OPERATOR MANUAL

Hand/Wrist MRI Coil 16-Channel - Siemens 1.5T and 3.0T

Model 316SI1501 (1.5T) and 316SI3001 (3.0T)

UDI: (01)00859193006661(21)xxx (3T)
UDI: (01)00859193006678(21)xxx (1.5T)

Approved by: _____
Brad de Koning, CEO/President

Date: September 13, 2023

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Licenses and Trademarks

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

The Siemens Verio, Trio, Espree, Avanto, Aera, Prisma, Skyra, Vida, Sola and the SI logo are registered trademarks of the Siemens (SI) Company.

This manual describes the use and operation of the 16 Channel Hand/Wrist Array on Siemens 1.5T and 3.0T MRI systems.

Proper performance of this coil is warranted only on the system (hardware/ software level) specified at the time of purchase. Upgrades and other modifications to the system software and/or hardware may affect compatibility. Prior to upgrading your MR system, please contact your Siemens Medical Systems representative and/or ScanMed representative to discuss coil compatibility issues. 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.

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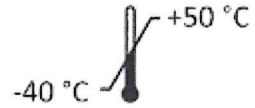
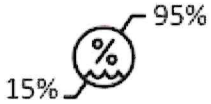
1.0 TRANSPORTATION & STORAGE CONDITIONS

Store the coil on a flat surface. Excessively tight bending of the cable 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:

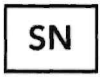
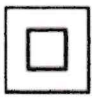
	Ambient temperature of -40 °C to +50 °C
	Relative humidity of 15% to 95% (non-condensing)
	Atmospheric pressure of 76.5 kPa to 101 kPa
	Protect from water
	Fragile, handle with care

CAUTION:

This product may contain contain chemicals, including lead, known to the State of California to cause birth defects or other reproductive harm.

WASH HANDS AFTER HANDLING.

2.0 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
	Model number
	Class II ordinary equipment, suitable for continuous operation
	Non-sterile

	Manufacturer name, address, and date of manufacture
	Medical device
	Do not cross or loop cables. Arcing and patient burns could result.
	NOTE FOR THE OPERATOR: There is a possibility of pinching one's fingers when working with this coil, particularly when opening and closing the coil.

3.0 INTRODUCTION

This manual describes the safety precautions, features, use and care of the ScanMed LLC 16 channel Hand/Wrist coil, compatible with the Siemens 1.5T and 3.0T MR systems.

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

(402)934-2650

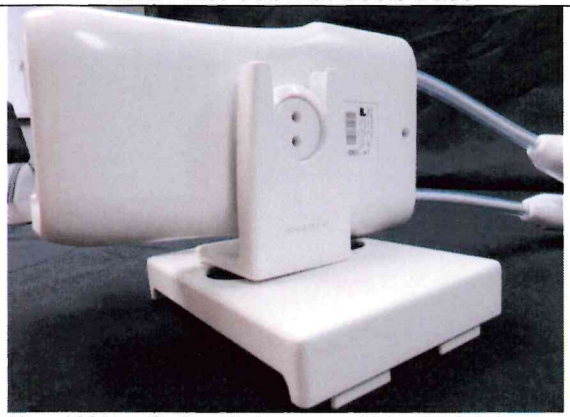
Email: CustomerService@scanmed.com

Description

This Hand/Wrist coil interfaces with the Siemens 1.5T or 3.0T MRI systems and has been designed to collect image data throughout the region of wrist. This 16-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 MRI 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.

Hand/Wrist Coil with Basic Base

Hand/Wrist Coil with Basic Base

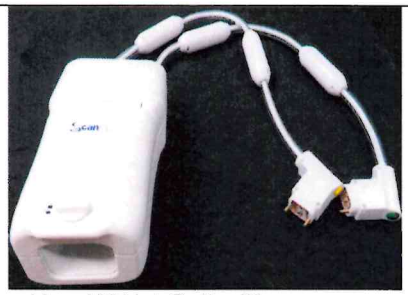


Hand/Wrist Coil with Base and Vertical Adapter (back side)

Hand/Wrist Coil with Base and Vertical Adapter (front side)

16-Channel Hand/Wrist Coil Parts List

The following photographs demonstrate the items that are shipped with your new coil. Please inspect upon receipt to make sure all parts have arrived and are in good order. Use this guide to refer to part names throughout this manual.



1. Hand/Wrist Coil with Cable set (connected)

2. Base Plate

3. Vertical Adapter

4. Wrist Hand Pad, top

5. Wrist Hand, Pad bottom

6. Hand Phantom (top)
7. Wrist Phantom (bottom)

ID #	Part Number	Description
1	316SIxx01 (1.5T or 3T)	Wrist coil
2	HOU00058+R	Baseplate
3	HOU31x007+R	Vertical Adapter
4	PAD00015+R	Pad (top)
5	PAD00016+R	Pad (bottom)
6	PHA00018+R	Hand Phantom
7	PHA00020+R	Wrist Phantom

If necessary, these items may be ordered for replacement by contacting ScanMed Customer Service at (402)934-2650.

Do not force the latched opening on the coil farther than it will smoothly open. It will snap if pushed too far, rendering the coil inoperable and in need of repair.

Indications For Use

The indications for use for this coil are as follows.

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

Compatibility

This manual applies to the following models of the Hand/Wrist coil and MR scanners:

Model	MRI System Compatibility
316SI1501	1.5T Siemens Espree, Avanto, Aera, and Sola
316SI3001	3.0T Siemens Verio, Trio, Prisma, Skyra, and Vida,

4.0 PATIENT SAFETY

Training

This manual contains detailed information on the set-up, positioning and use of your Hand/Wrist coil. The instructions should be read carefully and thoroughly before attempting to scan patients with the coil.

Quality Assurance

The procedure described in the Quality Assurance Section of this manual should be performed upon receipt of the coil to establish a baseline of coil performance. The procedure should be repeated at regular intervals.

Indications

The coil is indicated for use, on the order of a physician, in conjunction with an MR scanner as an accessory to produce images of the wrist.

Contra-Indications

The coil is indicated for use, on the order of a physician, in conjunction with an MR scanner as an accessory to produce images of the wrist.

Scanning is contraindicated for patients who have electrically, magnetically or mechanically activated implants (for example, cardiac pacemakers). The magnetic and electromagnetic fields produced by the MR System and coil may interfere with the operations of these devices.

Scanning patients with intracranial aneurysm clips is contraindicated.

Precautions

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

Greater than normal potential for cardiac arrest.

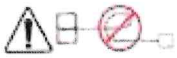
An increased likelihood for developing seizures or claustrophobia.

Unconscious, heavily sedated, or confused patients.

Patients with whom reliable communications cannot be maintained.

Cautions

The following general warning statements apply to scanning with a magnetic resonance system. For further details, review the warnings in your MR system Operator Manual.



Do not cross or loop cables. Arcing and patient burns could result. Route cables out of the magnet so that they do not touch the patient.

Ensure that the patient is not touching the bore. If necessary, place pads between the patient and the surface of the bore.

If the patient complaints of warming, tingling, stinging, or similar sensations, promptly stop the scan procedure, examine the patient, and contact the responsible physician before continuing the procedure. Pay special attention to very young, sedated, or other compromised patients who may not be able to communicate effectively.

Patients with ferromagnetic metal implants should not be scanned because the magnetic field may interact with implanted surgical slips or other ferromagnetic materials.

Persons with cardiac pacemakers or other implanted electronic devices should not enter the magnetic field zone delineated by the MR system manufacturer.

There is a risk to scanning feverish or decompensated cardiac patients.

Facial makeup such as eyeliner and mascara should be removed before scanning because it may contain ferromagnetic material which can cause skin and eye irritation. Permanent eyeliner tattoos may cause eye irritation due to 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 undergoing an MR scan or exam.

Visually inspect the cable insulator jackets, strain reliefs and connector boxes before each use. If the insulation is broken, or if the cable is frayed, immediately discontinue use of the device.

Use caution when lifting the coil base assembly from the patient table to storage.

Advise the patient to remain still throughout the scan to avoid nausea.

Patients must be supervised at all times during scans.

The safety of scanning fetuses has not been established.

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.
- Remove the patient from the scan room if medical treatment is needed.

Technical Considerations

The coil and accessories require special conditions regarding electromagnetic compatibility. The coil must be installed and used in a shielded scan room provided with the MR magnet and system. The user must ensure that the scan room door is closed during system use. Failure to do so may cause reciprocal interference with any portable or mobile RF communications equipment, affecting the performance of the MR coil and/or such equipment.

The coil should only be used with the accessories specified in the Operator Manual.

The use of accessories other than those specified in the Operator Manual may result in decreased ESD immunity of the coil or MR system, causing damage to the coil and/or system.

The equipment should not be used with other coils or equipment present in the MR scanner except as specified in the Operator Manual.

Tampering with the cable pins and connector may damage the connector and affect coil or system performance. Please verify that connector and pins are not damaged before use.

Do not force the latched opening on the coil farther than it will smoothly open. It will snap if pushed too far, rendering the coil in need of repair.

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

Do not use the coil if it appears to be damaged, i.e., broken pieces, etc. Return the coil to the manufacturer for repair and/or replacement.

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

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

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 coils and cause patient burns.

5.0 INSTALLATION, STORAGE AND MAINTENANCE

Installation and Configuration

There is no installation of the MRI coil. ScanMed coils are engineered to be "plug and play" with the appropriate MRI scanner.

Contact ScanMed LLC for assistance or questions regarding the Siemens 1.5 and 3.0T 16 channel Hand/Wrist coil.

Storage

Store the coil and baseplate in an air-conditioned scan room or equipment room.

To store the coil, cable and baseplates, a minimum storage space of 46cm/18" (width) x 50.8 cm/20" (depth) x 28 cm/11" (height) is required.

Cleaning

The 1.5T and 3.0T Hand/Wrist coil, patient comfort pads and baseplate must be cleaned and stored using the following procedures:

- Wipe with a cloth that has been dampened in a solution of 10% bleach and 90% tap water, or 30% isopropyl alcohol and 70% tap water.
- **Do not pour any cleaning solution directly on the coil or baseplate!**
- Let the coil housing, base plate, and pads dry before use.
- **Under no circumstances should the coil be placed into any type of sterilizer.**

The Siemens Hand/Wrist coil is plug-and-play. It will be automatically recognized by the MRI system. No other installation procedures are required.

If your installation raises questions or causes issues, contact **ScanMed LLC Customer Service at (402)934-2650**.

Please follow the QA procedure in Section 6 to verify the coil is working properly and establish the baseline SNR specific to your system and setup.

Connect the Hand/Wrist coil to your Siemens MRI system using the table below.

System	Patient	Connectors
Siemens 1.5 or 3.0T	Head-First	Two 8-Channel connectors nearest the magnet
		NOTE: Depending on the model of your specific MRI scanner, two adapters may be required. These adapters will need to be obtained from Siemens directly. The 3T adapter is Model #10500092 and the 1.5T adapter is Model # 10500086.

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.

System	Tesla	Model	Width	Length
Espree, Avanto, Aera, and Sola	1.5	316SI1501	440 mm	440 mm
Verio, Trio, Prisma, Skyra, and Vida,	3.0	316SI3001	440 mm	440 mm

6.0 OPERATION

Set-Up and Use

Set-up of the coil is self-explanatory, as it is plug and play. Follow the information found later in this section called "Positioning" for additional instructions.

No modification of this device is allowed.

Do not modify this equipment without specific authorization from ScanMed.

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

Selecting the Coil Name

Ensure that the correct coil is chosen from the menu selection on the surface coil screen. Menu selections must be installed by your MR system service representative. Contact ScanMed LLC for assistance.

Coil and Phantom Setup

The 1.5T and 3.0T 16 Channel Siemens Hand/Wrist coil is equipped with a baseplate to support the coil. The baseplate is designed to rest directly on the patient table for stability. The coil cable should exit away from the patient's wrist.

Position the baseplate toward the magnet end of the patient table. Center as illustrated.

Unlock the latch and lift to open the coil.

	NOTE FOR THE OPERATOR: There is a possibility of pinching one's fingers when opening and closing the coil.

Latch. Refer to latch lock label.

CAUTION: Do not force the latched opening on the coil farther than it will smoothly open. It will snap if pushed too far, rendering the coil inn need of repair.

Insert the hand phantom first, pushing it into the hand portion of the coil. Then insert the wrist phantom into the coil as illustrated.

Hand Phantom.

Wrist Phantom.

Close coil for testing with phantoms inserted.

Connecting the Cable

Connect the coil to the scanner by plugging the coil connector into the coil interface.

Connector varies by scanner. Photo is not included here.

NOTE: Run the cable in the most direct way to the coil 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 the able jacket is torn or ripped, or if metal or wiring is exposed. Return the coil to the manufacturer for repair and/or replacement.

Selecting the Coil Name

Ensure that the correct coil is chosen from the menu selection on the surface coil screen. Menu selections must be installed by your MR system service representative. Contact ScanMed LLC for assistance.

Coil Landmark

Advance the coil into the magnet and landmark the coil using the reference marks on the top of the Hand/Wrist coil.

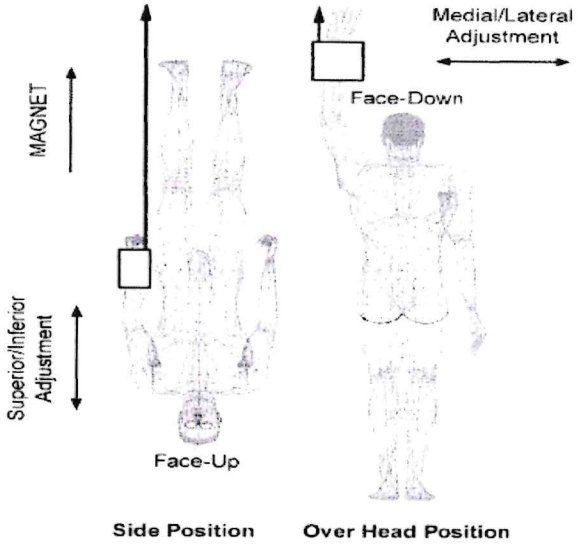
Explanation of QA Pre-scan and Scan

If pre-scan does not compete successfully, do not use the coil clinically. Upon completion of pre-scan, execute the scan. Window the scan as usual (window levels vary from system to system depending upon the hardware revision level). The scan should appear uniform.

If the phantom image shows voids or striations, the coil is malfunctioning. Discontinue use of the coil and contact ScanMed LLC for assistance.

7.0 POSITIONING

Choosing the Best Coil Position



The 16-Channel Hand/Wrist coil package includes a Vertical Adapter for scans performed at the patient's side. Patient size, comfort and scan preference will dictate which position you use.

To ensure the coil cable will reach the coil port, over-head scans are performed head-first, while side scans are performed feet-first.

The patient will be in the prone position (Over-head position), 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.

Patient Positioning

For Side Imaging

Unlatch the 16-Channel Hand/Wrist coil and open the housing. Have the patient position the wrist into the small of coil. The coil may be placed in the base side rail prior to patient positioning.

This figure shows right side positioning.

Close the coil and latch securely. Use pads to ensure the patient is comfortable.

	NOTE FOR THE OPERATOR: There is a possibility of pinching one's fingers when opening and closing the coil.

For Over-Head Imaging

For head-first over head imaging of the hand and/or wrist, use the baseplate as shown.

One the coil has been slid into the base as shown, the coil can be moved to the right or left depending on the wrist being scanned.

The coil is closed once the patient's hand and wrist have been place appropriately and the patient is comfortable.

	NOTE FOR THE OPERATOR: There is a possibility of pinching one's fingers when opening and closing the coil.

Patient Hearing Protection

Provide ear plugs for the patient after all instructions have been given.

Hearing protection is required for all people in the scan room during a scan to prevent hearing impairment. Acoustic levels may exceed 99 dB(A).

Hearing protection must have a Noise Reduction Rating (MRR) of 29 dB or better (e.g., 30 dB, 32 dB, etc.)

8.0 SCANNING

Autoshim

Generally, when the coil is used at the patient's side, image quality is often improved by enabling autoshim. It does this by improving the magnetic field homogeneity within the OV selected. The improvement in image quality is often dramatic when the selected FOV is far off center, and when acquiring FSE or T2 weighted scans.

Localizing

The 3.0T 16 Channel Hand/Wrist coil is designed to allow the body coil to be used while the coil is in the scanner. This allows use of a large FOV (40 cm) body coil localizer, which is helpful in determining the left or right offset required for imaging the wrist or hand.

You may scan using the body coil at any time, but the coil must be connected.

Fat Saturation Techniques

Off-center FOV imaging is a more difficult technique since it is dependent upon the homogeneity of the magnetic field, and a definite fat peak signal. A small wrist on the edge of the imageable field may produce poor fat saturation.

For best fat saturation results, position the patient with his hand over his head and position the coil as close to the isocenter as possible.

For axial imaging, use an axial localizer but before prescribing slices, localize using the same FOV you intend to use in your study, or localized explicitly. Use of graphic prescription from large FOV localizer sometimes results in software miscues producing blank slices, shifted slices, or both.

Scan Protocols

ScanMed LLC recommends that you select imaging protocol that have been established by your radiologist or radiology department.

9.0 QUALITY ASSURANCE

Quality Assurance Procedures

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

Arrange the specific hand/wrist 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:

Scan Plane: Axial	Pulse Sequence: TSE
Base Resolution: 256	Phase Resolution: 70%
Averages: 1	TR/TE: 600/14
Slice Thickness: 5	Slice Groups: 1
FOV: 300 mm	BW: 122Hz/Pixel
Phase Direction: A/P	No Filters or Normalizing
Turbo Factor: 3	Phase Oversampling: 0%

Hand/Wrist Coil showing phantom placement

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)

10.0 PREVENTIVE MAINTENANCE AND CLEANING

QA Test
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 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. Check the connector to ensure the pins are not bent.

Do not use a damaged coil on a patient.
Return the coil to ScanMed 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.

NOTE: Do not remove the coil cover, as this will void the coil 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 gently 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.

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

11.0 TROUBLESHOOTING

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
Email: CustomerService@scanmed.com

1. **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.

2. **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.

3. 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.

12.0 DISPOSAL

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

Dispose of RF coil properly.

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Manufacturer Information:

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