# OPERATOR MANUAL

## 1.5T & 3.0T 8-Ch Hi-Res Wrist MRI Coil


**Applicable Models: 318SI1501 and 318SI3001**
**UDI: (01)00859193006364(21)xxx (3.0T)**

**Siemens Hi-Res Wrist 8-Channel**
RECEIVE-ONLY MRI COIL

OM318SI01 Rev 2
Release Date: 10/9/2023

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

Approved by: _____ Date: 10/9/2023
Brad de Koning CEO/President

## Licenses and Trademarks

The ScanMed® Logo is a registered trademark of ScanMed, LLC.

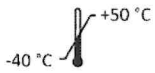
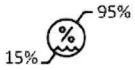
Aera, Avanto, Espree, Trio A Tim, Skyra, Prisma, Verio, and the Siemens logo are registered trademarks of the Siemens Healthcare Company.

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/or ScanMed representative prior to operating the new software, as failure to do so may void your warranty.

## Transportation/Storage Conditions:

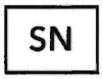
Store the coil on a flat surface. Excessive bending can cause damage to the system cable.

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 |
|  | This side up |

# 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 |
|  | Model number |
|  | 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 |
|  | Medical device |
|  | Do not cross or loop cables. Arcing and patient burns could result. |
|  | Authorized Representative<br>Emergo Europe<br>Westervoortsedijk 60<br>6827 AT Arnhem<br>The Netherlands |

# 1.0 Introduction

This manual describes the safety precautions, features, use and care of the ScanMed LLC, SI (Siemens) 1.5T and 3.0T Hi-Resolution Wrist 8-channel coil. This coil is compatible with the 1.5T Aera, Avanto, Espree and 3.0T Trio A Tim, Skyra, Prisma and Verio systems.

If you have any questions or comments about this manual, or need any assistance with the use of this product, please contact ScanMed, LLC:

**+1 (402) 934-2650**

**Email: CustomerService@scanmed.com**

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

# 2.0 Description

The Hi-Resolution Wrist Coil interfaces with the Siemens 1.5T or 3.0T MRI systems as listed above. It has been designed to collect image data throughout the region of the wrist.

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.

Cable Assembly

The cable is identified to connect to its respective receiving port of the MRI scanner. Connect the Wrist coil to the MRI system as directed by the MRI system manual.

## Coil Specifications (Not Including Base)

| | US Measurements | Metric Measurements |
|---|---|---|
| Height: | 4.725" | 120mm |
| Width: | 8.2" | 208.3mm |
| Full Length | 14.125" | 35.9mm |
| Weight: | 8.5 lb. (pounds) | 3.85kg |

## Base Specifications

| System | Part Number | Height (US/Metric) | Width (US/Metric) | Length (US/Metric) |
|---|---|---|---|---|
| Skyra/Prisma | ASYHOU00060+R | 2.23" / 56.65mm | 7.9" / 200.0mm | 20.9" / 531.4mm |
| Avanto/Verio | ASYHOU00057+R | 2.23" / 56.65mm | 7.9" / 200.0mm | 21.0" / 534.7mm |
| All Systems (Supine-Short Base) | ASYHOU00058+R | 2.23" / 56.65mm | 7.9" / 200.0mm | 10.0" / 254.0mm |

The approximate weight of the short base (10" long (US) / 25.4cm metric)) is 24oz (US) / 680.4g (metric).

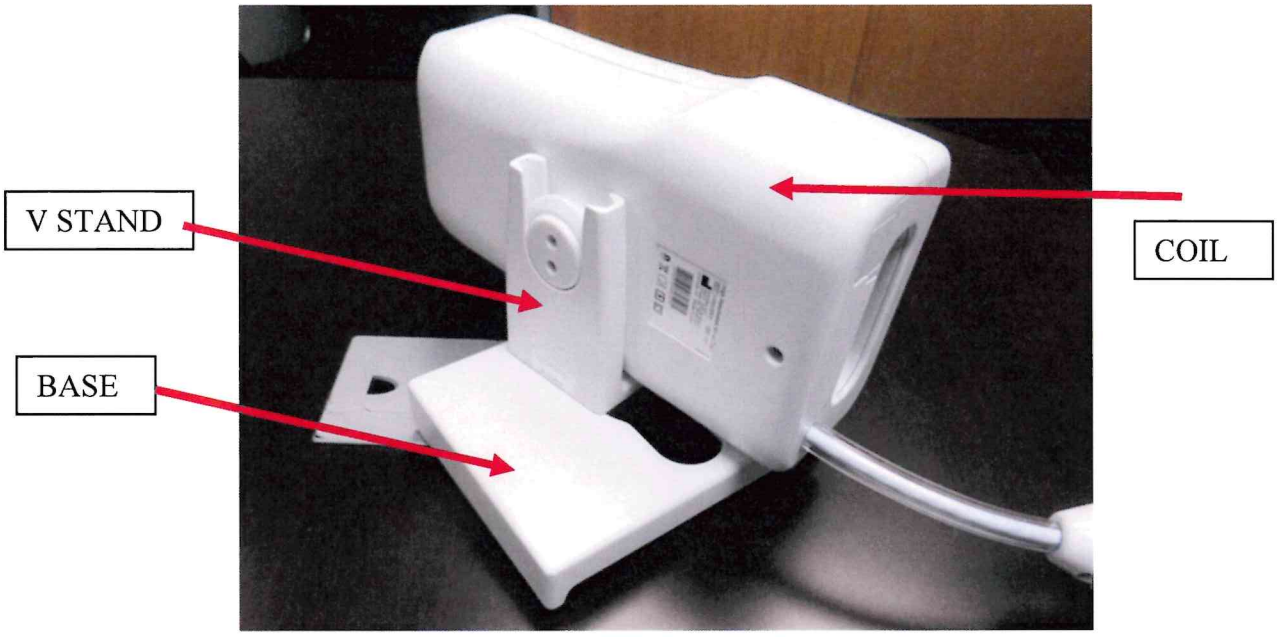
The approximate weight of the regular base (21" long (US) / 53.34cm metric) is 13.3oz (US) / 377.05g (metric).

**NOTE:** Not all bases are sent with all coils. Only customer specified system base is sent.

Vertical Stand Specifications (not including base)

Part Number: ASYHOU31X008+R

| | US Measurements | Metric Measurements |
|---|---|---|
| Height: | 6.325" | 160.7mm |
| Width: | 4.0" | 101.6mm |
| Full Length | 4.104" | 104.2mm |
| Weight: | 18oz | 510.3g |




## 3.0 MRI Coil Label and Location

A sample ScanMed Siemens Hi-Resolution (Hi-Res) wrist coil label is shown here, as well as its location on the coil itself.


## 4.0 Intended Purpose

The intended purpose of this 8-Channel Hi-Res Wrist coil is to provide high-quality images of the wrist in an easy-to-position design.

## 5.0 Indications for Use

Indications for use for this coil are as follows.

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

The coil is indicated for use by the order of a physician to be used as an accessory to its approved OEM-specific magnetic resonance scanner for the human wrist. These images, when interpreted by a trained physician, may assist in medical diagnosis.

## 6.0 Applicable Models and Coil Selection

The Siemens Hi-Resolution Wrist Coil is compatible with the 1.5T Aera, Avanto, and Espree, as well as the 3.0T Trio A Tim, Skyra, Prisma and Verio systems.

| WARNING:  | **Do not attempt to scan with the coil disconnected or unplugged from the scanner. Patient burns may result. Unconnected coils may cause damage to the coil.** |
|---|---|

Connect the 1.5T/3.0T Siemens 8-Channel Hi-Resolution Wrist coil to the appropriate Siemens MRI system.

## 7.0 Accessories

The following accessories are included with the purchase of the new coil. Replacements may be purchased separately as needed.

| PART NUMBER | DESCRIPTION |
|---|---|
| PAD00015 | Patient Comfort Pad, Top |
| PAD00016 | Patient Comfort Pad, Bottom |
| ASYHOU31X008+R | Vertical Stand |
| ASYHOU00060+R | Skyra/Prisma Base |
| ASYHOU00057+R | Avanto/Verio Base |
| ASYHOU00058+R | Supine – Short Base |

A replacement copy of this Operator Manual may be obtained at no charge by contacting ScanMed at: (402)934-2650 or email customerservice@scanmed.com

## 8.0 Inspection

Visually inspect the coil to ensure the coil and cables are in working order. Evaluate the coil for cracks or broken plastic, missing insulation around the connectors and the cables for missing insulation or damage to the coil cover.

Check the electrical contacts on the cable and the coil to ensure they appear straight, verifying that connection pins are not bent over. Do not force a connection fit, which could cause further damage.

# 9.0 Installation and Storage

## Installation

The Siemens Hi-Res Wrist 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.

**If you experience issues with the installation of this coil, contact:**

**ScanMed, LLC**
**Phone: (402) 934-2650**
**Email:** CustomerService@scanmed.com

## Storage

The Siemens Hi-Resolution Wrist Coil should be stored flat. The cable assembly is not removable and should not be pulled or twisted. The connector at the end of the cable should be protected so the connector pins do not get bent or otherwise damaged. The coil should be stored in an area sufficient to hold and protect the coil from damage or accidental events.

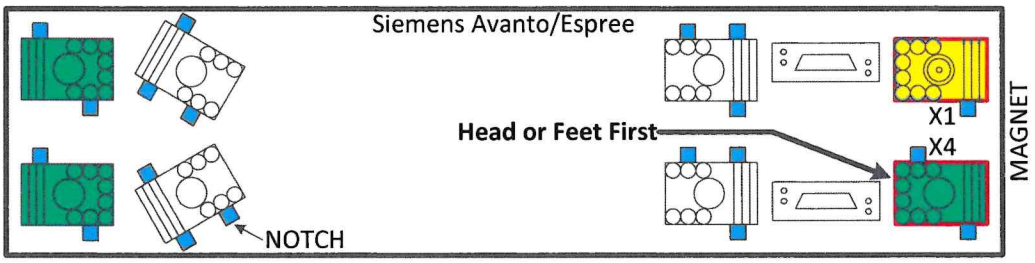
| | |
|---|---|
| **CAUTION:**  | **Do not hang the coil by the cable. Doing this may cause damage to the coil and cable.** |

# 10.0 Operation

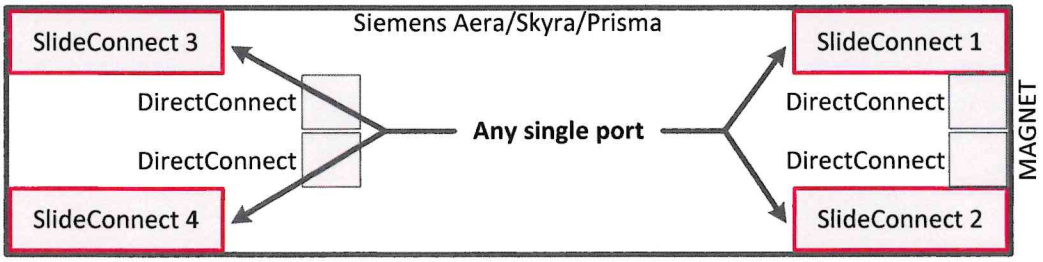
| | |
|---|---|
| **CAUTION:**  | **Remove any other coil or unused accessory device from the magnet before using the coil. Unconnected coils may cause patient burns.** |
| **WARNING:**  | **Do not attempt to scan with the coil disconnected or unplugged from the scanner.**<br><br>**Patient burns may result.** |

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

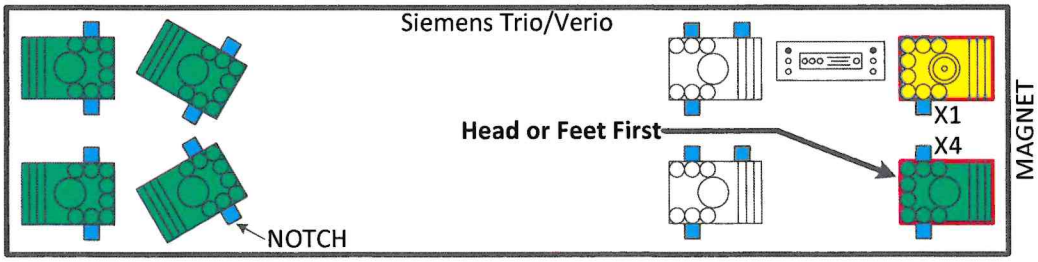
| System | Patient | Connectors |
|---|---|---|
| 1.5T Avanto/Espree | Headfirst | Green (X4) nearest magnet |
| | Feet First | Green (X4) nearest magnet |
| 1.5T Aera | Headfirst | Any single Slide-Connect port via TIM Box and custom coil config |
| | Feet First | |
| 3T Trio/Verio | Headfirst | Green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




*Top view of Siemens Avanto/Espree patient table diagram.*




*Top view of Siemens Aera/Skyra/Prisma patient table diagram.*




*Top view of Siemens Trio A Tim/Verio patient table diagram.*

# 11.0 Positioning

Prone Position

The patient should be head-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).

- Extend the arm above the patient's head and insert the wrist/hand into the coil. Use MRI table base to secure and position the coil in place.

Supine Position

The patient can also be scanned feet-first into the magnet. Place the wrist/hand into the coil and rest the arm and the coil against the patient. Use the small MRI table base to secure and position the coil.

A vertical stand may be used, as necessary for the patient and the needed scan. The photo of the vertical stand can be found on page 7.

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

| | |
|---|---|
| **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.** |

## 12.0 Landmarking and Imaging

Landmark on the anatomy positioned within the coil volume.

The coil will provide imaging data throughout the entire length of the coil with proper coil selection. It is compatible with all array sequences.

## 13.0 Cleaning

13.1 The coil cover is not completely impermeable.
13.2 Safeguards should be put in place to minimize its contamination when required.
13.3 Surface cleaning of the material is the only action allowed using the solutions specified below.
13.4 If the coil is damaged during cleaning, contact ScanMed for repair at (402)934-2650.
13.5 This product contains no user replaceable or serviceable parts.
13.6 Do not remove the coil cover as this will cancel 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.**<br>**Apply cleaning liquid to a soft cotton cloth and proceed to clean.** |
|---|---|

The coil pads may be cleaned in the same method as noted above.

## 14.0 Quality Assurance

Locate and utilize the appropriate 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:

| | |
|---|---|
| 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 an axial 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 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)** |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## 15.0 Safety

Patient safety and comfort must be the 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. Contact ScanMed at (402)934-2650 for assistance.** |

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

## 16.0 Contraindications and Precautions

| | |
|---|---|
| **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 of developing seizures or claustrophobia.
- Unconscious, heavily sedated, confused patients or those with whom no reliable communications can be maintained.

Cautions and Warnings

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 of 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.

## 17.0 Emergency Procedures

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.
- **IMPORTANT:** Notify ScanMed LLC Customer Service at (402)934-2650.
    - Be prepared to relay all details of the event.
    - Take photos of the coil, the scanner, and the patient body where the coil was applied.
    - Provide names and contact information of the technician/health care provider that was conducting the scan.
    - Name and contact information of the patient.

## 18.0 Material Safety Information

| | |
|---|---|
| **CAUTION:**  | This product contains chemicals, possibly including lead, known to the state of California to cause birth defects or other reproductive harm. Lead solder may be present only in internal electronic circuitry and is not present in any outer contact surfaces.<br><br>Wash hands after handling any internal components.<br><br>**NOTE: There are no user serviceable components inside of the coil. DO NOT OPEN THE COIL.** |

ScanMed coils are manufactured using biocompatible materials on all surfaces that come into contact with the user and the patient. Contact ScanMed at CustomerService@scanmed.com if additional information is necessary.

## 19.0 Troubleshooting

**There are no user-serviceable components.**

All service or repairs 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
Email: Customerservice@scanmed.com

QA Testing

Perform a system quality assurance phantom test as outlined in 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 Customer Service department for assistance, if necessary.

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

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 to 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.

## 20.0 Disposal

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

| | | |
|---|---|---|
| **CAUTION:**  | **Dispose of RF coil properly.** |  |

**Manufacturer Information:**

ScanMed, LLC
9840 S 140 Street, St #8
Omaha, NE 68138
(402)934-2650

ScanMed®
a DirectMed company

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