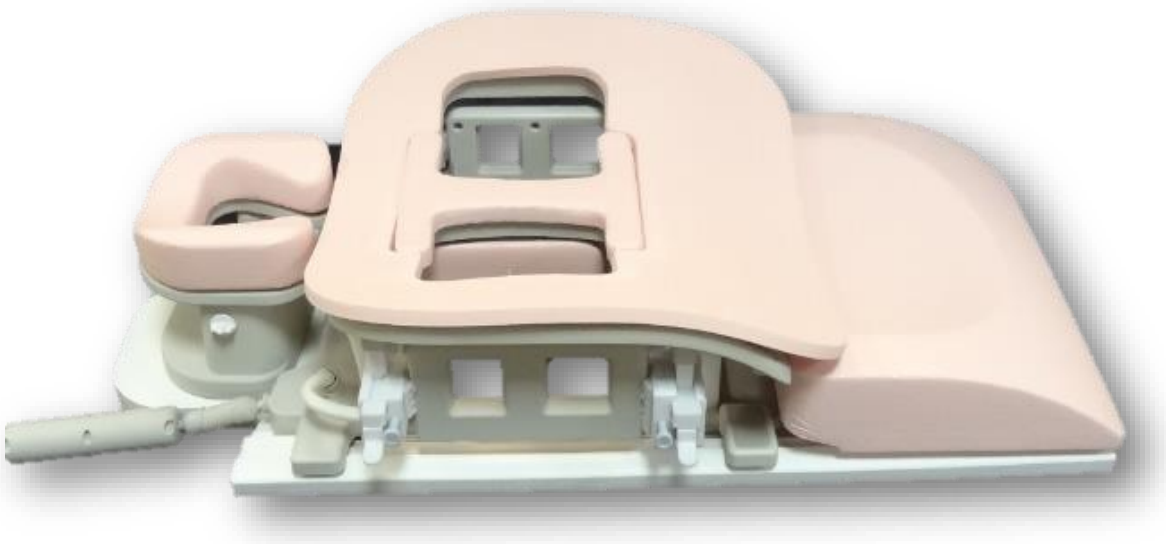
Operator's Manual

Breast SPEEDER CX

for Canon 1.5T MRI Systems



www.qualityelectrodynamics.com

Canon Model #	QED REF
MJAM-147A	Q7000125

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 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 Breast SPEEDER CX is used to examine the breast.

1.2 Operating Environment and Compatibility

The Breast SPEEDER CX is intended to be used in conjunction with the following Canon 1.5T MRI Systems in a specialized healthcare facility:

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

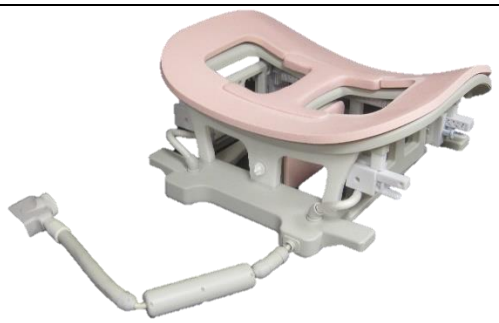
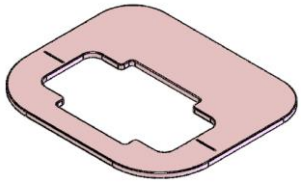
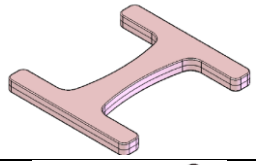
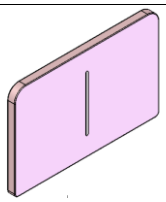
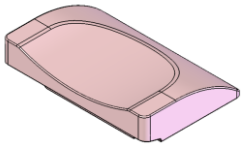
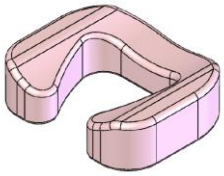
Age, health, condition – No special limitations. Do not use the coil for newborns or infants.

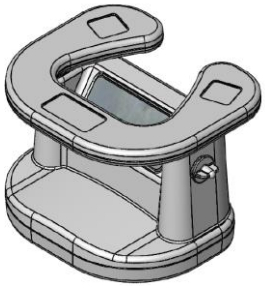
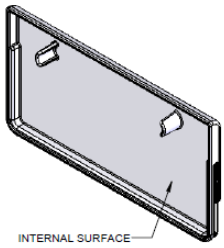
Weight – 255kg or less (consult the operation manual for the MRI system, and if the maximum allowable patient's weight for the system is lower than that for this coil, priority must be given to the maximum weight for the system).

Chapter 2 – Breast SPEEDER CX Components

2.1 Included Components

The Breast SPEEDER CX 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
	Breast SPEEDER CX Coil	1	MJAM-147A	Q7000125
	Comfort Pad	1	BSM41-6404	3003080
	Sternum Pad	1	BSM41-6405	3003081
	Medial Pad	2	BSM41-6406	3003084
	Transition Pad	1	BSM41-6407	3003082
	Head Rest Pad	1	BSM41-6408	3003079

Picture	Description	Quantity	Canon PN	QED PN
	Head Rest	1	BSM41-6409	2000588
	Compression Plate	2	BSM41-6410	3003225

2.2 Optional Accessories (Sold Separately)

Breast Riser CX MJCA-247A	This accessory is used to adjust the coil height. This option is for large-bore MRI systems (Vantage Titan, Vantage Orian, etc.).
Grid Holder CX MJCA-257A	This accessory is used to hold a biopsy grid. The grid itself is provided by a grid supplier.

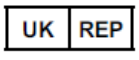
⚠ CAUTION Follow the instructions in the operation manuals for the Grid Holder CX and biopsy grids, if used.

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

Symbol	Number	Standard	Title, Meaning
	N/A	EN50419 EU2012/18/EU	The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information concerning the return and recycling of this product, please consult the supplier from whom you purchased the product.
	5.1.8	ISO 15223-1	Importer
	5.1.9	ISO 15223-1	Distributor

3.2 Indications

The Breast SPEEDER CX is intended for use with Canon 1.5T MR systems to produce diagnostic images of the breast 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

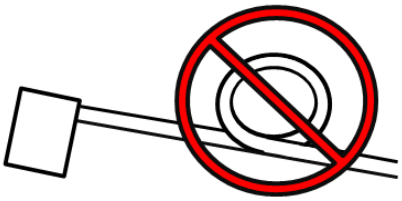
Do not place any disconnected devices (RF coils, cables, etc.) in the gantry during scanning. Remove unneeded RF coils from the couchtop and confirm that RF coils in use are connected to the connector port before scanning.

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.

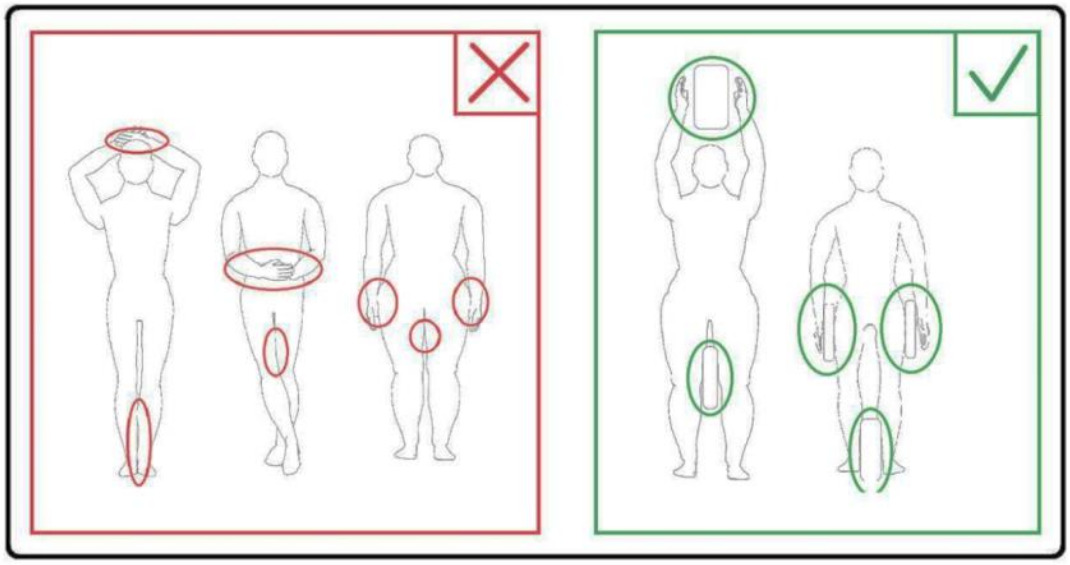


Do not cross or loop coil cables. A high-frequency current may form and burns may occur.

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.



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).

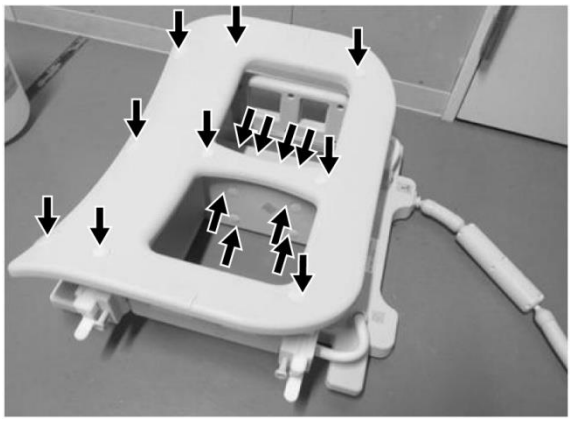
If a coil is found to be defective, stop using the coil immediately and contact your Canon representative.

Use only the accessories described in this manual with the coil.

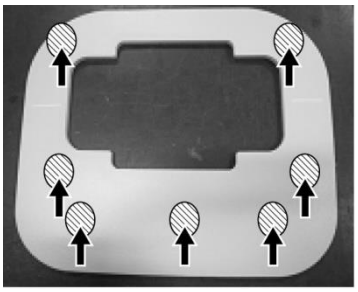
3.6 Cautions – Breast SPEEDER CX

⚠ Do not allow the hook surface of hook-and-loop fasteners to come into contact with the patient. Hook-and-loop fasteners are used on the coil and pads to facilitate immobilization using belts. Scraping the hook surface of these fasteners against the patient's skin may result in injury to the patient. Be careful when handling items with hook-and-loop fasteners.

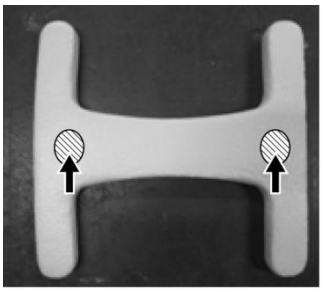
Hook-And-Loop Fastener Positions



Coil Main Unit (on the Side and Top)



Comfort Pad (on the Bottom)



Sternum Pad (on the Bottom)

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 Image Test Using the Automatic SNR Measurement Tool

If descriptions concerning the automatic SNR measurement tool are included in the operation manual for the system, the image test can be performed using the automatic SNR measurement tool.

Coil	Phantom	Part number
Octave SPEEDER Spine	5-L copper sulfate phantom	BSM41-1623

When the automatic SNR measurement tool is used, prepare the required tools referring to the operation manual for the system.

For system software version V6.0 or later, different scan sequences are used. 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 and set the patient weight to 60 kg.

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

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

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

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

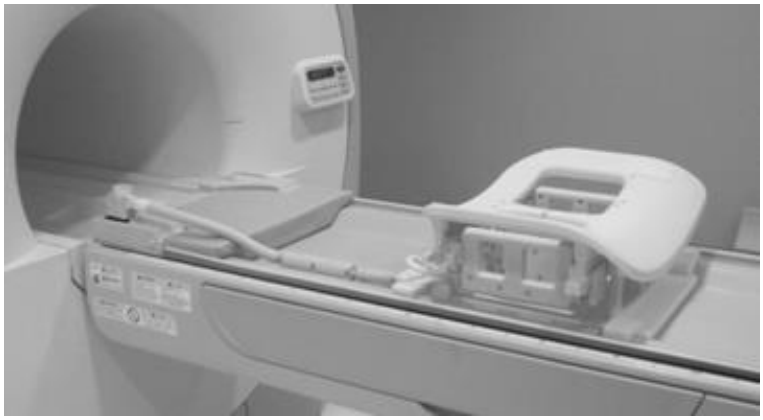
(3) Perform SNR measurement as described in section 4.2 using the sequences selected in step (2). The parameters should be changed according to the SNR measurement procedures.

4.3 SNR Measurement

(1) Read the temperature in the shield room and confirm that the temperature is between 16°C and 24°C.

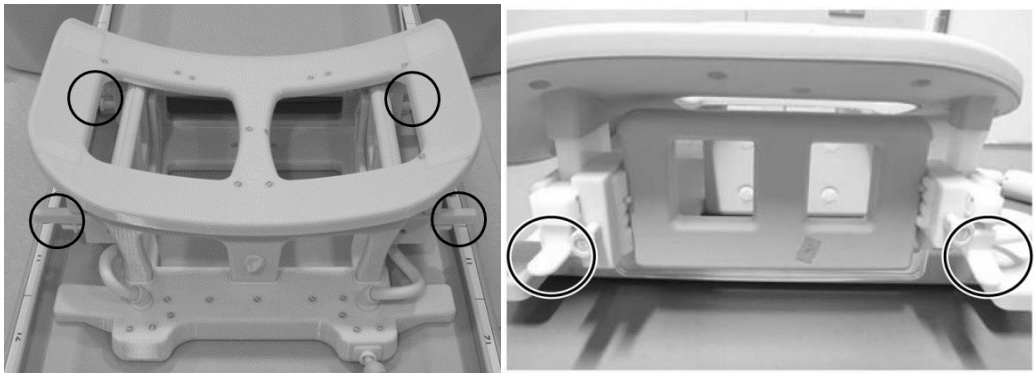
(2) Place the coil on the couchtop with the orientation shown below and connect to port A1 on the couchtop.

Coil Placement

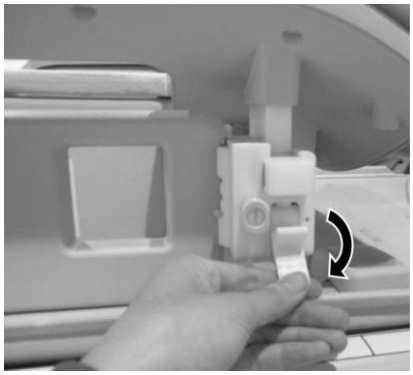


(3) Unlock the four locking tabs by moving them downward as shown below.

Locking Tabs

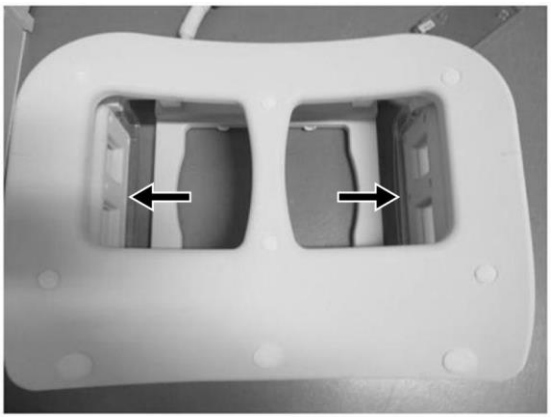


Unlock the Locking Tabs



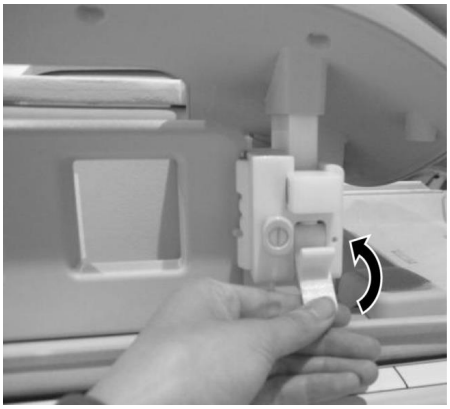
(4) Move lateral coils to the limit positions in the horizontal direction.

Position Lateral Coil



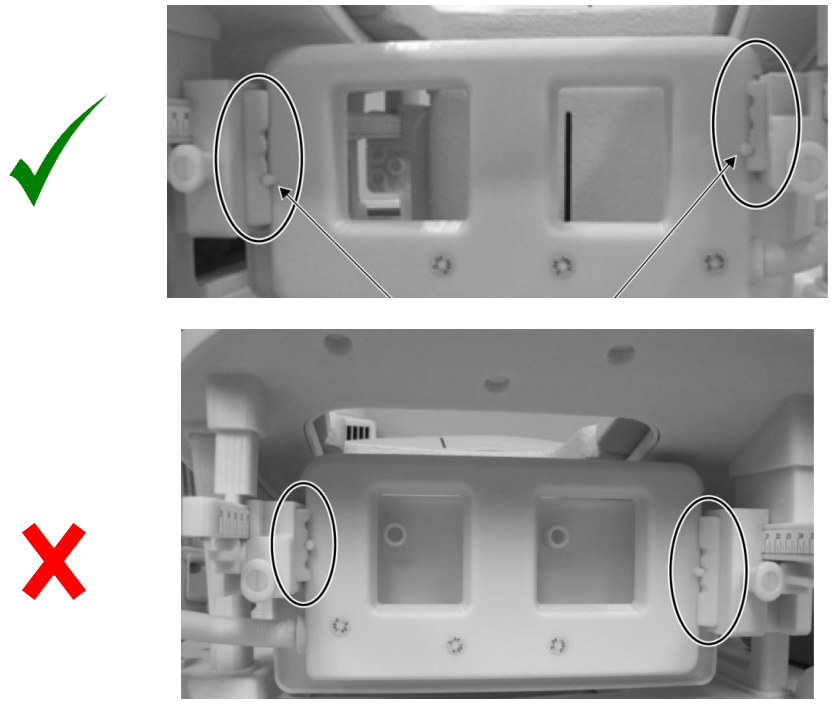
(5) Lock the four locking tabs by moving them upward.

Lock the Locking Tabs

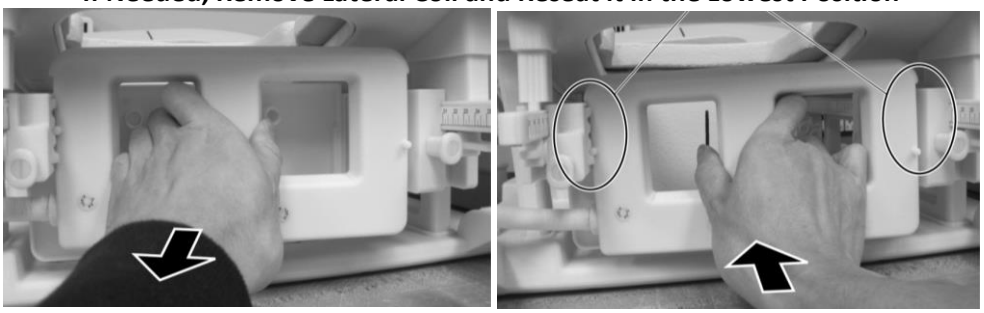


(6) Confirm that lateral coils are in the lowest position. If the coils are not in lowest position, remove the lateral coils and place the lateral coils in the lowest position.

Confirm Correct Lateral Coil Position

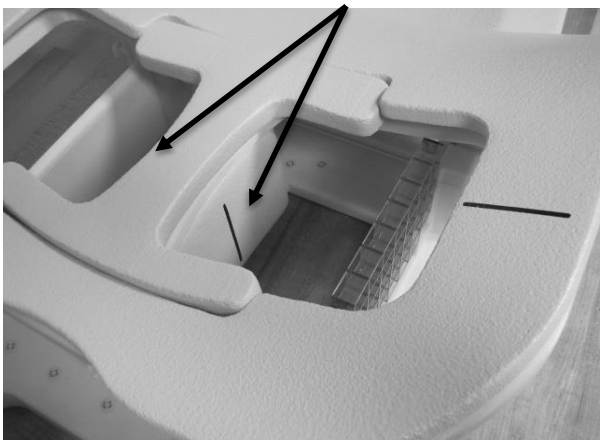


If Needed, Remove Lateral Coil and Reseat it in the Lowest Position



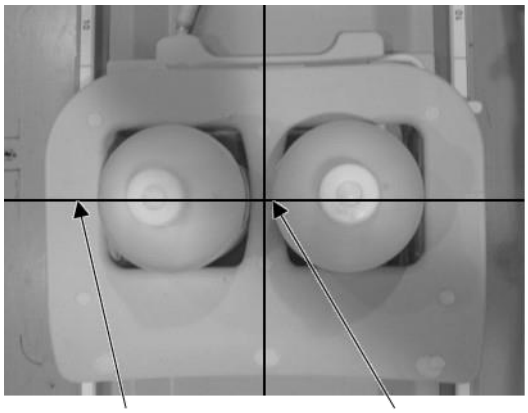
(7) Place medial coil pads on both sides of the medial coil.

Position Medial Pads



(8) Place two 5-L CuSO4 phantoms to the coil. Align the positioning projector beam with the center of the lateral coil and send Breast SPEEDER CX to the magnetic field center.

Place Phantoms



Center marker for lateral coil

Projector beam

(9) Wait for approximately 5 minutes to allow the liquid in the phantom to stabilize.

(10) Select the FE_slt sequence from SEQ folder. Set a sequence parameters as follows.

<Scan conditions>

FE_slt, Special Plan (Axial: 1, Sagittal: 1, Coronal: 1), TR: 50, NS: 3, ST: 8 mm,
FA: 90, FOV : 50 cm, MTX: 256 × 256

(11) Set the parameters as follows.

RF coil : BreastCX Bilat

Patient orientation : Prone

SAR region : Breast

Insertion direction : Head first

Viewing direction : Foot

(12) Run the locator scan.

(13) Select the SE15 sequence from SEQ folder and set a sequence parameters as follows. Then set slice position. (Figure 6.3-11)

<Scan conditions>

SE15, CO: HF, TR200, NS: 3, ST: 5 mm, Gap: 2 mm, FA: 90/180,
FOV: 45 cm × 45 cm, MTX: 256 x 256, NoWrap: PE 1.0/ RO 2.0

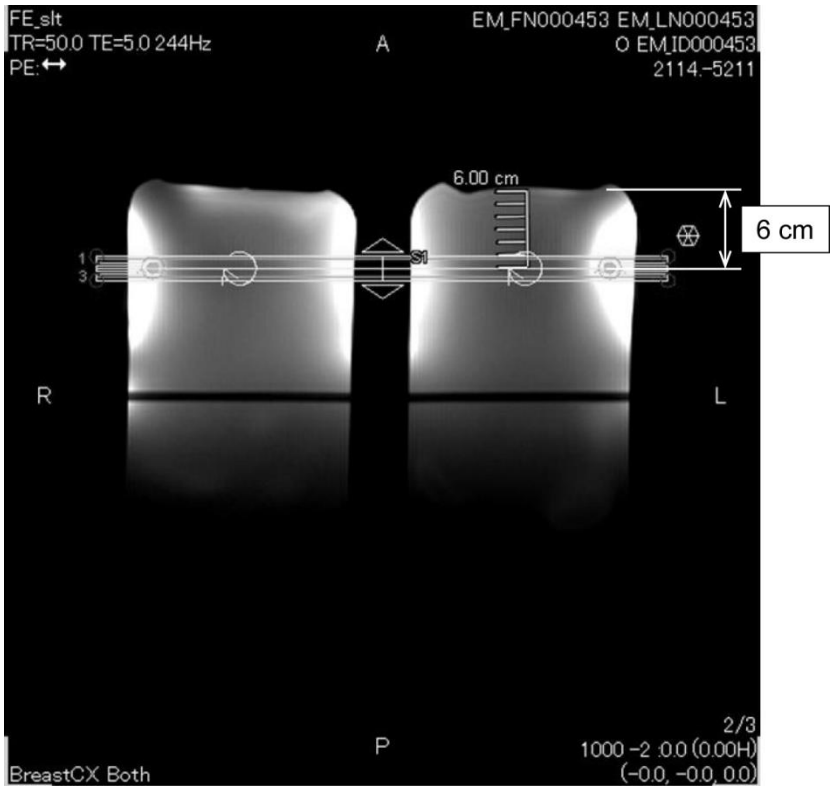
<Slice positioning>

Position the slices using the locator image.

H-F direction and R-L direction : Set the FOV center position at the midpoint between the two phantoms.

A-P direction : Set the center slice position 6 cm lower than phantom bottom.

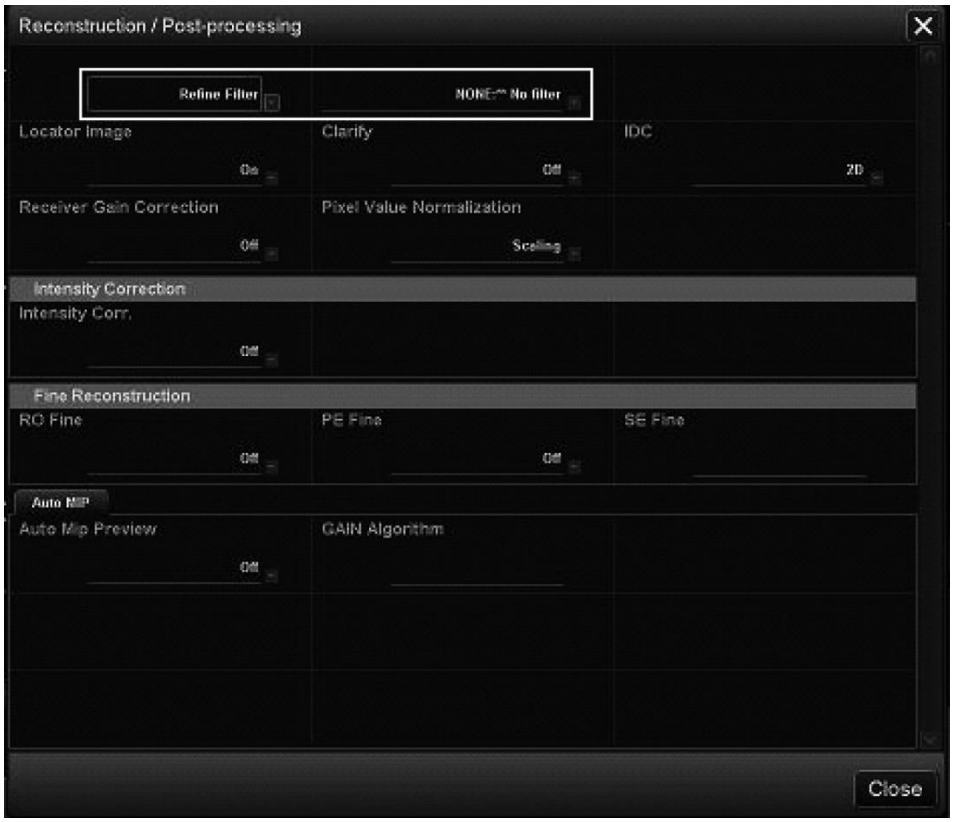
Slice Position



(14) Right-click in the Sequence Editor window and select "Reconstruction" from the pop-up menu. In the displayed filter selection window, select "Refine Filter" and "NONE: No filter".

Select "Reconstruction"

Select "Refine Filter" and "NONE: No filter"



(15) Close the Scan Plan window by clicking [Queue & Exit] and run the sequence.

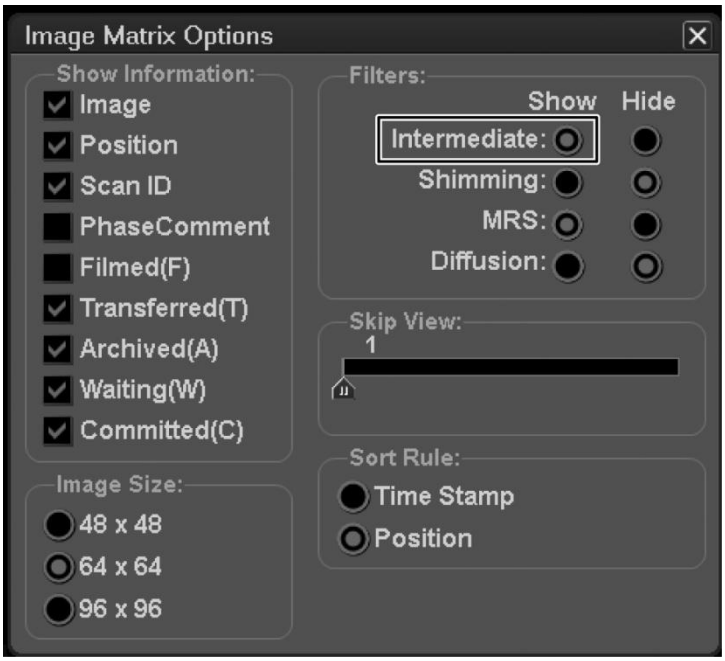
(16) Select "PostProc." tab, choose "File" and "Options" in the Image Matrix window.

PostProc. Tab

Image Matrix Window

(17) Select "Show" for "Intermediate" in the Image Matrix Options window.

Imaging Matrix Options

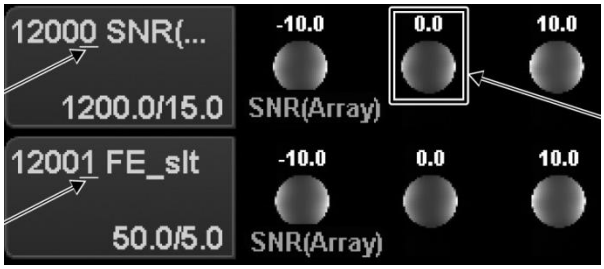


(18) Display the center slice of the acquired phantom image on which last ID number is 0.

Phantom Image

Last ID is 0

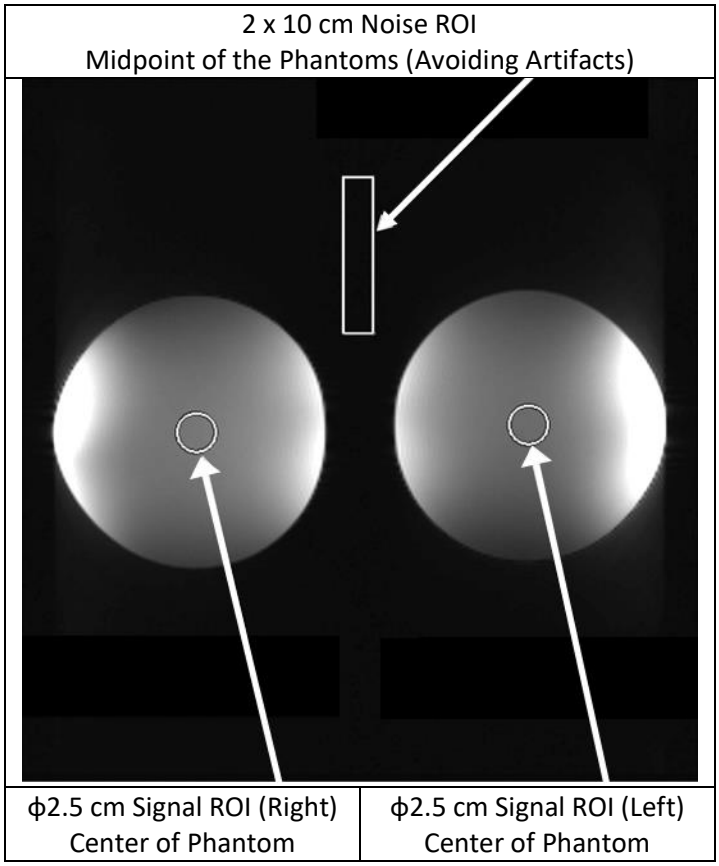
Last ID is 1



Display this Image

(19) Set the signal ROI and noise ROI at the positions indicated below.

ROI Position



(20) Measure the signal value (Mean) and background noise value (NoiseSD).

(21) Calculate the SNR using the equation below.

(22) SNR calculation equation

SNR = S/N × C

where:

S: Measured signal value (Mean) (for the signal ROI)

N: Background noise value (NoiseSD value)

C: Temperature coefficient (refer to the table below)

Shield room temperature (°C)	Temperature coefficient C
16	0.840
17	0.863
18	0.888
19	0.913

20	0.940
21	0.969
22	1.000
23	1.033
24	1.068

<Standard>

SNR (Right) ≥ 180

SNR (Left) ≥ 180

Chapter 5 – Coil Setup and Use

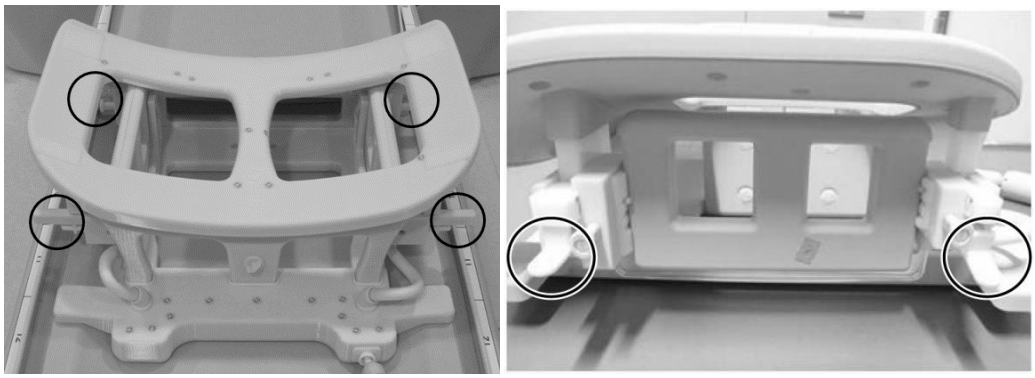
5.1 Coil Setup

5.1.1 Installing and Removing the Lateral Coils

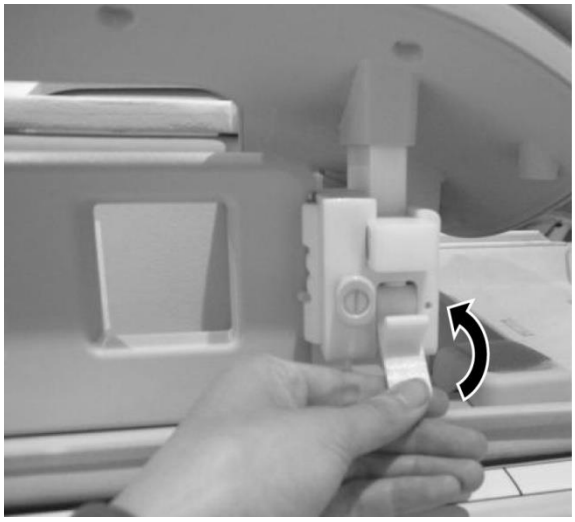
The lateral coil must be installed for imaging.

(1) Lock the lateral coils in place by rotating the locking tabs up and confirm that the coils cannot move horizontally.

Locking Tabs

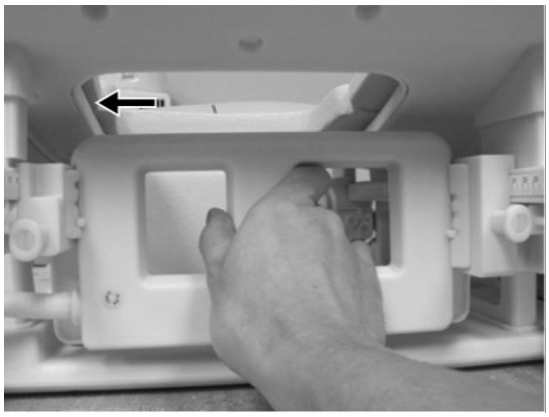


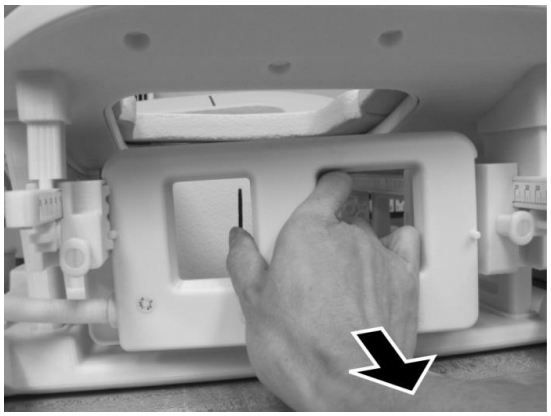
Lock the Locking Tabs



(2) To remove the lateral coil, grasp the coil and push it toward the cable side. At the same time, pull the opposite side out of the frame.

Grasp the Coil, Push Slightly Towards the Cable Side While Pulling Opposite Side Out of Frame





⚠ CAUTION

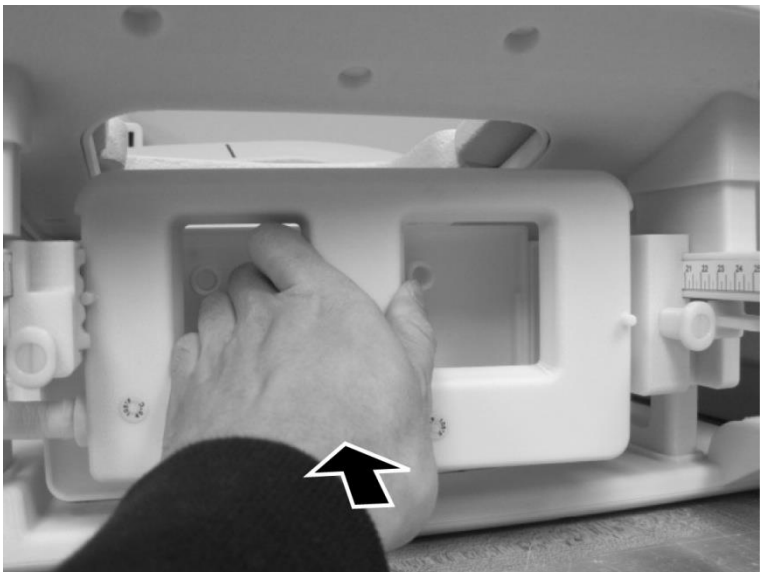
Be careful not to pinch a finger when removing the lateral coil. Injury may result.

1. When removing the lateral coil, hold the coil gently. Do not use excessive force and do not pull or twist the cable. Failure to observe these precautions may result in contact failure or wire disconnection.

2. When moving the patient into the gantry, confirm that the lateral coils are placed on the frame or couchtop. If the removed lateral coils are in the gap between the couchtop and the gantry, the lateral coil may be caught by the couchtop during movement.

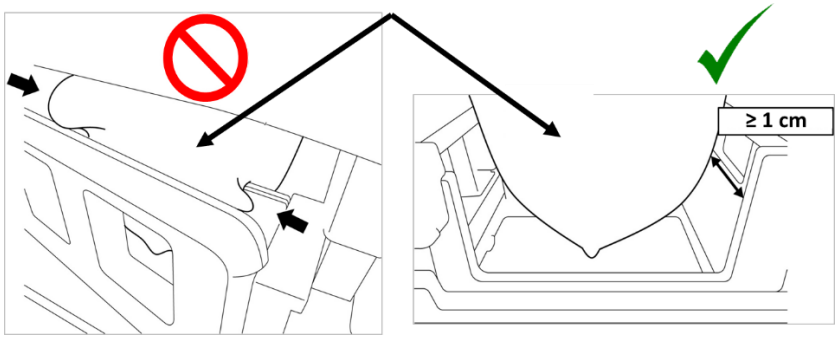
(3) To install the lateral coil, position the lateral coil against the left side of the frame. Then, push the opposite side in. The coil should snap into the frame.

Lateral coils installation



CAUTION

Remove or install the lateral coil when the coil frame is 1 cm or more from patient breast to prevent potential pinching. Injury may result.



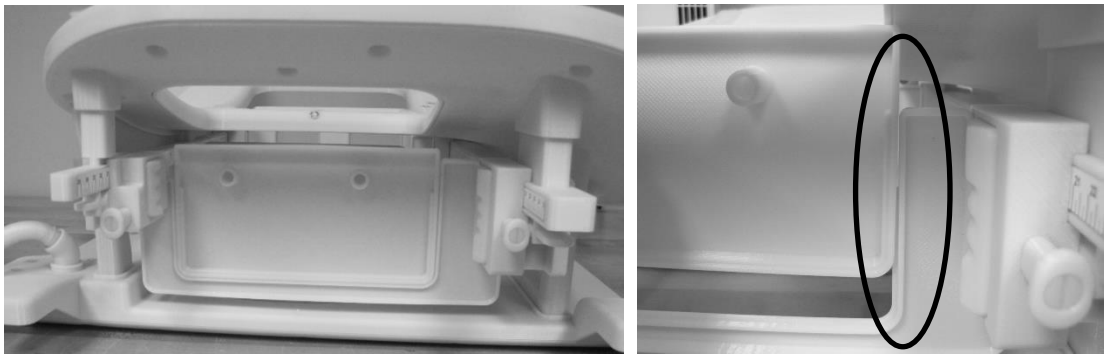
5.1.2 Installing and Removing the Compression Plates

To image with the compression plates, both the compression plates and lateral coils must be installed.

(1) To install the compression plate, remove the lateral coil as described in Section 5.1.1.

(2) Insert the compression plate as shown below. Ensure that the plate "tabs" face outward. Plate should be installed from the side, not from the top opening of the coil. Ensure that the grooves on the side of the compression plate mate with the protruded thin walls of the frame.

Installing the Compression Plate



(4) Install the lateral coil as instructed in Section 5.1.1.

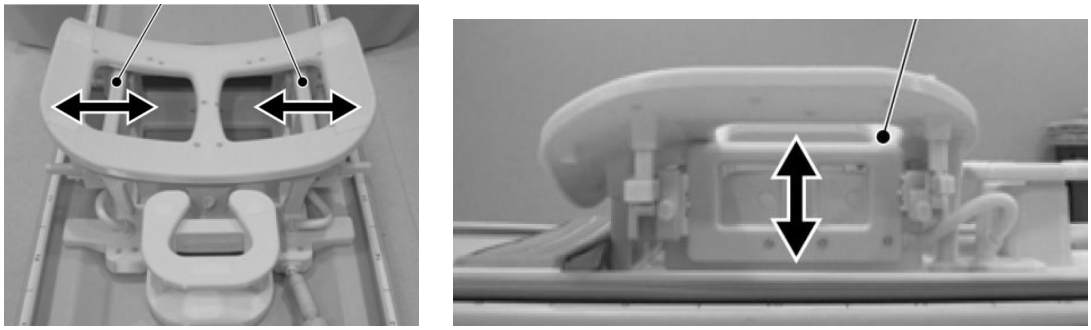
i	1. The lateral coil must be in place to compress the breast tissue. 2. The lateral coil and compression plate should move together.

(5) To remove the compression plate, remove the lateral coil as described Section 5.1.1 and then remove the compression plate.

5.1.3 Adjusting the Horizontal and Vertical Position of the Lateral Coils

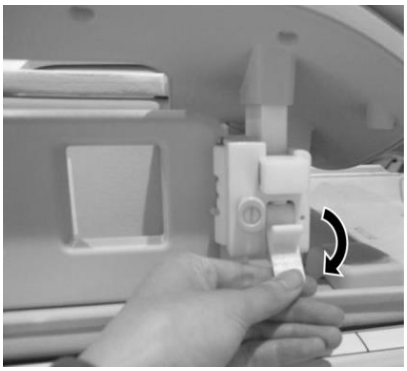
The lateral coils can be moved in the vertical and horizontal directions in order to optimize their positions based on breast size.

Lateral Coil Adjustment Options

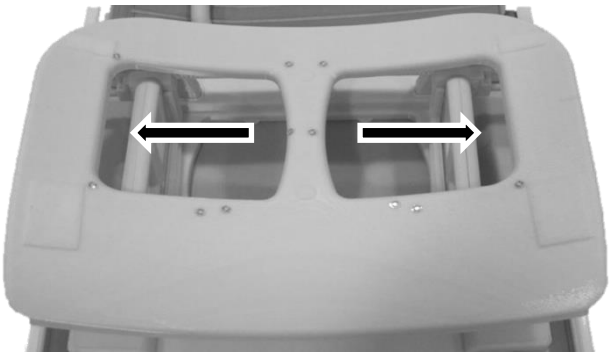


(1) To adjust the horizontal position of the lateral coils, unlock the locking tabs by rotating the tabs down then move the lateral coils to the maximum horizontal positions. Lock the coils in place by rotating the locking tabs up. Confirm that the coils cannot move horizontally.

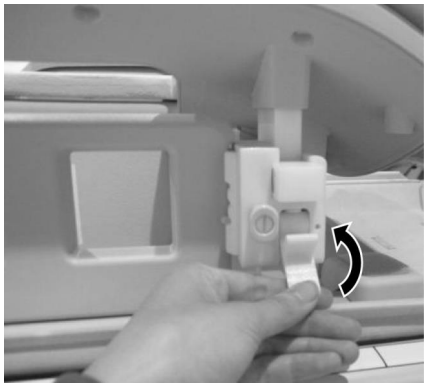
Unlock the Locking Tabs



Move the Lateral Coil to the Maximum Horizontal Position

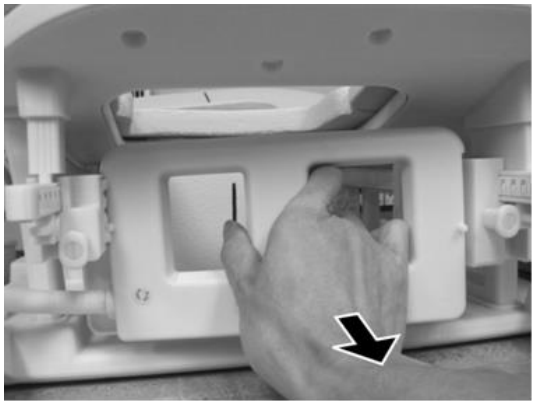


Lock the Locking Tabs



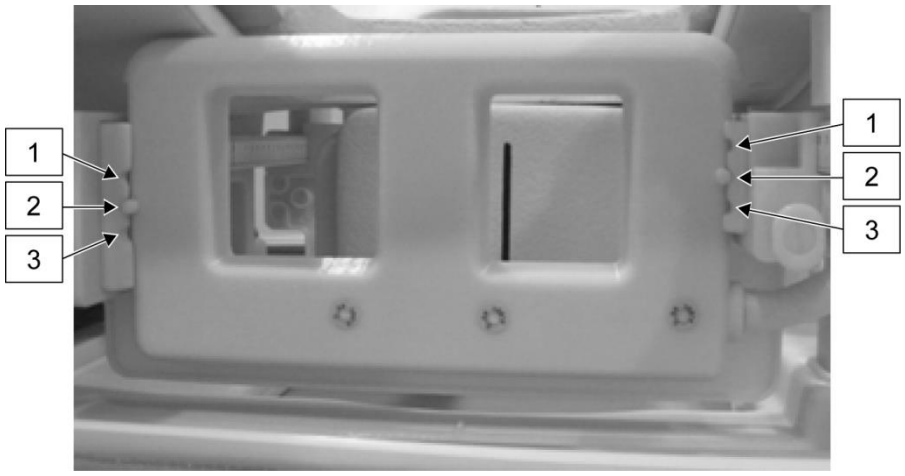
(2) To adjust the vertical position of the lateral coils, remove the lateral coil.

Remove the Lateral Coil



(3) Reinstall the lateral coil at the required vertical position. The lateral coil can be installed at three different vertical positions.

Three Available Vertical Positions for Lateral Coil



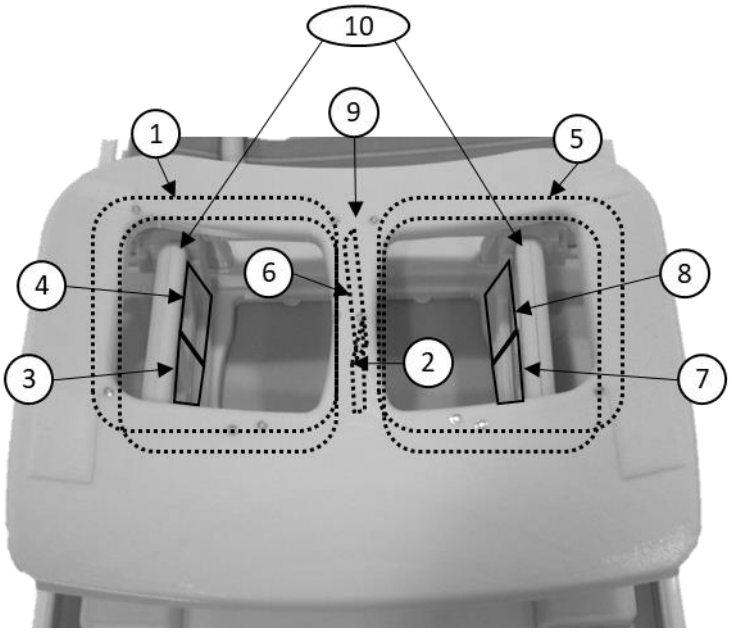
1. When moving the lateral coil vertically, confirm that the lateral coil is installed in the same vertical position on the left and right side of the coil. If the lateral coil is tilted, the coil may not remain in place on the frame. If the coil moves during scanning, it may affect the image quality.

2. If the lateral coil is installed in the middle or highest vertical position, horizontal movement will be limited.

5.2 Choosing the Coil Elements Used for Imaging

The Breast SPEEDER CX coil contains the coils and elements shown in the diagram below. The elements in use during imaging are chosen by the coil type that is displayed, as shown in following table.

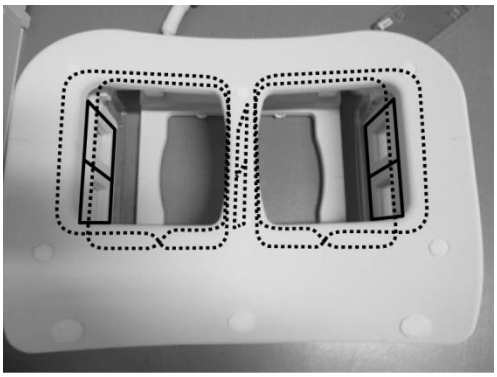
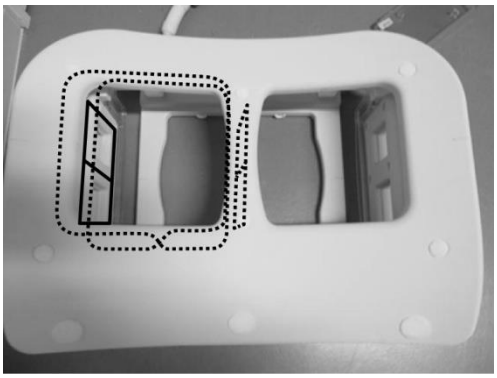
Diagram of Coils and Elements Found on Breast SPEEDER CX

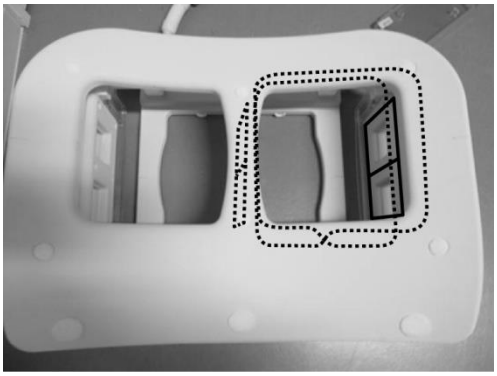
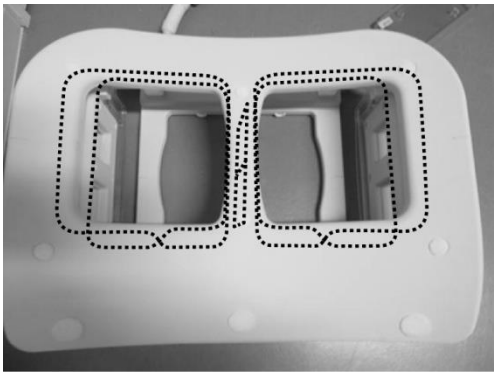
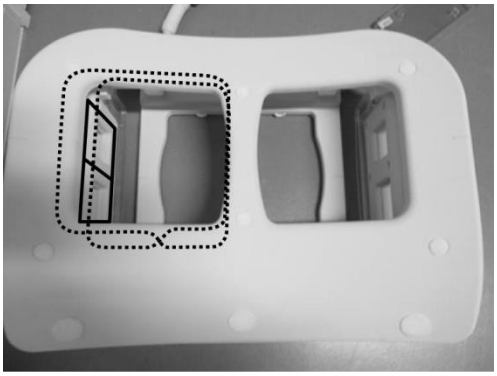


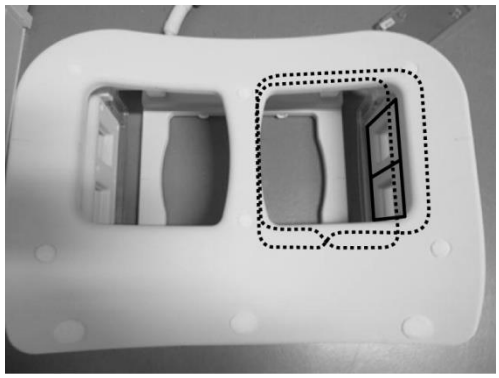
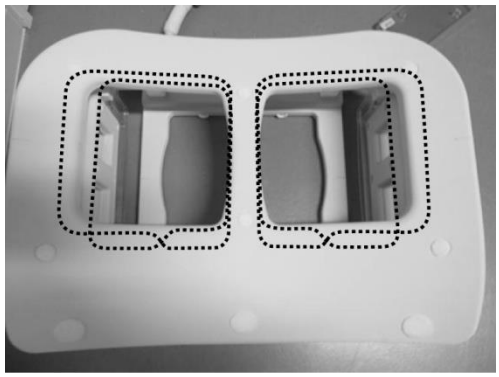
Left Breast Right Breast

Number	Description
1	Left saddle coil element
2, 6	Medial coil elements
3, 4	Left lateral coil elements
5	Right saddle coil element
7, 8	Right lateral coil elements
9	Medial coil
10	Lateral coils

Elements in Use for Each Coil Type

No.	Coil type	Description
1	BreastCX Bilat	Bilateral imaging by all elements Used elements: 1, 2, 3, 4, 5, 6, 7, 8 Available SPEEDER factor: Max 2.0 (RL direction, PE) Max 1.6 (RL direction, SE*) * This may not be operable in some software packages of the Titan and Orian systems. Max 1.3 (AP direction, PE) 
2	BreastCX Left	Unilateral imaging for the left breast of the patient Used elements: 1, 2, 3, 4 SPEEDER is not available. 

No.	Coil type	Description
3	BreastCX Right	Unilateral imaging for the right breast of the patient Used elements: 5, 6, 7, 8 SPEEDER is not available. 
4	BreastCX LatA Bilat	Bilateral imaging, lateral coil elements not used Used elements: 1, 2, 6, 5 SPEEDER is not available. 
5	BreastCX MedA Left	Unilateral imaging for left breast, Medial coil elements not used Used elements: 1, 3, 4 SPEEDER is not available. 

No.	Coil type	Description
6	BreastCX MedA Right	Unilateral imaging for right breast, Medial coil elements not used Used elements: 5, 7, 8 SPEEDER is not available. 
7	BreastCX DualA Bilat	Bilateral imaging, lateral and medial coil elements not used Used elements: 1, 5 SPEEDER is not available. 

5.3 Patient Positioning and Scanning

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

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

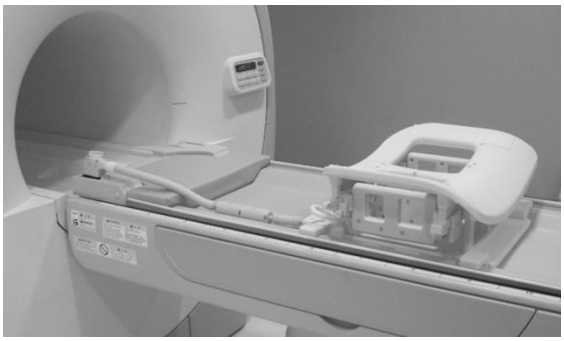
CAUTION	Ensure all other coils are removed from the couchtop. If an unplugged RF coil is left on the couchtop during scanning, burn injury, abnormal images, or coil failure may result.

(3) Confirm the orientation of the coil and place it on the couchtop.

For Vantage Titan and Vantage Orian systems, this coil can be used for head-first scans and foot-first scans (option).

For Vantage Elan systems, this coil can be used for head-first scans.

Coil Orientation

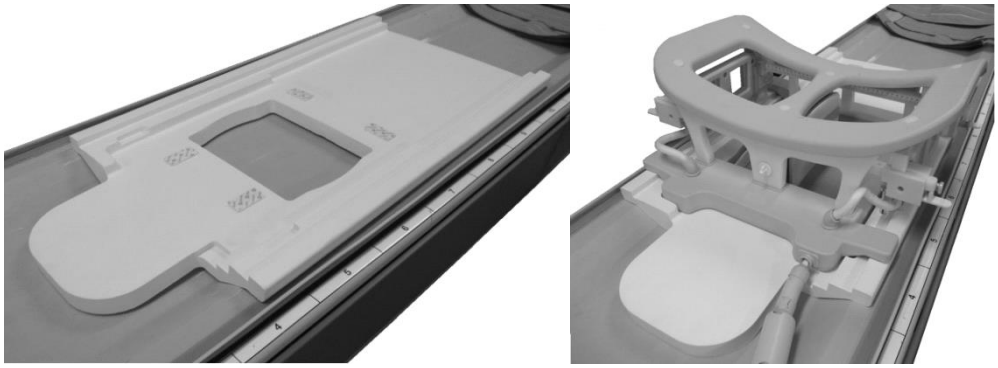


Head End Foot End

> For Vantage Titan and Vantage Orian systems, the couch modification kit, which is an option for the MRI system, must be installed in order to perform foot-first scanning with this coil. If an attempt is made to perform foot-first scanning without installing the couch modification kit, the coil center cannot reach the magnetic field center, resulting in poor image quality or abnormal images. If you are not sure whether the couch modification kit has been installed, contact your Canon Medical Systems service representative.

For Vantage Titan and Vantage Orian systems, place the Breast Riser CX (optional, sold separately) on the couchtop first if it is required due to the patient's size and physique or the system bore size. Then place the coil on top of the Breast Riser CX.

Breast SPEEDER CX with Breast Riser CX



Handle this coil carefully. Injury could occur while carrying the coil. If the coil is dropped, injury or damage may occur.

(4) Connect the breast coil cable to the port on the couchtop.

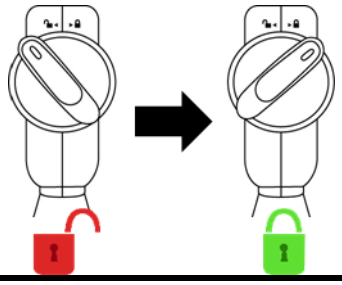
Coil connector ports to be used for this coil

For Vantage Titan and Vantage Orian systems : Port A1 or A7

For Vantage Elan systems : Port A1

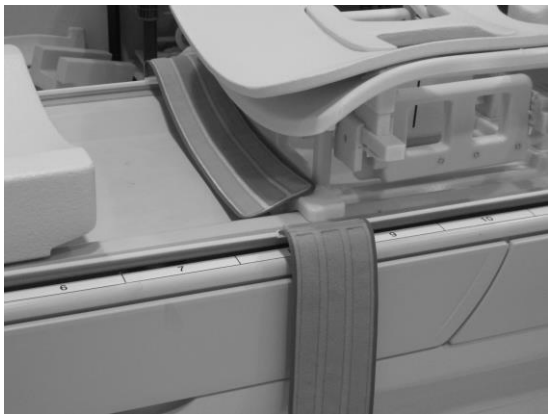
CAUTION

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



(5) Overlay the movable patient immobilization belt as shown below to secure the coil to the couchtop.

Secure the Coil to the Couchtop

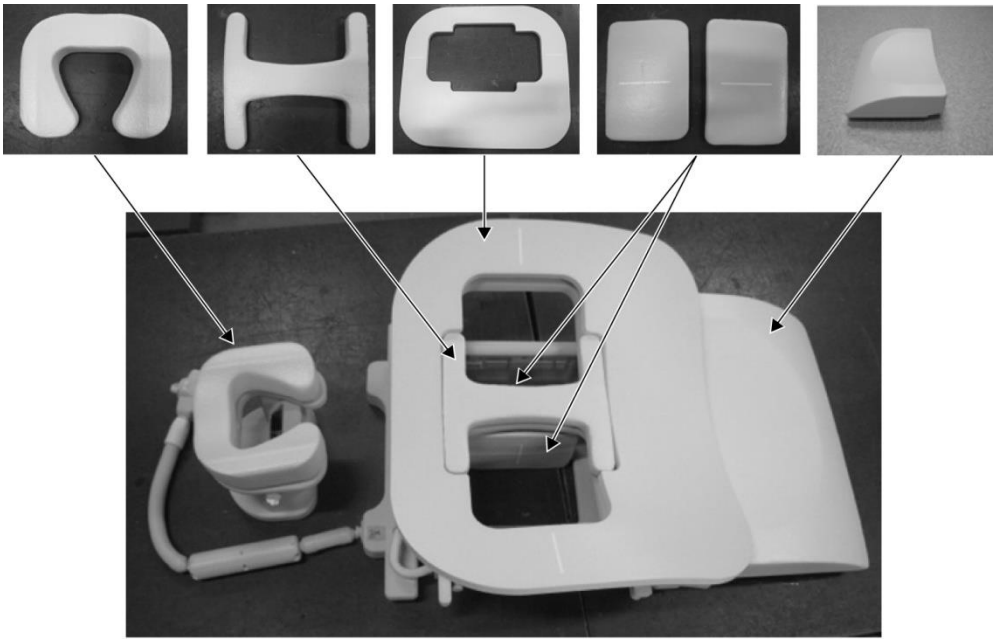


CAUTION

Confirm that the coil is fastened to the couchtop before patient positioning. If the coil is not secured, injury may result.

(6) Place the pads and accessories on the patient support as required.

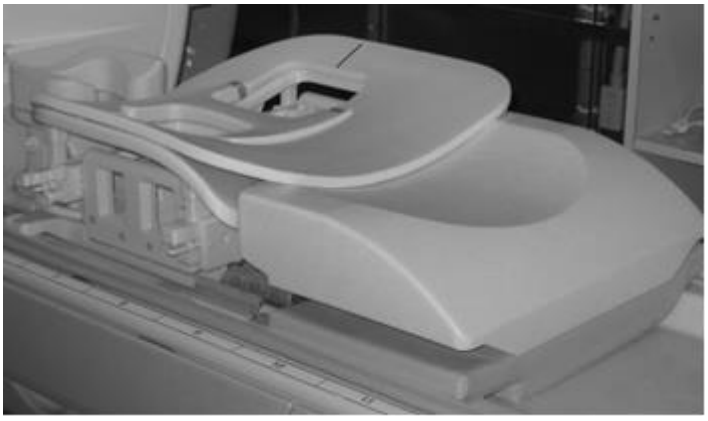
Pad Positioning



CAUTION

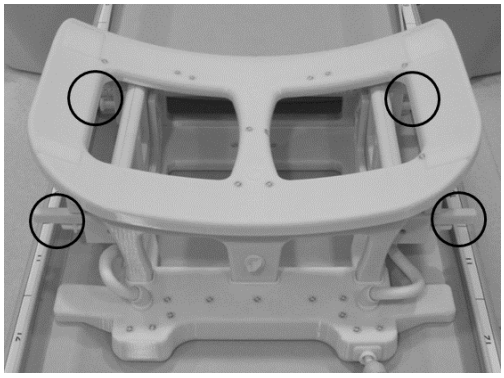
Do not allow the hook surface of hook-and-loop fasteners to come into contact with the patient. Scraping the hook surface of these fasteners against the patient's skin may result in injury to the patient.

If the patient's body is thin and/or they experience rib pain or discomfort, adding the MRI system pad under the transition pad as shown below should reduce discomfort.

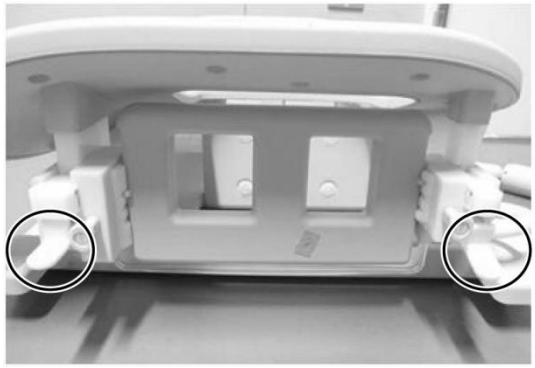


(7) Unlock the locking tabs by rotating the tabs down then move the lateral coils to the maximum horizontal positions. Lock the coils in place by rotating the locking tabs up. Confirm that the coils cannot move horizontally.

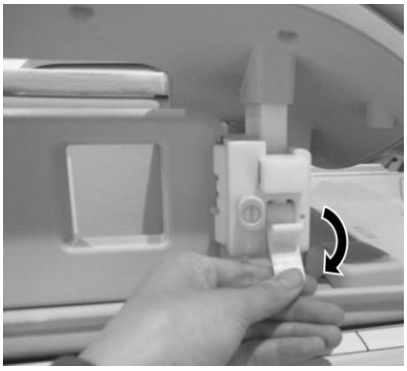
Locking Tabs

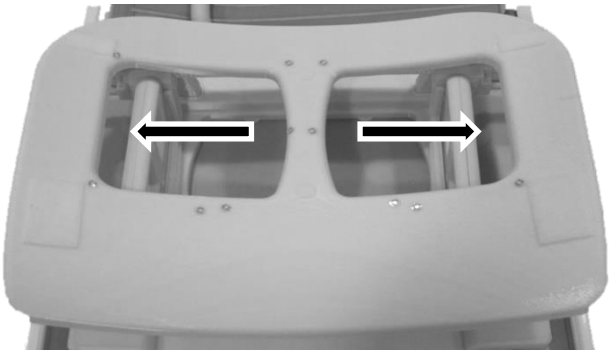


Unlock the Locking Tabs

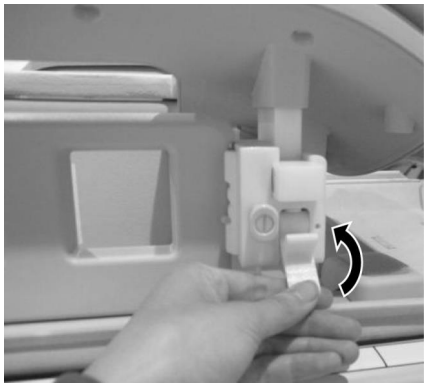


Move the Lateral Coil to the Maximum Horizontal Position

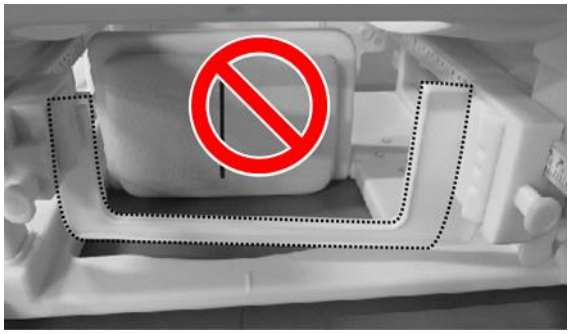




Lock the Locking Tabs



When moving the frame horizontally, do not bend the frame. The frame may be damaged.



(8) Position the patient face down on the coil. Adjust the position of the target region according to the breast size.

If lateral coil or compression plate adjustment, removal, or reinstallation is required, refer to Section 5.1.

(9) Adjust the headrest height using the screw on the side of the headrest.

Headrest and Screw

Ensure the headrest screw is tightened after height adjustment.

(10) Unlock the locking tabs by rotating the tabs down, then move the lateral coils toward the patient until the coils are in close contact with the breast. Lock the coils in place by rotating the locking tabs up. Confirm that the coils cannot move horizontally.

(11) Confirm that no pads, accessories, removed lateral coils, or parts of the patient's body are projecting out from the couchtop and then raise the couchtop.

(12) Apply the light of the positioning projector on the region to be scanned. Confirm again that the region to be scanned is positioned within the center of the lateral coil.

(13) Press the AUTO IN button to send the patient on the couchtop to the center of the magnet.

(14) Perform patient registration and choose the imaging sequences for breast imaging.

> Confirm that the actual patient insertion direction matches the setting displayed on the screen of the MRI system. If the insertion direction is set incorrectly, the left and right sides of the patient may be displayed reversed.

(15) Choose the coil types for required imaging, which is described Section 5.2.

(16) Set the states as below and start scanning.

Patient position: "Prone"

SAR region: "Chest".

For the other settings and scanning procedures, refer to the operation manual for the system and to the imaging manual.

(17) When scanning is completed, press the OUT button to remove the couchtop from the gantry.

(18) Remove the patient from the couch.

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

Manufacturer:
Quality Electrodynamics, LLC. (QED)
6655 Beta Drive, Suite 100
Mayfield Village, OH 44143
U.S.A.

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EC REP

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