**Operator's Manual** 



# 16ch Foot/Ankle SPEEDER For Canon 3.0T MRI Systems





Canon Model #	QED REF
MJAJ-262A	Q7000073

www.qualityelectrodynamics.com



#### Warranty and Liability

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product. The warranty does not cover the following items, even during the warranty period:

- Damage or loss due to misuse or abuse.
- Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
- Damage or loss caused by failure to meet the specified conditions for this equipment, such as inadequate power supply, improper installation, or unacceptable environmental conditions.
- Damage due to changes or modifications made to the product.

In no event shall QED be liable for the following:

- Damage loss or problems caused by relocation, modification, or repair performed by personnel not explicitly authorized by QED.
- Damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operation manual.

#### **Transportation and Storage Conditions**

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

	Temperature	-10°C to +50°C
<u>کی</u>	Relative humidity	20% to 95%
9	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.



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 <u>www.qualityelectrodynamics.com</u>. To request a paper copy of the operator's manual, please email <u>info@qualedyn.com</u> 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 is necessary to avoid a hazardous situation, which, if not avoided, could result in minor or moderate injury.

INFORMATION



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



# Table of Contents

About T	his Manual	3
Legen	ıd	3
Table of	Contents	4
Chapter	1 – Introduction	5
1.1	Description	5
1.2	Operating Environment and Compatibility	5
1.3	User Profile	5
1.4	Patient Information	5
Chapter	2 – 16ch Foot/Ankle SPEEDER Components	6
2.1	Included Components	6
2.2	Parts of the Coil	7
Chapter	3 – Safety	8
3.1	Symbol Glossary	8
3.2	Indications	9
3.3	Contraindications	9
3.4	Precautions	9
3.5	Cautions – RF Coil	10
3.6	Emergency Procedures	12
Chapter	4 – Quality Assurance	13
4.1	SNR Measurement When the Automatic SNR Measurement Tool is Not Used	13
Chapter	5 – Coil Setup and Use	22
5.1	Carrying the coil	22
5.2	Coil Setup	
5.3	Patient Positioning and Scanning	
Chapter	6 – Cleaning, Maintenance, Service, and Disposal	
6.1	Cleaning the RF Coil	
6.2	Maintenance	
6.3	Service	32
6.4	Disposal	
6.5	Expected Service Life	32
Chapter	7 – Guidance and Manufacturer's Declaration – Electromagnetic Compatibility (EMC)	33
7.1	Classification	
7.2	Environment and Compatibility	33
7.3	Electromagnetic Emission	
7.4	Electromagnetic Immunity	



# 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 16ch Foot/Ankle SPEEDER is used to examine the foot and ankle.

### **1.2** Operating Environment and Compatibility

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

• Vantage Galan 3T (STD, XGO, and ZGO)

### 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 – 16ch Foot/Ankle SPEEDER Components

### 2.1 Included Components

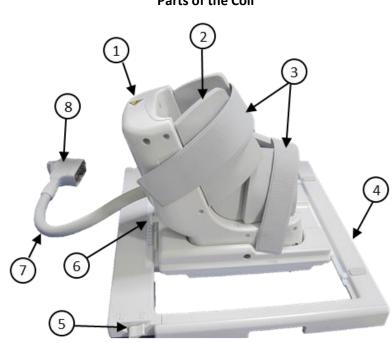
The 16ch Foot/Ankle SPEEDER is shipped with the parts shown below. Upon receipt, please ensure that all parts are included in the shipment. Please contact your Canon Medical Systems representative for replacement or replenishment of any accessories listed here.

Picture	Description	Quantity	Canon PN	QED PN
2	16ch Foot/Ankle SPEEDER Coil	1	MJAJ-262A	Q7000073
	Comfort Pad	1	BSM41-7859E	3004970
	U-Shaped Pad	1	BSM41-7860E	3005088
	Phantom Alignment Pad	1	BSM41-7862E	3005188
	Phantom	2	BSM41-7861E	3005190



## 2.2 Parts of the Coil

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



Number	Description
1	Rigid Section
2	Flexible Section (Flaps)
3	Straps
4	Base Frame
5	Base Movement Lock/Unlock Lever
6	Base Tilt Locking Knob
7	Connector Cable
8	Connector

Parts of the Coil



# Chapter 3 – Safety

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



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

## 3.1 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
Ŕ	5333	ISO 7000 IEC 60417	Type BF applied part
	3082	ISO 7000 IEC 60417	Manufacturer and Date of Manufacture
$\langle \rangle$	6192	ISO 7000 IEC 60417	RF Coil, Receive
MR MR	N/A	IEC 60601-2-33 IEC 62570	MR Safe
EC REP	5.1.2	ISO 15223-1	Indicates the Authorized Representative in EU
UK REP	5.1.2	ISO 15223-1 ISO 20417	Indicates the UK Responsible Person
CH REP	5.1.2	ISO 15223-1 SwissMedic	Indicates the authorized representative in Switzerland
REF	2493	ISO 7000 IEC 60417	Catalog Number
SN	2498	ISO 7000 IEC 60417	Serial Number
	0632	ISO 7000 IEC 60417	Temperature limit
<u>(</u>	2620	ISO 7000 IEC 60417	Humidity limitation
<u></u>	2621	ISO 7000 IEC 60417	Atmospheric pressure limitation
MD	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 16ch Foot/Ankle SPEEDER coil is intended for use with Canon 3.0T MR systems to produce diagnostic images of the 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 highfrequency current may form and burns may occur.



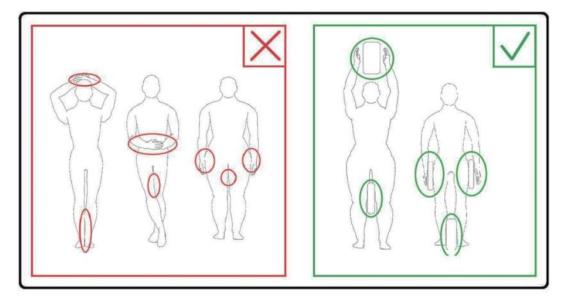
Ensure that the patient does not come into direct contact with the coil cables. Burn injuries may result due to the electric field that is generated in the RF coil when a high-frequency magnetic field is transmitted.



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.



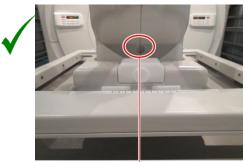
# Chapter 4 – Quality Assurance

The coil and the phantoms to be used are specified below.

Coil	Phantom	Part number
16ch Foot/Ankle SPEEDER	Phantom for Foot/Ankle SPEEDER (1-L copper sulfate bottle phantom) × 2	BSM41-7861E

# 4.1 SNR Measurement When the Automatic SNR Measurement Tool is Not Used

(1) Place the 16ch Foot/Ankle SPEEDER on the couchtop. Confirm that the tilt angle of the coil is 0° and the coil position in the X direction is 0 cm from the center. Connect the coil cable connector to port A1 or port A2 of the couchtop.



#### **Correct vs. Incorrect Coil Tilt Angle**

Position the coil so that the hole for adjusting the tilt angle to 15° is visible.





(2) Place one of the phantoms supplied with the coil as shown in the figure below. Confirm that the phantom is fully inserted into the coil.



#### **Phantom Placement**





Top view

(3) Place the supplied phantom alignment pad on the phantom.



#### **Phantom Alignment Pad Placement**

Phantom Alignment Pad



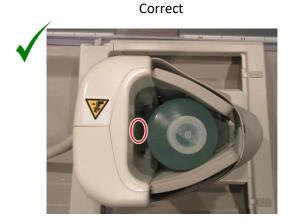
(4) Place the other phantom as shown in the figure below. At this time, confirm that the second phantom is perpendicular to the patient couch.



#### **Second Phantom Placement**

(5) Secure the flaps using the straps so that the flaps cover the phantoms. Secure the flaps so that the phantom is not tilted.

#### Secure the Flaps Using the Straps



There is sufficient space around the phantom.

Incorrect

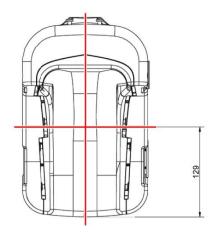


• The phantom is in contact with the inner surface of the coil.



(6) Align the coil-center mark with the crosshairs of the positioning projector and send the coil into the center of the gantry.

#### Align the Coil-Center Mark



- (7) Wait approximately 1 minute to allow the phantom solution to stabilize.
- (8) Register the patient.

Set the patient weight to 100 kg.

(9) Select "FE\_slt" from the FE PASs in the SEQ folder.

For Windows 10 or later, select "Typical PAS"  $\rightarrow$  "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.

Set the scan parameters as specified below.

FE\_slt, Special Plan (Axial:1, Sagittal:1, Coronal:1), TR50, NS3, ST8mm, FA25, FOV38cm, MTX256×256, NoWrap RO1.0/PE1.0

(10) Select the coil type and select Ankle for the anatomical region.

Coil type : 16ch Foot/Ankle SPEEDER

Section : FAC



#### Select the Coil



- (11) Select "Queue & Exit" to close the coil selection window and then perform scanning with the set sequence.
- (12) Select "FFE\_map" from the FFE PASs in the SEQ folder.

For Windows 10 or later, select "Typical PAS"  $\rightarrow$  "Coil QA" and select "FFE\_map" from Other PAS in the Other folder.

Set the scan parameters as specified below.

FFE\_map, AX, TR6, NS20, ST 8mm, Gap 0, FA20, FOV38cm, MTX64×64, NoWrap PE1.0/RO2.0

Position the phantom so that it is at the center of the gantry in both the A-P and H-F directions.

- (13) Select "Queue & Exit" to close the coil selection window and then perform scanning with the set sequence.
- (14) Select "SE15" from the SE PASs in the SEQ folder.

For Windows 10 or later, select "Typical PAS"  $\rightarrow$  "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:1, ST:5mm, FOV:38.0cm×38.0cm, Matrix:256×256, No Wrap(PE/RO):1/2, Sagittal plane, PE=AP

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.



	Time <b>0:5</b> 2	Cover 1 R	F%	PNS <=8	0% BAV 163 SNR Reconstruction	220.3 % Advanced
SE15		38 / 256 38 / 256	-	No Wrap 1 2 Im) 0 EDIT	Gate Source Gate Source Dynamic Scan InScan Plan Imaging Tech. ASL Plan Moving Bed Coordination Mode Fixed Resolution Mode Voice Mode	<ul> <li>OO Min 330</li> <li>I</li> <li>ER</li> <li>EDIT</li> </ul>
	Plane Sagittal	AP 🗉		<b>TE</b> 15	Update SAR Seq. SE15	EDIT
	Flip / Flop 90	180 Max 180	IR Pulse	т	Fatsat Pulse	Off 🔳

#### Set the Reconstruction Conditions

Refine Filter	L2:73 Smoothing(le
Locator Image	H1:B1 Edge enhance (weak)
Locator image	H2:D1 Edge enhance (strong)
On	L1H1:77 Smooth(very weak)+Edge(weak)
	L1H2:78 Smooth(very weak)+Edge
Receiver Gain Correction	L2H1:79 Smooth(weak) +Edge(weak)
<b></b>	L2H2:7A Smooth(weak) +Edge
Off a	L3H1:7B Smooth +Edge(weak)
WWWL	L3H2:7C Smooth +Edge
	L4H1:7D Smooth(strong) +Edge(weak)
Default	L4H2:7E Smooth(strong) +Edge
	NL1:8" k-space LSI only (level 1)
Intensity Correction	NL2:7* k-space LSI only (level 2)
Intensity Corr.	NL2.5:N <sup>s</sup> k-space LSI only (level 2.5)
	NL3:6" k-space LSI only (level 3)
Off _	NL4:5" k-space LSI only (level 4)
	NL4.5:G" k-space LSI only (level 4.5)
Fine Reconstruction	NL5:4* k-space LSI only (level 5)
RO Fine	NL6:3" k-space LSI only (level 6)
off _	NL7:2 <sup>*</sup> k-space LSI only (level 7) =
	NL8:1.5" k-space LSI only (level 8)
Post-processing	NL9:1* k-space LSI only (level 9)
InScan	NL10:0.5" k-space LSI only (level 10)
in to wait	NL11:0.3* k-space LSI only (level 11)
Off _	JT1:0° Jet (level 1)
	EP1:M° Epi (level 1)
Auto MIP	EP2:Q° Epi (level 2)
Auto Mip Preview	UTE1:GF UTE (level 1)
	UTE2:GG UTE (level 2)
Off _	UTE3:GH UTE (level 3)
	A1:P* NONE:** No filter

#### **NONE: No Filter**

Position the phantom so that it is at the center of the gantry in both the A-P and R-L directions.

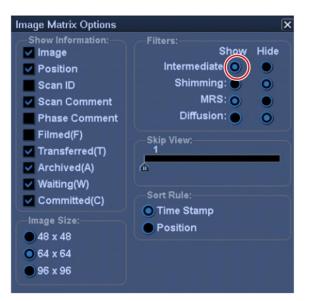
- (15) Select "Queue & Exit" to close the coil selection window and then perform scanning with the set sequence.
- (16) Display an intermediate image by selecting the following items.

File  $\rightarrow$  Options  $\rightarrow$  Intermediate: Show



#### **Image Matrix**





#### Intermediate: Show

#### **Intermediate Image**

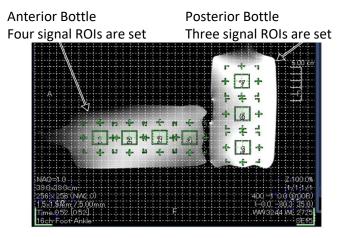


(17) Display the acquired intermediate image in the SE15 sequence and then set the signal ROIs and the noise ROIs (\* all ROIs must be 2 cm  $\times$  2 cm).



#### Signal ROI

Set seven signal ROIs on the anterior and posterior bottles as shown in the figure below.

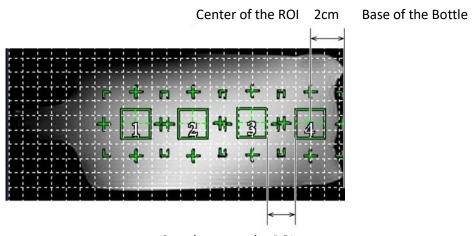


#### Setting the Signal ROIs

ROIs on the anterior bottle:

Set a ROI at the center in the H-F direction and 2 cm from the base of the anterior bottle. Set three more ROIs at 2-cm intervals from the ROI that was set first (a total of four ROIs are set).

#### ROIs on the Anterior Bottle

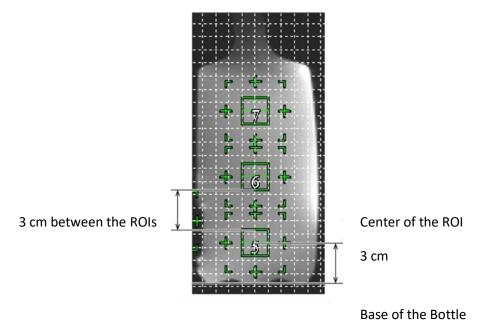


2 cm between the ROIs



ROIs on the posterior bottle:

Set a ROI at the center in the A-P direction and 3 cm from the base of the posterior bottle. Set two more ROIs at 3-cm intervals from the ROI that was set first (a total of three ROIs are set).



#### **ROIs on the Posterior Bottle**

#### Noise ROI

Set ROIs at the four corners of the image (a total of four ROIs). Set the noise ROIs at positions where ghosting is not present.

- (18) Measure the signal value (Mean) and background noise value (NoiseSD).
- (19) Obtain the mean noise SD value of the four noise ROIs.
- (20) From the mean signal value and mean background noise value, calculate the SNR using the equation below.

SNR calculation equation

SNR = S/N

- S : Measured mean signal value (mean value of the signal ROIs)
- N : Noise value (NoiseSD)

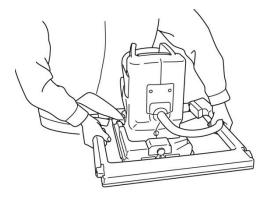
S/N ratio standard	ROI 1≥745	ROI 5 ≥ 1125
	ROI 2≥860	ROI 6≥885
	ROI 3≥850	ROI 7 $\ge$ 1060
	ROI 4 ≥ 705	

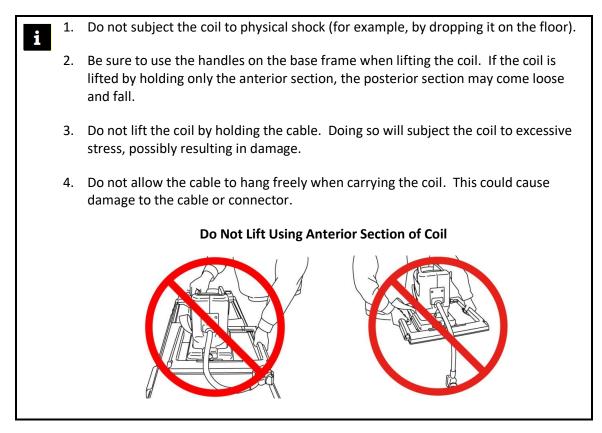


# Chapter 5 – Coil Setup and Use

### 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.







### 5.2 Coil Setup

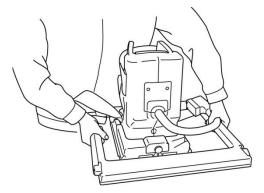
- (1) Lower the patient couch to the lowest position.
- (2) Remove all RF coils that are connected to the connector ports on the gantry and RF coils that are not connected to the connector ports on the couch top.



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



- (4) Slide the coil to adjust the position in the X direction (movement range: ±5 cm from the center).
  - 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.)

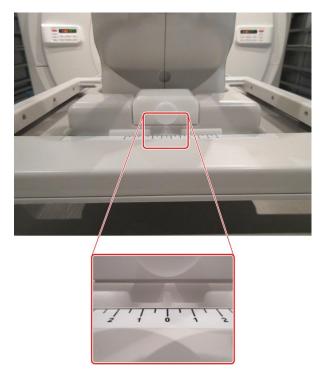


#### Unlock the levers



b. Adjust the position of the coil.

### Slide Coil Left or Right to Desired Position





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) Adjust the tilt of the coil to the desired angle (0° or 15°).
  - a. While pulling the base tilt locking knob, adjust the tilt angle of the coil to 0° or 15°.

### Adjust the Tilt Angle of the Coil





b. Release the tilt locking knob and confirm the coil cannot be moved.

#### Lock the Tilt Angle



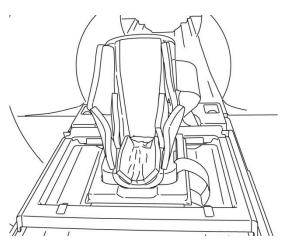
### 5.3 Patient Positioning and Scanning

This RF coil is intended to be used for imaging of the foot and ankle.



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

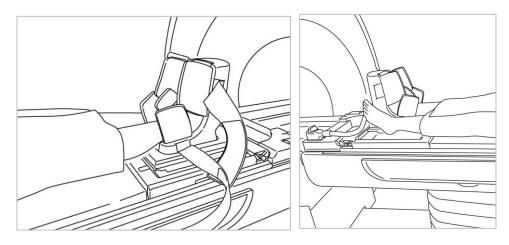
(1) Place the comfort pad supplied with the coil as shown in the figure below.



#### **Place the Comfort Pad**



(2) Position the patient on the couchtop as shown in the figure below.

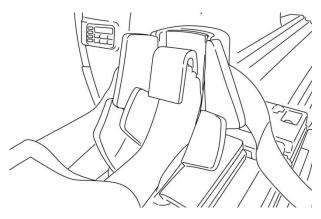


#### **Position the Patient**



Be sure to prevent the foot to be scanned from coming into direct contact with the inner surfaces (including the flexible sections) of the coil. In addition, be sure CAUTION to prevent the foot which is not to be scanned from coming into contact with the exterior of the coil or cable. Doing so would cause a high-frequency induction current loop to be formed, resulting in an increase in the patient's body temperature or a risk of burn injury.

(3) Place the U-shaped pad supplied with the coil over the patient's toe.



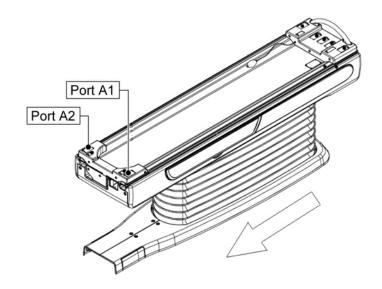
#### Place U-shaped Pad over Patient's Toe



(4) Secure the flexible sections of the coil (hereinafter referred to as "flaps") using the straps so that the flaps cover the foot or ankle.

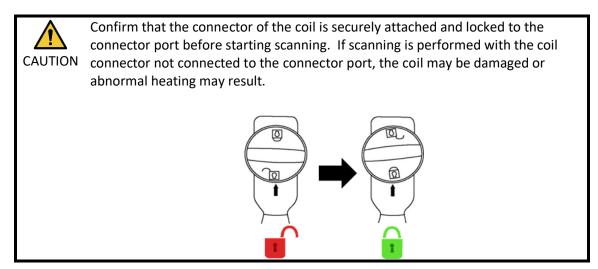
**Secure Coil Flaps Using Straps** 

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



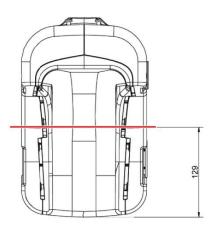
#### Connect the Connector to Port A1 or A2





(6) Align the coil-center mark with the positioning projector beam. Note that it is not necessary to center the coil in the left/right direction because the coil has already been positioned in the left/right direction.

#### 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.



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



- (8) Register the patient.
- (9) Set the scanning conditions.

Set the RF coil type to 16ch Foot/Ankle.

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

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

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

### 7.2 Environment and Compatibility

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



- 1. Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services.
- 2. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 3. Use of accessories and cables other than those specified or provided in this manual could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 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 ± 2kV、±4kV、±6kV 、±8kV
Electrostatic discharge (ESD), air discharge	IEC 61000-4-2 ±2kV, ±4kV, ±8kV, ±15kV



# **CE**<sub>2797</sub> **UK** 0086



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