Operator's Manual

Ankle Array Coil

ANKLE ARRAY
RECEIVE-ONLY COIL

OM118SI01
Revision 1 (03/9/17) AH

FOR USE WITH SIEMENS 8-CHANNEL
1.5 TESLA AERA/AVANTO/ESPREE/SYMPHONY
AND
3.0 TESLA TRIO/SKYRA/PRISMA/VERIO SYSTEMS

Applicable Models:

118SI1501 118SI3001

ScanMed®
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Licenses and Trademarks
The ScanMed® Logo is a registered trademark of ScanMed, LLC.
Aera, Avanto, Espree, Symphony, Trio, Skyra, Prisma, Verio, and the Siemens logo are registered trademarks of the Siemens Healthcare Company.

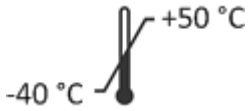
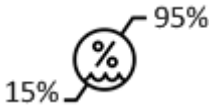
Proper performance of this coil is warranted only on the system software for which it was specified at the time of purchase. Software or firmware upgrades may affect compatibility and performance. Please contact your Siemens representative and ScanMed representative prior to operating on new software, as failure to do so may void your warranty.

CAUTION:  **Federal law restricts this device to sale, distribution, and use by or on the order of a physician**.

Transportation/Storage Conditions:

Please store the coil on a flat surface and do not wrap the cable into the coil itself. Cable damage can result from excessive bend radii.

Transport and store this product under the following environmental conditions only, for a period not exceeding two weeks:

	Ambient temperature of -40 °C to +50 °C
	Relative humidity of 15% to 95% (non-condensing)
	Atmospheric pressure of 76.5 kPa to 101 kPa
	Protect from water
	Fragile, handle with care

CONTENTS

EXPLANATION OF SYMBOLS

	Caution/warning, consult accompanying documents
	Attention, consult accompanying documents
	Type BF applied part
	Class II ordinary equipment, suitable for continuous operation
	For use on specified field strength
	Dispose of the coil by returning to manufacturer or via facility equipped to handle electronic products
	Part number and revision
	Serial number
	Manufacturer name, address, and date of manufacture

1.0 INTRODUCTION

DESCRIPTION 1-1

The Ankle Coil interfaces with the SIEMENS 1.5T or 3.0T MRI systems and has been designed to collect image data throughout the region of the ankle. This eight-channel design incorporates a set of unique antenna elements whose geometry has been optimized to image this anatomy. The design is “recognized” as a receive-only coil on the SIEMENS system. The coil form geometry has been formed to facilitate close coupling of the imaging coil's region-of-sensitivity to the anatomy of interest.

INDICATIONS FOR USE 1-2

The indications for use for this coil are as follows.

- Soft tissue and bone imaging of the ankle as allowed by the MRI system.
- Magnetic resonance peripheral angiography.

APPLICABLE MODELS 1-3

This manual applies to the following models of the Elbow Array Coil.

Model	MRI System Compatibility
118SI1501	1.5T Siemens Aera, Avanto, Espree, Symphony
118SI3001	3.0T Siemens Trio, Skyra, Prisma, Verio

Your coil is supplied with the following accessories.

Quantity	Part Number	Description
1	PAD00014	Patient Comfort Pad

2.0 INSTALLATION

SETUP 2-1

The Ankle coil is plug-and-play and will be automatically recognized by the MRI system. Please contact ScanMed for assistance if you have questions or the coil is not recognized. Please follow the QA procedure in Section 4 to verify the coil is working properly and establish the baseline SNR specific to your system and setup.

3.0 OPERATION

CAUTION: **Remove any other coil or unused accessory device from the magnet before using the coil. Unconnected coils may cause patient burns.**

CAUTION: **Do not attempt to scan with the coil disconnected or unplugged from the scanner. Patient burns may result.**

The patient should be in the supine position, feet-first into the magnet. The orientation of the coil is such that the cable end of the coil enters the bore first (do not loop the cable to connect to the scanner).

- Place the coil base into the S1 table location. Base should be oriented such that the insertion hole is opposite the extremity to be imaged. Place coil into base and remove anterior section of coil.
- Position patient as required.
- Place the ankle into the coil and attach the anterior coil section. Be sure to fully engage the latching mechanism.
- Secure coil/patient by using the MRI table positioning straps and/or sandbags.

Run the cable in the most direct way to the coil connector port. Plug the connector to the MRI system connector port.

Connect the Ankle Coil to your Siemens MRI system using the table and figures below. For the Aera, Skyra, and Prisma, please contact ScanMed for assistance.

System	Patient	Connectors
1.5T Avanto/Espree	Feet First	Green (X4) nearest magnet
		Green (X4) nearest magnet
1.5T Aera	Feet First	Any single SlideConnect port via TIM Box and custom coil config
3T Trio/Verio	Feet First	Green (X4) nearest magnet
		Green (X4) nearest magnet
3T Skyra/Prisma	Feet First	Any single SlideConnect port via TIM Box and custom coil config

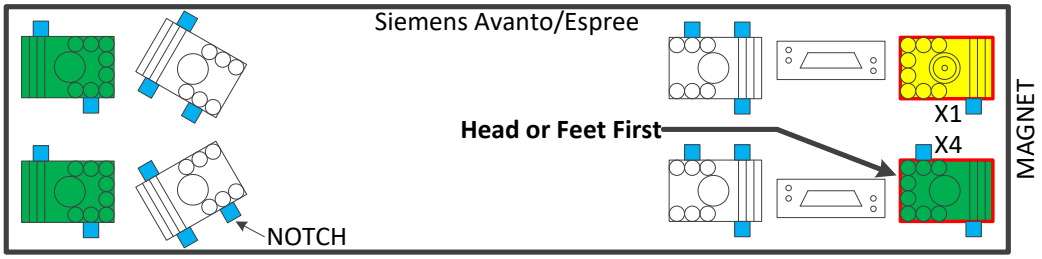


Figure 5: Top view of Siemens Avanto/Espree patient table diagram.

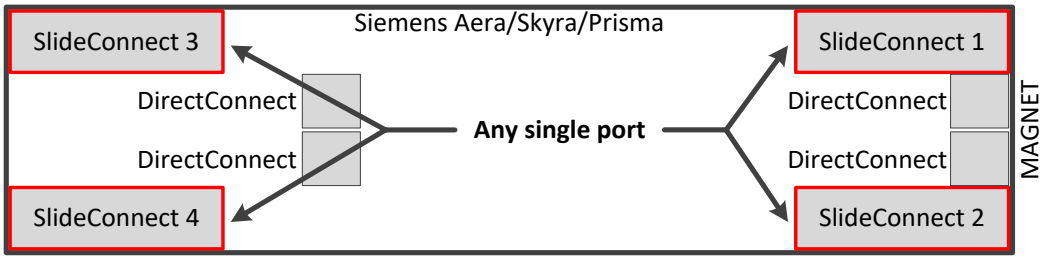


Figure 6: Top view of Siemens Aera/Skyra/Prisma patient table diagram.

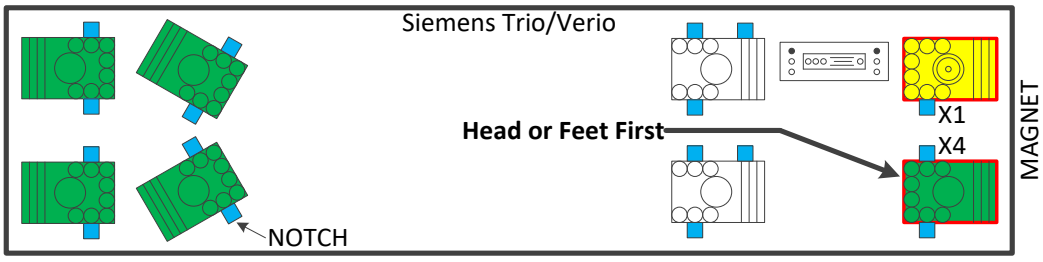


Figure 7: Top view of Siemens Trio/Verio patient table diagram.

CAUTION: **Do not allow the cable to loop or contact the patient as this could create an RF burn hazard.**

CAUTION: **Do not use the coil if tears are present in the foam covering. Return the coil to the manufacturer for repair and/or replacement.**

CAUTION: **Do not use the coil if the cable jacket is torn or ripped, or if metal is exposed. Return the coil to the manufacturer for repair and/or replacement.**

Landmark on the anatomy positioned within the coil volume.

COIL SELECTION 3-3

Select the coil by deselecting the spine elements and turning on the surface coil elements in system tab. You can save these settings later so that you do not have to repeat every time.

OPERATION 3-4

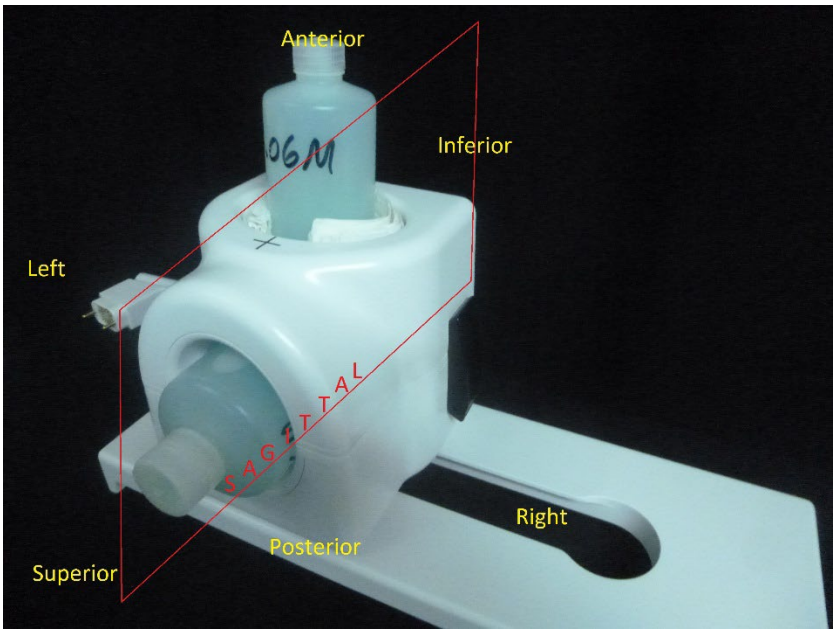
Note that the coil will provide imaging data throughout the entire length of the coil with proper coil selection.

4.0 QUALITY ASSURANCE

Select a phantom to fill the volume of the coil as best as possible to ensure that all elements are providing signal.

Arrange the chosen phantom as shown below. Landmark at the center of the coil for a 3 plane localizer and perform an initial QA of the coil assembly. Run the sequence as follows, prescribing 3 slices as outlined in Figure 9:

Scan plane: Axial	Pulse Sequence: TSE
Base Resolution: 256	Phase Resolution: 70%
Turbo Factor: 3	Phase Oversampling: 0%
AVG: 1	TR/TE: 500/14
Slice Thickness: 5	Slice Groups: 1
FOV: 300 mm	BW: 122 Hz/Px
Phase Direction: A/P	No Filters or Normalizing



Run a sagittal sequence through the center of the coil.

After the acquisition, perform the following steps.

1) Place a 3 square centimeter ROI in the center of the phantom. Record the Signal mean below
2) Place another 3 square centimeter ROI in the top right corner of the image. And record the Standard deviation below
3) Calculate the SNR by completing Table 2

ROI	Parameter	Value	
1	Signal Mean (m)		Box A
2	Standard Deviation (sd)		Box B

Table 1: Initial Measurement Values

ROI	Calculation	Calculated Value (SNR Ratio)	Specification Value
1	Box A divided by Box B		

Table 2: Initial SNR Values

Refer back to these numbers and periodically repeat the measurement as a quality assurance test or if you suspect problems with the coil. If QA test results produce a value less than the specification value, call ScanMed® Technical Support at (402) 934-2650 for further instructions.

Periodic QA Checks		
Date	**SNR Value**	**Percent Deviation (Column 2 ÷ C)**

5.0 SAFETY

Patient safety and comfort must be your primary concern during the scanning procedure. Always follow proper safety procedures to ensure patient safety.

CAUTION: **Remove any other coil or unused accessory device from the magnet before using the coil. Unconnected coils may cause patient burns.**

CAUTION: **Do not attempt to scan with the coil disconnected or unplugged from the scanner. Patient burns may result.**

CAUTION: **Do not allow the cable to loop or contact the patient as this could create an RF burn hazard.**

Route cables in the most direct way possible, without forming loops. Place cables under a cushion whenever possible, and keep them from contacting the patient.

CAUTION: **Do not use the coil if tears are present in the fabric covering. Return the coil to the manufacturer for repair and/or replacement.**

CAUTION: **Do not use the coil if the cable jacket is torn or ripped, or if metal is exposed. Return the coil to the manufacturer for repair and/or replacement.**

WARNING: **No modification of this device is allowed. Do not modify this equipment with authorization from ScanMed.**

Under NO circumstance should this coil ever be picked up, held, or maneuvered by the cable.

WARNING: Do not scan patients who have MRI incompatible implants, metallic fragments, or other contraindications. Refer to your MRI system manufacturer's safety information.

The operator should be aware of the following contraindications for use related to the strong magnetic field of the MR system:

- Scanning is contraindicated for patients who have electrically, magnetically or mechanically activated implants (for example, cardiac pacemakers), because the magnetic and electromagnetic fields produced by the MR device may interfere with the operations of these devices.
- Scanning patients with intercranial aneurysm clips is contraindicated.

Precautions should be taken when scanning patients with the following conditions:

- A greater than normal potential for cardiac arrest.
- An increased likelihood for developing seizures or claustrophobia.
- Unconscious, heavily sedated, confused patients or those with whom no reliable communications can be maintained.

The following general caution statements apply to scanning with a magnetic resonance system. For further details, review the cautions/warnings included in your MR system operations manual.

- Cables should not be looped or crossed. Arcing and patient burns could result.
- Route all cables so that they do not contact the patient.
- Patients with ferromagnetic metal should not be scanned, because the magnetic field may interact with implanted surgical clips or other ferromagnetic materials.
- The safety of scanning fetuses has not been established.
- Persons with cardiac pacemakers or other implanted electronic devices should not enter the magnetic field delineated by the system's manufacturer.
- There is a risk to scanning feverish or decompensated cardiac patients.

- Facial makeup should be removed before scanning because many eye makeups contain metal flakes which can cause skin and eye irritation. Permanent eyeliner tattoos may cause eye irritation due to the presence of ferromagnetic particles.
- Patients who work in environments in which there is a risk of having embedded metallic fragments in or near the eye should be carefully screened before having an MR exam.

EMERGENCY PROCEDURES 5-4

In the unlikely event that a coil creates smoke, sparks or makes an unusually loud noise or if the patient requires emergency assistance:

- Stop the scan if one is in progress.
- Disconnect the coil.
- Remove the coil from the patient.
- Remove the patient from the scan room if medical treatment is needed.

MATERIAL SAFETY INFORMATION 5-5

CAUTION:  **This product contains chemicals, including lead, known to the state of California to cause birth defects or other reproductive harm. Lead solder is present only in internal electronic circuitry and is not present in any outer contact surfaces. Wash hands after handling any internal components.**

6 MAINTENANCE, TROUBLESHOOTING, AND DISPOSAL

- **QA Test**

  Perform a system quality assurance phantom test as outlined in Section 4 of this manual. If the values you obtain do not fall within normal operating parameters, then there may be a problem with the coil. Contact ScanMed service department for assistance.

- **Storage**

  Coils should be stored lying flat and used at the same room temperature as your MR system.

- **Inspection**

  Visually inspect the coil cover and cable assembly for cracks or missing insulation about the copper conductors of either assembly. Check the cable connector for secure fit within the coil housing and also check the electrical contacts on the cable end to ensure that they appear straight. Verifying that connection pins are not bent over before forcing a poor connection will ensure proper electrical connection and prevent further damage.

CAUTION: Do not use a damaged coil. Return the coil to the manufacture for repair if the coil is damaged.

- **Cleaning**

  The coil cover is not completely impermeable. Safeguards should be put in place to minimize its contamination when required. Surface cleaning of the material is the only action allowed using the solutions specified below. If the coil is damaged during cleaning, contact ScanMed for repair. This product contains no user replaceable or serviceable parts. Do not remove the coil cover as this will void your warranty.

  The cleaning solutions listed below have been tested and are recommended for cleaning the coil(s) and pad(s). Spray or pour the cleaning liquid onto a soft cotton cloth and proceed to clean.

  - Warm water: Safe for all areas of the coil or pads.

- Commercial dishwashing liquid solution 1oz/gallon (30ml/liter) of water: Safe for all areas of the coil.
- Alcohol solution (70% isopropyl / 30% water): Do not apply to adhesive backed materials such as labels, decals or Velcro® fasteners.
- Cydex/Lysol: Do not apply to adhesive backed materials such as labels, decals or Velcro® fasteners.

CAUTION:  **Do not spray or pour cleaning liquid directly onto the coil or cables. Apply to a soft cotton cloth and proceed to clean.**

The following is a list of common problems and solutions for those problems. If you cannot solve a problem by following the procedures in the manual, contact ScanMed between the hours of 7:30 AM and 5:30 PM (CT), Monday through Friday to arrange for service/repair. There are no user-serviceable components. All service must be performed by ScanMed or an authorized representative.

- **ScanMed Customer Service**
  9840 South 140th Street, Suite 8
  Omaha, NE 68138 USA
  Tel: +1 (402) 934-2650
  Fax: +1 (402) 778-9699

- **Receiving No Signal**

  Problem: You are scanning and yet receiving no signal.

  Solutions:
  1. Verify that you are transmitting with the body coil and receiving with the imaging coil.
  2. Verify that you have the appropriate coil selected for your scanner (see Section 3-2).
  3. Verify that the cable is correctly connected to the system. The coil cable should be connected to the coil port.
  4. If all of the above check out and you still cannot get a signal, try to scan (transmit and receive) with the body coil. For this test, be sure to remove the imaging coil from the magnet bore before you scan with the body coil. If you still receive no signal the problem probably lies with the MR system. If the body coil scan is satisfactory, there is probably a problem with the ScanMed coil. Contact ScanMed for assistance.

- **Image Quality**

  Problem: The SNR percentage obtained in the periodic quality assurance check is not greater than 85%, or the image quality is not what you expected it should be, given the parameters selected.

  Solutions:
  1. Review the selected protocol.

2. Verify that there are no loops in the cables.

3. Verify that there are no metal or magnetic objects close to the coil, patient or magnet (e.g., safety pin, hair pin).

4. Verify that the coil is properly positioned.

5. Verify that your center frequency is within the frequency adjustment range for your system.

- **Artifacts**

Problem: There is a black line or signal void on the image (similar to an artifact seen when metal is present in the scanned area).

Solutions:

1. Verify that there is no metal present in the area being scanned.

2. If the above checks out, it is possible the coil has failed. Call ScanMed.

DISPOSAL 6-3

Dispose of the coil by returning to the manufacturer or through a disposal facility equipped to handle electronic products.

CAUTION: Dispose of RF coil properly.