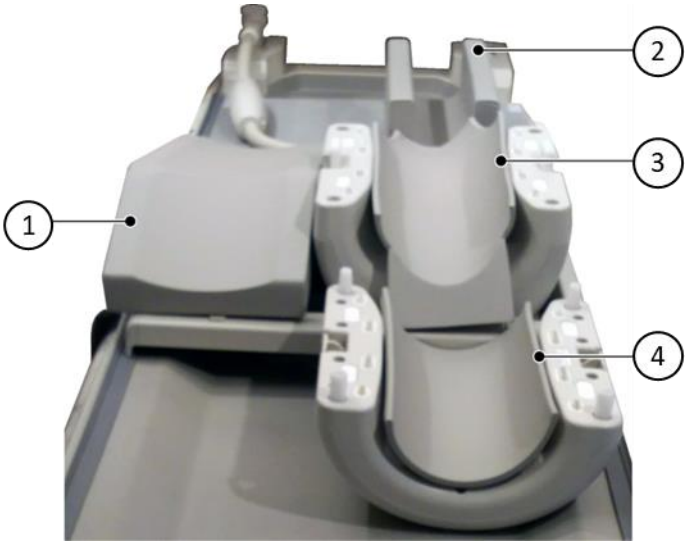
⚠ CAUTION	Be sure to read this manual and the safety manual supplied with the MRI system before operating the system.

5.3.1 Patient Positioning for Knee Imaging

(1) Set the two movable immobilizing bands (long) supplied with the system on both sides of the couchtop.

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

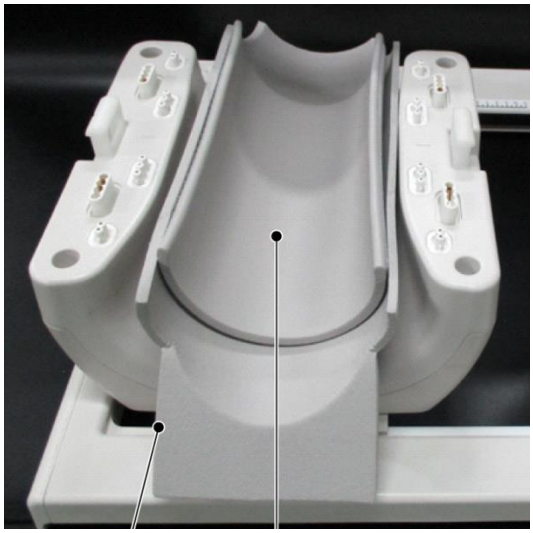
Place Pads



Number	Description
1	Free-Leg Pad
2	Inferior Leg Pad*
3	Bottom Pad
4	Anterior Knee Pad**

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

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

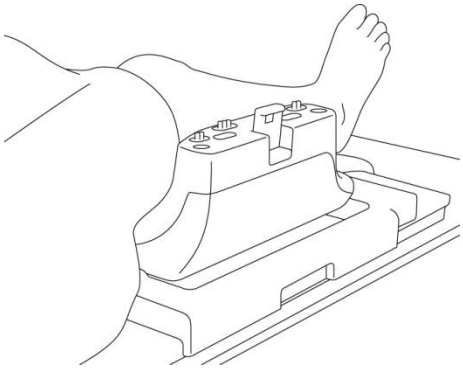


Bottom Pad

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

(3) Place the patient on the couchtop with the patient's feet at the gantry end. Perform positioning so that the region to be scanned is positioned at the center of the coil.

Position the Patient



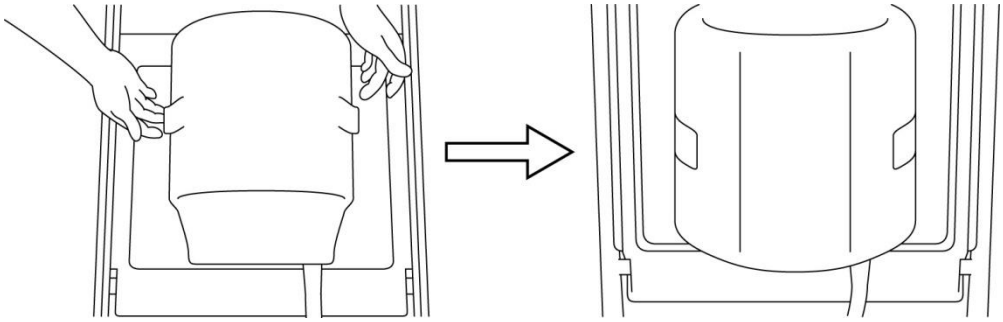
If the region to be scanned is not positioned at the center of the coil, there is possibility of image deterioration (this can be particularly significant in FatSAT images).

(4) Confirm that the coil and mats are not protruding from the couchtop and raise the couchtop.

(5) Reconfirm that the region to be scanned is positioned at the center of the coil and connect the anterior section to the posterior section. Press the latches to lock the anterior section.

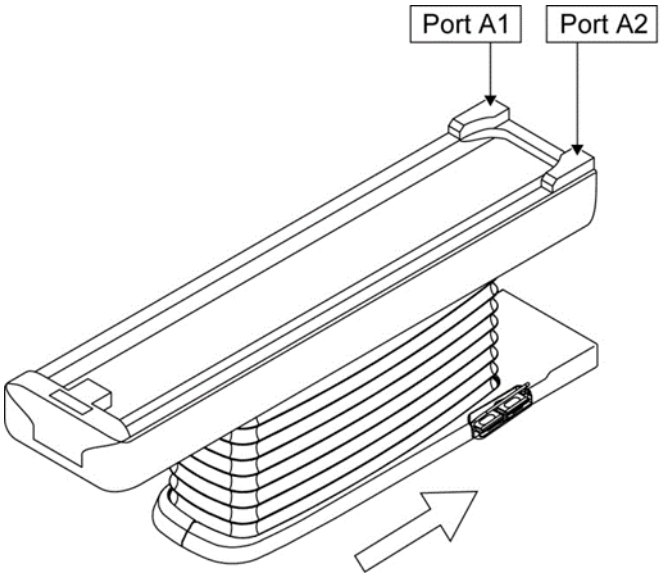
Lock the Anterior Section

Confirm that the anterior and posterior sections are fully connected and that the latch flaps are pushed in.

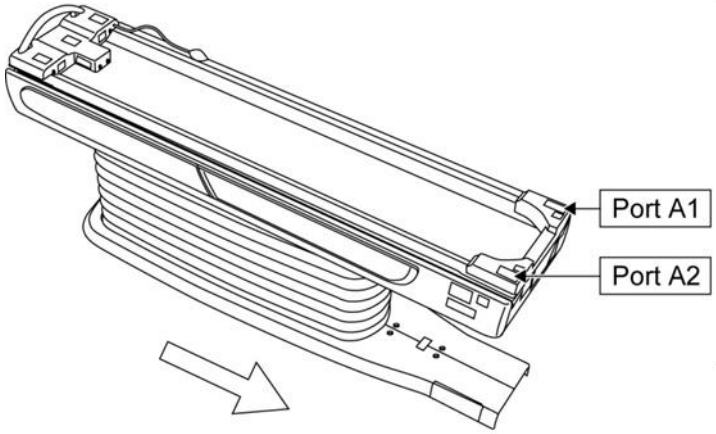


(6) Confirm that the coil cable is not in direct contact with the patient and connect the connector to port A1 or A2 on the couchtop. Then, lock the connector.

On Vantage Elan Systems, Connect to Ports A1 or A2

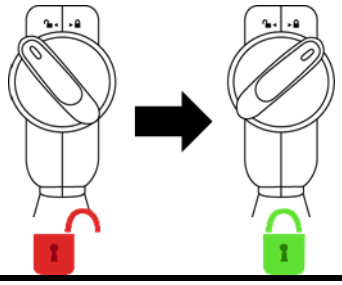


On Vantage Titan and Vantage Orian Systems, Connect to Ports A1 or A2



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.

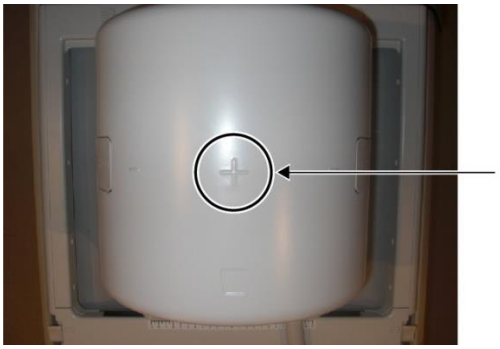


CAUTION

Do not allow the cable or cable balun to come into contact with the inner wall of the gantry. Failure to do so may lead to excessive heating of the cable balun, possibly resulting in burn injury to the patient. Ensure a space of at least 10 mm (at the most compressed status) between the inner wall of the gantry and cable or cable balun using a foam pad.

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

Align Coil-Center Mark with Projector Beam



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

CAUTION

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

(9) Register the patient.

(10) Set the scanning conditions.

Set the RF coil type to 8ch Knee.

Select Knee for the SAR region.

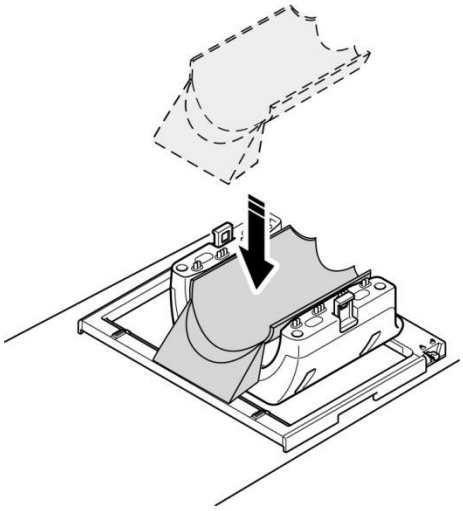
(11) Start scanning per the instructions in the MRI system manual.

> 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 Coil and Patient Positioning for Hand or Wrist Imaging

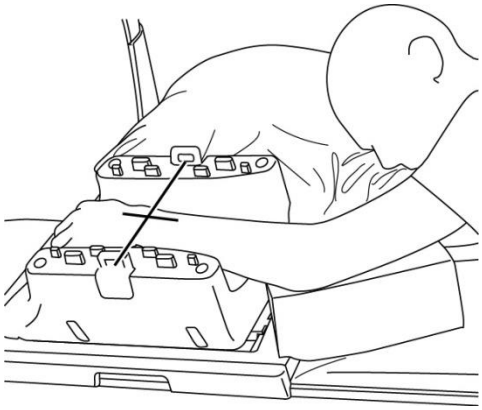
(1) Place the bottom pad supplied with the coil in the posterior section.

Place the Bottom Pad



(2) Position the patient using the pads supplied with the system (or other suitable materials) as shown below.

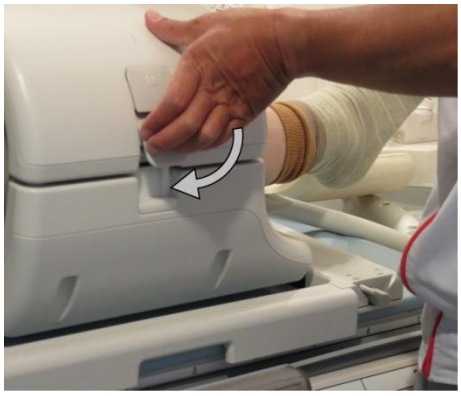
Position the Patient



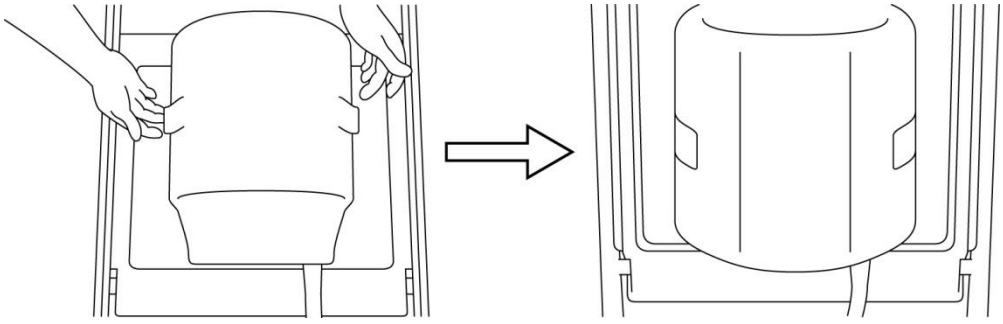
(3) Confirm that the coil and mats are not protruding from the couchtop and raise the couchtop.

(4) Reconfirm that the region to be scanned is positioned at the center of the coil and connect the anterior section to the posterior section. Press the latches to lock the anterior section.

Lock the Anterior Section

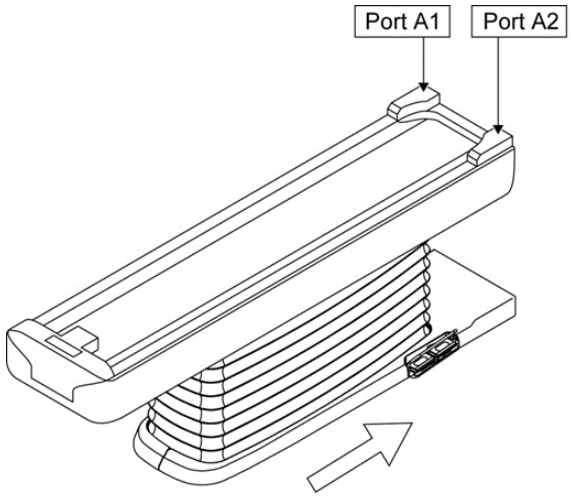


Confirm that the anterior and posterior sections are fully connected and that the latch flaps are pushed in.

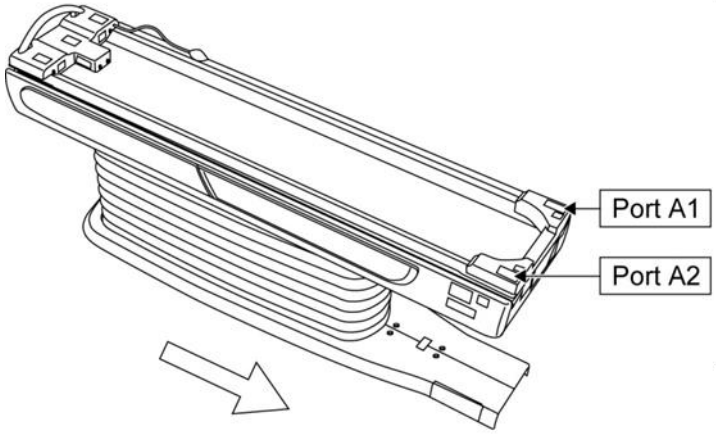


(5) Confirm that the coil cable is not in direct contact with the patient and connect the connector to port A1 or A2 on the couchtop. Then, lock the connector.

On Vantage Elan Systems, Connect to Ports A1 or A2

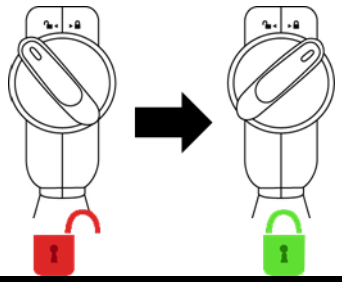


On Vantage Titan and Vantage Orian Systems, Connect to Ports A1 or A2



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.

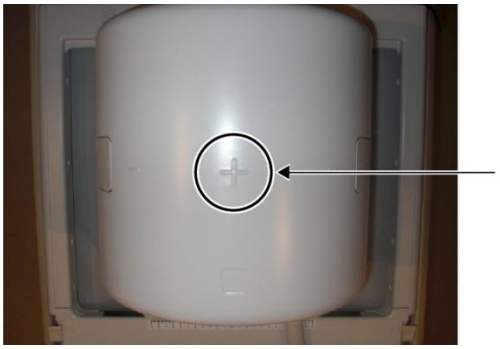


CAUTION

Do not allow the cable or cable balun to come into contact with the inner wall of the gantry. Failure to do so may lead to excessive heating of the cable balun, possibly resulting in burn injury to the patient. Ensure a space of at least 10 mm (at the most compressed status) between the inner wall of the gantry and cable or cable balun using a foam pad.

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

Align Coil-Center Mark with 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.

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

(8) Register the patient.

(9) Set the scanning conditions.

Set the RF coil type to 8ch Knee.

Select Hand or Wrist for the SAR region.

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

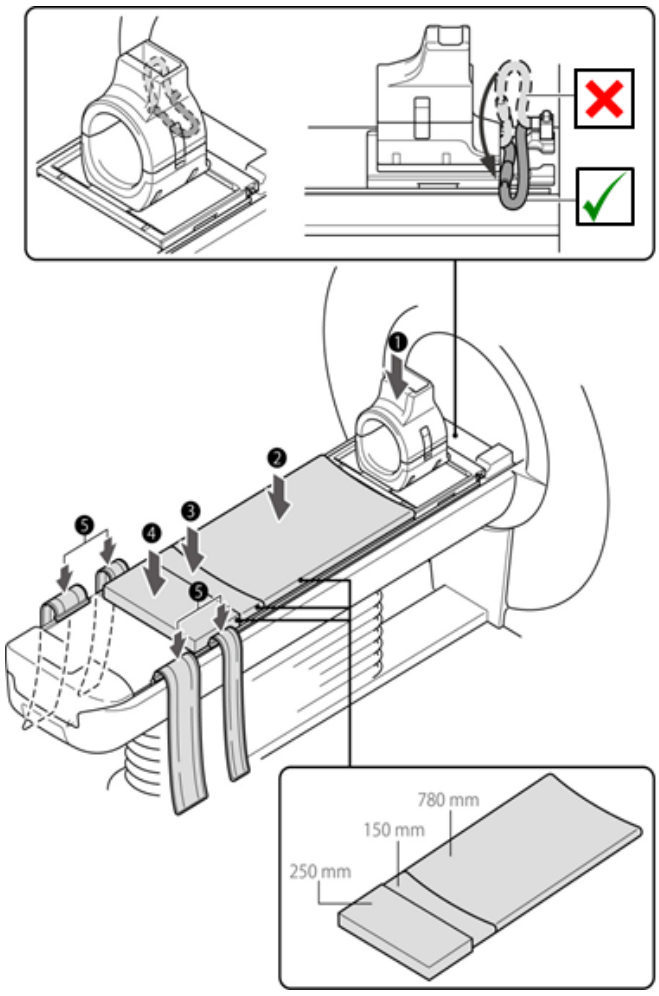
i	When removing the coil from couchtop, rotate the coil to facilitate access to the handles and then lift the coil using the handles.

5.3.3 Coil and Patient Positioning for Foot or Ankle Imaging

(1) For Vantage Elan systems: Starting at the gantry end of the couchtop, place the coil, 780-mm mat (or spine coil), 150-mm mat, and 250-mm mat (in that order) on the couchtop. Route the coil cable in the space between the coil and the gantry end of the couchtop. Make sure that the cable is laid flat and does not protrude upward (refer to the figure below).

For Vantage Titan and Vantage Orian systems: Refer to operation manual for the system.

Coil and Pad Placement on Vantage Elan Systems



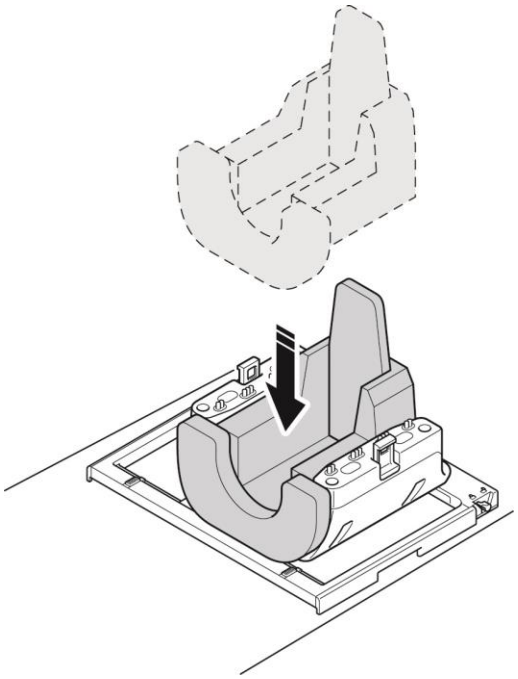
Number	Description
1	Coil
2	780 mm Mat*
3	150 mm Mat*
4	250 mm Mat*
5	Moveable Immobilizing Band (Long x 2)*

*: Use the accessories provided with the MRI system. Note that the accessories are subject to change. For details, refer to the operation manual.

(2) Place the two movable immobilizing bands (long) supplied with the system on both sides of the couchtop.

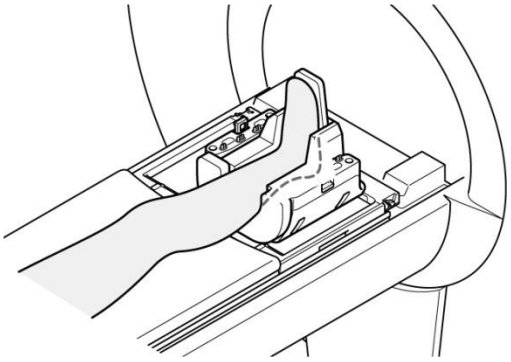
(3) Place the Foot Positioning Pad in the posterior section.

Place the Foot Positioning Pad in Posterior Section



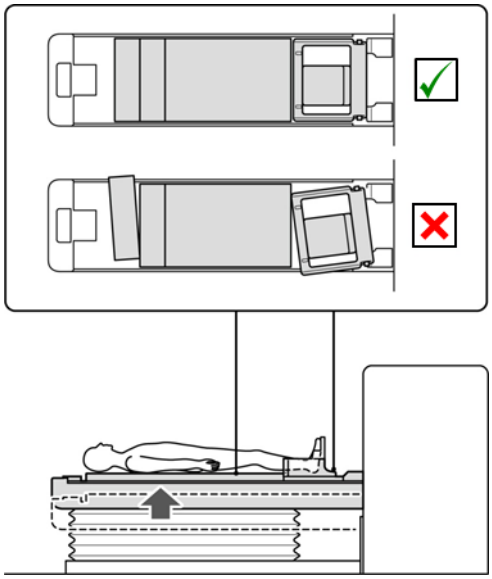
(4) Place the patient on the couchtop with the patient's feet at the gantry end.

Position the Patient



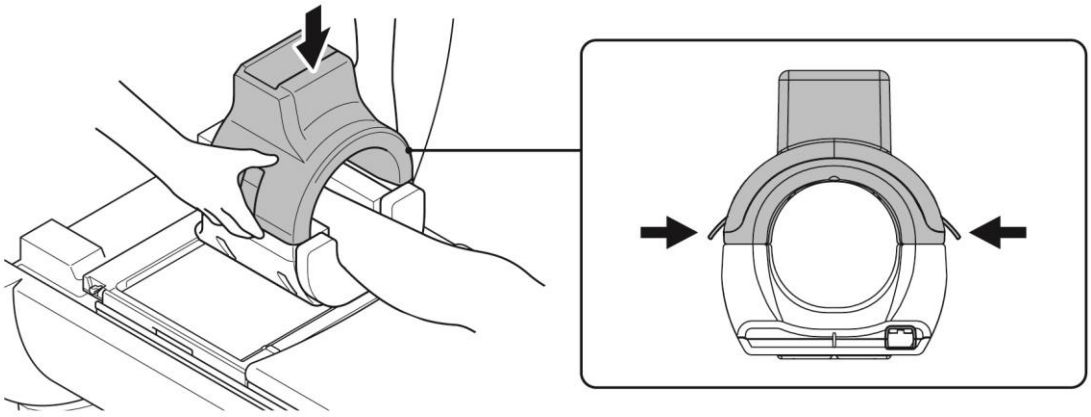
(5) Confirm that the coil and mats are not protruding from the couchtop and raise the couchtop.

Confirm Coil and Mats are Not Protruding

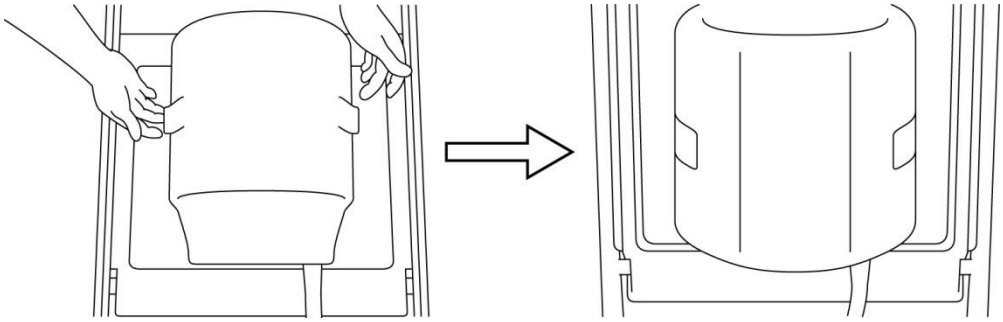


(6) Position the patient's toe in the chimney-shaped part of the anterior section and connect the anterior section to the posterior section. Press the latches to lock the anterior section.

Position Patient's Toe in Chimney Portion of Anterior Section

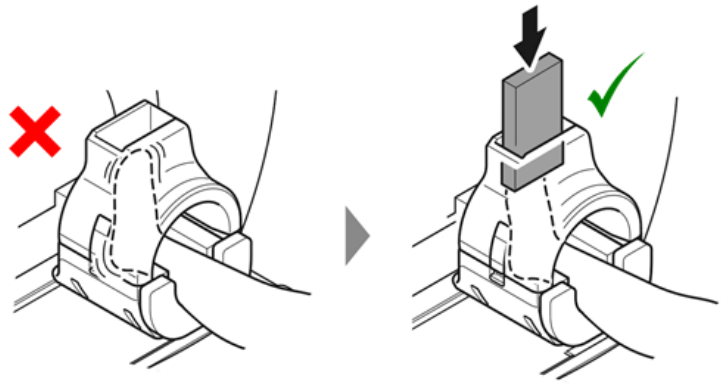


Confirm that the anterior and posterior sections are fully connected and that the latch flaps are pushed in.



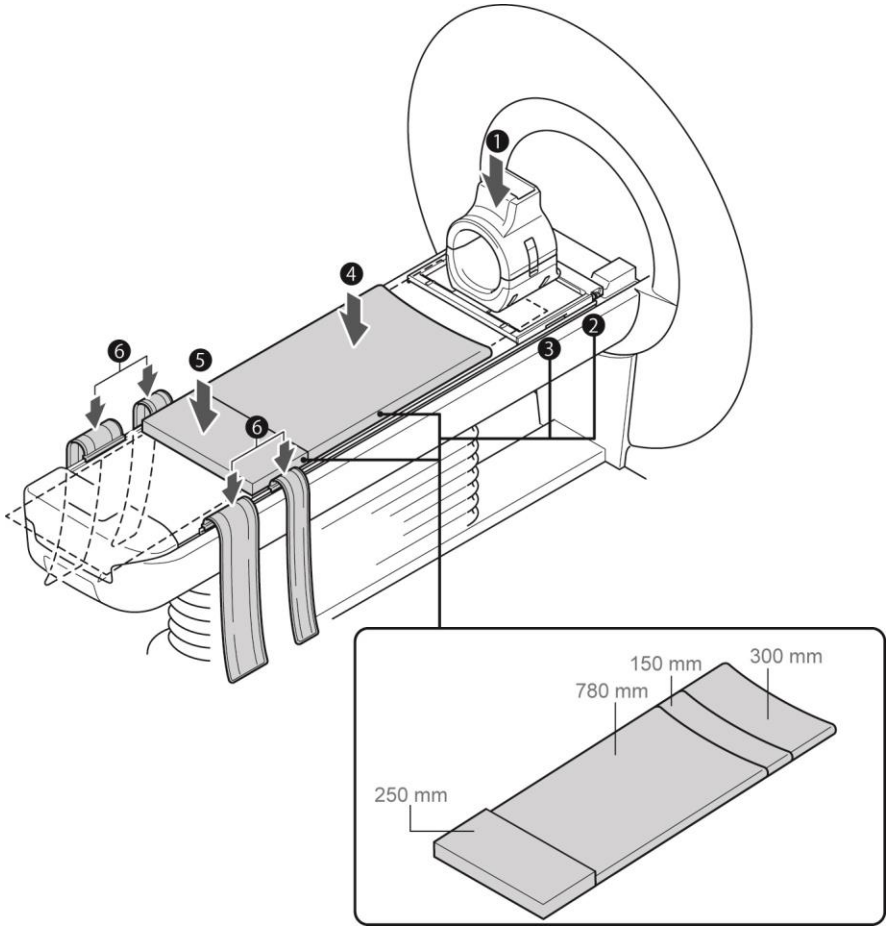
(7) If the foot can be moved inside the coil, use the supplied wedge pad to secure the foot in the coil.

Use Wedge Pad to Immobilize Foot



If the coil needs to be set more securely on the couchtop of Vantage Elan systems.

1. Placing the 300-mm mat and 150-mm mat under the coil allows the coil to be placed more securely.



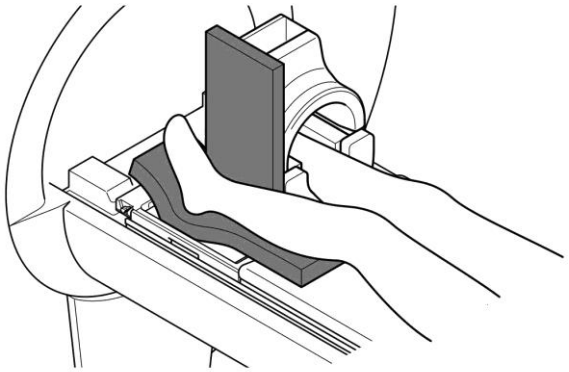
Number	Description
1	Coil
2	300 mm Mat*
3	150 mm Mat*
4	780 mm Mat*
5	250 mm Mat*
6	Moveable Immobilizing Band (Long x 2)*

*: Use the accessories provided with the MRI system. Note that the accessories are subject to change. For details, refer to the operation manual.

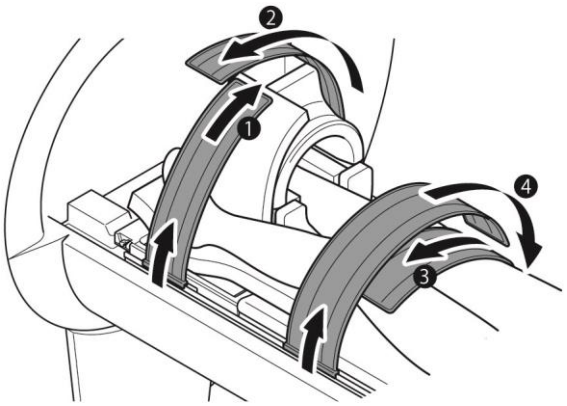
2. Cover the spine coil cable with the mat supplied with the spine mat to prevent the cable from coming into contact with the patient's body.

(8) Place a mat between the coil and the other foot.

Place Mat between Coil and Non-Imaged Foot

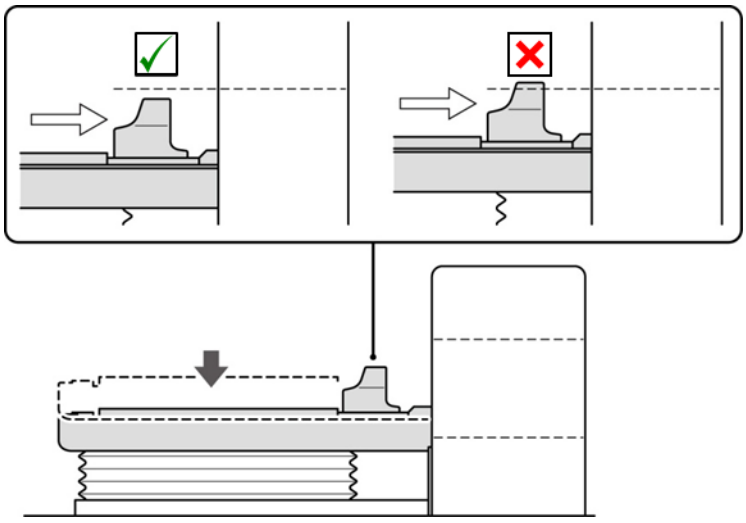


To secure the coil to the patient couch, use the belts provided with the couch and secure the coil as shown in the figure below.



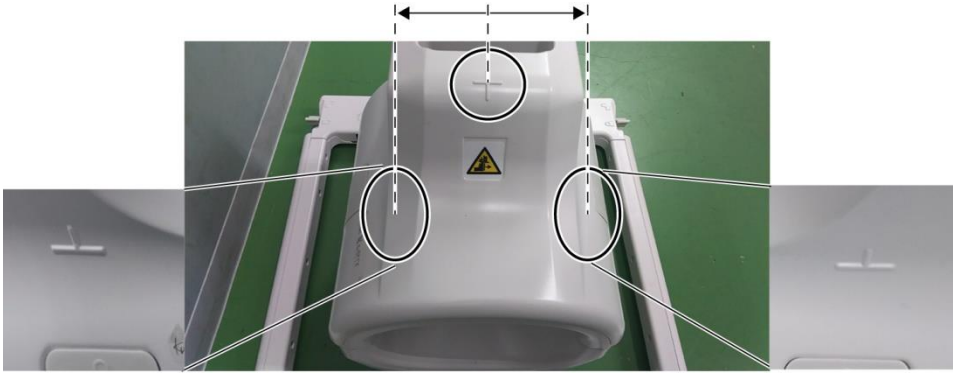
(9) Confirm that the coil cannot collide with the gantry upon entry. If collision is possible, lower the couch.

Confirm Coil Cannot Collide with Gantry



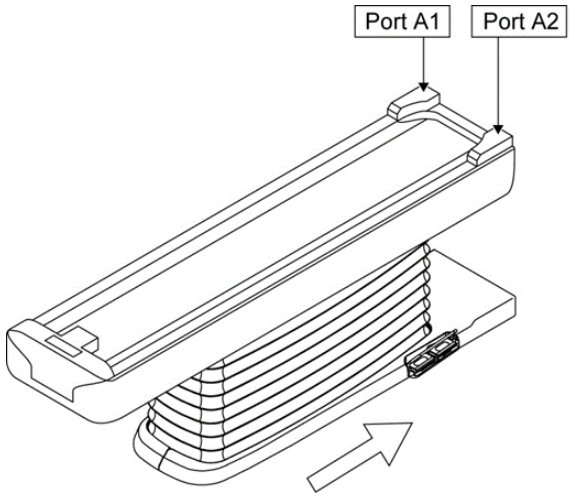
(10) Move the couch to check the position of the laser.

Position the couch so that the laser is within the range specified in the figure below.

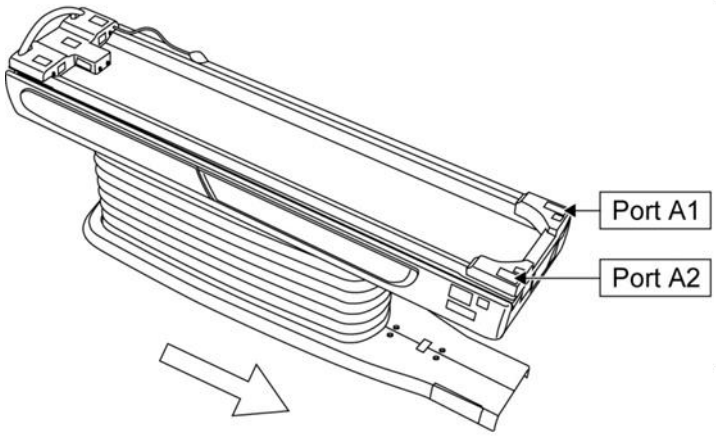


(11) Confirm that the coil cable is not in direct contact with the patient and connect the connector to port A1 or A2 on the couchtop. Then, lock the connector.

On Vantage Elan Systems, Connect to Ports A1 or A2

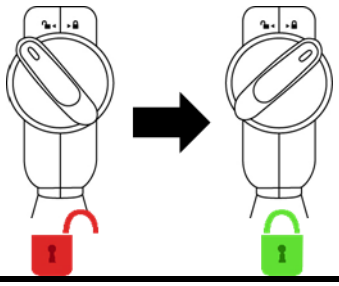


On Vantage Titan and Vantage Orian Systems, Connect to Ports A1 or A2



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.

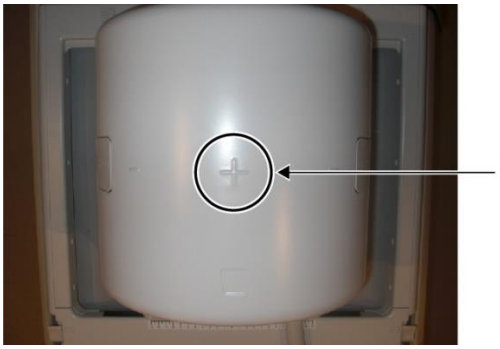


CAUTION

Do not allow the cable or cable balun to come into contact with the inner wall of the gantry. Failure to do so may lead to excessive heating of the cable balun, possibly resulting in burn injury to the patient. Ensure a space of at least 10 mm (at the most compressed status) between the inner wall of the gantry and cable or cable balun using a foam pad.

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

Align Coil-Center Mark with Projector Beam



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

CAUTION	Ensure that the patient and coil do not come into contact with the gantry during patient couch movement. This could result in patient injury.

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

(14) Register the patient.

(15) Set the scanning conditions.

Set the RF coil type to 8ch Knee.

Select Ankle for the SAR region.

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

i	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 straps 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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