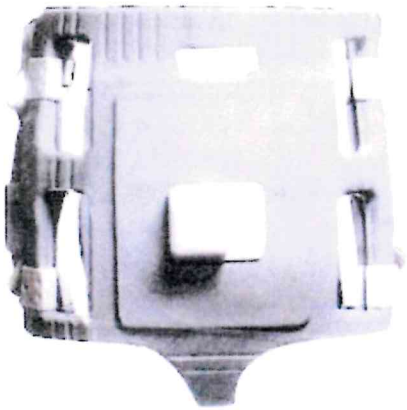
OPERATOR MANUAL

PROCURE™ 3.0T 16-Channel Siemens Pelvic Coil



Model: 588SI3001, Revision 10
UDI: (01)00859193006005(21)xxx

PROCURE™ Coil 16-Channel
3.0T RECEIVE-ONLY COIL

FOR USE WITH SIEMENS 3.0 TESLA

Siemens Healthineers has tested and approved this MRI coil on:

NON-parallel Transmit MRI Systems including MAGNETOM Skyra Fit (Skyra system family) and MAGNETOM Lumina (Vida system family) – both non-pTx versions.

Approved by: _____ Date: 2023-May-1
Brad de Koning, CEO

LICENSES AND TRADEMARKS

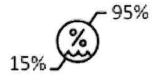
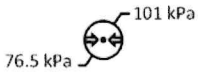
The ScanMed® logo is a registered trademark of ScanMed, LLC.

Magnetom Vida, Lumina, Vida Fit, Skyra, Prisma, Prisma Fit, 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 new software, as failure to do so may void your warranty.

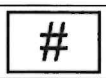
TRANSPORTATION/STORAGE CONDITIONS

Transport and store this product under the following environmental conditions only, for a period 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
	Model number
	Class II ordinary equipment, suitable for continuous operation
	Non-sterile
	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.
EC REP	EU 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 Siemens 3T PROCURE 16-channel pelvic coil, compatible with the Siemens NON parallel Transmit MRI Systems including MAGNETOM, Skyra Fit (Skyra system family) and on MAGNETOM Lumina (Vida system family) – both non-pTx versions.

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

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

This unique and first-of-a-kind wearable PROCURE™ Coil provides high-quality images of the reproductive and urological anatomies in an easy to position, wearable, 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, biocompatible materials.

This coil Model 588SI3001 has been tested and approved by Siemens Healthineers on NON parallel Transmit MRI Systems including MAGNETOM Skyra Fit (Skyra system family) and on MAGNETOM Lumina (Vida system family) – both non-pTx versions.

WARNING: 	**Do not use in Parallel Transmit mode as this may cause burns to the patient and damage to the coil.**

2. DESCRIPTION

The Siemens PROCURE™ Array Coil interfaces with a 16-channel Siemens 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 anterior pelvic region. Refer to Figure 3 for the demonstrative photographs.

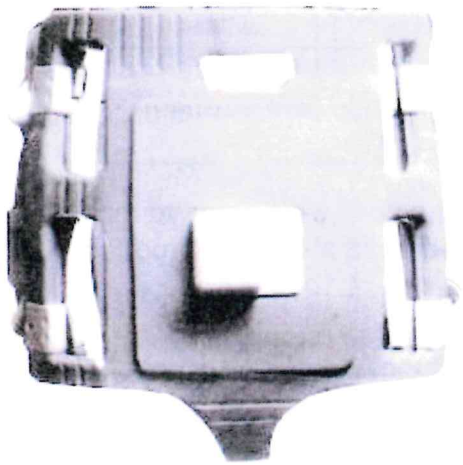
The non-patient side of the PROCURE coil is that side with the labeling and center cable connector receptacle, while the patient-side is smooth with no labeling. The posterior half of the coil is that portion with the center triangular opening that aligns with the patient's anus while the anterior half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

CABLE ASSEMBLY

Two detachable cable assemblies are identified to connect to their respective anterior and posterior portions of the PROCURE coil. The anterior cable assembly (marked with a blue band and single black hash mark) connects to the anterior half of the coil at the central connector receptacle and to the coil receptacle on the patient's left at either end of the table. The posterior cable assembly (no blue band, but two black hash marks) connects to the patient right side of the posterior coil half and the coil receptacle on the patient's right side.

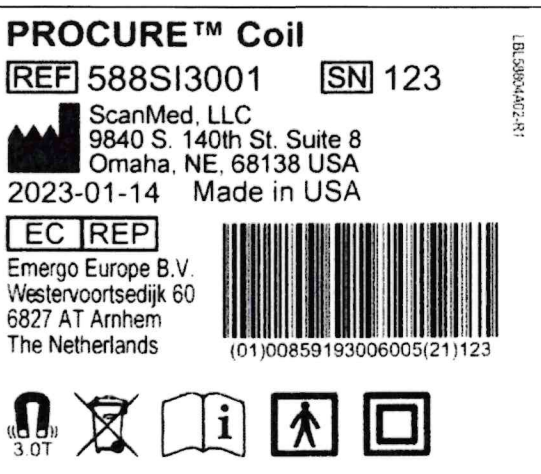
Connect the PROCURE coil to your Siemens MRI system using the table below.

System	Patient	Connectors
3.0T Siemens	Head-First	Two 8-channel connectors into the 8-channel ports.
	Feet-First	Two 8-channel connectors into the 8-channel ports.

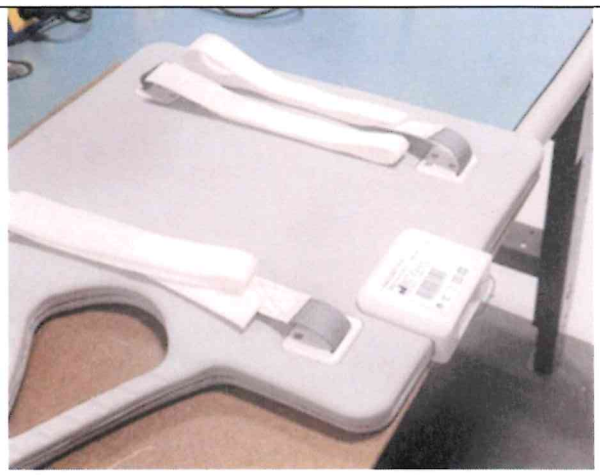


3. MRI COIL LABEL LOCATION

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



Sample PROCURE SI 3T 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 an approved Siemens magnetic resonance scanner for general human anatomy imaging as supported by the scanner. These images, when interpreted by a trained physician, may assist in medical diagnosis.

6. APPLICABLE MODELS

This manual applies only to the following Siemens 3T model (588SI3001) of the PROCURE Coil.

Model	IMPORTANT: MRI System Compatibility
588SI3001	**This coil Model 588SI3001 has been tested and approved by Siemens Healthineers on NON parallel Transmit MRI Systems including MAGNETOM Skyra Fit (Skyra system family) and on MAGNETOM Lumina (Vida system family) – both non-pTx versions.**

WARNING: 	**Do not use in Parallel Transmit mode as this may cause burns to the patient and damage to the coil.**
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.

7. ACCESSORIES

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

Part Number	Description
MSC5X803	PROCURE Surgical Liners (pack of 20 single-use)
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 prior to using the coil.

Check the electrical contacts on the cable end to ensure that they appear straight. Verifying that connection pins are not bent over.

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

9. INSTALLATION and STORAGE

INSTALLATION

The PROCURE coil is plug-and-play. It will be automatically recognized by the MRI system. 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:
(402) 934-2650
Email: CustomerService@scanmed.com

STORAGE

The PROCURE coil should be stored flat. The PROCURE coil has two 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.**

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 not 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. Place a level table pad on the patient table or spine coil prior to positioning the patient.

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 non-patient side down and the anterior end facing the bore (left in Figure 1).
2) After positioning the coil as shown in Figure 1, connect the posterior cable assembly to the posterior coil receptacle. Move the coil so that the posterior cable can connect to the patient right coil connector as shown in Figure 2.
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.

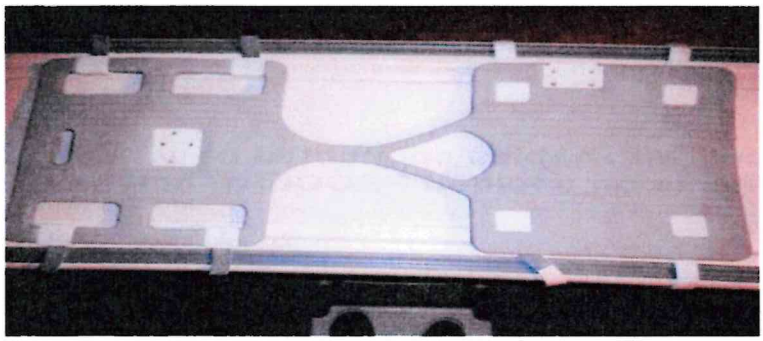


Figure 1: Initial feet-first setup prior to loading patient. Bore is to the left, and the anterior side of the coil is on the left side.

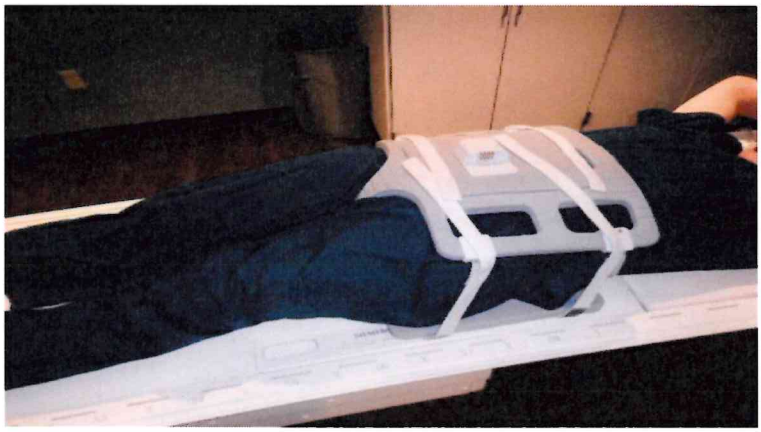


Figure 2: Supine. Feet-first patient ready to scan. Bore is to the left.

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 (no in-bore biopsy capability), 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.

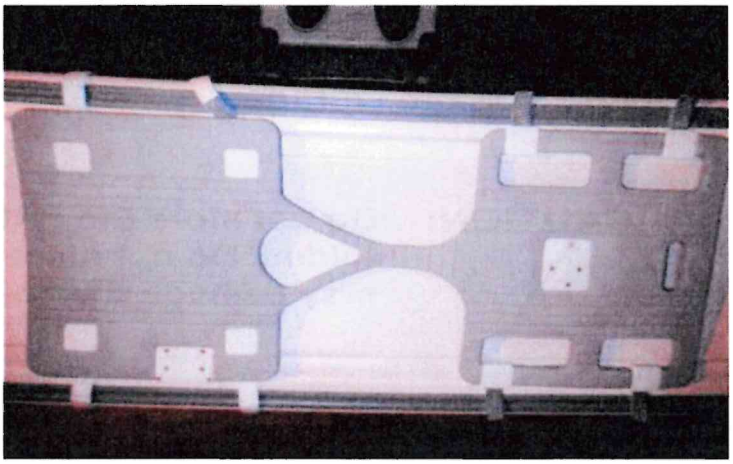


Figure 3: Initial head-first setup prior to loading patient. Bore is to the left and the anterior side of the coil is on the right of the photo.

The patient should be in the supine position, head-first into the magnet. Place a level table pad on the patient table prior or spine coil to position 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 sit 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.

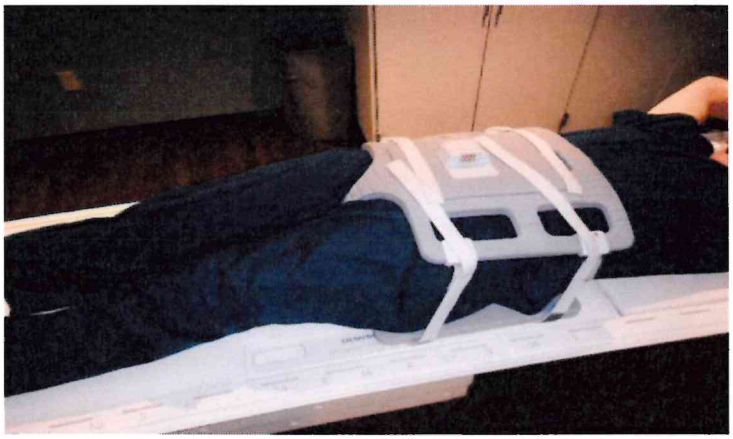


Figure 4: Supine. Head-first patient ready to scan. Bore is to the right.

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

Lay the PROCURE coil out flat with the non-patient side down and the anterior end facing ***away*** from the bore (Bore on right in Figure 4).

After positioning the coil, connect the posterior cable assembly to the posterior coil receptacle. Move the coil so that the posterior cable can connect to the patient-right coil connector at the far end of the table.

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.

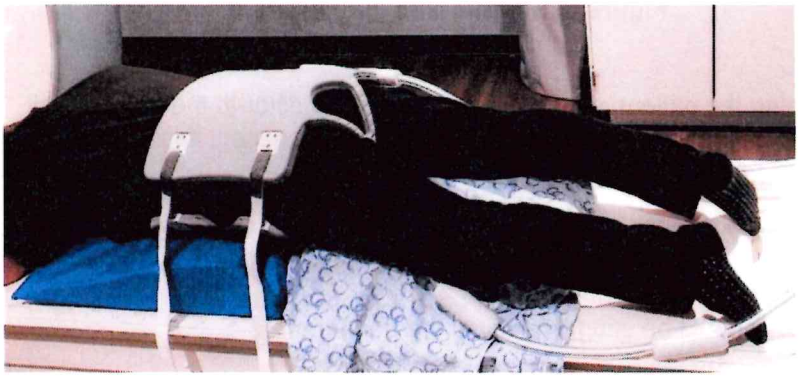


Figure 6: Prone head-first patient ready to scan. Bore is to the left.

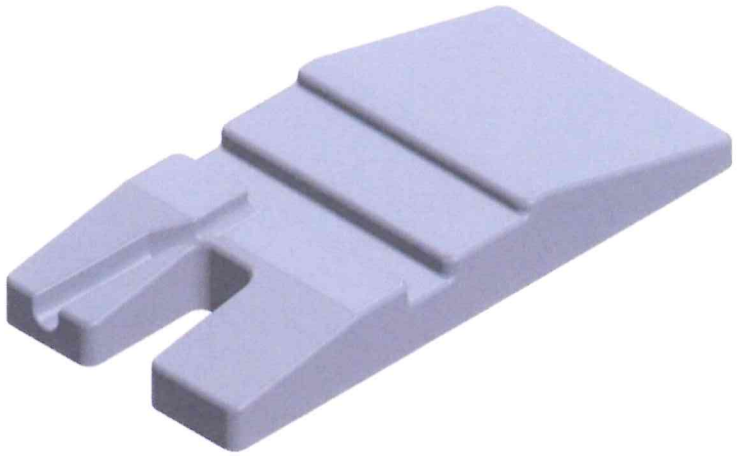


Figure 7: Optional prone positioning pad.

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).

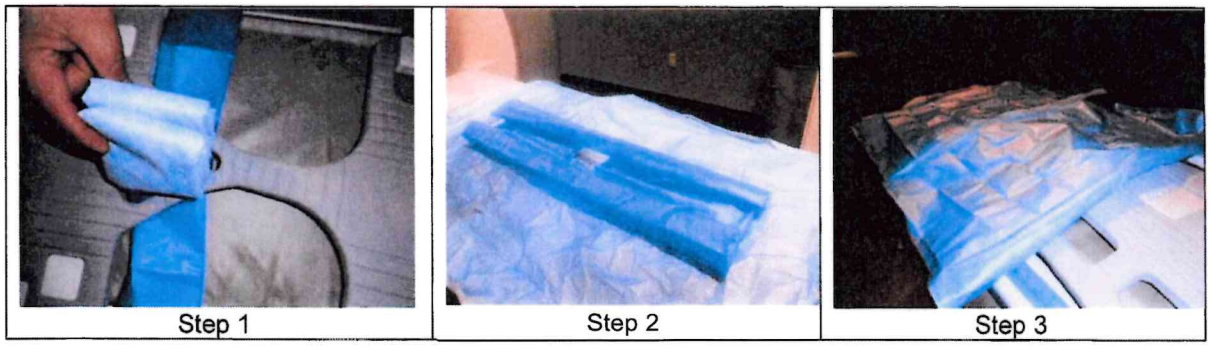


Figure 8: Surgical liner (drape) setup.

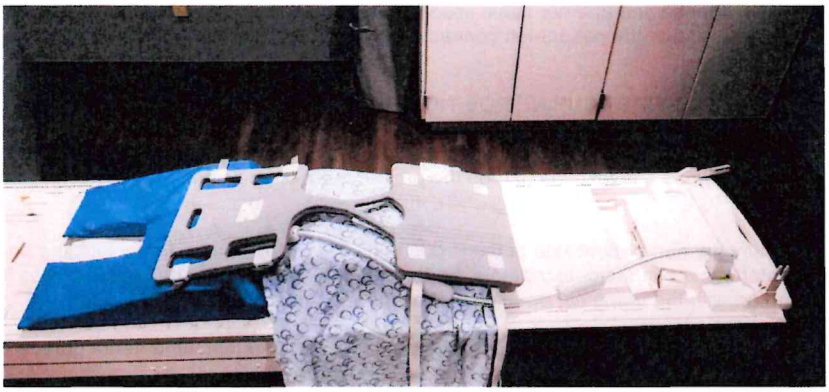


Figure 9: Initial head-first setup prior to loading patient. Note the anterior cable is connected, positioned in a prone s canning pad (prototype rendition shown) and connected to the coil receptable.

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.

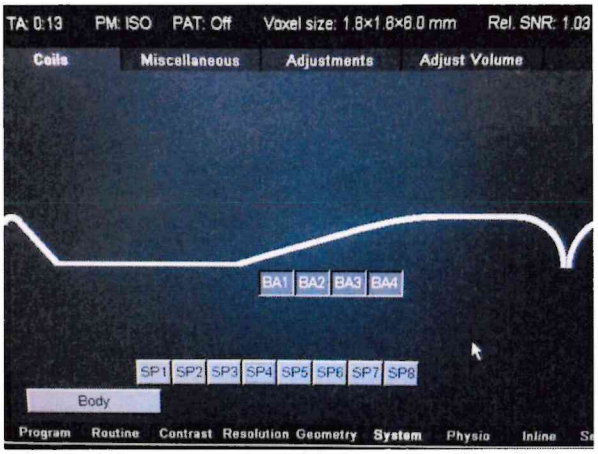


Figure 10: Systems tab screenshot. Make sure all coil elements are "on".

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.

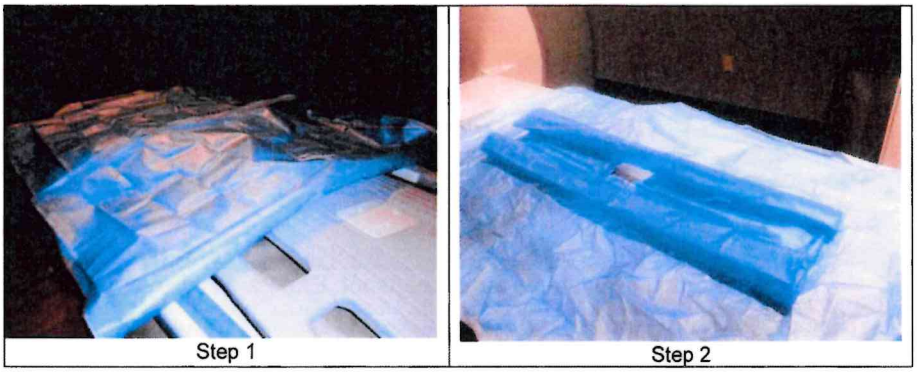


Figure 12: Steps to remove surgical liner (drape) after use.

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.

15. QUALITY ASSURANCE

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

Position the coil flat on the table for feet-first positioning and connect the posterior cable assembly to coil and system as in figures above.

Use the four 1.9-liter phantoms that came with your Siemens system. Position them on the phantom positioner as shown in Figures 13 and 14 below.

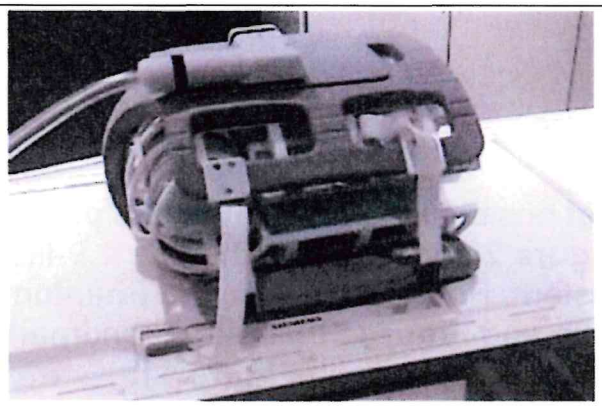


Figure 13: Side View. Phantom strapped in.

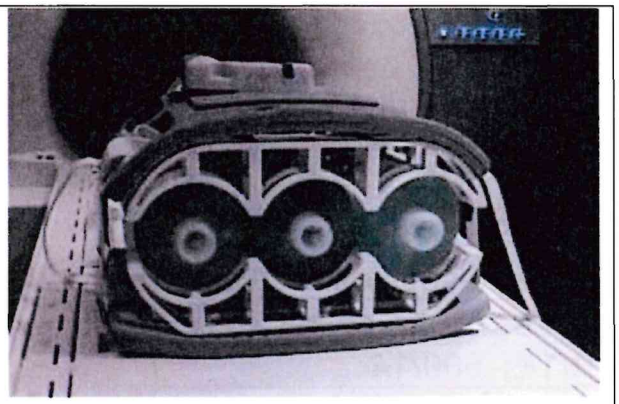


Figure 14: Front View. Phantom strapped in.

Run the following sequence, prescribing 4 slices: one at A/P center (A0) and one each at +/- 30mm from center (A30, P30) and one at A80- that slice not through a phantom.

Scan plane: Coronal	Pulse Sequence: TSE
Base Resolution: 256	Phase Resolution: 100%
Turbo Factor: 2	Phase Over-sampling: 0%
AVG: 1	TR/TE: 600/14
Slice Thickness: 5	Slice Groups: 3
FOV: 400 mm	BW: 122 Hz/Px
Phase Direction: R/L	No Filters or Normalizing

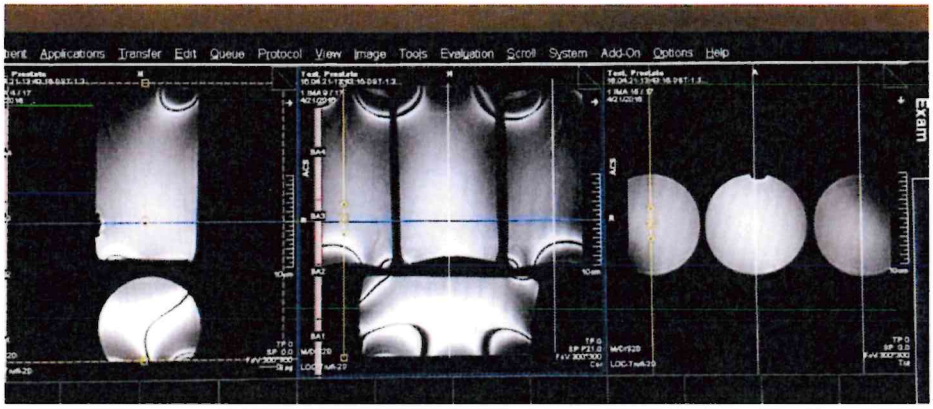


Figure 15: Three Slice groups.

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).

If any voids in the resulting images are present, call for further instructions:

ScanMed Customer Service

(402)934-2650

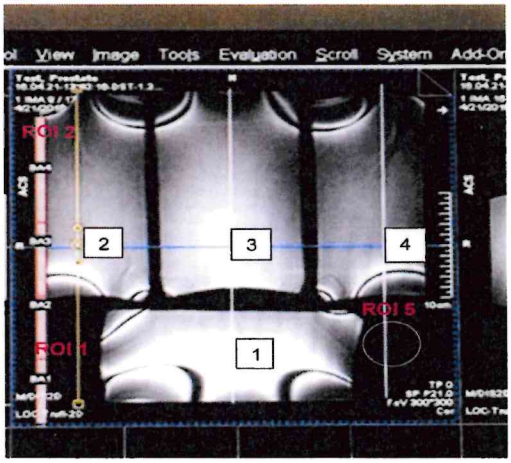


Figure 16: ROI placement

INITIAL QA DATA

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 Customer Service at (402)934-2650** for further instructions.

Record the results of each periodic test in Table 3. Make additional copies of the following data tables as needed.

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

Table 1: Data table.

DATA TABLE FOR PERIODIC QA CHECKS

Original Install Data	
DATE	**SNR0**

Table 2: Original installation 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 ScanMed 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.** **Contact ScanMed at (402)934-2650 during normal business hours 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 system 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.

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 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.

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 photographs of the coil, the scanner, and the patient's 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 may be present only in internal electronic circuitry and is not present in 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.**

Refer to the Attachment at the end of this document for specific Biocompatibility 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.

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,
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 the appropriate coil selected for your scanner (see Section 3-2). Also, check the Systems tab to ensure all the elements are on for each sequence.
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.
6. 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 there is no metal present in the area being scanned.
2. If the above checks out, it is possible the coil has failed. Contact ScanMed.

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