Operator's Manual

Shape Coil/Shape Coil W

For Canon 1.5T and 3.0T MRI Systems

www.qualityelectrodynamics.com

Model	Canon Model #	QED REF
Shape Coil (1.5T) Shape Coil W (1.5T)	MJAB-207A MJAB-217A	Q7000198
Shape Coil (3.0T) Shape Coil W (3.0T)	MJAB-202A MJAB-212A	Q7000199

Warranty and Liability

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

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

In no event shall QED be liable for the following:

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

Transportation and Storage Conditions

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

	Temperature	-10°C to +50°C
	Relative humidity	20% to 95%
	Atmospheric pressure	700 hPa to 1060 hPa


CAUTION

If the coil packaging is exposed to environmental conditions outside of the transportation and storage conditions, the packaging is damaged, or the packaging is opened prior to delivery, complete Quality Assurance testing prior to actual use. If the coil passes QA testing, it may be used normally.

United States Federal Law

Caution: Federal law restricts this device to sale, distribution, and use by or on the order of a physician. The device is limited by Federal Law to investigational use for indications not in the Indications Statement.

About This Manual

This manual contains detailed information on the safety precautions, use, and care of the RF coil.

> 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 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 Shape Coil is used to examine general human anatomy, such as torso, pelvis, joints, bones and extremities.

1.2 Operating Environment and Compatibility

The 1.5T and 3T 16ch Shape Coils are intended to be used in conjunction with the following Canon MRI Systems in a specialized healthcare facility:

- Vantage Orian 1.5T
- Vantage Fortian 1.5T
- Vantage Galan 3T (STD & XGO)
- Vantage Centurian 3T

1.3 User Profile

Operator – Radiologic technologists, laboratory technologists, physicians.

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

1.4 Patient Information

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

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

Chapter 2 – Shape Coil Components

The Shape Coil 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.

Shape Coil Contents

Item #	Description	Quantity	Canon Part #	QED Part #
1	Shape Coil	1	MJAB-207A (1.5T) MJAB-202A (3.0T)	Q7000198 (1.5T) Q7000199 (3.0T)
2	Hook-and-Loop Fastener Strap	2	BSM41-8764E	3006899

Shape Coil W Contents

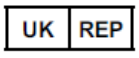
Item #	Description	Quantity	Canon Part #	QED Part #
1	Shape Coil W	2	MJAB-217A (1.5T, W) MJAB-212A (3.0T, W)	Q7000198 (1.5T) Q7000199 (3.0T)
2	Hook-and-Loop Fastener Strap	4	BSM41-8764E	3006899

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
	6193	ISO 7000 IEC 60417	RF Coil, Receive
	5.1.2	ISO 15223-1	Indicates the Authorized Representative in EU
	5.1.2	ISO 15223-1 ISO 20417	Indicates the UK Responsible Person
	5.1.2	ISO 15223-1 SwissMedic	Indicates the authorized representative in Switzerland
	2493	ISO 7000 IEC 60417	Catalog Number
	2498	ISO 7000 IEC 60417	Serial Number
	0632	ISO 7000 IEC 60417	Temperature limit
	2620	ISO 7000 IEC 60417	Humidity limitation
	2621	ISO 7000 IEC 60417	Atmospheric pressure limitation
	5.7.7	ISO 15223-1	Medical Device

Symbol	Number	Standard	Title, Meaning
	N/A	EN50419 EU2012/18/EU	The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information concerning the return and recycling of this product, please consult the supplier from whom you purchased the product.
	5.1.8	ISO 15223-1	Importer
	5.1.9	ISO 15223-1	Distributor
	N/A	N/A	Separate the RF coil from the gantry inner wall by at least 50 mm. Burn injuries may result due to the electric field that is generated in the RF coil when a high-frequency magnetic field is transmitted.

3.2 Indications

The Shape Coil is intended for use with Canon 1.5T or 3.0T MR systems to produce diagnostic images of general human anatomy 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

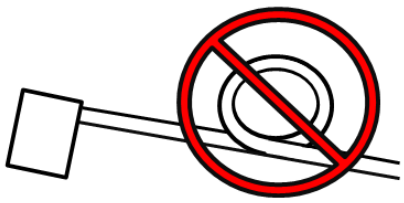
Do not place any disconnected devices (RF coils, cables, etc.) in the gantry during scanning. Remove unneeded RF coils from the couchtop and confirm that RF coils in use are connected to the connector port before scanning.

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.

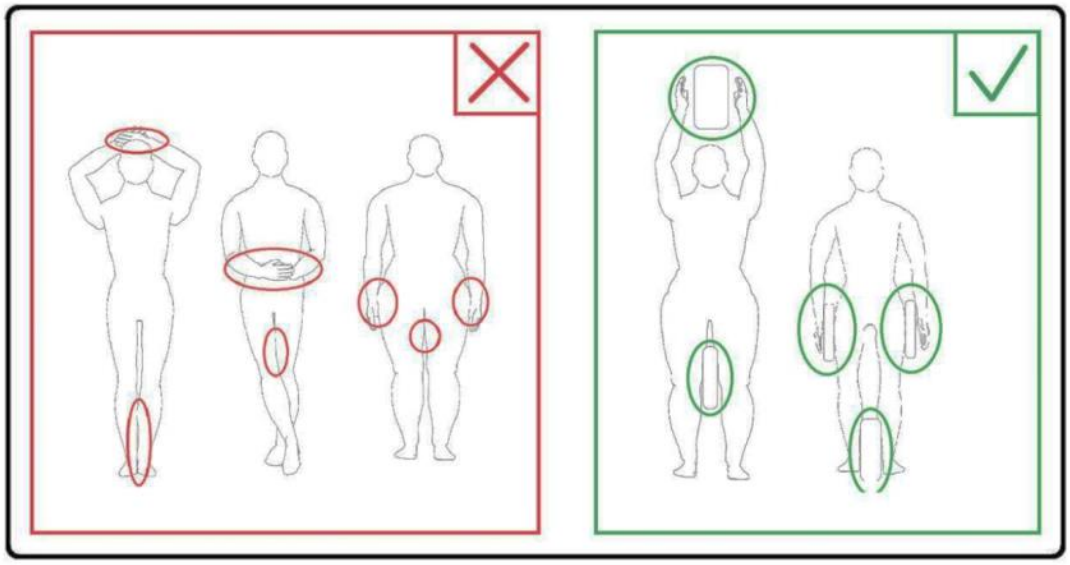


Do not cross or loop coil cables. A high-frequency current may form and burns may occur.

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.



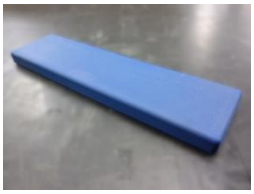
Separate the patient from the gantry inner wall by at least 10 mm using foam pads. Separate the patient from the RF coil cable by at least 10 mm using foam pads. Separate the RF coil cable from the gantry inner wall by at least 10 mm using foam pads. Burn injuries may result due to the electric field that is generated in the RF coil etc. when a high-frequency magnetic field is transmitted.

Separate the RF coil from the gantry inner wall by at least 50 mm using foam pads. Do not allow the RF coil to come into contact with the gantry inner wall while imaging.

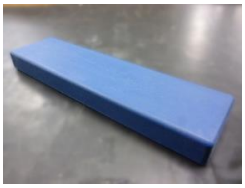
Damage to the RF coil may occur and/or image quality may be degraded if the RF coil is within 50 mm of the gantry inner wall during imaging. Foam pads of 50 mm or greater

thickness when fully compressed that are supplied with the MR system can be used to ensure suitable spacing when placed between the RF coil and the gantry inner wall.

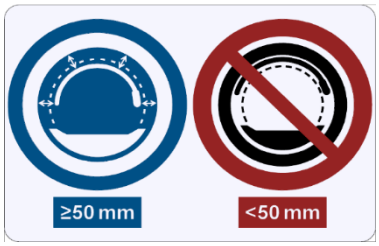
MR System Pads That Can be used to Separate Shape Coil from Gantry Wall



W300, D80, T20mm pad



W300, D80, T30 mm pad



⚠ 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 Cautions – Shape Coil

⚠ Do not use the coil for examining newborns or infants. Heat dispersal will be inhibited if the coil covers most of the body surface. This would likely cause a rise in body temperature, possibly resulting in burn injuries.

Do not route the coil cable along the inner surface of the gantry in the circumferential direction. Doing so will cause induction current to flow in the cable, resulting in heating of the cable.

Do not fold the coil by 180° near the case of the coil (as shown in the figure below). Doing so will apply excessive stress to the folded part of the coil, possibly damaging the coil.

Do not set the coil under the trunk of the patient. Doing so will subject the coil to excessive stress, possibly damaging the internal circuit of the coil.

When storing the coil, be sure to spread the coil and do not place heavy objects on it. Doing so will subject the coil to in excessive stress to the coil, possibly damaging internal circuits.

If metal parts of the coil or printed circuit board are exposed because the outer cover of the coil is torn or other sections are damaged, immediately stop using the coil. There is a risk of electric shock.

When two coils are used in combination, use the supplied hook-and-loop fastener strap. If they are connected without using the supplied hook-and-loop fastener strap, image quality may be degraded.

Be sure to prevent the hook-and-loop fastener strap from coming into direct contact with the patient's skin. Scraping the hook surface of the strap against the patient's skin may result in injury to the patient.

Make sure that there is no possibility of the belt or cable becoming looped or twisted around the patient's neck. Failure to do so may result in injury or choking of the patient.

3.7 Emergency Procedures

In case of an emergency during the scan, stop the scan immediately, remove the patient from the room, and obtain medical assistance, if necessary.

If a serious incident occurs in the EU, it should be reported to the manufacturer and the Competent Authority of the Member State in which the user facility is established.

Chapter 4 – Quality Assurance

4.1 Phantom Image Test – 1.5T MRI System

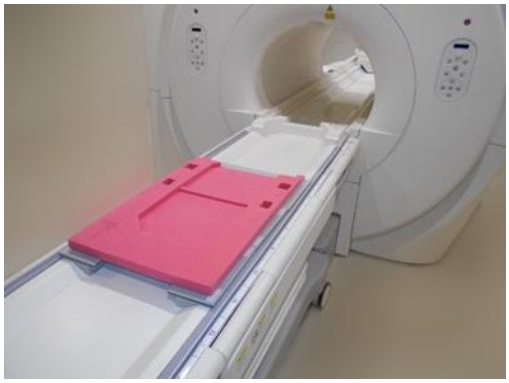
Use the following procedure for 1.5T MRI Systems.

Before starting the Quality Assurance test, measure the temperature of the shield room. The image test can be performed using the automatic SNR measurement tool.

Coil	Phantom	Part number
Shape Coil	10-L copper sulfate phantom × 2	BSM41-3176

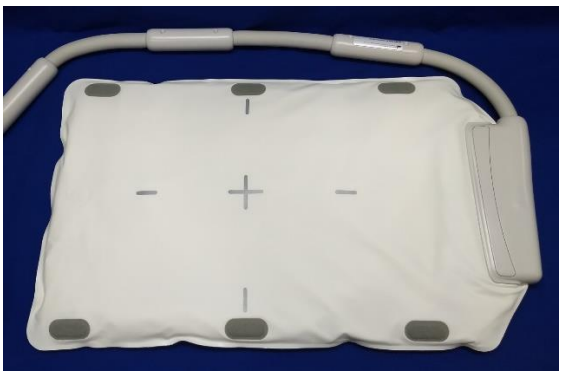
The procedure for performing the image test without using the automatic SNR measurement tool is described below.

(1) In this order, place the mat, phantom holder 2 (supplied with the system), and phantoms on the couchtop as shown in the figure below.



(2) Connect the coil connector to the connector port at the head end of the couchtop.

(3) Position the coil so that the center of the coil is over the border between the two phantoms. The crosshair marked on the coil main unit indicates the center of the coil.



(4) Secure the coil to the phantoms using the belt supplied with the system. Place the belt in a position that is not at the center of the coil so that the center of the coil is visible for alignment with the positioning projector.

(5) Adjust the position of the coil so that the positioning projector beam is aligned with the center of the coil and then send the coil to the center of the gantry. Using the couch operation button, move the couchtop to a position where the couchtop position indicator on the gantry operating panel reads 200.

(6) Register the patient. Enter 170 cm for the height and 60 kg for the weight.

(7) Select "Typical PAS" → "Coil QA" and click [Other]. Select the following sequences in the PAS "Other" field.

Sequence name	Required / Not required
FE_slt	Required
FE_map	Required
SNR	Required

(8) Set the parameters for the sequence as specified below.

FE_slt: Setting change is not required.
(The set value of each parameter is described in the table below.)

Parameter	Set value	Change from default setting required
FOV	35 × 35 cm^2	
Matrix	256 × 256	
No Wrap	(PE) 1.0 / (RO) 1.0	
TR	50 ms	
NAQ	1	
Slice Num.	3	
Thick	8 mm	
Gap	0 mm	
Plane	Other	
Encode direction	Other	
TE	5 ms	
Flip angle	90	

FE_Map: Change the FOV to 35 cm × 35 cm.
Other setting changes are not required.
(The set value of each parameter is described in the table below.)

Parameter	Set value	Change from default setting required
FOV	35 × 35 cm^2	○
Matrix	64 × 64	
No Wrap	(PE) 1.0 / (RO) 2.0	
TR	185 ms	
NAQ	1	
Slice Num.	20	
Thick	6 mm	
Gap	6.5 mm	
Plane	Axial	
Encode direction	RL	
TE	4 ms	
Flip angle	20	

SNR: Change the FOV to 35 cm × 35 cm.
Change No Wrap to RO:2.0 / PE:2.0.
Other setting changes are not required.
(The set value of each parameter is described in the table below.)

Parameter	Set value	Change from default setting required
FOV	35 × 35 cm^2	○
Matrix	256 × 256	
No Wrap	(PE) 2.0 / (RO) 2.0	○
TR	200 ms	
NAQ	1	
Slice Num.	1	
Thick	5 mm	

Gap	1 mm	
Plane	Axial	
Encode direction	RL	
TE	15 ms	
Flip/Flop	90/180	

When the couchtop is moved with phantoms placed on the couchtop, wait approximately 5 minutes to allow the liquid in the phantoms to stabilize before starting the image test. If scanning is started before the liquid in the phantoms stabilizes, the resulting sensitivity nonuniformity in the image causes incorrect measurement of the SNR.

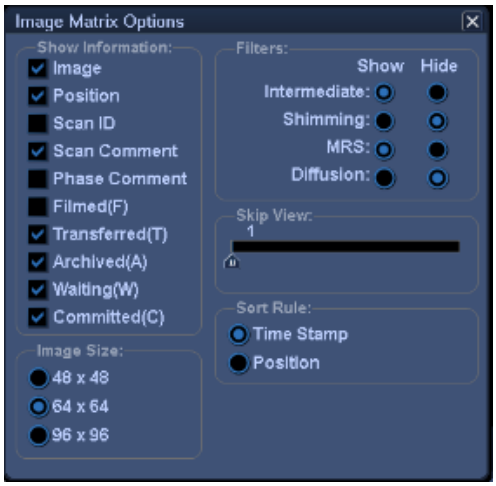
(9) Start scanning using any of the above sequences. Now, record the RF Level and TGC value (TGC RFOut ratio:x.xxxxxx) displayed in the Acquisition window. Record the TCG value that is displayed after the RF Level. When recording the TGC value and RF level, round three decimal places to two decimal places. In addition, record the receiver gain that is displayed in the Acquisition window when the SNR sequence is executed.

(10) Display the intermediate images acquired using the SNR sequence.

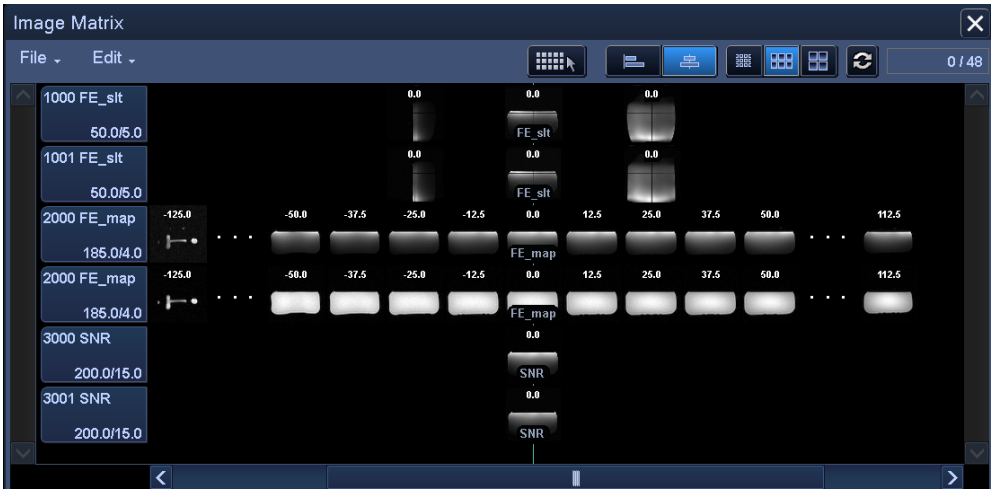
NOTE: How to display the intermediate images

1. In the Image Matrix window, select "File" and then "Options".

2. Select the show radio button for "Intermediate" under "Filters" in the Image Matrix Options window.



3. The images displayed with an even-numbered scan ID in the Image Matrix window are intermediate images.



(11) Set the signal ROI and noise ROI as shown in the figure below. Now, record the mean signal value (mean value) of the signal ROI and the noise variance (Noise SD value) of the noise ROI in section 1 of the installation quality check sheet.

Signal value (mean value)

ROI size : 25 cm × 2 cm

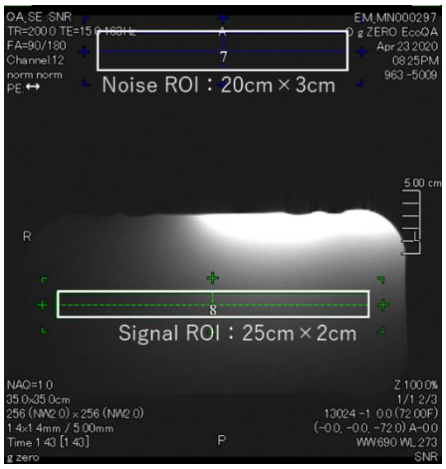
Position AP direction : Center of the phantom

RL direction : Center of the phantom

Noise value (SD value)

ROI size : 20 cm × 3 cm

Position AP direction : Position free from the influence of the flow in the encode direction in the signal area



(12) Calculate the SNR using the formula below.

SNR calculation

$$SNR = \frac{\text{Signal value (mean)}}{\text{Noise value (SD)}} \times \text{correction value k}$$

Phantom temperature	Correction value k
18°C	0.90
19°C	0.92
20°C	0.94
21°C	0.97
22°C	1.00
23°C	1.03
24°C	1.06

Measure the temperature of the phantom using the thermolabel attached to the phantom. If the phantom temperature differs from the shield room temperature, the calculation result using the above formula may not be correct. To avoid this, place the phantom in the shield room 1 hour before starting image testing so that the phantom temperature matches the shield room temperature.

(13) Obtain the SNR for the acquired images and confirm the measurement SNR is pass or fail the specification for section 1.

Specification for section 1

SNR ≥ 70

(14) Perform SNR measurement for section 2 and subsequent sections. The couchtop position for measurement and the required SNR for each section are specified in the table below. Repeat steps (4) to (12) for each section.

	Couchtop position indicator on the operating panel	SNR specification
Section 2:	55	≥70
Section 3:	-55	≥70
Section 4:	-200	≥70

4.2 Phantom Image Test – 3.0T MRI System

Use the following procedure for 3.0T MRI Systems.

Before starting the image test, measure the temperature of the shield room. The image test can be performed using the automatic SNR measurement tool.

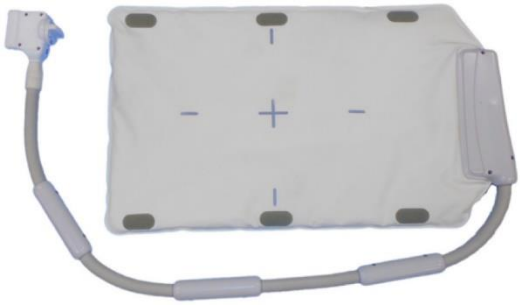
Coil	Phantom	Part number
Shape Coil	10-L oil phantom × 2	BSM41-4885

The procedure for performing the image test without using the automatic SNR measurement tool is described below.

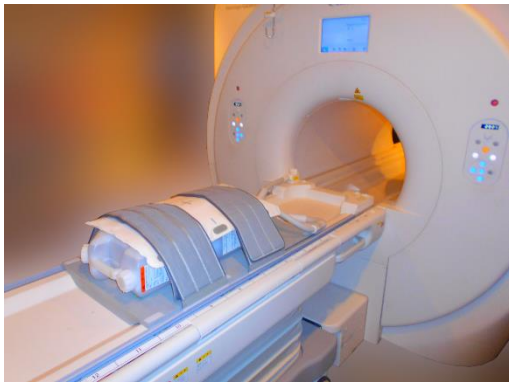
(1) Place the system mat and phantoms on the couchtop as shown in the figure below. At this time, place the phantoms so that their bases are in contact with each other.


(2) Connect the coil connector to the connector port at the head end of the couchtop.

(3) Position the coil so that the center of the coil is over the border between the two phantoms. The crosshair marked on the coil main unit indicates the center of the coil.




(4) Secure the coil to the phantoms using the belt supplied with the system. Place the belt in a position that is not at the center of the coil so that the center of the coil is visible for alignment with the positioning projector.




(5) Adjust the position of the coil so that the positioning projector beam is aligned with the center of the coil and then send the coil to the center of the gantry. Using the couch

operation button, move the couchtop to a position where the couchtop position indicator on the gantry operating panel reads 200.

(6) Register the patient. Enter 170 cm for the height and 60 kg for the weight.

(7) Select "Typical PAS" → "Coil QA" and click [Other]. Select the following sequences in the PAS "Other" field.

Sequence name	Required / Not required
FE_slt	Required
FFE_map	Required
SNR	Required

(8) Set the parameters for the sequence as specified below.

FE_slt: Setting change is not required.
(The set value of each parameter is described in the table below.)

Parameter	Set value	Change from default setting required
FOV	35 cm × 35 cm	
Matrix	256 × 256	
No Wrap	(PE) 1.0 / (RO) 1.0	
TR	50 ms	
NAQ	1	
Slice Num.	3	
Thick	8 mm	
Gap	0 mm	
Plane	Other	
Encode direction	Other	
TE	5 ms	
Flip angle	90	

FFE_Map: Change the FOV to 35 cm × 35 cm.
Other setting changes are not required.
(The set value of each parameter is described in the table below.)

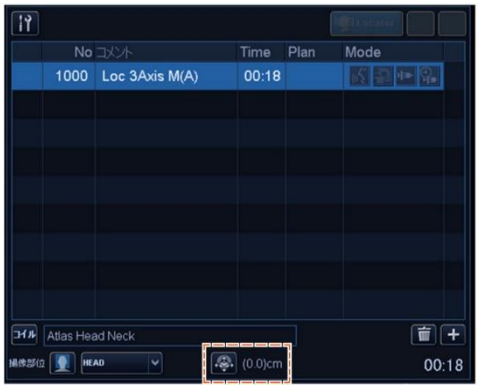
Parameter	Set value	Change from default setting required
FOV	35 cm × 35 cm	○
Matrix	64 × 64	
No Wrap	(PE) 1.0 / (RO) 2.0	
TR	6 ms	
NAQ	1	
Slice Num.	20	
Thick	8 mm	
Gap	0 mm	
Plane	Axial	
Encode direction	RL	
TE	2.3 ms	
Flip angle	10	

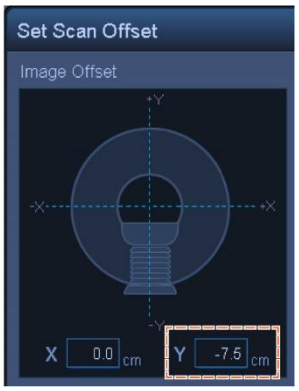
SNR: Change the FOV to 35 cm × 35 cm.
Change No Wrap to RO: 2.0 and PE: 1.0.
Change Slice Num. to 3.
Change Gap to 2 mm.
Change the Scan offset Y to -7.5 cm (Galan) or -3.5 cm (Centurian).

Other setting changes are not required.
(The set value of each parameter is described in the table below.)

Parameter	Set value	Change from default setting required
FOV	35 cm × 35 cm	○
Matrix	256 × 256	
No Wrap	(PE) 1.0 / (RO) 2.0	○
TR	200 ms	
NAQ	1	
Slice Num.	3	○
Thick	5 mm	
Gap	2 mm	○
Plane	Axial	
Encode direction	RL	
TE	15 ms	
Flip/Flop	90/180	
Scan offset Y (Refer to NOTE 2.)	Galan 3T: -7.5 cm Centurian 3T: -3.5 cm	○

1. When the couchtop is moved with phantoms placed on the couchtop, wait approximately one minute to allow the liquid in the phantoms to stabilize before starting the image test. If scanning is started before the liquid in the phantoms stabilizes, the resulting sensitivity nonuniformity in the image causes incorrect measurement of the SNR.
2. Scan offset can be set from sequence queue window.



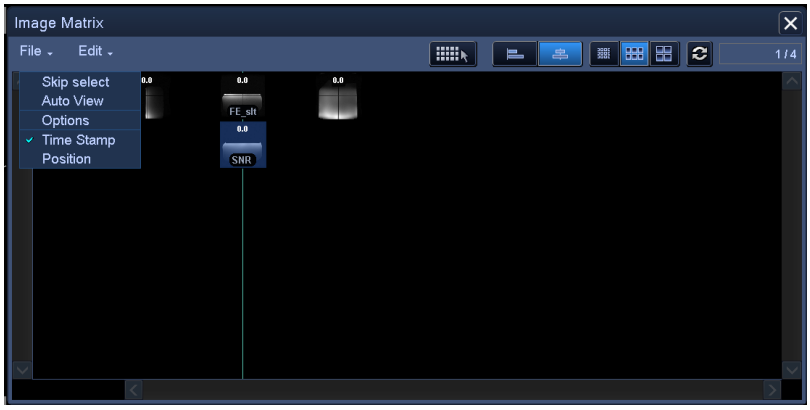


(9) Start scanning using any of the above sequences. Now, record the RF Level and TGC value (TGC RFOut ratio:x.xxxxxx) displayed in the Acquisition window. Record the TCG value that is displayed after the RF Level. When recording the TGC value and RF level, round three decimal places to two decimal places. In addition, record the receiver gain that is displayed in the Acquisition window when the SNR sequence is executed.

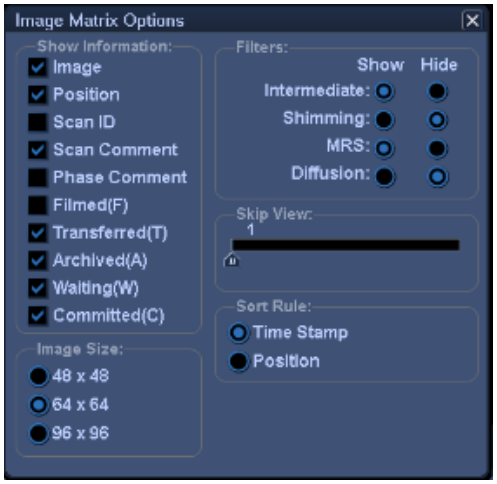
(10) Display the intermediate images acquired using the SNR sequence.

How to display the intermediate images

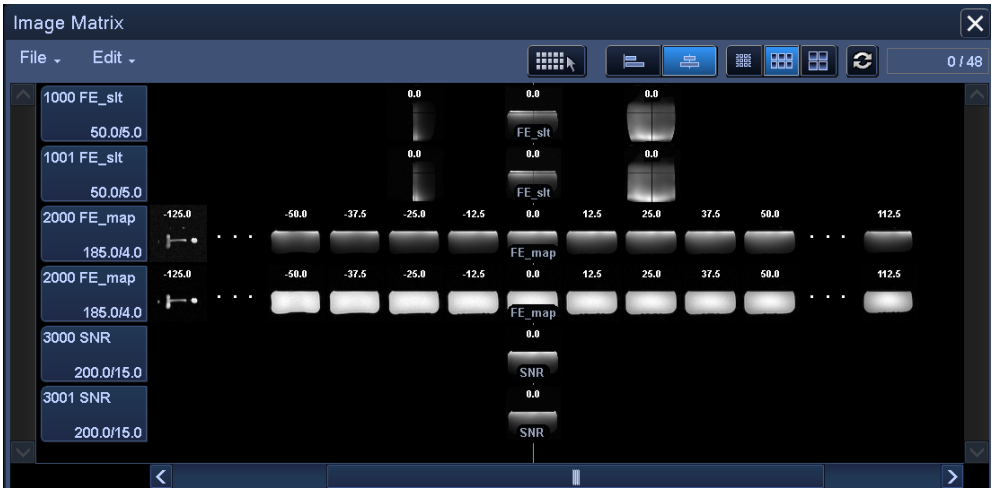
1. In the Image Matrix window, select "File" and then "Options".



2. Select the show radio button for "Intermediate" under "Filters" in the Image Matrix Options window.



3. The images displayed with an even-numbered scan ID in the Image Matrix window are intermediate images.



(11) Display the center slice of the acquired image and set the signal ROI and noise ROIs as shown in the figure below. Now, record the mean signal value (mean value) of the signal ROI and the noise variance (Noise SD value) of the noise ROIs.

Signal value (mean value)

ROI size : 25 cm × 2 cm

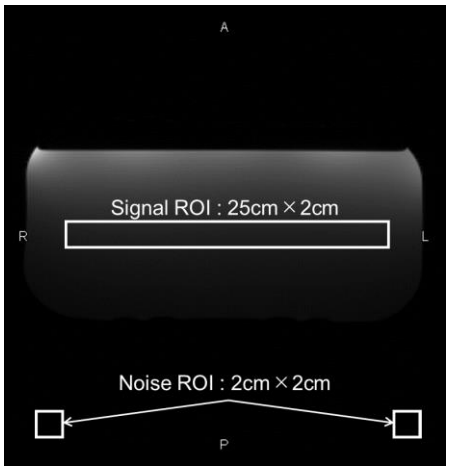
Position AP direction : Center of the phantom

RL direction : Center of the phantom

Noise value (SD value)

ROI size : 2 cm × 2 cm

Position AP direction : 2 positions free from the influence of the flow in the encode direction in the signal area



(12) Calculate the SNR using the formula below.

SNR calculation

$$SNR = \frac{\text{Signal value (mean)}}{\text{Noise value (SD)}}$$

* Noise value (SD) is average of two Noise ROIs SD values.

(13) Obtain the SNR for the acquired images and confirm the measurement SNR is pass or fail the specification for section 1.

Specification for section 1

SNR ≥ 160

(14) Perform SNR measurement for section 2 and subsequent sections. The couchtop position for measurement and the required SNR for each section are specified in the table below. Repeat steps (4) to (12) for each section.

	Couchtop position indicator on the operating panel	SNR specification
Section 2:	55	≥160
Section 3:	-55	≥160
Section 4:	-200	≥160

Chapter 5 – Coil Setup and Use

5.1 Coil Setup

The Shape Coil requires no preparation prior to patient positioning unless two coils are being used in combination. This section describes how to connect two Shape Coils and how to secure the Shape Coil to the patient if the coil could slide off the patient and cause coil misalignment.

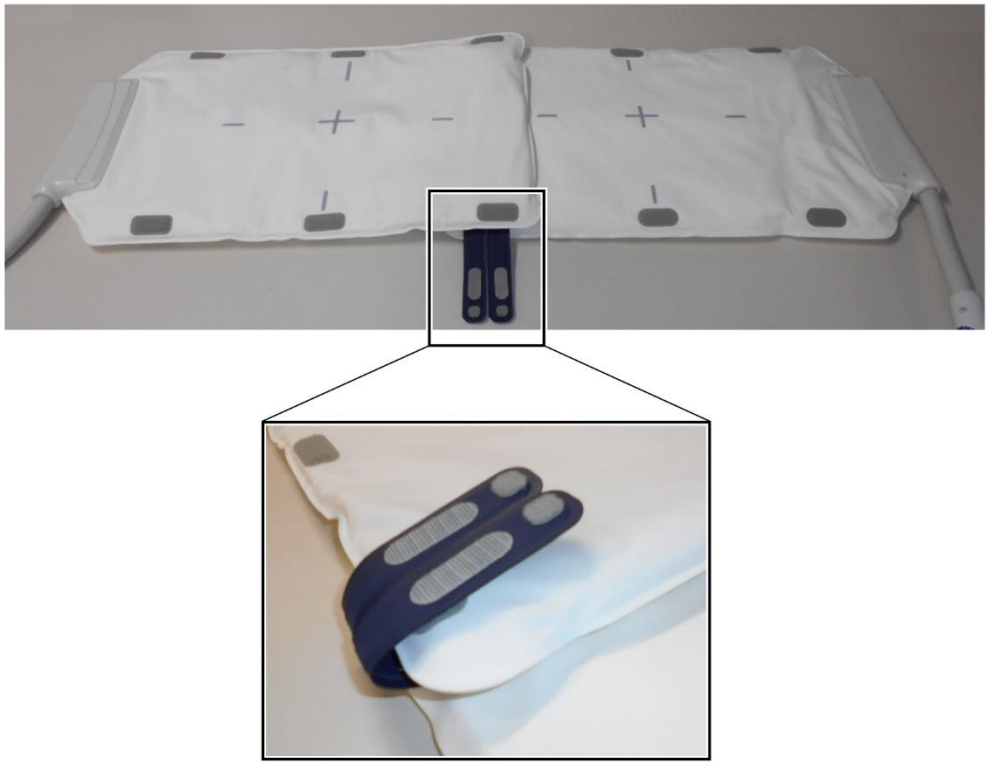
i	Handle this coil carefully. If the coil is dropped, it may be damaged.

5.1.1 Connecting Two Shape Coils

To use two Shape Coils in combination, first attach the supplied hook-and-loop fastener strap to the hook-and-loop fastener on the side of the coil. Then attach the hook-and-loop fastener of the other coil to the hook-and-loop fastener strap. Below figures are representative.

Connecting Two Shape Coils - Horizontal

Connecting Two Shape Coils - Vertical



When imaging is performed using two coils, attach the coils so that their cables do not come into contact with each other.

Correct Attachment **Incorrect Attachment**

5.1.2 Securing the Coil to the Patient (Optional)

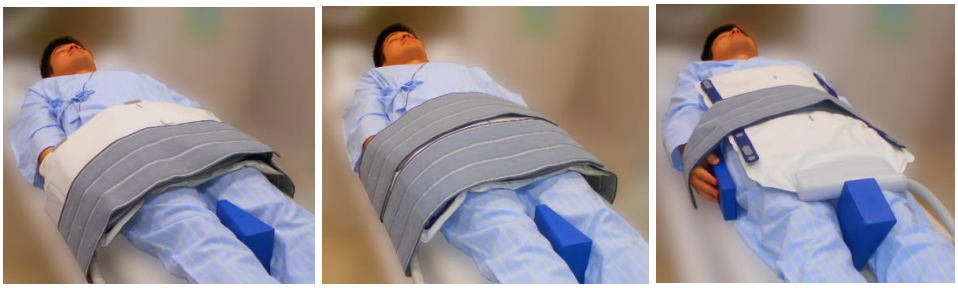
When coil misalignment may be caused by the coil's sliding to one side, the hook-and-loop fastener strap supplied with the coil may be used to secure the coil to the patient.

(1) Attach the hook-and-loop fastener strap to the side of the coil that will not be in contact with the patient. Two hook-and-loop straps may be used for extra security.

Examples of Hook-and-Loop Strap Placement Options

(2) Wrap the belt supplied with the system around the patient and coil. Attach the belt to the hook-and-loop strap.

Examples of System Belt Placement Options



i	Ensure that the positioning and retention force do not cause discomfort.

5.2 Patient Positioning and Scanning

This RF coil is intended to be used for imaging of general human anatomy. Instructions for specific anatomies are provided in this section.

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

5.2.1 Patient Positioning for Trunk Imaging

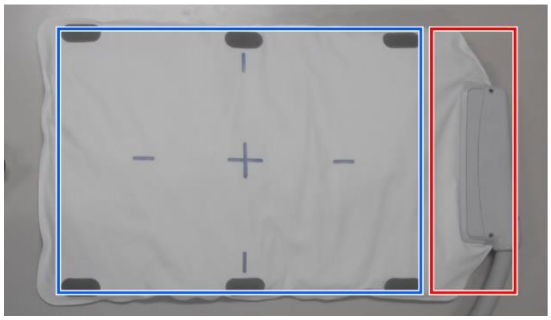
(1) Lower the patient couch and place the spine coil or mats supplied with the MRI system on the couchtop.

(2) Position the patient on the couchtop.

(3) Place the coil so that the scan region of the patient is within the imaging area of the coil. The coil can be placed in the gantry in any orientation. At this time, be sure not to drop the coil. Doing so may injure the patient.

When imaging the trunk, it is possible to use two coils in combination.

Imaging Area of Shape Coil

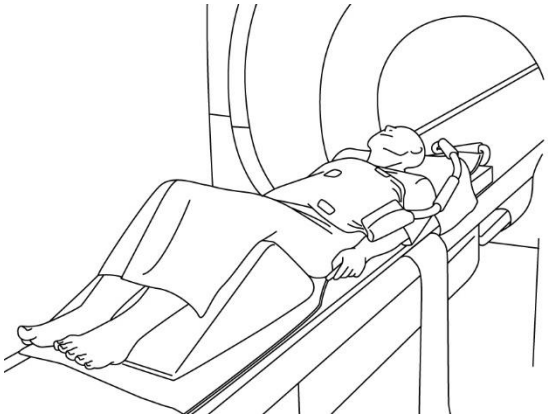


Center of the coil

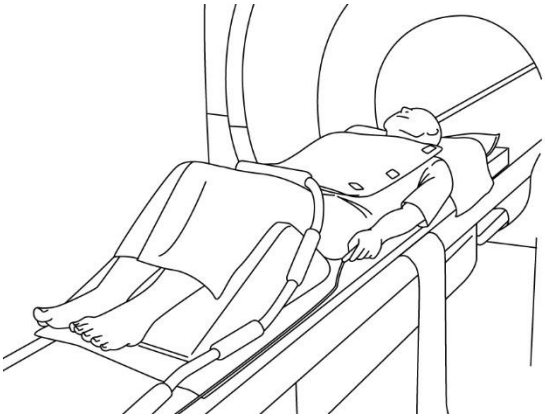
Imaging area

Outside the imaging area

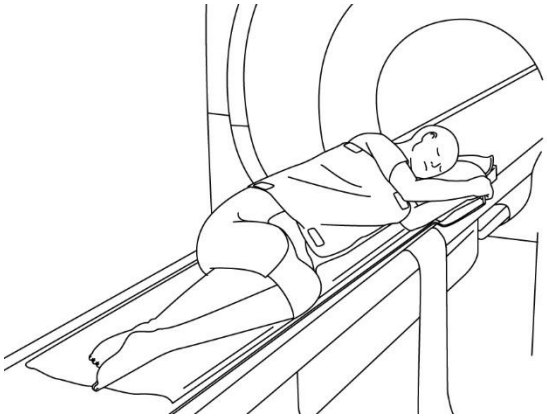
Positioning Patient and Coil for Trunk Imaging with Single Coil



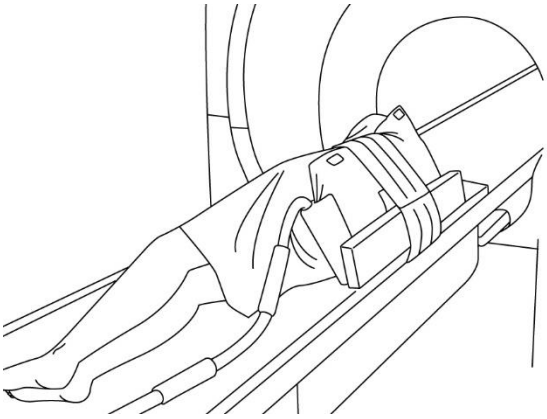
Trunk imaging (supine position, coil placed across the patient): Used for imaging of the trunk, such as for visualization of the heart or liver



Trunk imaging (supine position, coil placed in line with the patient): Used for imaging over an extensive range of the trunk, such as for visualization of blood vessels

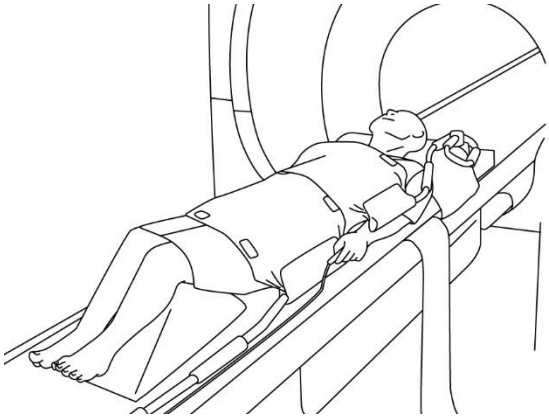


Trunk imaging (lateral position, coil placed across the patient): Used for imaging of the trunk of patients who are difficult to set in the supine position, such as pregnant patients

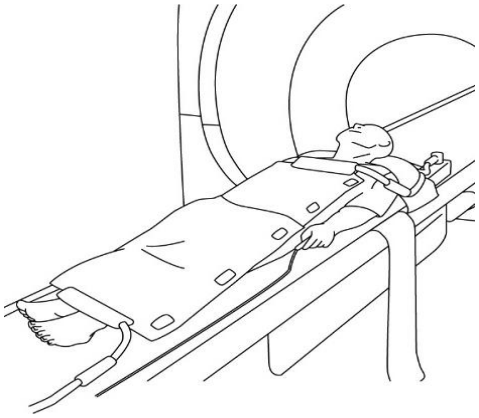


Trunk imaging (lateral position, coil placed in line with the patient): Used for imaging over an extensive range of the trunk, such as for visualization of the spine or blood vessels of patients who are difficult to set in the supine position

Positioning Patient and Coil for Trunk Imaging with Two Coils

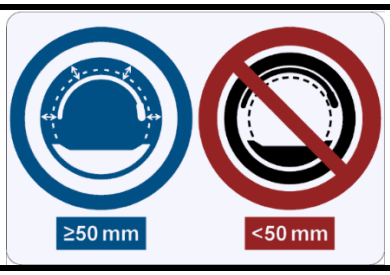


Trunk imaging (supine position, coils placed across the patient): Used for imaging of the trunk



Trunk imaging (supine position, coils placed in line with the patient): Used for imaging over an extensive range of the patient body, such as whole-body imaging.

CAUTION



Separate the RF coil from the gantry inner wall by at least 50 mm using foam pads before and during imaging.

CAUTION

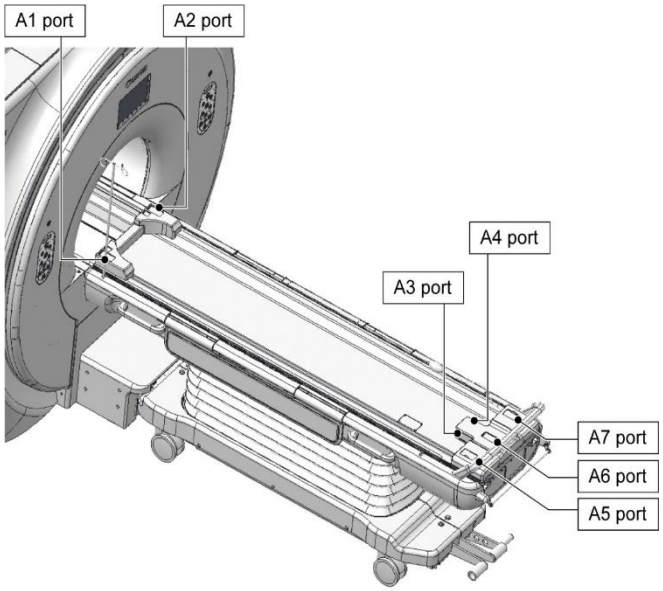
When imaging is performed using two coils, set up the coils so that their cables do not come into contact with each other per Section 5.1.1.

Do not set the coil under the trunk of the patient. Doing so will subject the coil to excessive stress, possibly damaging the internal circuit of the coil.

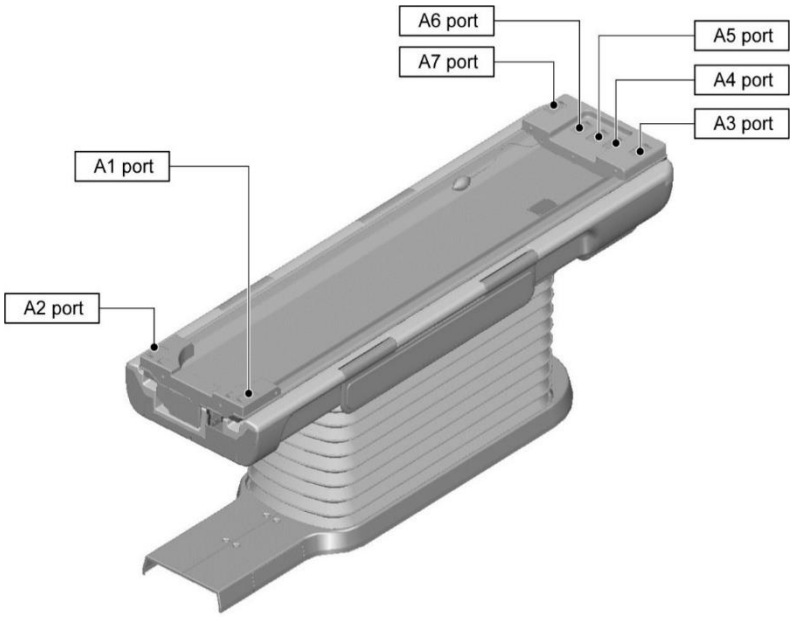
(4) If required, use the belt supplied with the system to secure the coil to the patient; see Section 5.1.2.

(5) Connect the coil connector to the connector port of the couch using the information for the systems shown below. Lock the connector.

Vantage Orian 1.5T: All the coil connector ports can be used for this coil.
(A1, A2, A3, A4, A5, A6, A7)

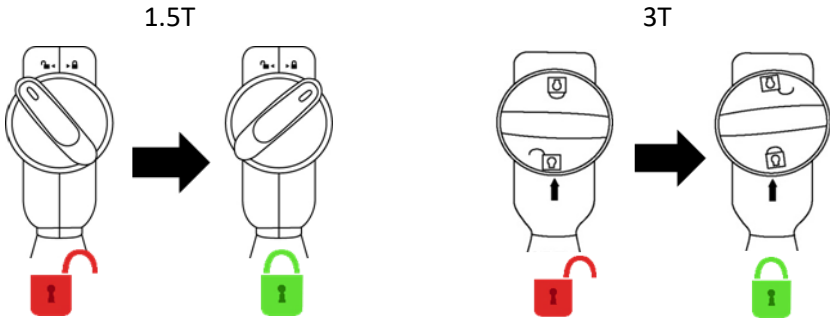


Vantage Galan 3T, Vantage Centurian 3T: All the coil connector ports can be used. (A1, A2, A3, A4, A5, A6, A7)



CAUTION

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



(6) Move the couch to position the patient and the coil so that the region to be scanned is set at the center of the magnetic field.

(7) Operate the MRI system to send the patient and coil into the gantry.

(8) Enter the scan conditions, referring to the operation manual for the MRI system. The coil name is "Shape Coil" and its abbreviation (displayed in the coil section selection window) is "SHP".

CAUTION	Set the SAR region according to the target region for scanning. If scanning is performed with incorrect SAR region setting, excessive RF energy could be output and burn injury may result.

1. When scanning with this coil, use the PAS set apart for "Shape Coil". If using other sequences, image quality is not guaranteed. If other sequences must be scanned, use this coil with the intensity correction "RX/TX Correction plus".
2. If the total number of activated coil channels exceeds the number of channels of the RF reception system, imaging cannot be performed. Set the total number of channels to be less than the number of channels of the RF reception system or switch to another coil. Each Shape Coil requires a minimum 8 channels of RF reception system.

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

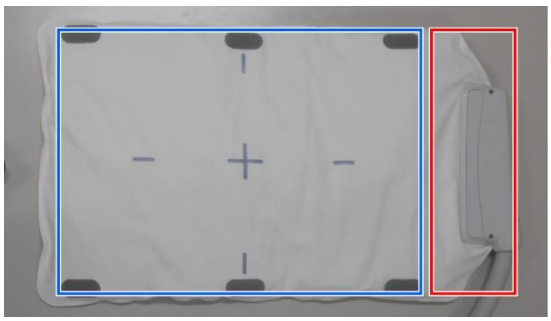
5.2.2 Patient Positioning for Arm Imaging

(1) Lower the patient couch and place the spine coil or mats supplied with the MRI system on the couchtop.

(2) Position the patient on the couchtop.

(3) Place the coil on the arm so that the scan region of the patient is within the imaging area of the coil. At this time, be sure not to drop the coil.

Imaging Area of Shape Coil

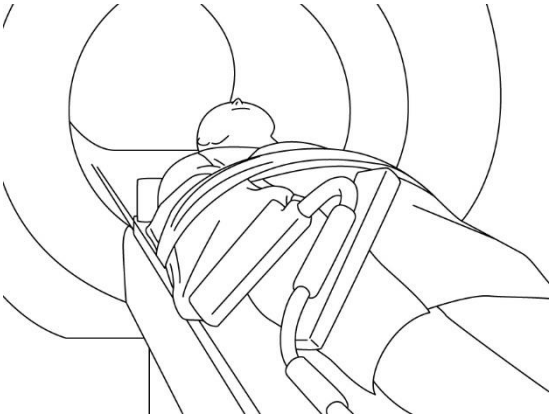


Center of the coil

Imaging area

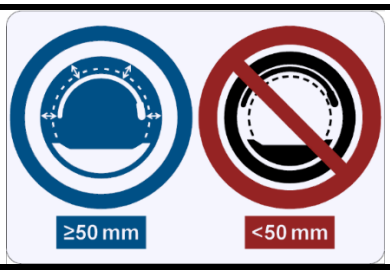
Outside the imaging area

Positioning Patient and Coil for Arm Imaging



Arm imaging (supine position, coil set in line with the arm): Used for imaging of arm joints and long bones

CAUTION



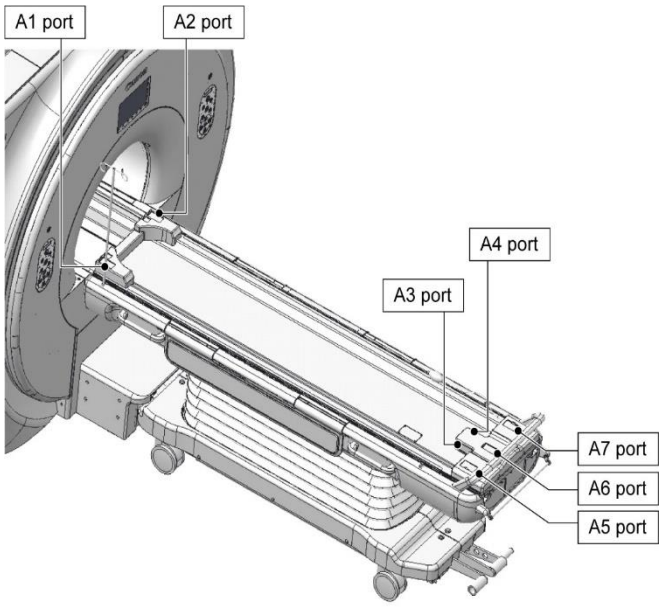
Separate the RF coil from the gantry inner wall by at least 50 mm using foam pads before and during imaging.

1. Do not set the coil under the trunk of the patient. Doing so will subject the coil to excessive stress, possibly damaging the internal circuit of the coil.
2. Ensure the coil does not overlap itself when scanning small anatomy, such as the arm or leg. Image quality is not guaranteed when the coil overlaps itself.

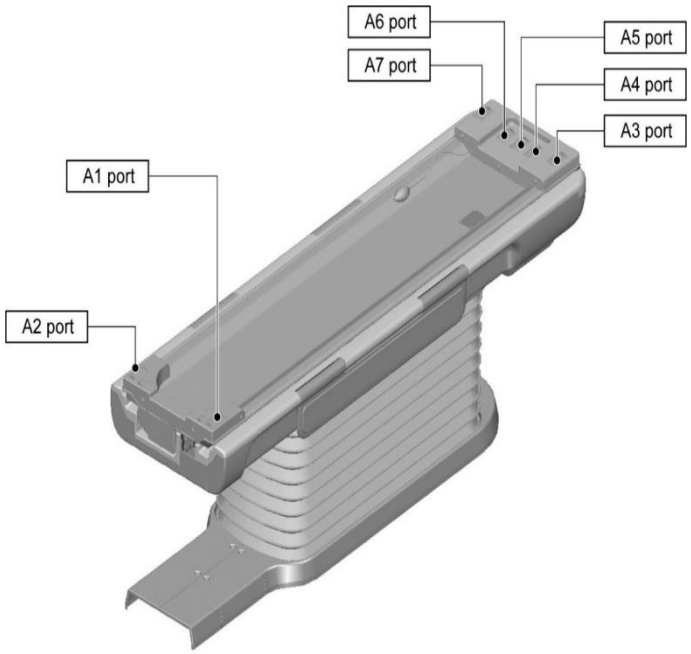
(4) If required, use the belt supplied with the system to secure the coil to the patient; see Section 5.1.2.

(5) Connect the coil connector to the connector port of the couch using the information for the systems shown below. Lock the connector.

Vantage Orian 1.5T: All the coil connector ports can be used for this coil.
(A1, A2, A3, A4, A5, A6, A7)

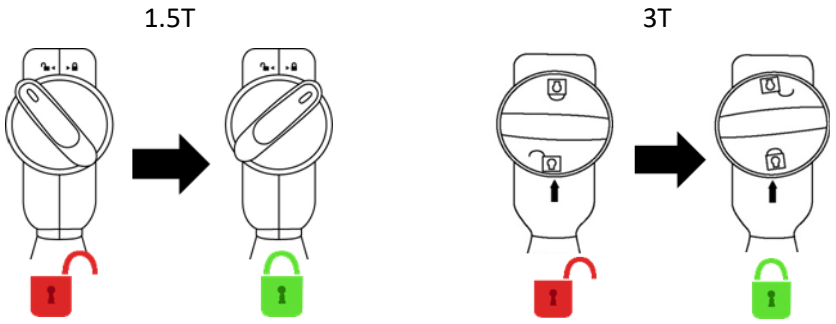


Vantage Galan 3T, Vantage Centurian 3T: All the coil connector ports can be used.
(A1, A2, A3, A4, A5, A6, A7)



CAUTION

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



(6) Move the couch to position the patient and the coil so that the region to be scanned is set at the center of the magnetic field.

(7) Operate the MRI system to send the patient and coil into the gantry.

(8) Enter the scan conditions, referring to the operation manual for the MRI system. The coil name is "Shape Coil" and its abbreviation (displayed in the coil section selection window) is "SHP".

CAUTION

Set the SAR region according to the target region for scanning. If scanning is performed with incorrect SAR region setting, excessive RF energy could be output and burn injury may result.

1. When scanning with this coil, use the PAS set apart for "Shape Coil". If using other sequences, image quality is not guaranteed. If other sequences must be scanned, use this coil with the intensity correction "RX/TX Correction plus".
2. If the total number of activated coil channels exceeds the number of channels of the RF reception system, imaging cannot be performed. Set the total number of channels to be less than the number of channels of the RF reception system or switch to another coil. Each Shape Coil requires a minimum 8 channels of RF reception system.

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

5.2.3 Patient Positioning for Leg Imaging

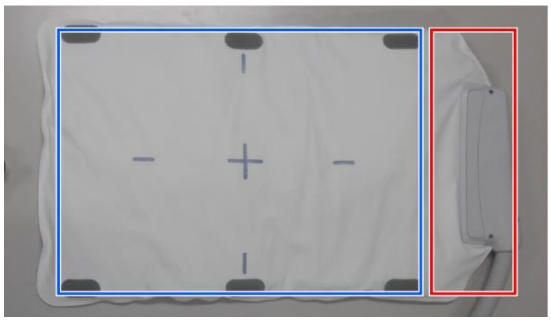
(1) Lower the patient couch and place the spine coil or mats supplied with the MRI system on the couchtop.

(2) Position the patient on the couchtop.

(3) Wrap the coil around the leg or place the coil on the leg so that the scan region of the patient is within the imaging area of the coil. When setting the coil, be sure not to drop it. Doing so may injure the patient.

When imaging the legs, it is possible to use two coils in combination.

Imaging Area of Shape Coil

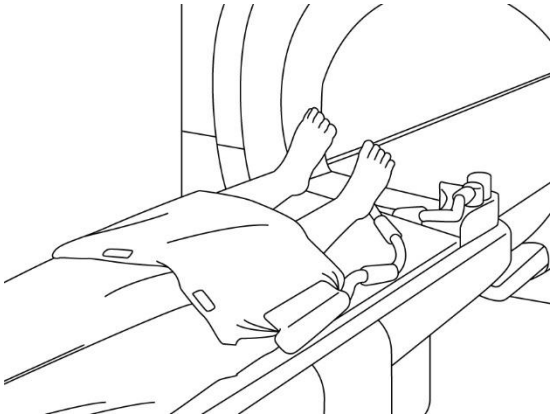


Center of the coil

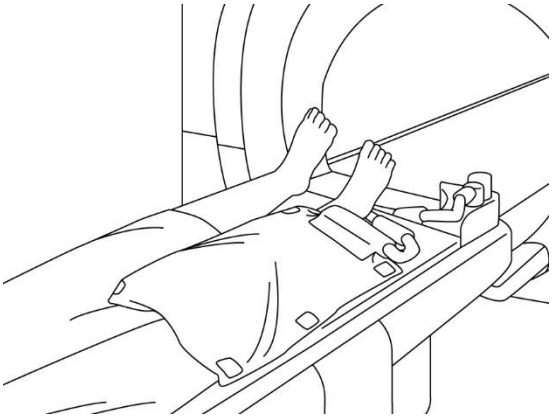
Imaging area

Outside the imaging area

Positioning Patient and Coil for Leg Imaging

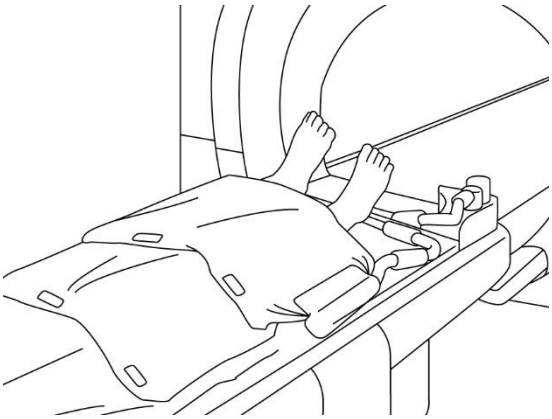


Leg imaging (supine position, coil placed across the legs): Used for imaging of leg joints



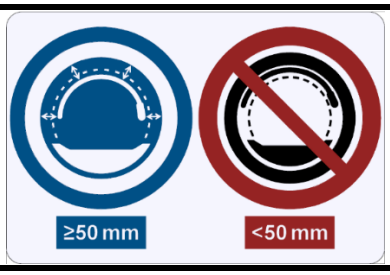
Leg imaging (supine position, coil placed in line with the patient): Used for imaging over an extensive range of the leg, such as for visualization of blood vessels.

Leg imaging (supine position, coil wrapped around the leg): Used for imaging of leg joints.



Leg imaging (supine position, coils placed across the legs): Used for imaging over an extensive range, such as for visualization of blood vessels in the lower extremities.

CAUTION



Separate the RF coil from the gantry inner wall by at least 50 mm using foam pads before and during imaging.

CAUTION

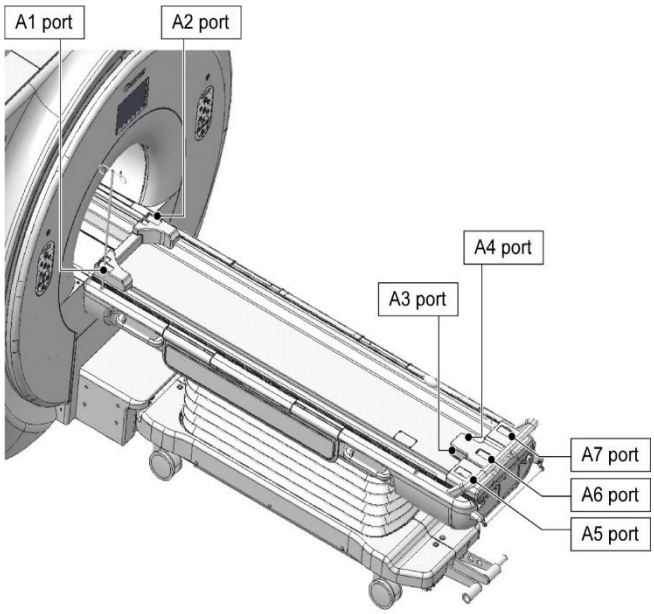
When imaging is performed using two coils, set up the coils so that their cables do not come into contact with each other per Section 5.1.1.

1. Do not set the coil under the trunk of the patient. Doing so will subject the coil to excessive stress, possibly damaging the internal circuit of the coil.
2. Ensure the coil does not overlap itself when scanning small anatomy, such as the arm or leg. Image quality is not guaranteed when the coil overlaps itself.

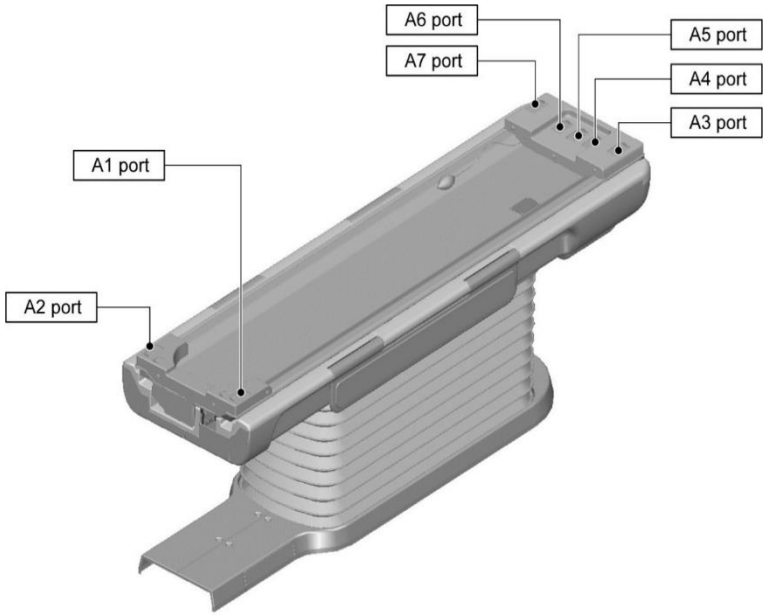
(4) If required, use the belt supplied with the system to secure the coil to the patient; see Section 5.1.2.

(5) Connect the coil connector to the connector port of the couch using the information for the systems shown below. Lock the connector.

Vantage Orian 1.5T: All the coil connector ports can be used for this coil.
(A1, A2, A3, A4, A5, A6, A7)

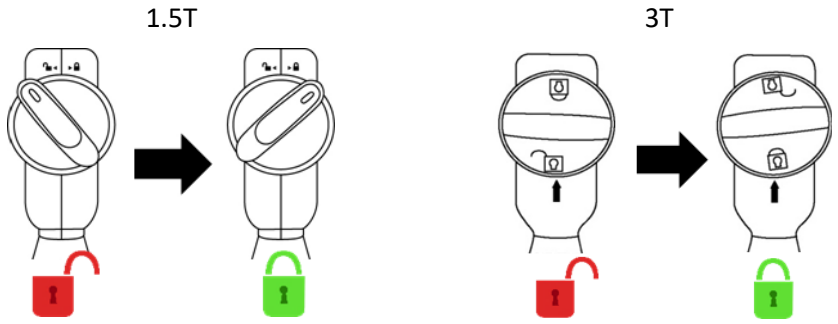


Vantage Galan 3T, Vantage Centurian 3T: All the coil connector ports can be used.
(A1, A2, A3, A4, A5, A6, A7)



CAUTION

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



(6) Move the couch to position the patient and the coil so that the region to be scanned is set at the center of the magnetic field.

(7) Operate the MRI system to send the patient and coil into the gantry.

(8) Enter the scan conditions, referring to the operation manual for the MRI system. The coil name is "Shape Coil" and its abbreviation (displayed in the coil section selection window) is "SHP".

CAUTION

Set the SAR region according to the target region for scanning. If scanning is performed with incorrect SAR region setting, excessive RF energy could be output and burn injury may result.

1. When scanning with this coil, use the PAS set apart for "Shape Coil". If using other sequences, image quality is not guaranteed. If other sequences must be scanned, use this coil with the intensity correction "RX/TX Correction plus".
2. If the total number of activated coil channels exceeds the number of channels of the RF reception system, imaging cannot be performed. Set the total number of channels to be less than the number of channels of the RF reception system or switch to another coil. Each Shape Coil requires a minimum 8 channels of RF reception system.

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

Chapter 6 – Cleaning, Maintenance, Service, and Disposal

6.1 Cleaning the RF Coil

CAUTION

1. Do not pour cleaning solution directly onto the coil or accessories.
2. Do not sterilize the coil or accessories.
3. Do not apply cleaning solution to electrical contacts.
4. Do not use benzine to clean the product. This may result in discoloration, distortion, deterioration, or damage.

The RF Coil and accessories should be cleaned after each use using the following procedure:

1. Disconnect RF coil from the MRI scanner before coil cleaning.
2. Wipe off any dirt on the coil surface using a dry cloth. If dirt is difficult to remove, clean it according to the procedures described below.
3. Wipe with a cloth or gauze that has been dampened with 70-99% isopropanol, 70% ethanol, mild detergent diluted with water, or water.
4. Allow the coil to dry completely, preferably for a full day.
5. Dispose of any materials used to clean the coil and the pads according to all federal, state, and local regulations.
6. Commonly available cleaning agents can also be used on the surface of the coils without compromising the safety of the device. Refer to the cleaning agent manufacturer's instructions for use and clean the coil according to the procedures specified by the healthcare facility.

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

6.2 Maintenance

No regularly scheduled maintenance is required for the RF coil.

6.3 Service

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

6.4 Disposal

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

6.5 Expected Service Life

This RF coil is designed for an expected service life of at least 6 years under normal usage conditions. The coil is safe to use beyond the expected service life as long as information in the Safety section is followed and Quality Assurance tests pass.

Chapter 7 – Guidance and Manufacturer's Declaration – Electromagnetic Compatibility (EMC)

This coil requires special attention regarding EMC and must be installed and used in accordance with the EMC guidelines provided in this manual. Only use the RF coil in the environment specified below; electromagnetic compatibility is not ensured in environments other than those specified.

7.1 Classification

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

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

7.2 Environment and Compatibility

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

CAUTION

1. Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services.
2. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
3. Use of accessories and cables other than those specified or provided in this manual could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
4. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RF coil, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

7.3 Electromagnetic Emission

The RF coil can only function when connected to the MRI system, which is contained within an RF-shielded environment. Therefore, IEC 60601-1-2 clause 7 regarding electromagnetic emission does not apply.

7.4 Electromagnetic Immunity

This RF coil complies with IEC 60601-1-2 clause 8 when used in the specified electromagnetic environment.

Immunity Test	Test and Compliance Level
Electrostatic discharge (ESD), contact discharge	IEC 61000-4-2 ±2kV, ±4kV, ±6kV, ±8 kV
Electrostatic discharge (ESD), air discharge	IEC 61000-4-2 ±2kV, ±4kV, ±8kV, ±15kV

CE 2797

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Date of First Issue: 2023-02 / Revision Date: 2023-02