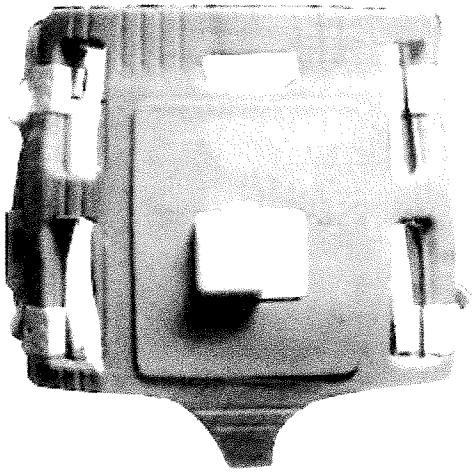
OPERATOR MANUAL

General Electric PROCURE™ 1.5T & 3.0T Coil



Models: 588GE1501 (1.5T) / 588GE3001 (3.0T)
UDI: (01)00859193006197(21)xxx (1.5) / (01)00859193006203(21)xxx (3.0T)

GE PROCURE™ Coil 16-Channel
RECEIVE-ONLY COIL

For Use with GE 1.5 And 3.0 Tesla 450,
450W, 750, 750W Systems and 16-Channel
HDx Systems Only

Approved by: _____ Date: June 19, 2023
Brad de Koning, CEO/President

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LICENSES AND TRADEMARKS

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

450, 750, HDx and the GE logo are registered trademarks of GE Healthcare.

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 GE representative and a ScanMed, LLC representative prior to operating on new software, as failure to do so may void your warranty.

TRANSPORTATION/STORAGE CONDITIONS

Transport and store this product under the following environmental conditions only; for a period that does not exceed two weeks:

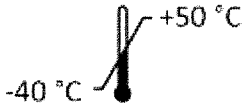
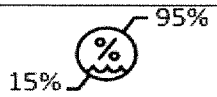
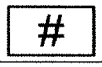
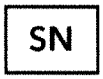
	Ambient temperature of -40 °C to +50 °C
	Relative humidity of 15% to 95% (non-condensing)
	Atmospheric pressure of 76.5 kPa to 101 kPa
	Protect from water
	Fragile, handle with care
	This side up

TABLE OF 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
	Non-sterile
	Manufacturer name, address, and date of manufacture
	Medical device
	Do not cross or loop cables. Arcing and patient burns could result.
	Authorized Representative Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands

1. INTRODUCTION

This manual describes the safety precautions, features, use and care of the ScanMed LLC, GE (General Electric) 1.5T and 3T PROCURE™ 16-channel pelvic coils, compatible with the GE 1.5T and 3.0T 450, 450W, 750, 750W Systems and 16-Channel HDx Systems Only.

If you have any questions or comments about this manual, or need any assistance with the use of the 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. DESCRIPTION

The GE PROCURE™ Array Coil interfaces with a 16-channel GE MRI scanner and is a unique, first-of-a-kind wearable coil provides high-quality images of the reproductive and urological anatomies in an easy to position, and very flexible design. This lightweight SemiFlex™ design facilitates effortless and accurate positioning similar to wearing a diaper; and positions the multiple antenna elements as close as possible to the target anatomies regardless of patient size. The enclosure for the array is made of flexible, liquid impermeable, and biocompatible materials.

The PROCURE™ coil is intended to fold between the patient's legs and rest snuggly against the perineum; hence, it has a posterior half that the patient lays on, and anterior half that rests upon the patient's pelvic region.

The non-patient side of the PROCURE™ coil is the side with the labeling and center cable connector receptacle, while the patient-side is smooth with no labeling. The posterior half of the coil is that portion with the center triangular opening that aligns with the patient's anus while the anterior half has no center opening.

CABLE ASSEMBLY

As applicable to the MR scanner, either a 2-cable set or 1 "Y" cable are identified to connect to their respective anterior and posterior portions of the PROCURE™ coil. This is the same for the "Y" cable or 2-cable set, the anterior connector (with the blue band and single black hashmark) will connect to the anterior half of the coil at the

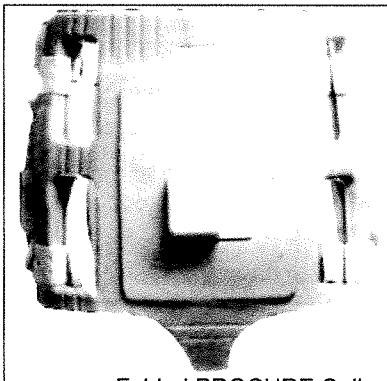
central connector receptacle. The posterior connector (no blue band and two black hashmarks) will connect the posterior half of the coil.

Each cable – either the "Y" cable or the 2-cable set will plug into the respective receptable port on the MR scanner.

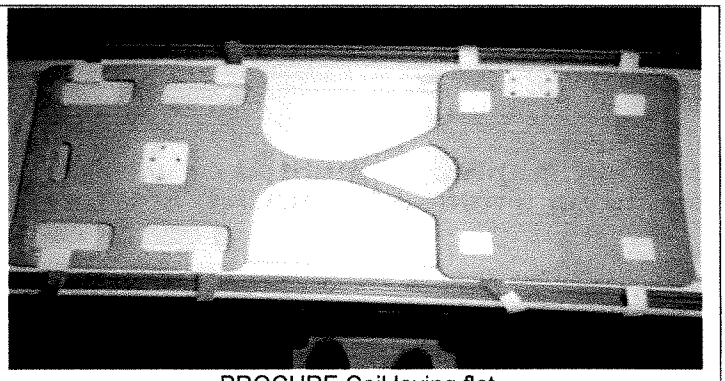
Connect the PROCURE coil to your GE MRI system as directed by the MRI system manual.

PROCURE COIL SPECIFICATIONS:

	US Measurements	Metric Measurements
Height (Thickness)	2.25 inches	5.715 cm
Width:	17 inches	43.18 cm
Full Length	37.2 inches	94.488 cm
Weight:	6 pounds 13.5oz	3.1044kg
Folded Length	18.6 inches	47.24 cm



Folded PROCURE Coil



PROCURE Coil laying flat

3. MRI COIL LABEL and LOCATION

A sample ScanMed GE PROCURE MRI coil labels is shown here, as well as its location on the coil:

Sample PROCURE GE 1.5T coil label.

Sample PROCURE GE 3.0T coil label.

Location of coil label on the PROCURE coil.

4. INTENDED PURPOSE

The intended purpose of 16-channel PROCURE™ Array Coil is to provide high-quality images of the reproductive and urological anatomies in an easy-to-position, wearable, and very flexible design.

5. INDICATIONS FOR USE

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 general human anatomy. These images, when interpreted by a trained physician, may assist in medical diagnosis.

6. APPLICABLE MODELS and COIL SELECTION

This manual applies to the GE PROCURE models as listed below:

MODEL	MRI SYTSTEM COMPATIBILITY
588GE1501 and 588GE3001	GE 1.5T And 3.0T 450, 450W, 750, 750W Systems and 16-Channel HDx Systems Only

Use one of the following coil configurations depending on the model of your GE scanner. The entire coil is activated by these modes.

MRI	Size	Model	Width	Length	Coil Modes
MR450	16CH	588GE1501	440 mm	440 mm	Extremity_Full
MR450W	16CH	588GE1501	440 mm	440 mm	NeoCoil Extremity
1.5T HDx	16CH	588GE1501	440 mm	440 mm	NV_Full
MR750	16CH	588GE3001	440 mm	440 mm	32 Ch. Torso Ant/FL:S
MR750W	16CH	588GE3001	440 mm	440 mm	16 ch flex LG
3T HDx	16CH	588GE3001	440 mm	440 mm	NV_Full

SYSTEM CONNECTOR LOCATION

Connect the PROCURE™ coil to your GE MRI system using the table below:

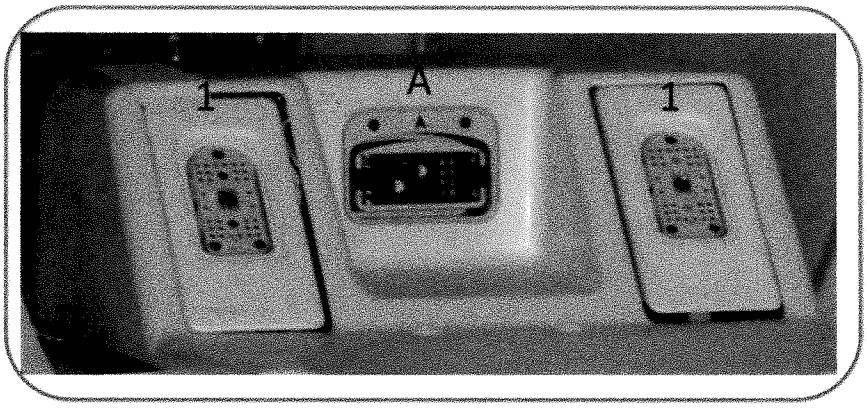
System	Connector Style	Patient	Connectors
1.5T/3T GE	HDx/Legacy	Head-First	Two 8-channel connectors nearest to the magnet
		Feet-First	Two 8-channel connectors nearest to the magnet
1.5T/3T GE	Dual HDx	Head-First	Two 8-channel connectors nearest to the magnet
		Feet-First	Two 8-channel connectors nearest to the magnet
1.5T/3T GE	16-Channel HDx	Head-First	One 16-channel connector nearest to the magnet
		Feet-First	One 16-channel connectors nearest to the magnet
1.5T/3T GE	P	Head-First	One 16-channel connector furthest from the magnet.
		Feet-First	One 16-channel connector nearest to the magnet.
1.5T/3T GE	PW	Head-First	One 16-channel connector furthest from the magnet.
		Feet-First	One 16-channel connector nearest to the magnet.

WARNING: 	**Do not attempt to scan with the PROCURE™ coil disconnected or unplugged from the scanner. Patient burns may result. Unconnected coils may cause damage to the coil.**
CAUTION: 	Remove any other coil or unused accessory device from the magnet before using the coil. Unconnected coils may cause patient burns.
CAUTION: 	Ensure that the spine coil and/or any other coils are connected to the scanner before use. The PROCURE™ coil may be used in conjunction with or without the spine coil on the table, but not selected.
NOTE:	Your PROCURE™ Coil is configured from the factory to be used in either a feet-first or head-first configuration. This configuration is not user changeable.

IMPORTANT: 	It is important to connect the quick-disconnect anterior and posterior cables to the correct GE system cable, or image quality will be compromised. The cable from the anterior section is colored BLUE and is to be connected to the system cable with the BLUE connector.

Connect the PROCURE™ coil to your GE MRI system using the figures below:

For 450, 450W, 750, and 750W, connect the coil to one of the scanner ports shown below on the left or right. Do not connect to the center port.

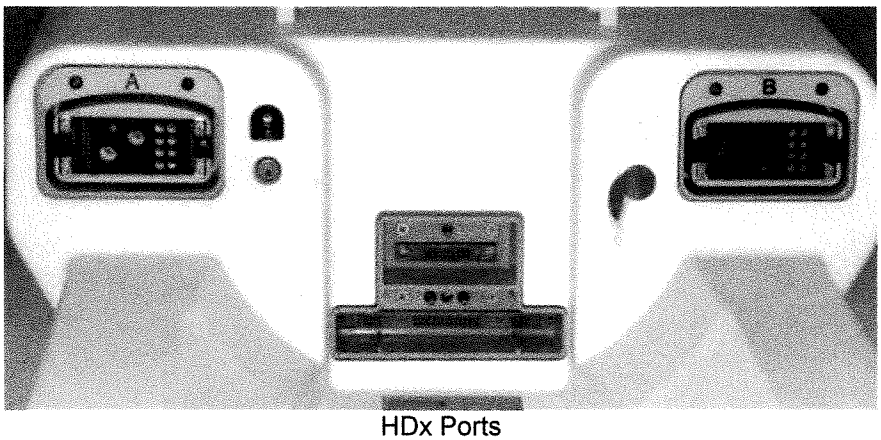


450/450w and 750/750w Ports

For 16-channel HDx systems:

For coils with two HDx connectors, connect both connectors to the corresponding "A" and "B" scanner ports shown below. The cable connectors will be labeled with an "A" or "B" for identification purposes. Do not connect to the center port.

For coils with one HDx and one legacy connector, connect the HDx connector to the corresponding "B" port, the cable connector will be labeled with a "B", and the legacy connector to the center port. Do not connect to "A".



HDx Ports

7. ACCESSORIES

The following accessories may be purchased separately as needed. The surgical liners are required only if performing in-bore biopsy procedures.

Part Number	Description
MSC5X803	PROCURE™ Surgical liners (pack of 20 single-use liners)
MSC5X804	PROCURE™ Prone Scanning Pad

The following accessories are included with this purchase and may be purchased as replacements are needed.

Part Number	Description
PHA5X801A/B+R	PROCURE™ Phantom Positioner, Assembly (2 pieces)

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. INSPECTION

Visually inspect the coil foam and cable assembly for cracks or missing insulation around the connectors of the assembly prior to using the coil.

Check the cable connector for secure fit within the coil housing.

Check the electrical contacts on the cable and coil 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.

9. INSTALLATION and STORAGE

INSTALLATION

The GE PROCURE™ coil is plug-and-play. It will be automatically recognized by the MRI system as one of the coil modes listed. No other installation procedures are required.

Please follow the QA procedures in Section 14 to verify the coil is working properly and establish the baseline SNR specific to your system and setup.

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

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

STORAGE

The PROCURE™ coil should be stored flat. The PROCURE™ coil has detachable cable assemblies for convenience in handling and storage, so it is recommended to detach the cables before storage.

CAUTION: 	**Do not store the PROCURE™ coil with cables connected or with the coil folded.** **Do not place other objects on a folded PROCURE™ coil as this may damage the coil.**

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

10. OPERATION

WARNING: 	**Do not attempt to scan with the coil disconnected or unplugged from the scanner.** **Patient burns may result.**
CAUTION: 	**Your PROCURE Coil is configured from the factory to be used in either a feet-first or head-first configuration. This configuration is <u>not</u> user changeable.**
CAUTION: 	**Ensure that the spine coil and/or any other coils are connected to the scanner before use. The PROCURE coil may be used in conjunction with or without the spine coil on the table, but not selected.**

11. POSITIONING

FEET-FIRST POSITIONING - SUPINE

For pelvic imaging only, the patient should be in the supine (face up) position, feet-first into the magnet. Use pillows and patient comfort pads as needed for patient comfort and positioning.

Identify the non-patient side of the PROCURE™ coil as that side with the labeling and center cable connector receptacle. Further identify the posterior half of the coil as that portion with the triangular opening that aligns with the patient anus. Note that this coil folds between the legs of the patient so that the anterior portion rests on the pelvis and stomach region after positioning.

1) Lay the PROCURE™ coil out flat with the non-patient side down and the anterior end facing the bore (left in Figure 1)
2) After positioning the coil as shown in Figure 5, connect the posterior cable connector to the posterior coil receptacle. Move the coil so that the cable can connect to the corresponding connector port on the MRI scanner. **DO NOT PLUG THE CABLE INTO THE SCANNER.**
3) Have the patient sit on the central area of the posterior portion of the coil so the anterior half of the coil can be folded upwards between their legs. Note that the coils should fit snuggly between the patient's legs and against their perineum.
4) After the patient is positioned, connect the anterior cable connector to the anterior coil receptacle.
5) Verify the patient is comfortable and both the anterior and posterior cables are connected to the coil before plugging the cable or cables into the scanner port.

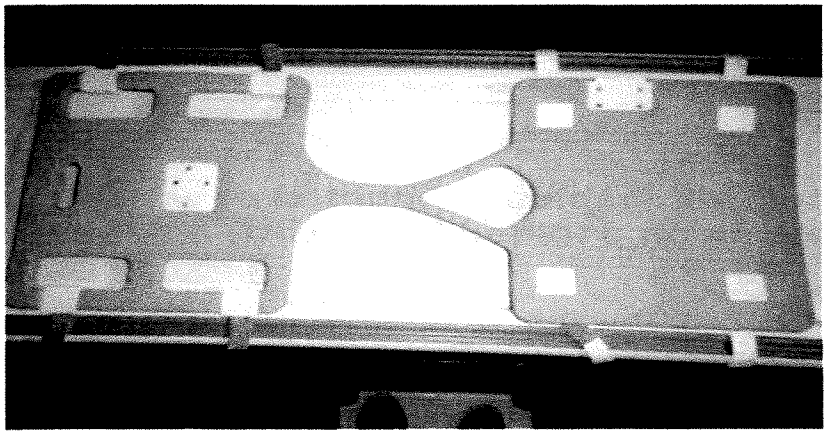


Figure 1: Initial feet-first setup prior to loading patient. Bore is to the left, and the anterior side of the coil is on the left side.

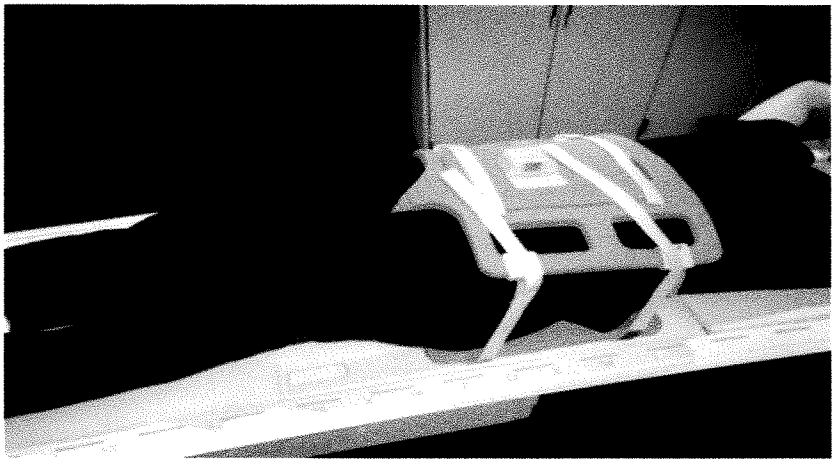


Figure 2: Supine. Feet-first patient ready to scan. Bore is to the left.

NOTE: This coil folds between the legs of the patient so that the anterior portion rests on the pelvis and stomach region after positioning.

HEAD-FIRST POSITIONING - SUPINE

For pelvic imaging only. The patient should be in the supine (face-up) position, head-first into the magnet. Use pillows and patient comfort pads as needed for patient comfort and positioning.

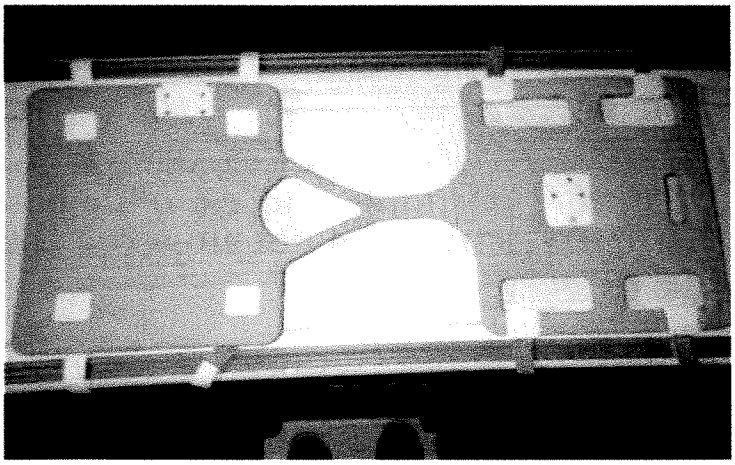


Figure 3: Initial head-first setup prior to loading patient. Bore is to the left and the anterior side of the coil is on the right side of the photo.

The patient should be in the supine position, head-first into the magnet. Place a level table pad on the patient table or spine coil prior to positioning the patient. Lay the PROCURE coil out flat with the posterior end facing the bore opening and the ScanMed logo facing the table. Have the patient site on the central area of the posterior portion of the coil, so the anterior half of the coil can be folded upwards between the legs. Note that the coil should be snuggly against the perineum.

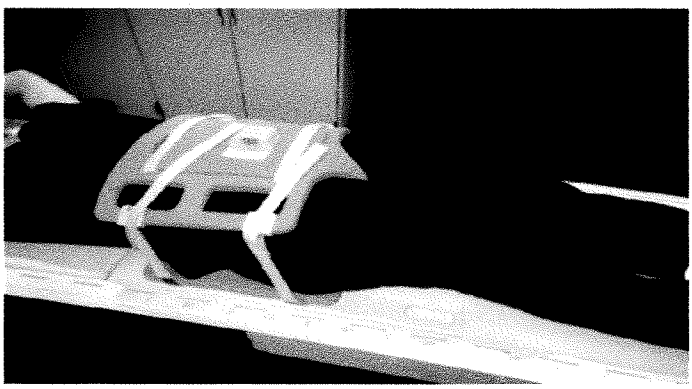


Figure 4: Supine. Head-first patient ready to scan. Bore is to the left.

NOTE: This coil folds between the legs of the patient so that the anterior portion rests on the pelvis and stomach region after positioning.

HEAD-FIRST POSITIONING - PRONE

For pelvic imaging only (no in-bore biopsy capability), the patient should be in the prone (face-down) position, head-first into the magnet. Use pillows and patient comfort pads as needed for patient comfort and positioning.

Identify the non-patient side of the PROCURE™ coil as that side with the labeling and center cable connector receptacle. Further identify the posterior half of the coil as that portion with the triangular opening that aligns with the patient's anus. Note that this coil folds between the legs of the patient so that the anterior portion rests on the pelvis and stomach region after positioning.

1) Lay the PROCURE™ coil out flat with the non-patient side down and the anterior end facing the bore (left in Figure 4) Use pillows and patient comfort pads as needed for patient comfort and positioning.
2) After positioning the coil as shown in Figure 4, connect the anterior cable connector to the anterior coil receptacle. Move the coil so that the cable can connect to the corresponding connector port on the MRI scanner, **DO NOT PLUG THE CABLE INTO THE SCANNER.**
3) Have the patient lay face-down on the central area of the anterior portion of the coil so the posterior half of the coil can be folded upwards between their legs. Note that the coils should fit snuggly between the patient's legs and against their perineum.
4) After the patient is positioned connect the posterior cable connector to the posterior coil receptacle.
5) Verify the patient is comfortable and both the anterior and posterior cables are connected to the coil before plugging the cable or cables into the scanner port.

After positioning the coil, connect the cable assembly to the coil receptacle. Adjust the coil so the cable can connect to the system easily.

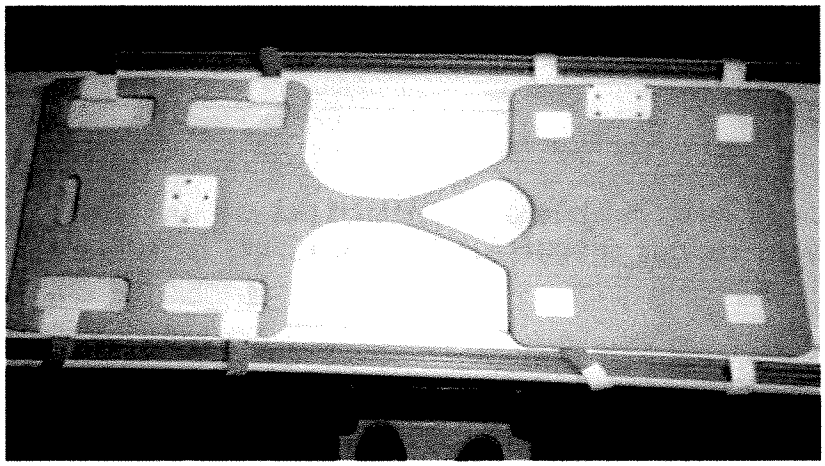


Figure 5: Prone head-first setup prior to loading patient. Bore is to the left and the anterior side of the coil is on the left side.

For biopsies, the patient should be in the prone (face-down) position, head-first into the magnet. Use pillows and patient comfort pads as needed for patient comfort and positioning.

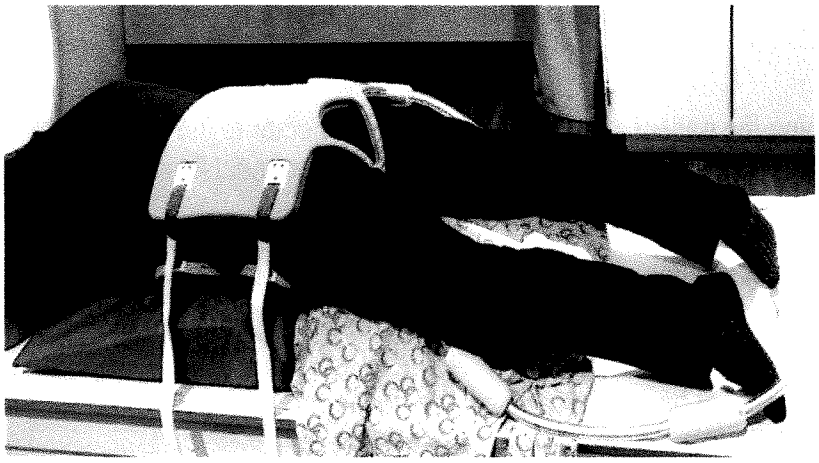


Figure 6: Prone head-first patient ready to scan. Bore is to the left.

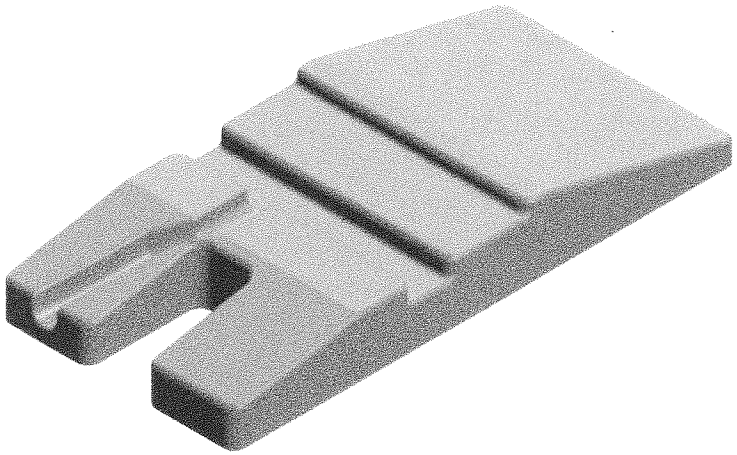


Figure 7: Optional prone positioning pad.

Identify the non-patient side of the PROCURE™ coil as that side with the labeling and center cable connector receptacle. Further identify the posterior half of the coil as that portion with the triangular opening that aligns with the patient's anus. Note that this coil folds between the legs of the patient so that the anterior portion rests on the pelvis and stomach region after positioning.

1) Lay the PROCURE™ coil out flat with the non-patient side down and the anterior end facing the bore (left in Figure 5) Use pillows and patient comfort pads as needed for patient comfort and positioning.
2) Remove a new liner from packaging and place the liner, still folded, on the table with the shiny side down. Pull the cotton side of the liner through the probe opening in the center of the coil (Figure 8, Step 1), leaving the shiny side of the coil to remain beneath the coil. Unfold the liner (Figure 8, Step 2), making sure to run parallel to coil length. Reach beneath the coil and unfold that liner side as well (Figure 8, Step 3).

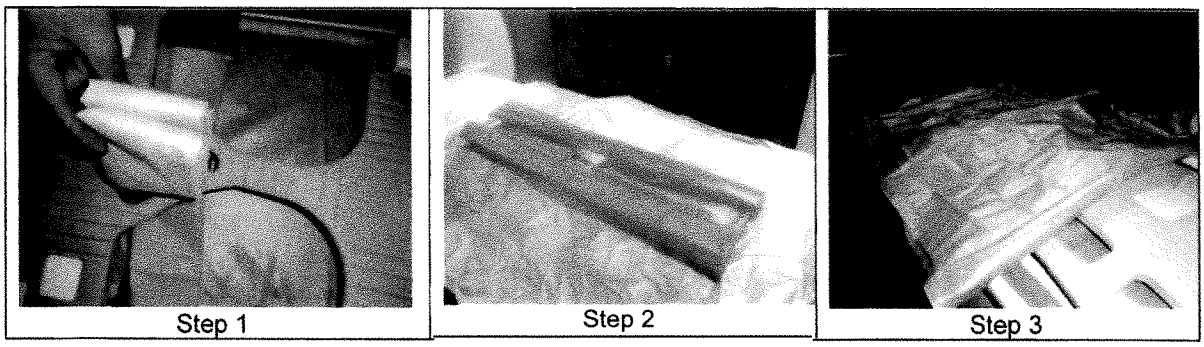


Figure 8: Surgical liner setup

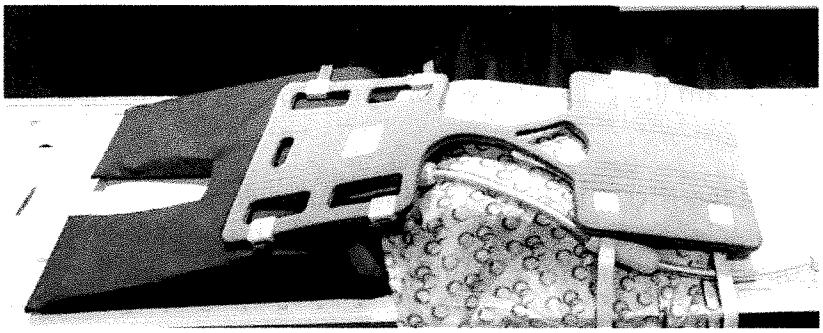


Figure 9: Initial head-first setup before loading patient and use of surgical liner. Bore is to the left.

3) After positioning the coil as shown in Figure 9, connect the anterior cable connector to the anterior coil receptacle, **tilt the coil on its side to connect the anterior connector to prevent the bending of the pins.** Route it through the prone scanning pad and move the coil so that the cable can connect to the corresponding connector port on the MRI scanner. **DO NOT PLUG THE CABLE INTO THE SCANNER.**
4) Have the patient lay face-down on the central area of the anterior portion of the coil so the posterior half of the coil can be folded upwards between their legs. Note that the coil should fit snuggly between the patient's legs and against their perineum.
5) Verify the surgical liner is positioned correctly so that the opening in the liner lines up with the correct anatomy for the biopsy probe.
6) After the patient is positioned connect the posterior cable connector to the posterior coil receptacle.
7) Make sure the patient is comfortable and both the anterior and posterior cables are connected to the coil before plugging the cable or cables into the scanner port.

WARNING: 	**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 cable jacket is torn or ripped, or if metal is exposed. Return the coil to the manufacturer for repair and/or replacement.

12. LANDMARKING and IMAGING

Landmark on the anatomy positioned within the coil volume. For the prostate this is about 15 cm from the inferior end of the coil.

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 CONNECTING THE COIL and OPERATION

In the systems tab, ensure that ALL the coil elements are selected "on" for each sequence. Even if the element does not appear to be within the selected FOV, all the elements must be "on" as seen in Figure 10 below.

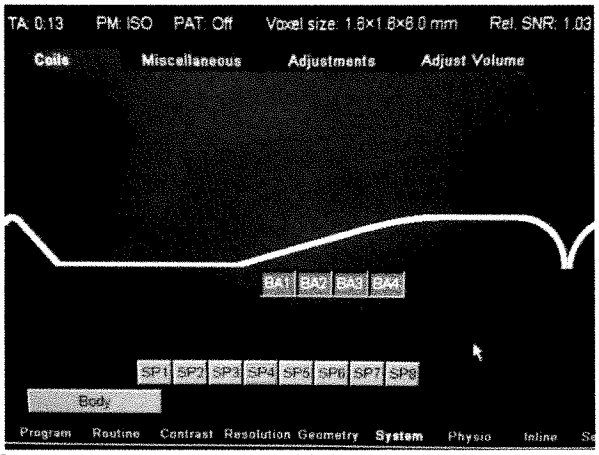


Figure 10: Systems tab screenshot. Make sure all coil elements are "ON".

14 CLEANING

GENERAL CLEANING

NOTE: 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.

NOTE: If the coil is damaged during cleaning, contact ScanMed for repair at (402)934-2650.

NOTE: This product contains no user replaceable or serviceable parts.

NOTE: Do not remove the coil foam, 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 cleaning liquid to a soft cotton cloth and proceed to clean.**

POST-BIOPSY CLEANING

After an in-bore biopsy or other invasive procedure, carefully unload the patient following these instructions:

1) While still gloved, fold the liner as shown on the next page to contain any bodily fluids that may be present.
2) Once the patient side of the liner is contained, carefully move the liner through the coil opening.
3) Use shiny side of liner to further contain the patient side of liner.
4) Dispose of the liner per your hospital/clinic biohazard protocol. Steps are illustrated below.

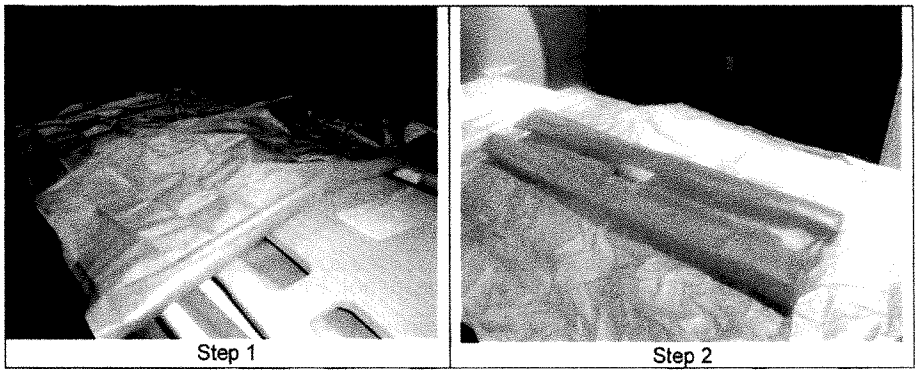


Figure 12: Steps to remove surgical liner (drape) after use.

NOTE: **If the coil is damaged during cleaning, contact ScanMed, LLC for repair at (402)934-2650.**

NOTE: **This product contains no user replaceable or serviceable parts.**

NOTE: **Do not remove the coil foam as this will void your warranty.**

Use the same cleaning solutions as described above in General Cleaning.

15 QUALITY ASSURANCE

Select a phantom set of 0.01 Molar CuSO4 plus 0.06 Molar of NaCl to fill the volume of the coil as best as possible to ensure that all elements are providing signal.

Ensure that the same phantom set is utilized for every QA scan conducted.

If any voids in the resulting images are present, call ScanMed, LLC Customer Service for further instructions.

NOTE: If the phantoms do not stay consistent, the QA data will not be accurate or verifiable.

Arrange the phantoms as shown in Figure 17 below, then perform an initial QA of the coil assembly. The coronal slice must be at the AP center of the inferior phantom, and also the SI center (approximately 10 cm from either SI edge).

Refer to these numbers and periodically repeat the measurements as a quality assurance test or if you suspect problems with the coil.

If QA test results reveal SNR degradation of greater than 15%, call ScanMed, LLC Customer Service for further instructions. Record the results of each periodic test in Table 3. Make additional copies of the following data tables as needed.

Run the sequence as follows:

Scan plane: Coronal	Pulse Sequence: FSE-XL
Matrix: 256 x 128	ETL: 2
NEX: 1	TR/TE: 600/MinFull
Slice Thickness: 5	Spacing: As needed
FOV: 30	BW: 15.36KHz
Frequency Direction: S/I	

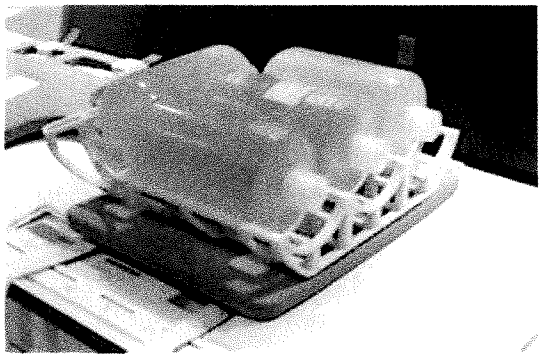


Figure 5: Phantom position in coil. Coil flat on table.

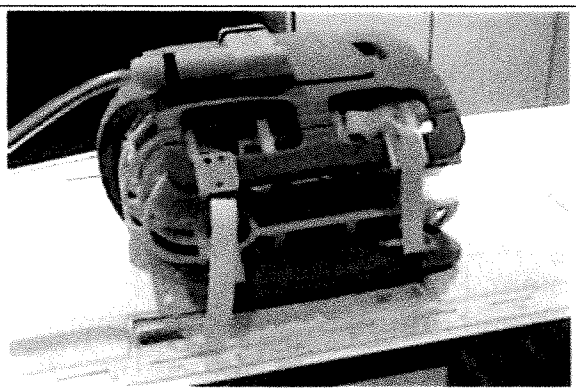


Figure 6: Coil wrapped around the phantom and phantom holder.

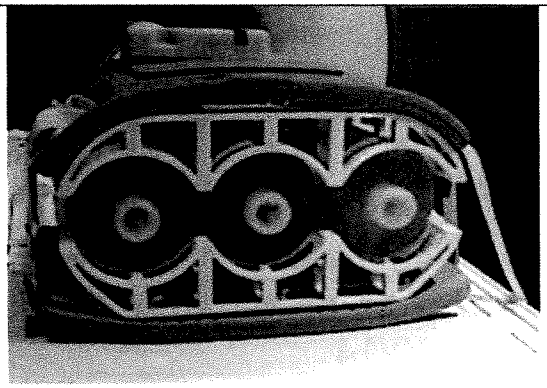


Figure 6a: Coil wrapped around the phantom and the phantom holder.

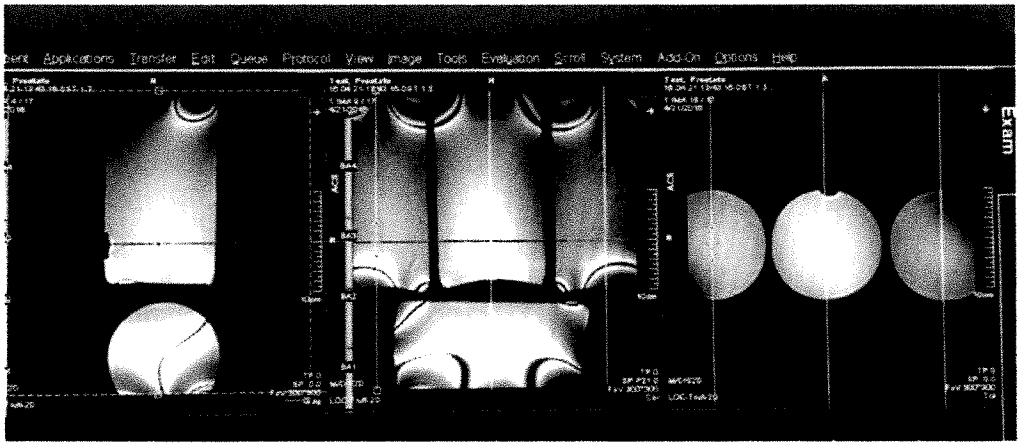


Figure 7: Three (3) slice groups.

After the acquisition of the images on the scanner, place rectangular ROIs as shown in Figure 20.

After the acquisition of images on the scanner, place 4 ROIs in the A0 slice as shown in Figure 16. ROIs 1, 2, 3, and 4 are approximately 3.00 cm^2 and placed in the L/R center of each phantom. ROI 5 is a large ROI (30-100 cm^2) taken in the center area of the background noise slice (A80). Use the standard deviation of ROI 5.

Record the signal mean of ROIs 1-4 inside the phantoms, and noise standard deviation (ROI 5) below the left or right phantom) in Table 1. Divide the signal means of ROI 1-4 by the standard deviation of the noise of ROI 5. Record these results in Table 1(SNR column). Calculate the average of the individual SNR values and record this result into Table 2 (SNR0) for the initial measurement otherwise record the average result into table 3 (Column2).

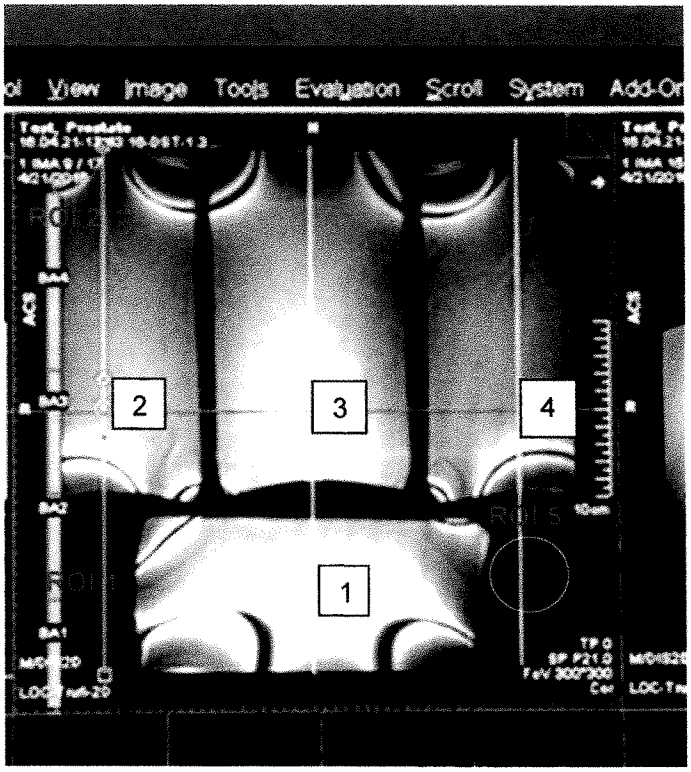


Figure 1: ROI placement, center phantom (left) and left/right phantom (right)

Refer back to these numbers and periodically repeat the measurements as a quality assurance test or if you suspect problems with the coil.

If QA test results reveal SNR degradation of greater than 15%, call **ScanMed, LLC Customer Service at +1(402)934-2650** for further instructions.

Record the results of each periodic test in Table 3. Make additional copies of table 1 as needed for subsequent SNR measurements.

INITIAL QA DATA

Results			
ROI	**Mean**	**Standard Deviation**	**SNR (Mean/SD5)**
1			
2			
3			
4			
5 (noise slice)		SD5	Average SNR

Table 1: Initial QA Data

Original Install Data	
DATE	**SNR0**

Table 2: Original install SNR value

Periodic QA Checks		
DATE	**SNR VALUE Column2**	**Percent Deviation ((Column2 – SNR0)/SNR0) x 100%**

Table 3: Periodic QA test results.

16. SAFETY

GENERAL SAFETY

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

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

WARNING: 	**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 foam, if the cable jacket is torn or ripped, or if metal is exposed. Return the coil to the manufacturer for repair and/or replacement.

CAUTION: 	Do not attempt to scan with the PROCURE coil disconnected or unplugged from the scanner. Patient burns may result. Unconnected coils may cause damage to the coils and patient burns.

CAUTION: 	Ensure that the spine coil and any other coils are connected to the scanner before use. The PROCURE coil may be used with the spine coil on the table but not selected. The PROCURE coil may be used without the spine coil on the table as well.

WARNING: 	**No modification of this device is allowed.** **Call ScanMed at (402)934-2650 for assistance.**

17. 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 MR scanner 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 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.

18. 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.
- 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.

19. MATERIAL SAFETY INFORMATION

CAUTION: 	This product contains chemicals, including lead, known to the state of California to cause birth defects or other reproductive harm. Lead solder is not present on any outer contact surfaces. Wash hands after handling the PROCURE coil. **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. Refer to the TR58805-R2 PROCURE Biocompatibility Report which can be found at the back of this Operator Manual for detailed information.

20. 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 (Central Time, USA), Monday through Friday to arrange for service/repair.

<u>There are no user-serviceable components.</u>

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

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 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. Notify **ScanMed, LLC at (402) 934-2650** to arrange for coil repair.

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, LLC Customer Service department for assistance.

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 selected "currently connected" or the appropriate coil mode from the Table in Section 3-2 from the coil selection list.
3. Verify that the cable is correctly connected to the system. The coil cable should be connected to the coil port.
4. If all 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 may lie with the MR system. If the body coil scan is satisfactory, there is most likely a problem with the ScanMed, LLC coil. Contact ScanMed, LLC 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.
5. Verify that there are no metal or magnetic objects close to the coil, patient or magnet (e.g., safety pin, hair pin).
6. Verify that the coil is properly positioned.
7. Verify that your center frequency is within the frequency adjustment range for your system.
8. Verify the anterior quick-disconnect connector is connected to the system cable with the blue connector.

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, LLC.

21. 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: ScanMed LLC® 9840 S 140 Street Suite 8 Omaha, NE 68138 USA	ScanMed® a DirectMed company

Product made in the USA