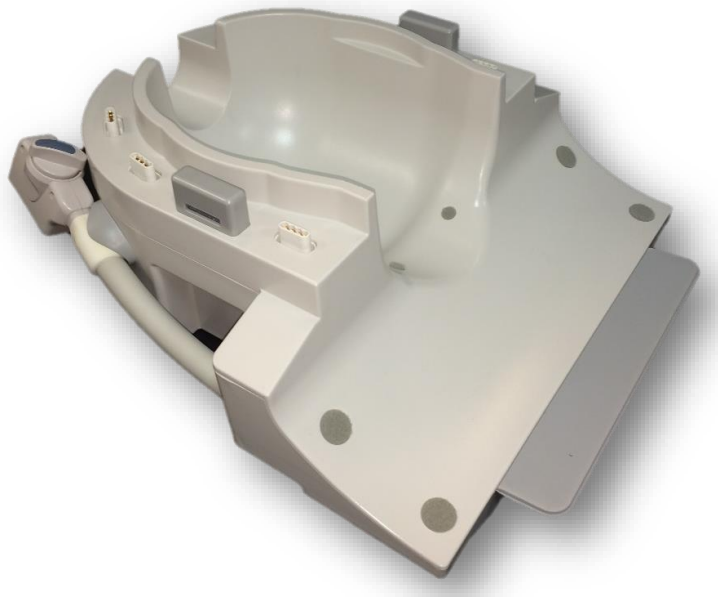
Operator's Manual

Atlas SPEEDER Head/Neck

For Canon 1.5T and 3.0T MRI Systems



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	Canon Model #	QED REF
1.5T	MJAH-177A	Q7000126
3.0T	MJAH-172A	Q7000146

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 Atlas SPEEDER Head/Neck is used to examine the head, neck, and feet.

1.2 Operating Environment and Compatibility

The Atlas SPEEDER Head/Neck is intended to be used in conjunction with the following Canon MRI Systems in a specialized healthcare facility:

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

1.3 User Profile

Operator – Radiologic technologists, laboratory technologists, physicians.

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

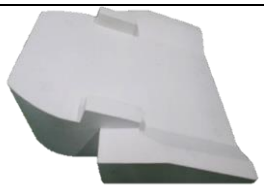
1.4 Patient Information

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

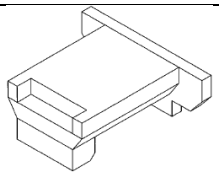
Weight – 255kg or less (consult the operation manual for the MRI system, and if the maximum allowable patient's weight for the system is lower than that for this coil, priority must be given to the maximum weight for the system).

Chapter 2 – Atlas SPEEDER Head/Neck Components

The Atlas SPEEDER Head/Neck 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
 Head/Neck Base  NV Adaptor  Cervical Adaptor  Base Cover	Atlas SPEEDER Head Neck Coil	1	MJAH-177A (1.5T) MJAH-172A (3T)	Q7000126 (1.5T) Q7000146 (3T)
	Tilt Pad (10 Degree)	1	BSM41-6568	3003153
	Tilt Pad (20 Degree)	1	BSM41-6569	3003154

Picture	Description	Quantity	Canon PN	QED PN
	Head Pad (Thick)	1	BSM41-6571	3003685
	Head Pad (Thin)	1	BSM41-6570	3003686
	Neck Pad	1	BSM41-6575	3003152
	Shoulder Pad	1	BSM41-6574	3003150
	Tapered Pad (25 mm)	2	BSM41-6572	3003813
	Tapered Pad (40 mm)	2	BSM41-6573	3003814
	Mirror	1	BSM41-6566	2001171

Picture	Description	Quantity	Canon PN	QED PN
	Combo Pad	1	BSM41-6636	3003579
	Combo Pad Strap (Left)	2	BSM41-6637	3003649
	Combo Pad Strap (Right)	2	BSM41-6638	3003683
	ACR Phantom Holder*	1	BSM41-6567	3003486
	Phantom Holder 10*	1	3M08-08716	N/A

*Used only for testing. Not to be used for patient scans.

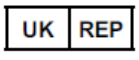
Chapter 3 – Safety

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 Atlas SPEEDER Head/Neck is intended for use with Canon 1.5T or 3.0T MR systems to produce diagnostic images of the head, neck, and feet that can be interpreted by a trained physician.

3.3 Contraindications

None.

3.4 Precautions

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

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

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

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

Patients who have difficulty regulating their body temperature or who are particularly sensitive to increases in body temperature (for example, patients with fever, cardiac failure, or impaired perspiration) are at increased risk of burn injury or their body temperature may increase.

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

3.5 Cautions – RF Coil

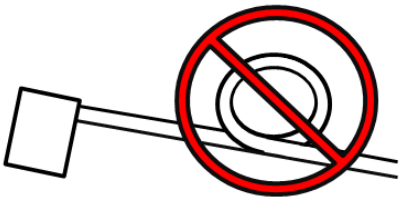
Do not place any disconnected devices (RF coils, cables, etc.) in the gantry during scanning. Remove unneeded RF coils from the couchtop and confirm that RF coils in use are connected to the connector port before scanning.

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

Connect only the designated RF coils to the RF coil connection port.

Do not use a defective RF coil, especially if the outer covering has been damaged or if metal parts are exposed. There is a risk of electric shock.

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

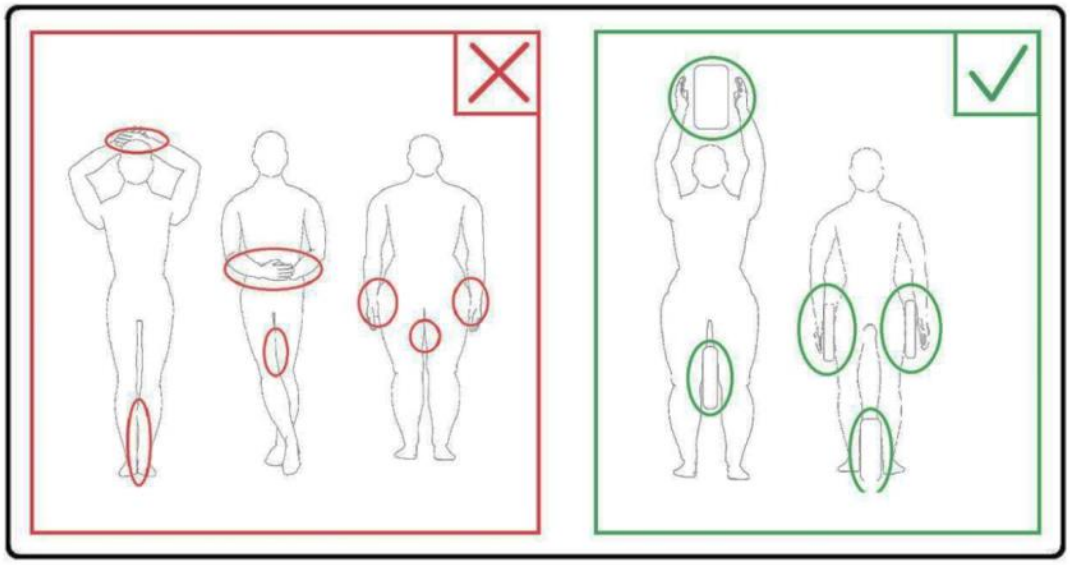


Do not cross or loop coil cables. A high-frequency current may form and burns may occur.

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

Do not allow the patient to form a loop with any body parts. Use pads to ensure that the patient's hands and legs do not touch the coil, MRI system, patient table, or another

body part that may form a loop. A high-frequency current may form and burns may occur.



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

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

Stop the scan immediately if the patient complains of warming, tingling, stinging, or similar sensations. Contact a physician before continuing with the scan.

Ensure that the coil does not come into contact with liquids, such as water or medications.

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

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

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

3.6 Emergency Procedures

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

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

Chapter 4 – Quality Assurance

4.1 Image Test Using the Automatic SNR Measurement Tool

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

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

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

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 100 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	FE_map	Required
SNR	QD Head, SE15	Required

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

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

4.3 SNR Measurement

This section includes instructions for measuring SNR for quality assurance purposes for the following:

- 1.5T and 3.0T systems,
- head, center, and neck regions of the Atlas SPEEDER Head/Neck coil, and

- NV mode (with the NV adaptor attached) and C-Spine mode (with the cervical adaptor attached).

> **i** Ensure that the correct instructions are followed based on the particular system and coil configuration being used.

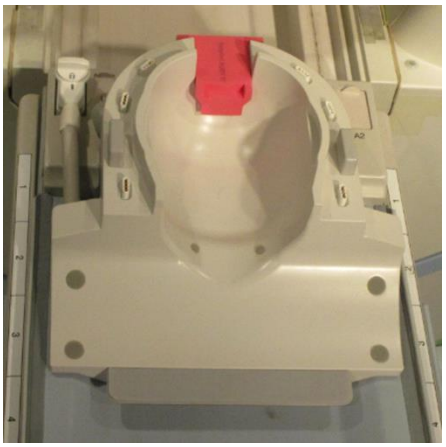
(1) Place the Head/Neck base on the couchtop and connect the connector to port A1 on the couchtop.

(2) Measure the temperature in the shield room.

Record the current temperature. The recorded temperature will be used later to calculate the SNR.

(3) Place the phantom holder 10 and align it with the hollow of the head base.

Place the Coil and Phantom Holder



(4) Using the phantoms listed below for the 1.5T and 3.0T systems, place the phantom cap on phantom holder 10.

Required Phantom for 1.5T and 3.0T Systems

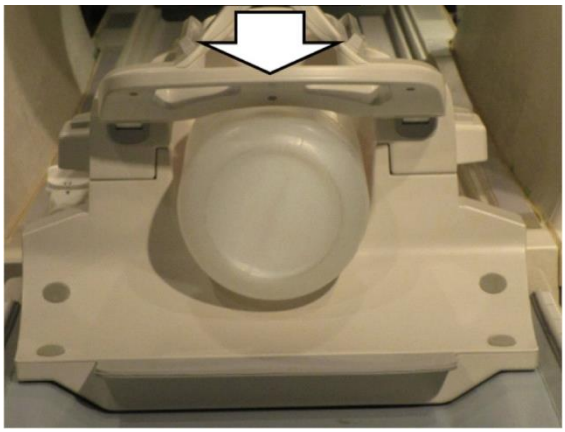
Coil	Phantom	Part number
Atlas SPEEDER Head/Neck (1.5T)	5-L copper sulfate phantom	BSM41-1693
Atlas SPEEDER Head/Neck (3.0T)	5-L oil bottle phantom	BSM41-4886

Place the Phantom

(5) Connect the NV Adaptor or Cervical Adaptor to the Head/Neck base and set the height of the chest section to the third level (lower the chest section by 2 levels from the top level.)

Connect NV or C-Spine Adaptor

Chest Section

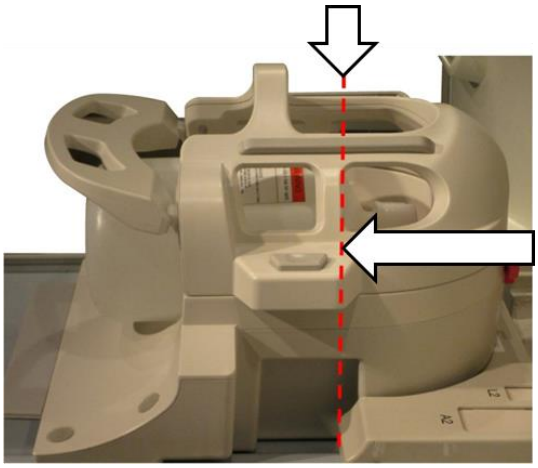


(6) Align the projector beam in relation to the mark on the coil as shown below depending on which section of the coil is being measured. Then, send the coil to the center of the gantry.

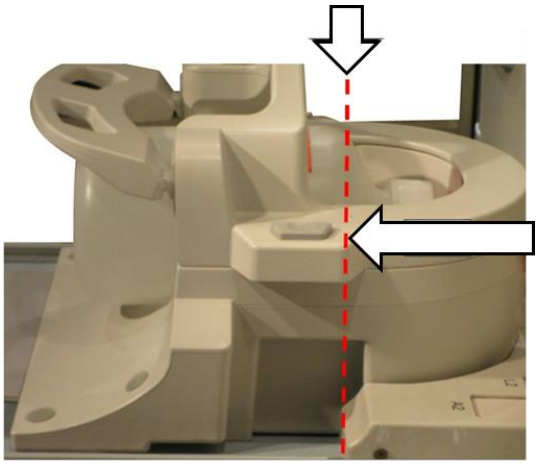
> **i** The projector beam is aligned differently for different sections of the coil. Ensure the coil is positioned as shown in the pictures.

Head Section - Align Projector Beam with Mark

NV Mode (with NV Adaptor)

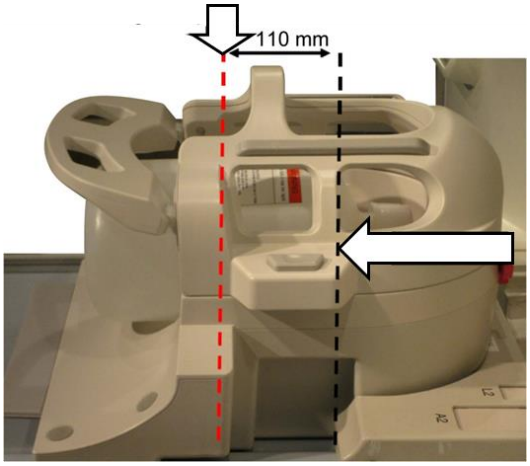


C-Spine Mode (with Cervical Adaptor)

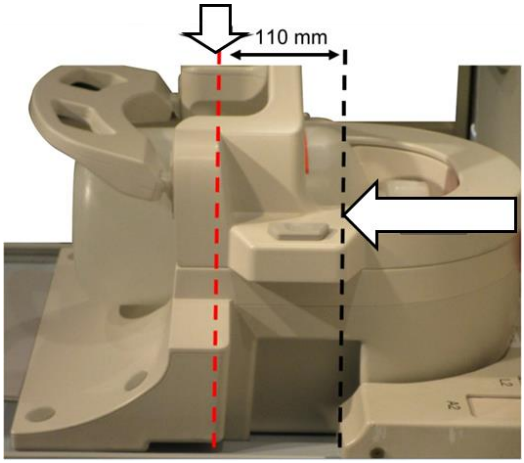


Center Section – Align Projector Beam 110 mm from Mark

NV Mode (with NV Adaptor)

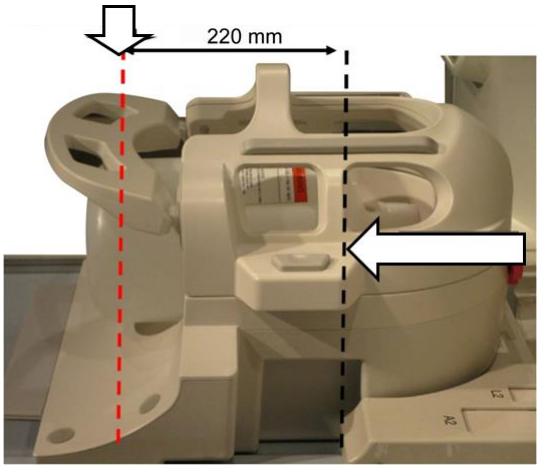


C-Spine Mode (with Cervical Adaptor)

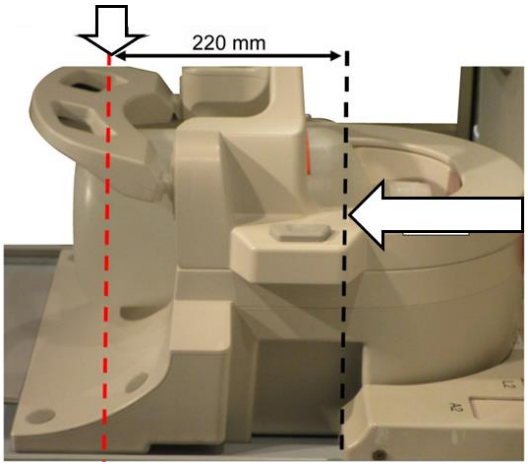


Neck Section – Align Projector Beam 220mm from Mark

NV Mode (with NV Adaptor)



C-Spine Mode (with Cervical Adaptor)



(7) Wait approximately 1 minute to allow the liquid in the phantom to stabilize.

(8) Register a patient.

Enter "100 kg" for the patient weight.

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

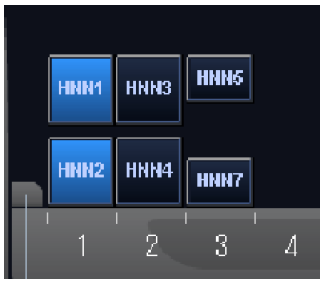
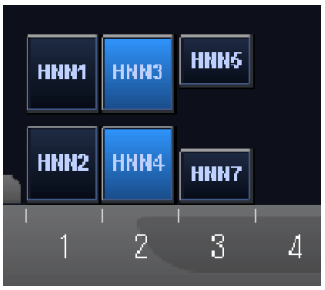
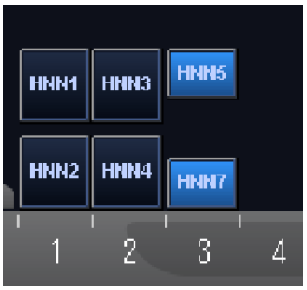
Set the parameters for the FE_slt sequence as follows.

1.5T Settings	3.0T Settings
FE_slt, Special Plan (Axial: 1, Sagittal: 1, Coronal: 1), TR: 50, NS: 3, ST: 8 mm, FA: 90, FOV: 35 cm, MTX: 256 × 256, NoWrap: RO1.0/PE1.0	FE_slt, Special Plan (Axial: 1, Sagittal: 1, Coronal: 1), TR50, NS3, ST 8 mm, FA25, FOV 35 cm, MTX 256 × 256, NoWrap RO1.0/PE1.0

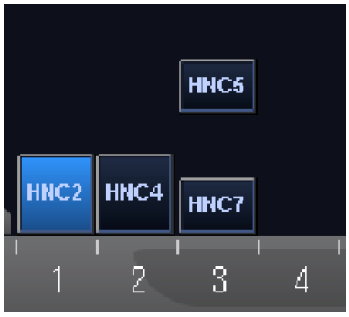
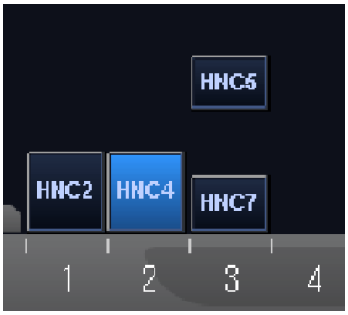
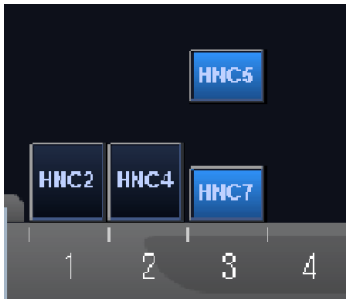
Note: the parameter settings that need to be changed from their default values are underlined.

(10) Select “Atlas Head Neck” for coil type and "Head" for anatomy. Select the coil sections depending on the section of the coil being tested as follows.

Coil Sections – NV Mode (with NV Adaptor Attached)

Head Section	Center Section	Neck Section
HNN1 and HNN2	HNN3 and HNN4	HNN5 and HNN7
		

Coil Sections – C-Spine Mode (with Cervical Adaptor Attached)

Head Section	Center Section	Neck Section
HNC2	HNC4	HNC5 and HNC7
		

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

(12) Select the "FE_map" (1.5T) or “FFE_map” (3.0T) sequence from the "FE" (1.5T) or “FFE” (3.0T) PAS of [SEQ] folder. For Windows 10 or later, select "Typical PAS" → "Coil QA" and select “FE_map” (1.5T) or "FFE_map" (3.0T) from Other PAS in the Other folder.

Set the parameters as follows.

1.5T Settings	3.0T Settings
FE_map, AX, TR: 185, NS: 20, ST: 6 mm, Gap: 6.5 mm, FA: 20, FOV: 30 cm, MTX: 64 × 64, NoWrap: PE1.0/RO2.0	FFE_map, AX, TR6, NS20, ST 8 mm, Gap 0, FA20, FOV 32 cm, MTX64 × 64, NoWrap PE1.0/RO2.0

Note: the parameter settings that need to be changed from their default values are underlined.

(13) Plan the scan in the Scan Plan window.

Plan the scan so that the phantom is at the center of the image in both the A-P and R-L directions.

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

(15) Select the "QD Head" sequence from the "QD Head" PAS of [QA] folder or "SE15" sequence from the "SE" PAS of [SEQ] folder. Set the parameters as follows. For Windows 10 or later, select "Typical PAS" → "Coil QA" and select "SNR" from Other PAS in the Other folder.

Set the parameters as follows.

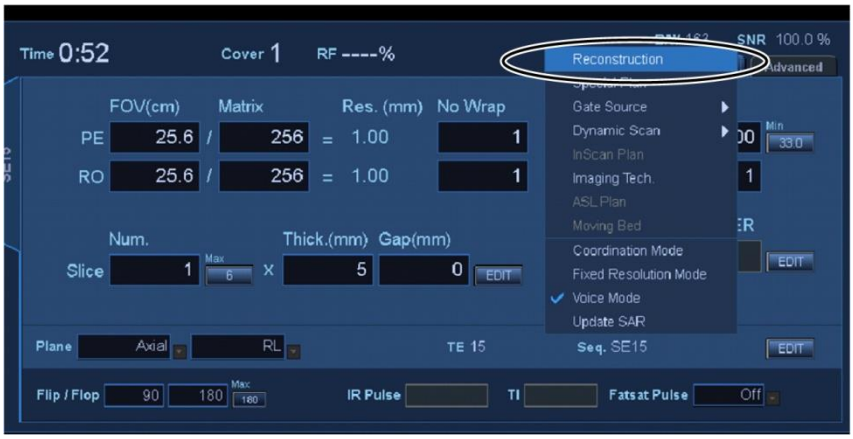
1.5T Settings	3.0T Settings
SE15, AX: RL, TR: 500, NS: 3, ST: 5 mm, GAP: 1 mm, FA: 90/180, FOV: 30.8 cm, MTX: 256 × 256, NoWrap: PE1.0/RO2.0	SE15 or QA_SE: SNR, AX: RL, TR500, TE15, NS3, ST 5 mm, Gap 1 mm, FA90/180, FOV 30.8 cm, MTX 256 × 256, NoWrap PE1.0/RO2.0

Note: the parameter settings that need to be changed from their default values are underlined.

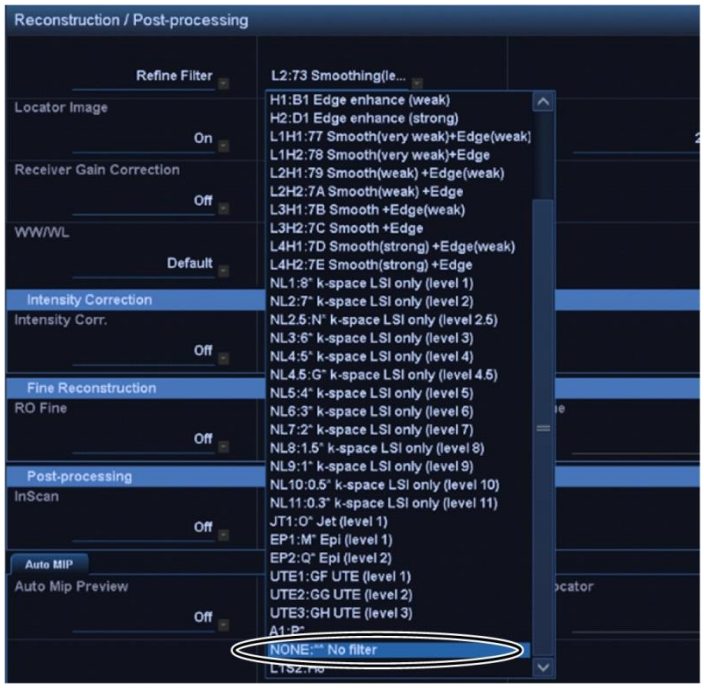
Plan the scan so that the phantom is at the center of the image in both the A-P and R-L directions.

If "SE15" is selected from the SEQ folder, right mouse click and select "Reconstruction", then "Refine Filter" and "NONE: No filter" in the sequence parameter window.

Reconstruction Window



Refine Filter

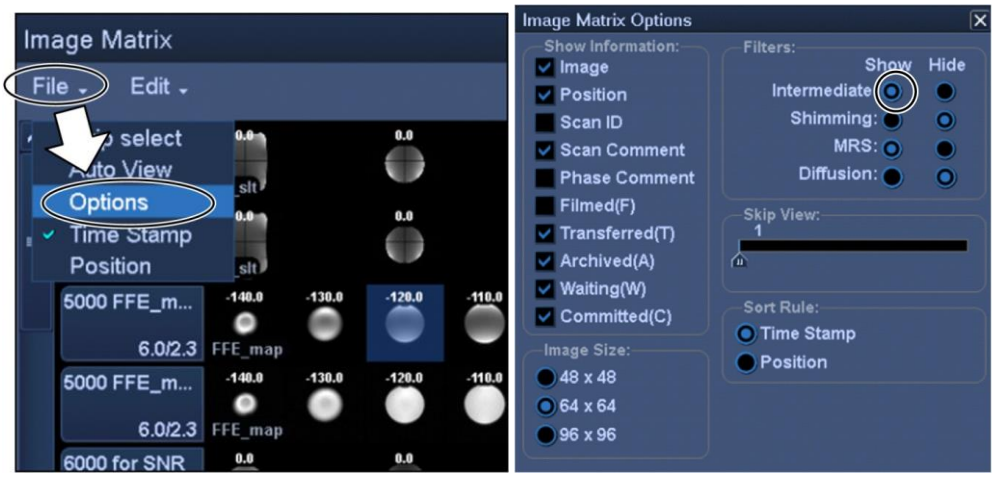


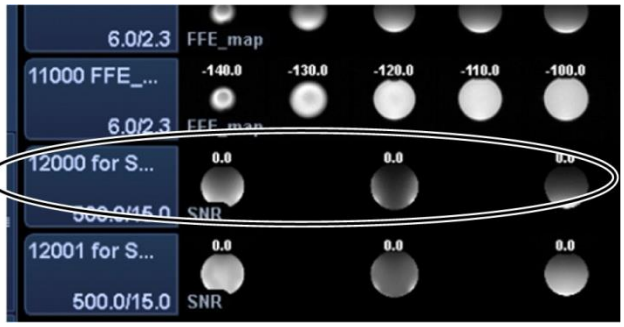
(16) Close the Scan Plan window by clicking [Queue & Exit] and run the sequence.

(17) Display an intermediate image by selecting the following items.

File → Options → Intermediate: Show

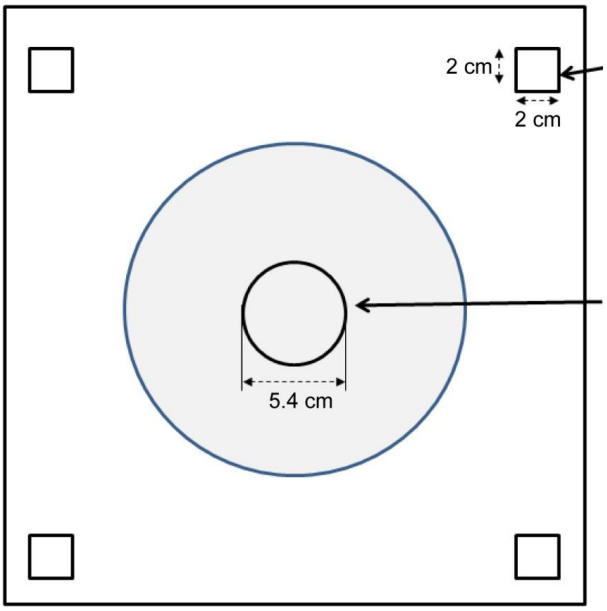
Intermediate





(18) Display the center slice of the acquired phantom image for "QD Head", “SNR”, or intermediate of "SE15". Set the signal ROI and noise ROIs at the position indicated below.

ROI Position



ROI for Background Noise Measurement (Four Positions)

ROI for Signal Measurement (Circle)

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

(20) Calculate the average of the NoiseSD values measured in the four noise ROIs.

(21) Calculate the SNR using the equation below.

SNR calculation equation

SNR = S/N × C

Where:

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

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

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

(22) Expected SNRs are shown below.

SNR

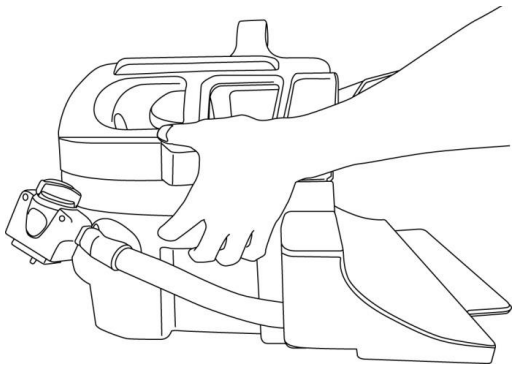
NV Mode			
System	Head Section	Center Section	Neck Section
1.5T	≥230	≥200	≥140
3.0T	≥620	≥550	≥450
C-Spine Mode			
System	Head Section	Center Section	Neck Section
1.5T	≥200	≥190	≥120
3.0T	≥590	≥550	≥450

Chapter 5 – Coil Setup and Use

5.1 Carrying the coil

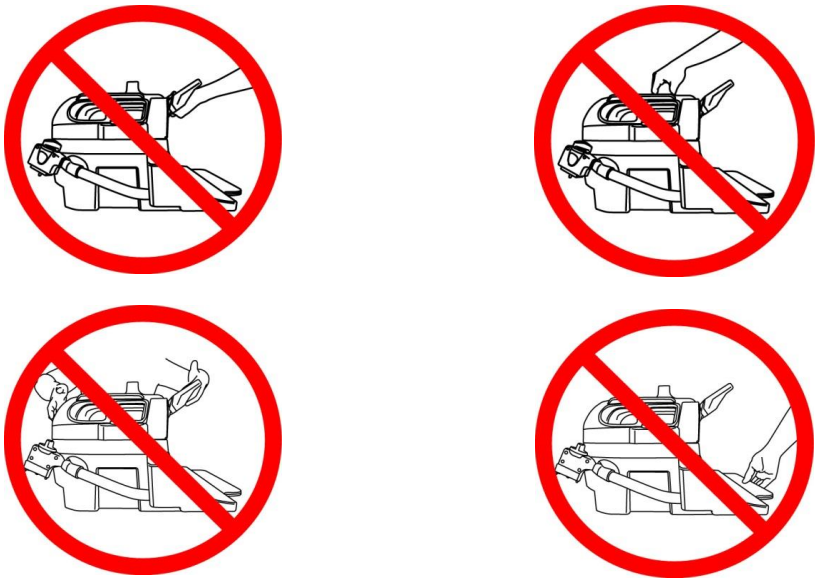
When moving the coil, connect the adaptor (Cervical, NV, or Base) securely to the Head/Neck base. Lift the coil by holding both sides of the Head/Neck base.

Lift Holding the Main Coil Unit



Do not subject the coil to physical shock (for example, by dropping it on the floor). If the coil is lifted by holding only the Cervical adaptor, the Head/Neck base may come loose and fall. In addition, do not lift the coil by holding the cable only. Doing so will subject the coil to excessive stress, possibly resulting in damage.

Do Not Lift by the Cervical or NV Adaptor or Using the Soft Section

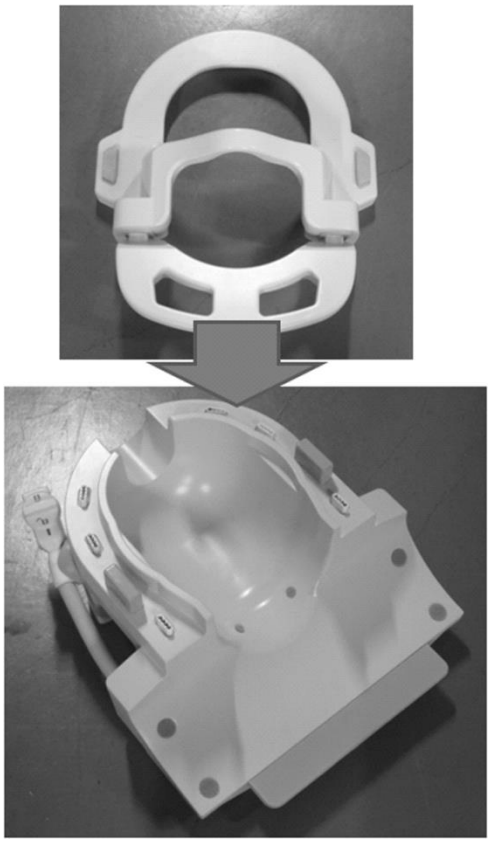


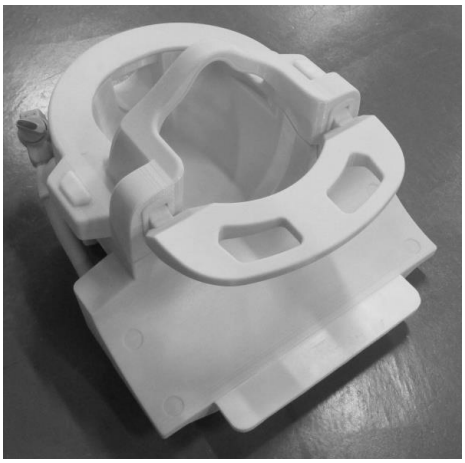
5.2 Coil Setup

5.2.1 Cervical Adaptor

The cervical adaptor is used for imaging the cervical spine region while allowing a more open patient experience.

Attaching the Cervical Adaptor

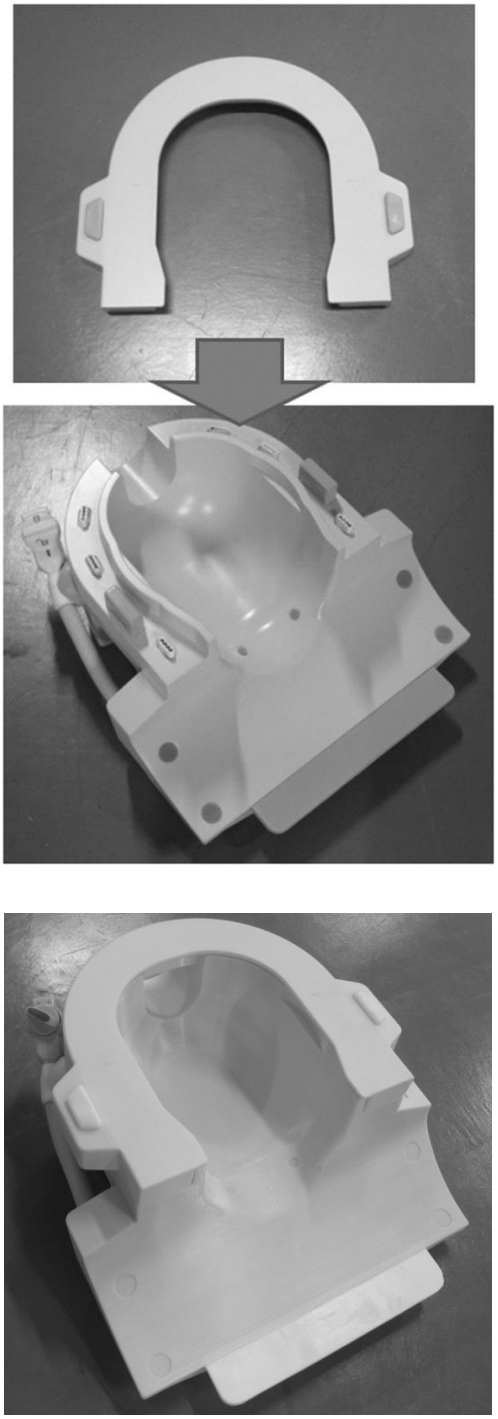




5.2.2 Base Adaptor

When only the Head/Neck base is to be used for scanning, attach the Base adaptor over the Head/Neck base.

Attaching the Base Adaptor



5.2.3 Mirror

The mirror can be attached to the NV adaptor. The mirror does not work with the Cervical or Base adapters.

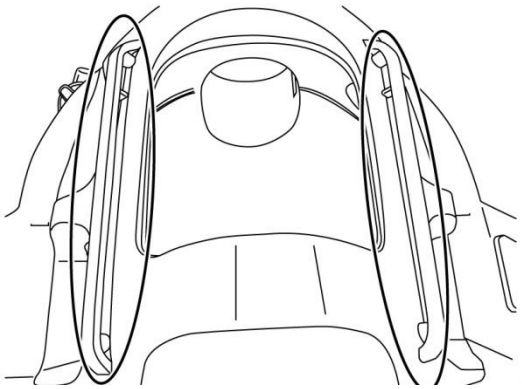
Attaching the Mirror

Depress the mirror buttons and place mirror on mounting rails. Release mirror buttons to secure the mirror.

Attach the Mirror to the NV Adaptor

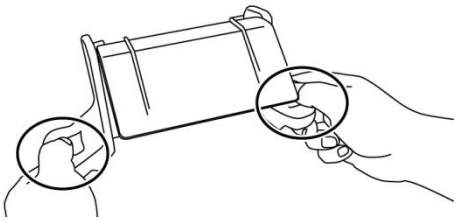
Mirror Attaches to Rail of NV Adaptor

(1)



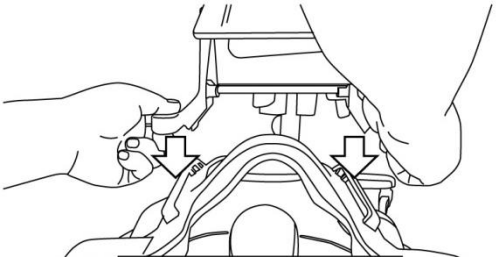
Push Button of Mirror

(2)



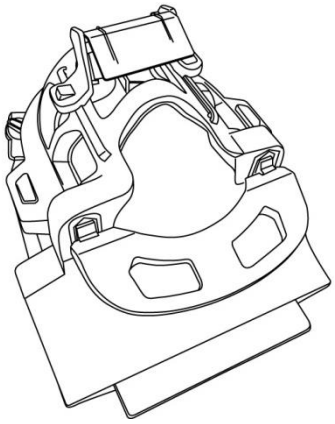
Attach Mirror to NV Adaptor

(3)



Setup is Complete

(4)



⚠ CAUTION	Do not attach the mirror when the tilt pad is to be used. The mirror will interfere with the inner wall of the gantry. Even if the mirror is attached, the patient cannot see outside the gantry when the tilt pad is used.

Adjusting the Mirror

To move the mirror to desired position, depress the mirror buttons and slide the mirror along the rails. Releasing the buttons locks the mirror in place.

Attach the mirror to the NV adaptor before connecting the NV adaptor to the Head/Neck base.

Cleaning the Mirror

Clean mirror surface with warm water and a non-scratch cloth to remove smudges and dust.

5.2.4 Tilt Pad

The tilt pad is used to tilt the Head/Neck base if the patient is unable to lie flat on the couch.

Place the tilt pad on the couchtop and place the Head/Neck base on it.

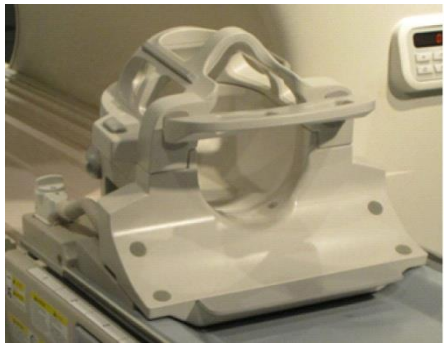
Position the Tilt Pad

10 Degree Tilt

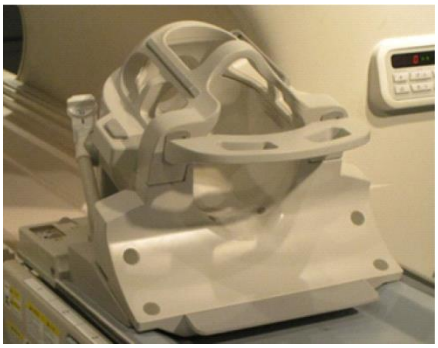
20 Degree Tilt

Position the Head/Neck Base

10 Degree Tilt



20 Degree Tilt



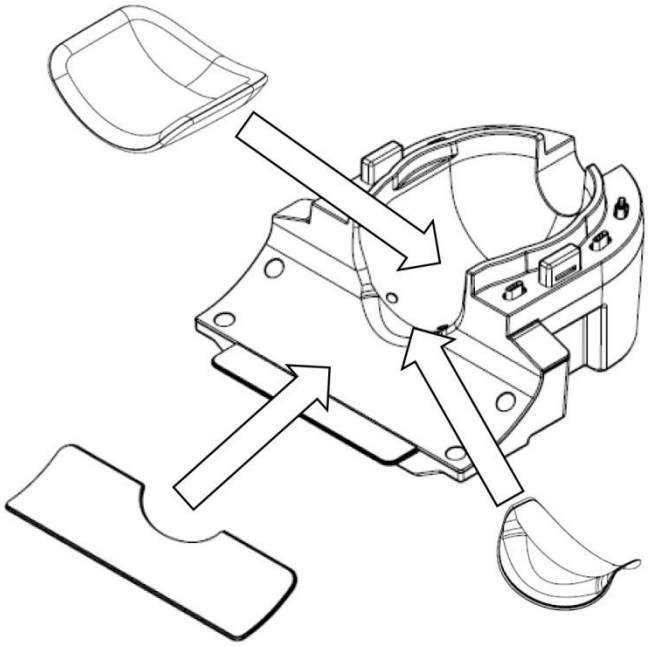
⚠ CAUTION	Do not use the tilt pad (20 degree) in Vantage Galan 3T ZGO. The coil will interfere with the inner wall of the gantry.

5.2.5 Comfort Pads

Neck Pad, Shoulder Pad, and Head Pad

The neck pad and shoulder pad fit onto the Head/Neck base using the Velcro fasteners, and the head pad is placed in the coil as shown below.

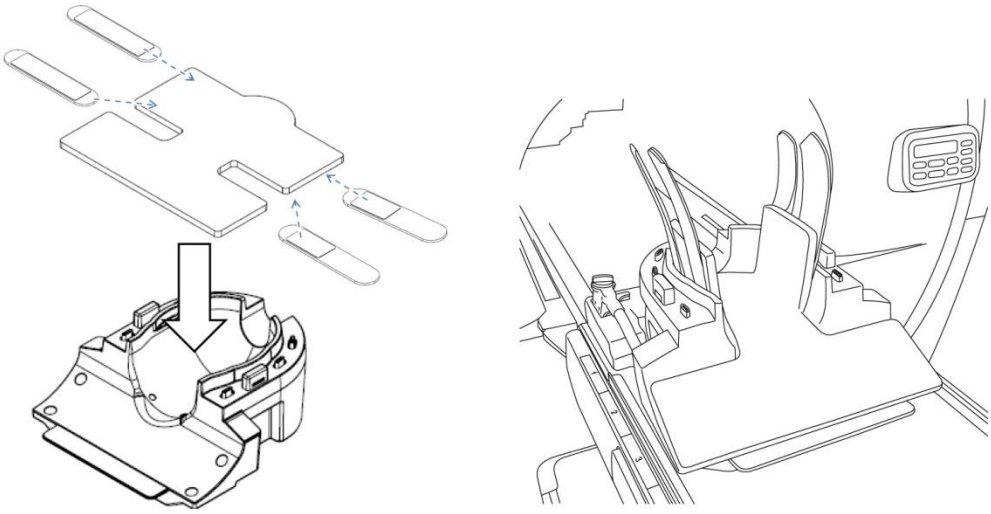
Position the Neck, Shoulder, and Head Pads



Combo pad

The combo pad is attached to the base coil using Velcro fasteners. If the combo pad straps are attached to the combo pad, the patient's head can be immobilized.

Position the Combo Pad



5.3 Choosing the Coil Elements Used for Imaging

5.3.1 Head/Neck Base with NV Adaptor

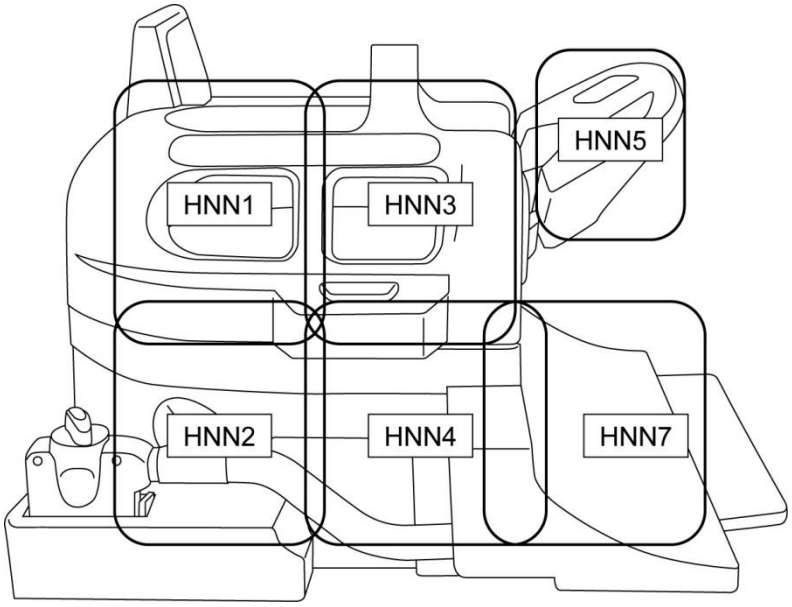
Coil name to select: Atlas Head Neck

The positional relationships between the coil sections displayed in the coil selection window and the actual coil sections are shown in the figures below.

HNN1 to HNN5, and HNN7 are coil section names.

Coil Sections

Location of Coil Elements



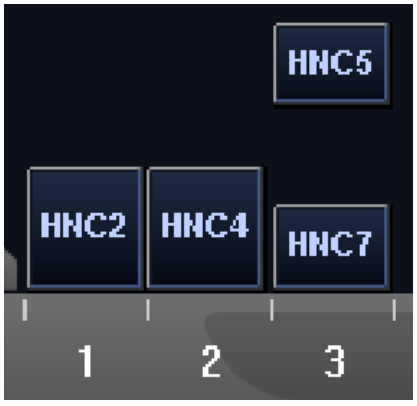
5.3.2 Head/Neck Base with Cervical Adaptor

Coil name to select: Atlas Cervical

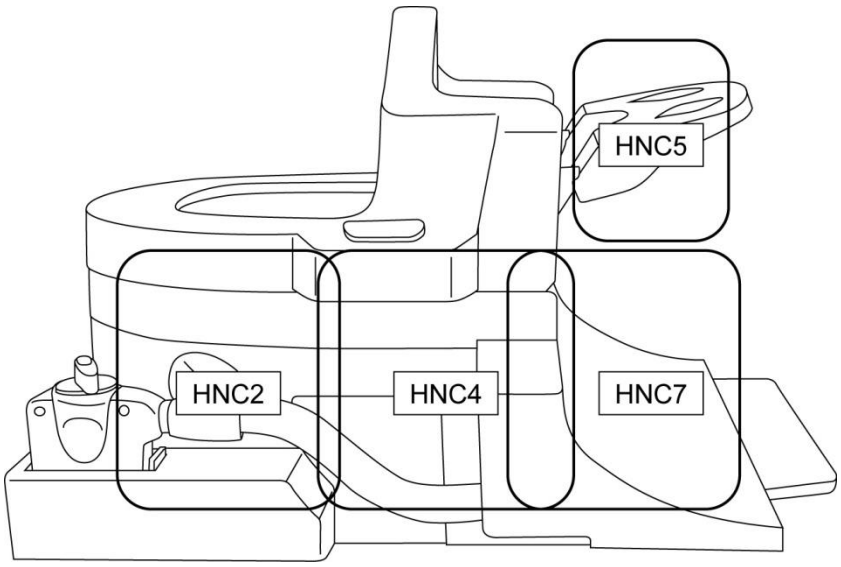
The positional relationships between the coil sections displayed in the coil selection window and the actual coil sections are shown in the figures below.

HNC2, HNC4, HNC5, and HNC7 are coil section names.

Coil Sections



Location of Coil Elements



5.3.3 Head/Neck Base with Base Adaptor

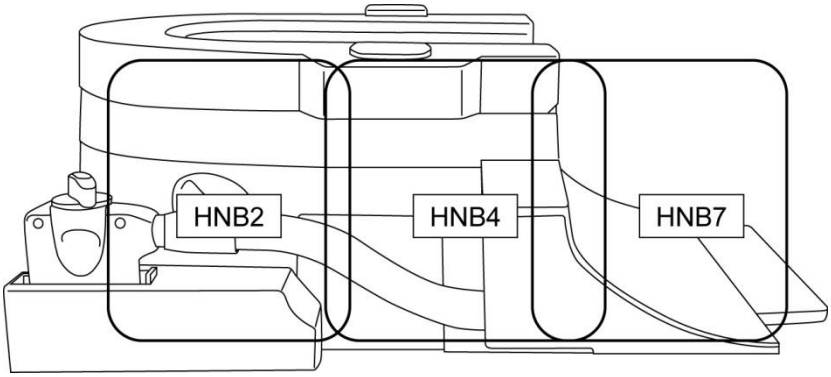
Coil name to select: Head Neck Base

The positional relationships between the coil sections displayed in the coil selection window and the actual coil sections are shown in the figures below.

HNB2, HNB4 and HNB7 are coil section names.

Coil Sections

Location of Coil Elements

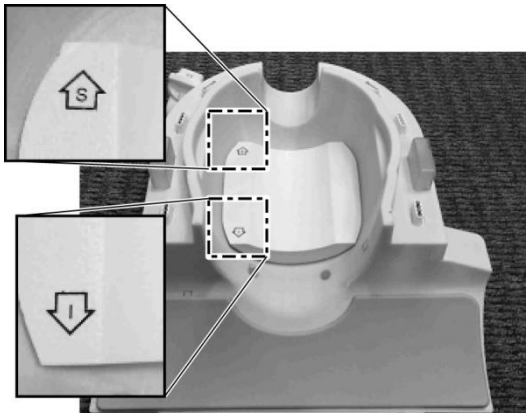


5.4 ACR Phantom Holder

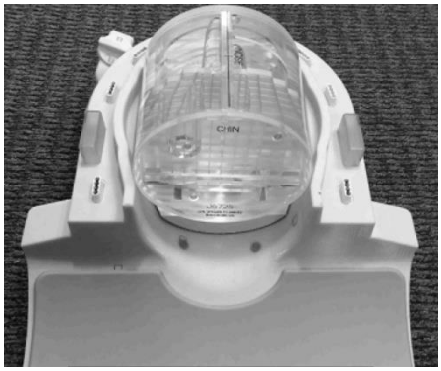
Position the ACR phantom holder as shown below to use the ACR phantom.

Position the ACR Phantom

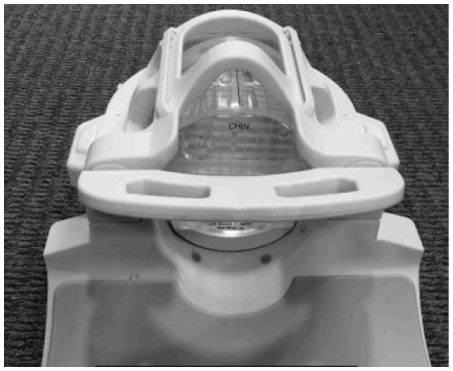
Position the ACR Phantom Holder



Position the ACR Phantom



Attach the Adaptor



5.5 Patient Positioning and Scanning

This RF coil is intended to be used for imaging the head and neck using the NV Adaptor, Cervical Adaptor, or Base Adaptor, discussed previously. Instructions for use with each anatomy and adaptor 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.

5.5.1 Patient Positioning for Head and Neck Imaging with NV Adaptor

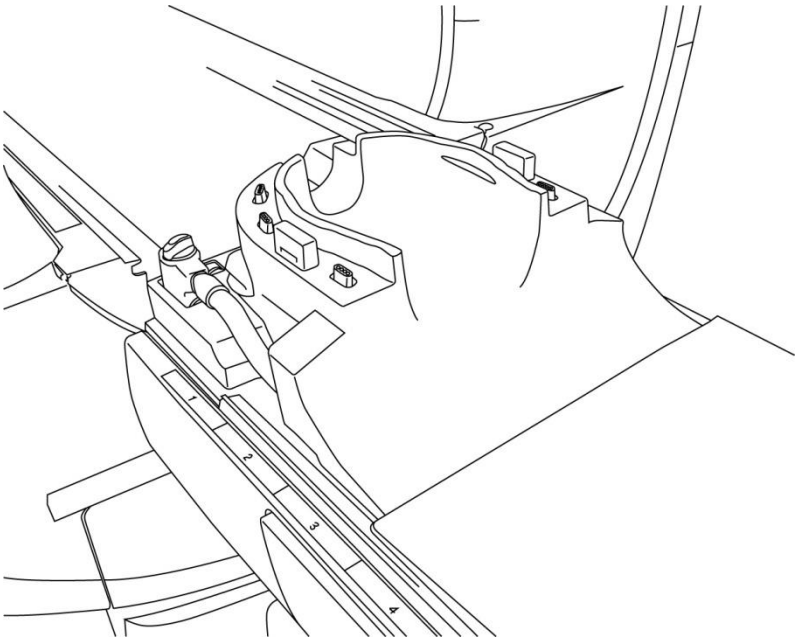
(1) Lower the patient couch to the lowest position.

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

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

(3) Place the mats supplied with the system on the couchtop as required and place the Head/Neck coil on the couchtop.

Position the System Mats and Coil

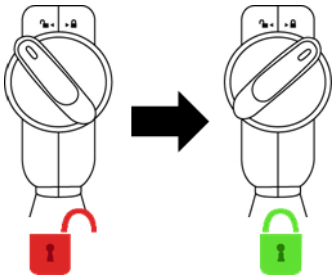


(4) Connect the connectors of the Head/Neck base cables to port A1 on the couchtop.

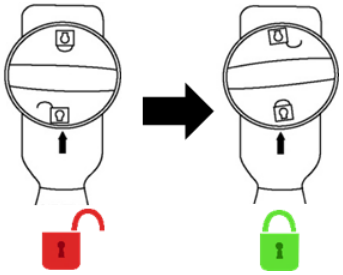
CAUTION

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.

1.5T



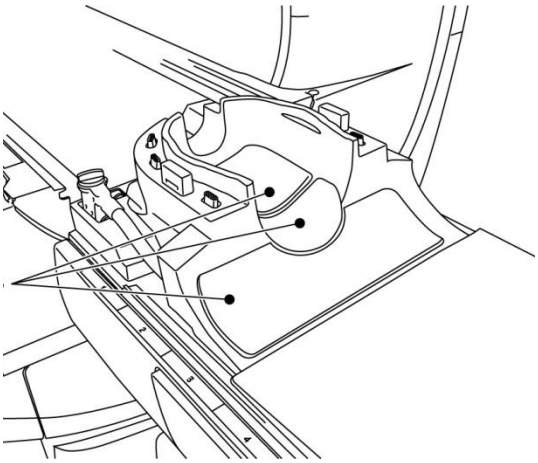
3T



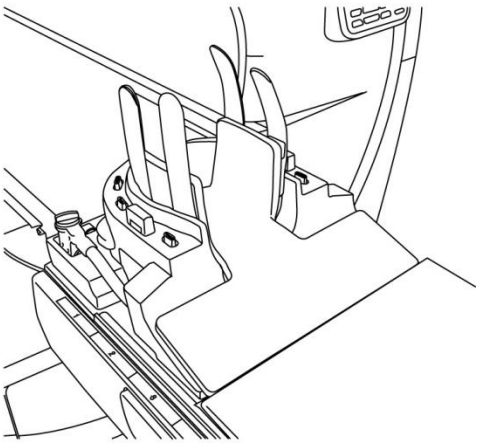
(5) Place the pads on the coil.

Position the Pads

Pad Placement when Head, Neck, and Shoulder Pads are Used



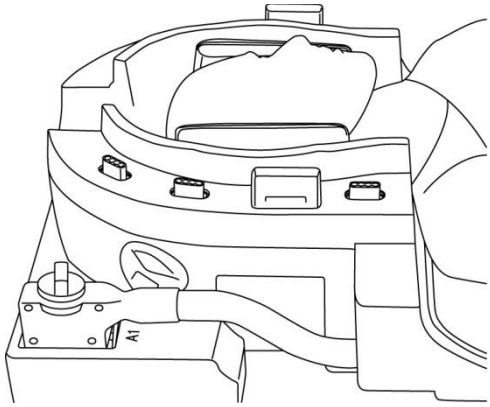
Pad Placement when the Combo Pad is Used



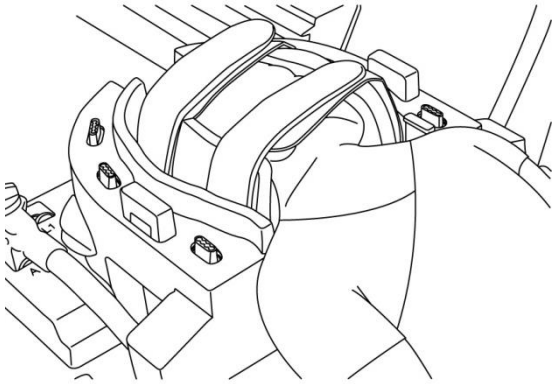
(6) Position the patient's head in the coil.

Position Patient's Head

Patient Position when Head, Neck, and Shoulder Pad are Used



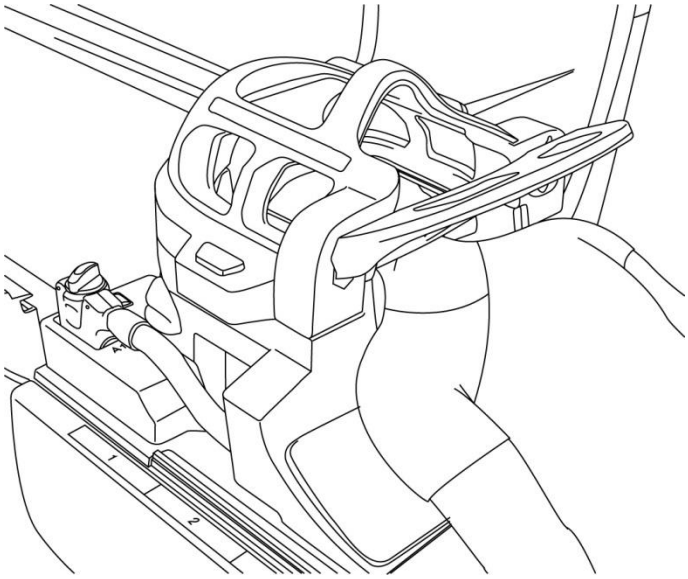
Patient Position when the Combo Pad is Used



(7) Insert a Tapered pad as needed.

(8) Attach the NV adaptor to the Head/Neck base.

Attach the NV Adaptor



⚠ CAUTION	1. Be careful not to pinch the patient's ears, hair, etc. between the NV adaptor and Head/Neck base.

2. Confirm that the patient's cheeks, chin, etc. are not in direct contact with the internal cover of the coil. If contact cannot be avoided, place pads between the patient and the coil internal cover to ensure a distance of at least 10 mm between the patient and the coil. Direct contact with the coil may cause a burn injury due to current induced by the high-frequency magnetic field.

3. When adjusting the mirror position, be careful not to allow the mirror to fall onto the patient's face. The mirror could come loose and fall during adjustment.

(9) Position the patient and coil, and adjust the couchtop position so that the target region is at the center of the magnetic field.

CAUTION

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

(10) Operate the MRI system to move the patient and coil into the gantry.

(11) Enter the scan conditions; refer to the operation manual for the MRI system.

Select "Atlas Head Neck" for RF coil.

(12) Select the coil sections of Atlas Head Neck.

Select Coil Sections for Head Scanning with NV Adaptor

If scanning using the Atlas SPEEDER Head/Neck and other coils is performed simultaneously, section 1 (HNN1) and section 2 (HNN2) must not be selected. The SNR is reduced if scanning is performed with these sections selected.

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

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

(15) Remove the patient from the couch.

(16) Clean and store the coil in the specified location as necessary.

i	Refer to the MR system operation manual for full scanning and system operation procedures and safety information.

5.5.2 Patient Positioning for Foot Imaging with NV Adaptor

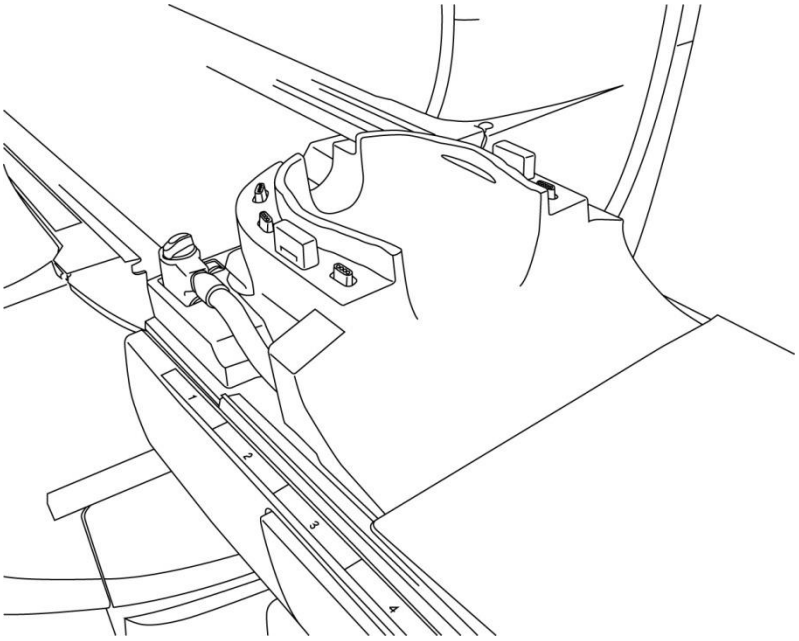
(1) Lower the patient couch to the lowest position.

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

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

(3) Place the mats supplied with the system on the couchtop as required and place the Head/Neck coil on the couchtop.

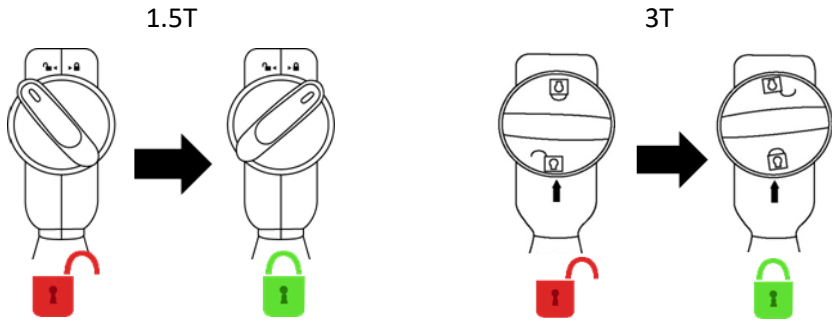
Position the System Mats and Coil



(4) Connect the connectors of the Head/Neck base cables to ports A1 on the couchtop.

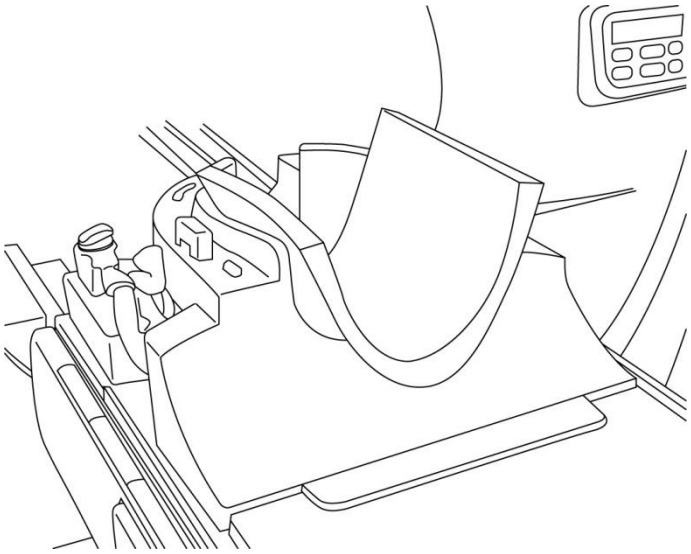
CAUTION

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.



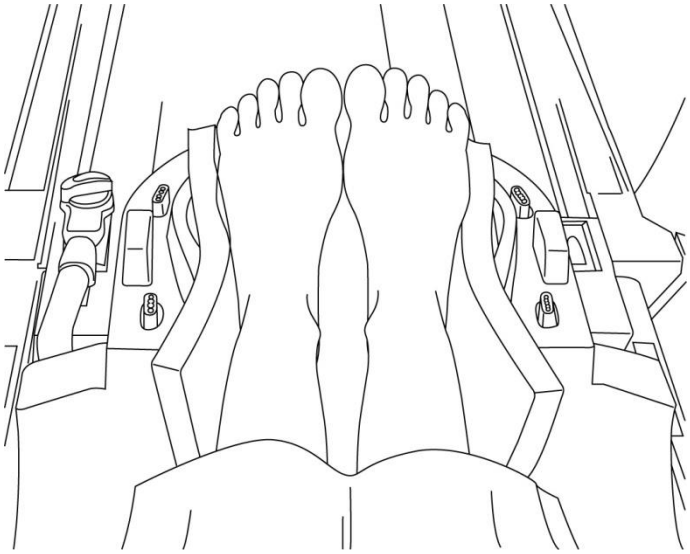
(5) Place coil or MR system pads or mats in the coil as needed, for example, Patient Pads for Head and Neck (MBPP-1501/S1) and Patient Pads for Spine and Extremities (MBPT-1503/S1) (System option).

Position the Pads



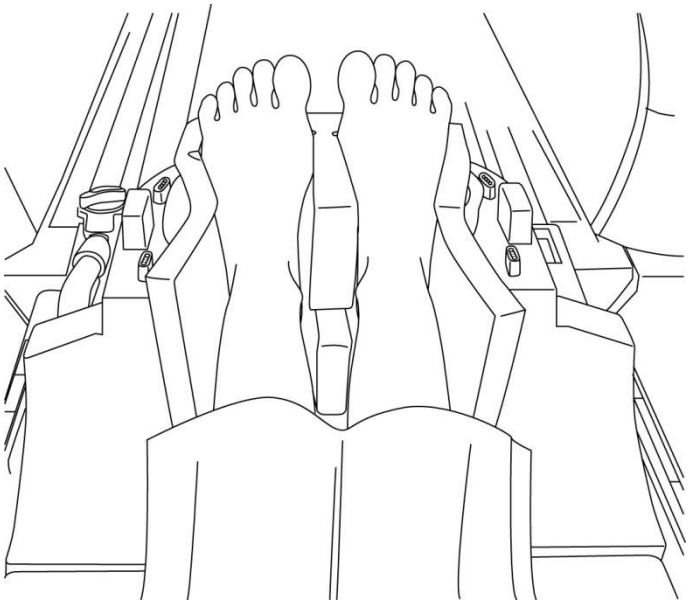
(6) Position the patient's feet in the coil.

Position Patient's Feet



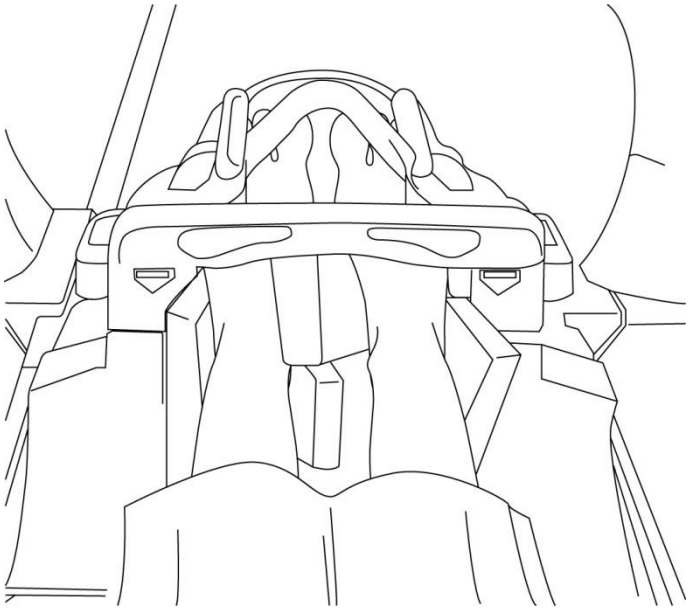
(7) Place small coil or MR system pad between patient's feet.

Separate Feet with Pad



(8) Attach the NV adaptor to the Head/Neck base.

Attach the NV Adaptor



CAUTION

1. Be careful not to pinch the patient's toes between the NV adaptor and Head/Neck base.

2. Confirm that the patient's feet are not in direct contact with the internal cover of the coil. If contact cannot be avoided, place pads between the patient and the coil internal cover to ensure a distance of at least 10 mm between the patient and the coil. Direct contact with the coil may cause the patient to sustain a burn injury due to current induced by the high-frequency magnetic field.

(9) Position the patient and coil, and adjust the couchtop position so that the target region is at the center of the magnetic field.

CAUTION

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

(10) Operate the MRI system to move the patient and coil into the gantry.

(11) Enter the scan conditions; refer to the operation manual for the MRI system.

Select "Atlas Head Neck" for RF coil.

(12) Select the coil sections of Atlas Head Neck.

Select Coil Sections for Feet Scanning with NV Adaptor

If scanning using the Atlas SPEEDER Head/Neck and other coils is performed simultaneously, section 1 (HNN1) and section 2 (HNN2) must not be selected. The SNR is reduced if scanning is performed with these sections selected.

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

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

(15) Remove the patient from the couch.

(16) Clean and store the coil in the specified location as necessary.

i	Refer to the MR system operation manual for full scanning and system operation procedures and safety information.

5.5.3 Patient Positioning for Neck Imaging with Cervical Adaptor

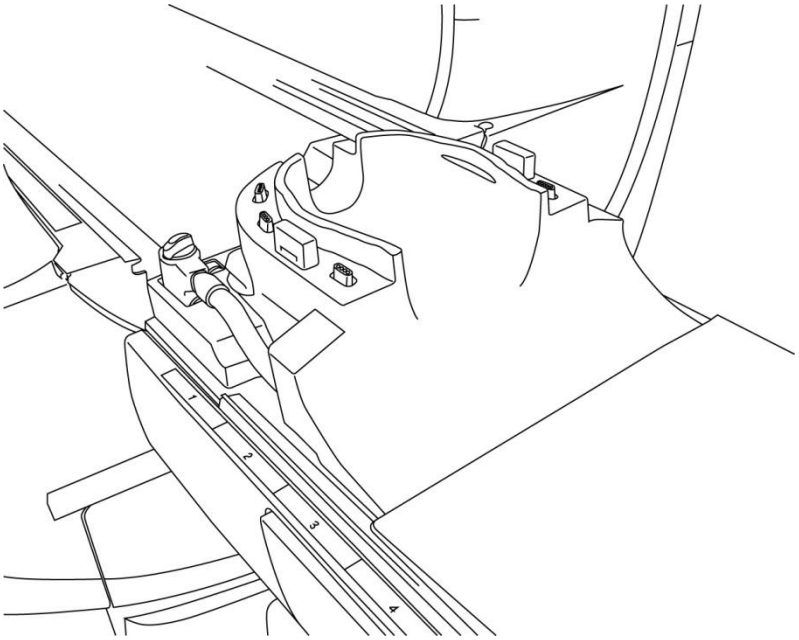
(1) Lower the patient couch to the lowest position.

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

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

(3) Place the mats supplied with the system on the couchtop as required and place the Head/Neck coil on the couchtop.

Position the System Mats and Coil

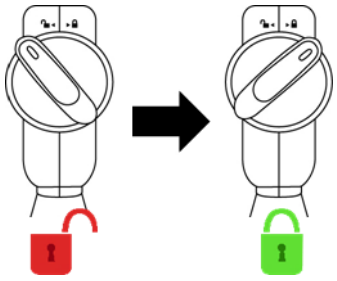


(4) Connect the connectors of the Head/Neck base cables to ports A1 on the couchtop.

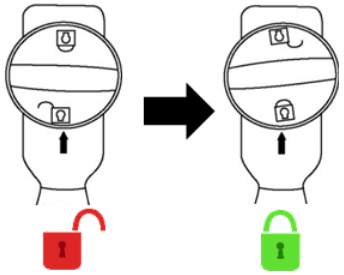
CAUTION

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.

1.5T



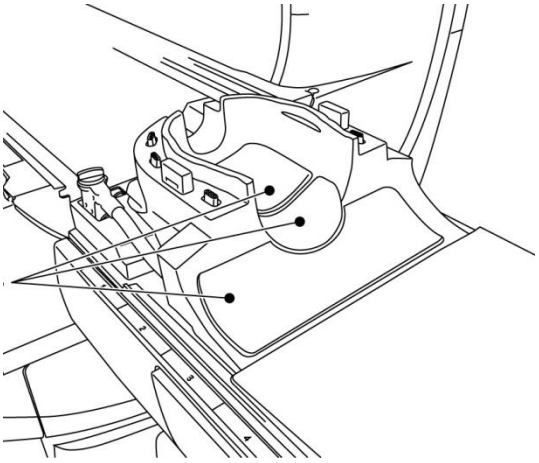
3T



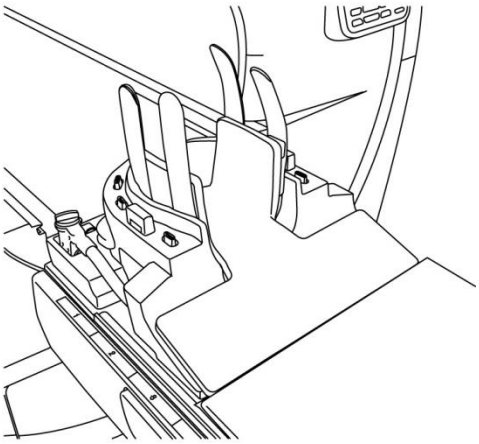
(5) Place the pads on the coil.

Position the Pads

Pad Placement when Head, Neck, and Shoulder Pads are Used



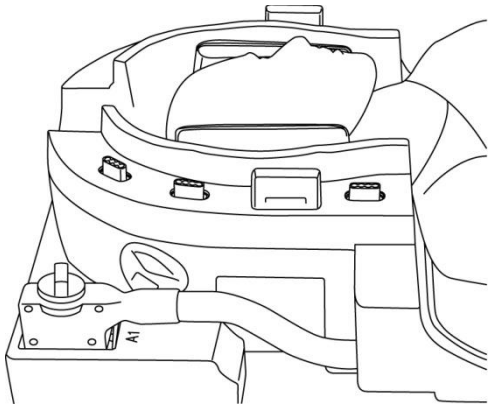
Pad Placement when the Combo Pad is Used



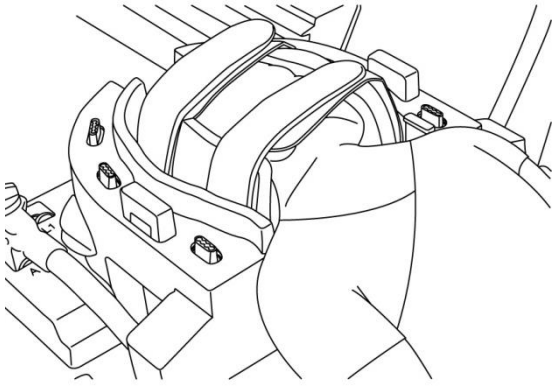
(6) Position the patient's head in the coil.

Position Patient's Head

Patient Position when Head, Neck, and Shoulder Pad are Used



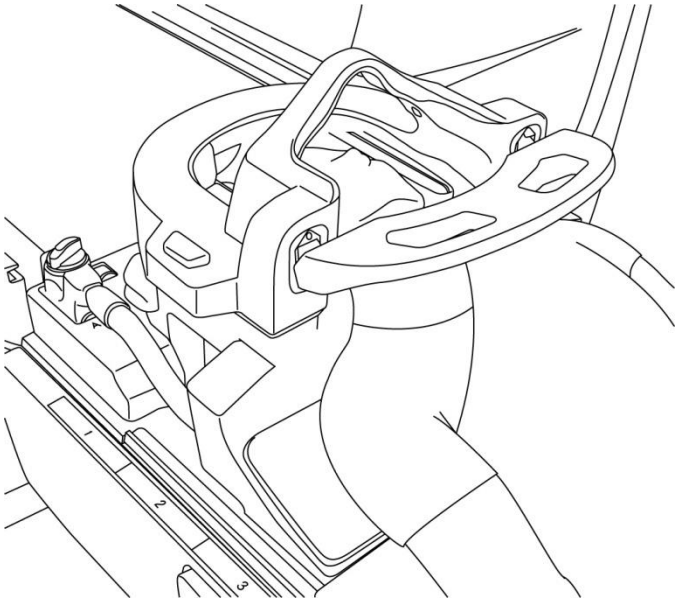
Patient Position when the Combo Pad is Used



(7) Insert a Tapered pad as needed.

(8) Attach the Cervical adaptor to the Head/Neck base.

Attach the Cervical Adaptor



CAUTION

1. Be careful not to pinch the patient's ears, hair, etc. between the Cervical adaptor and Head/Neck base.

2. Confirm that the patient's cheeks, chin, etc. are not in direct contact with the internal cover of the coil. If contact cannot be avoided, place pads between the patient and the coil internal cover to ensure a distance of at least 10 mm between the patient and the coil. Direct contact with the coil may cause a burn injury due to current induced by the high-frequency magnetic field.

(9) Position the patient and coil, and adjust the couchtop position so that the target region is at the center of the magnetic field.

CAUTION

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

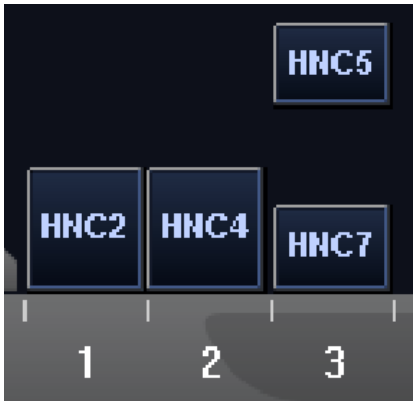
(10) Operate the MRI system to send the patient and coil into the gantry.

(11) Enter the scan conditions; refer to the operation manual for the MRI system.

Select "Atlas Cervical" for RF coil.

(12) Select the coil sections of Atlas Cervical.

Select Coil Sections for Head Scanning with Cervical Adaptor



If scanning using the Atlas SPEEDER Head/Neck and other coils is performed simultaneously, section 2 (HNC2) must not be selected. The SNR is reduced if scanning is performed with this section selected.

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

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

(15) Remove the patient from the couch.

(16) Clean and store the coil in the specified location as necessary.

i	Refer to the MR system operation manual for full scanning and system operation procedures and safety information.

5.5.4 Patient Positioning for Head Imaging with Base Adaptor

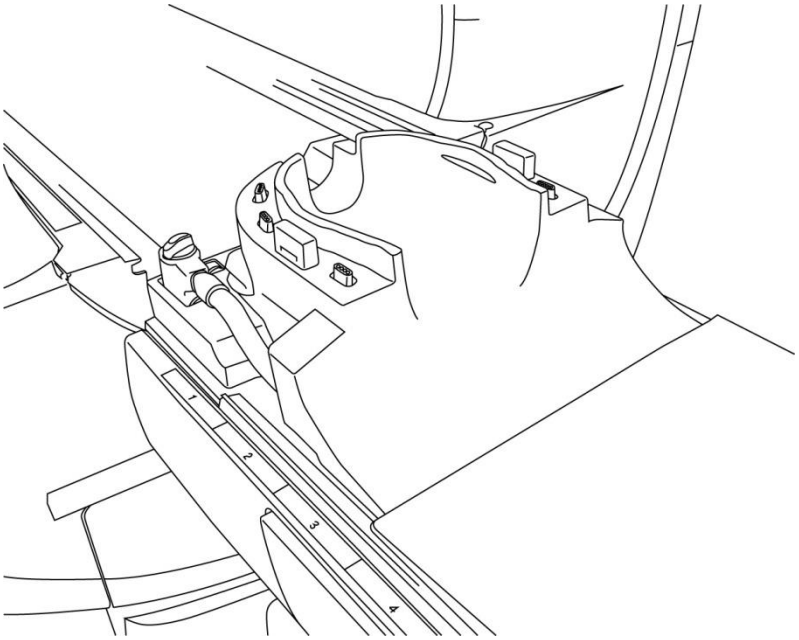
(1) Lower the patient couch to the lowest position.

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

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

(3) Place the mats supplied with the system on the couchtop as required and place the Head/Neck coil on the couchtop.

Position the System Mats and Coil

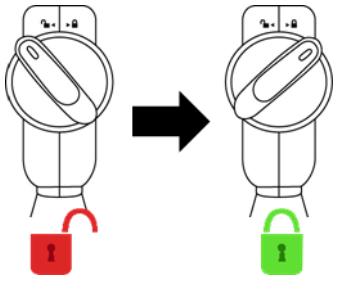


(4) Connect the connectors of the Head/Neck base cables to ports A1 on the couchtop.

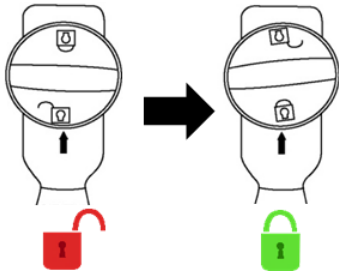
CAUTION

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.

1.5T

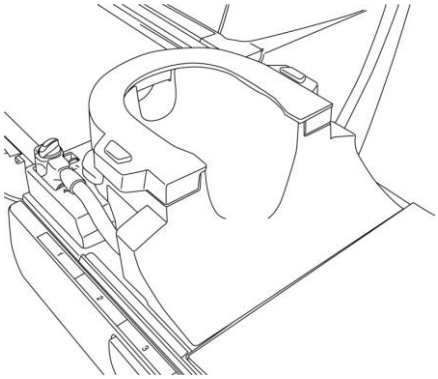


3T



(5) Attach the Base adaptor to the Head/Neck base.

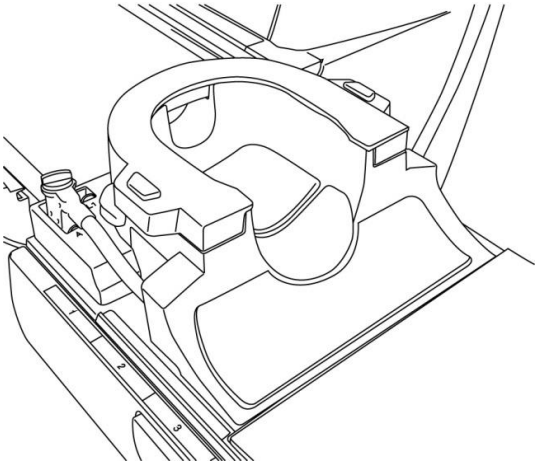
Attach Base Adaptor



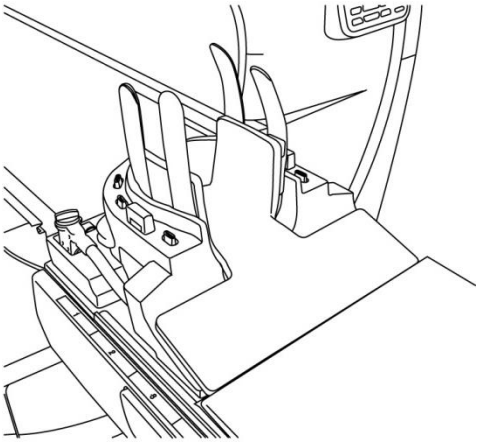
(6) Place the pad in the coil.

Position the Pads

Pad Placement when Head, Neck, and Shoulder Pads are Used



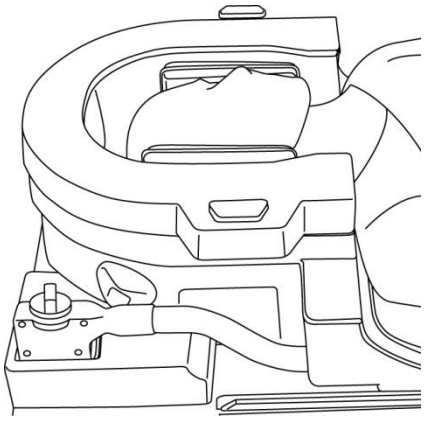
Pad Placement when the Combo Pad is Used



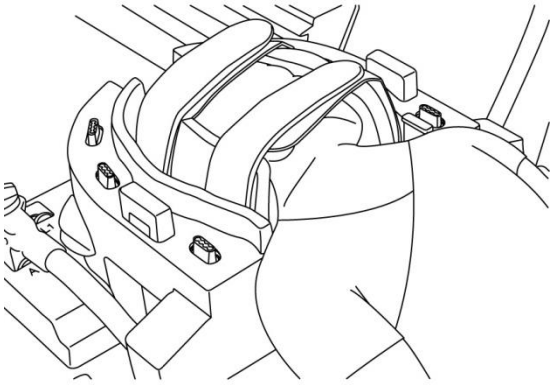
(7) Position the patient's head in the coil.

Position Patient's Head

Patient Position when Head, Neck, and Shoulder Pad are Used



Patient Position when the Combo Pad is Used



(8) Insert a Tapered pad as required.

CAUTION

1. Be careful not to pinch the patient's ears, hair, etc. between the Base Cover and Head/Neck base.

2. Confirm that the patient's cheeks, chin, etc. are not in direct contact with the internal cover of the coil. If contact cannot be avoided, place pads between the patient and the coil internal cover to ensure a distance of at least 10 mm between the patient and the coil. Direct contact with the coil may cause a burn injury due to current induced by the high-frequency magnetic field.

(9) Position the patient and coil, and adjust the couchtop position so that the target region is at the center of the magnetic field.

CAUTION

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

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

(11) Enter the scan conditions referring to the operation manual for the MRI system.

Select "Head Neck Base" for RF coil.

(12) Select the coil sections of Head Neck Base.

Select Coil Sections for Head Scanning with Base Cover

If scanning using the Atlas SPEEDER Head/Neck and other coils is performed simultaneously, section 2 (HNB2) must not be selected. The SNR is reduced if scanning is performed with this section selected.

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

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

(15) Remove the patient from the couch.

(16) Clean and store the coil in the specified location as necessary.

i	Refer to the MR system operation manual for full scanning and system operation procedures and safety information.

Chapter 6 – Cleaning, Maintenance, Service, and Disposal

6.1 Cleaning the RF Coil

CAUTION

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

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

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

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

6.2 Maintenance

No regularly scheduled maintenance is required for the RF coil.

6.3 Service

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

6.4 Disposal

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

6.5 Expected Service Life

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

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

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

7.1 Classification

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

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

7.2 Environment and Compatibility

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

CAUTION

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

7.3 Electromagnetic Emission

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

7.4 Electromagnetic Immunity

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

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

CE 2797

UK CA 0086

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Mayfield Village, OH 44143
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