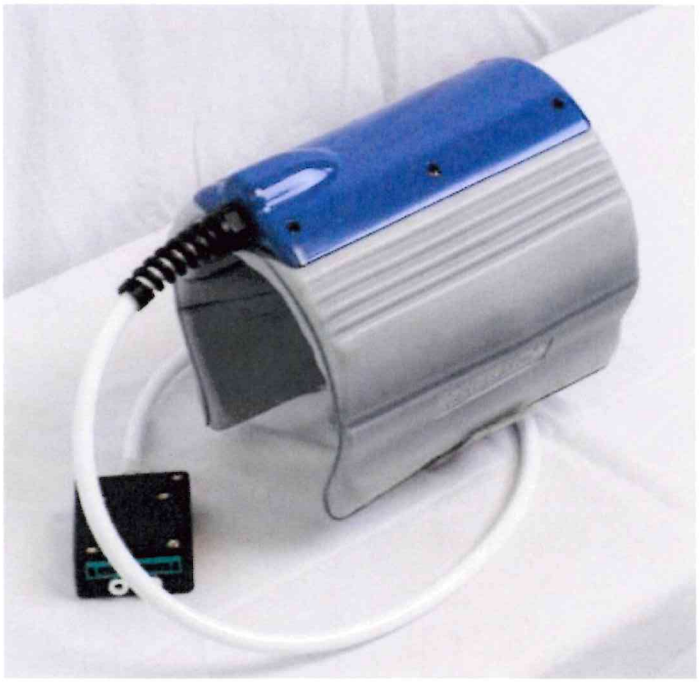
Manufactured by:
ScanMed, LLC
9840 S. 140th St., Suite 8
Omaha, Nebraska 68138 USA

ScanMed®
THE IMAGE IS EVERYTHING

Operator's Manual

Shoulder/Knee Array Coil



Applicable Models:

- 208GE1500
- 208GE3000
- 209GE1500
- 209GE3000
- 208GE1501
- 208GE3001
- 209GE1501
- 209GE3001

Approved by:

Randall Jones, CEO/President

March 22, 2022
Date

ScanMed LLC
Model: 20xGE 8CH 1.5T/3.0T
Release Date: 22 – MAR - 2022

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LICENSES AND TRADEMARKS

The ScanMed® Logo is a registered trademark of ScanMed, LLC.
Signa, Excite System, HDx and the GE logo are registered trademarks of the General Electric Company.

This manual describes the use and operation 1.5T and 3.0T 8-Channel HD and HDx General Electric systems only. Upgrades or other modifications to the system software and/or hardware may affect compatibility. Software or firmware upgrades may affect compatibility and performance. Please contact your GE representative and ScanMed Representative prior to operating on new software, as failure to do so may void your warranty.

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

GENERAL INFORMATION

This manual describes the safety precautions, features, use and care of the ScanMed 8 Channel Shoulder/Knee coil, compatible with the GE HD/HDx 1.5T and 3.0T MR scanner. Please review this manual thoroughly before using the device.

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

(402) 934-2650 or **CustomerService@scanmed.com**

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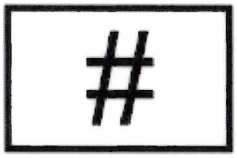
COMPATIBILITY

The ScanMed 1.5T/3.0T HD/HDx Shoulder – Knee Array is compatible with the HD/HDx 1.5T/3.0T MR scanner.

EXPLANATION OF SYMBOLS

SYMBOL	DESCRIPTION
	Manufacturer and Date of Manufacture: ScanMed LLC 9840 S 140 Street, Suite #8 Omaha, NE 68138 USA
	Authorized representative in the European Community / European Union Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands
	Serial Number
	Model Number
	Country of manufacture. The date of manufacture may be added adjacent to this symbol. Replace CC with USA designation number of 840.

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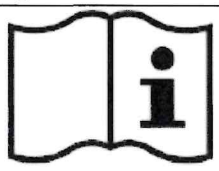
	Non-sterile. This medical device has not been subjected to a sterilization process.
	Do not use if package is damaged and consult *instructions for use*. Symbol indicates the *medical device* should not be used if the package has been damaged or opened.
	Fragile, handle with care. This *medical device* can be broken or damaged if not handled carefully.
	Keep *medical device* dry. This product should be protected from moisture.
50*C  -40*C	Temperature limit. Ambient temperature limits of between -40°C to +50°C Indicates the temperature limits to which the *medical device* can be safely exposed. The upper and lower limits of temperature will be indicated adjacent to the upper and lower horizontal lines.
	Consult instructions for use or consult electronic *instructions for use*. Indicates the need for the user to consult the *instructions for use*.
	Caution. Indicates caution is necessary when operating the medical device or control close to where the *symbol* is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

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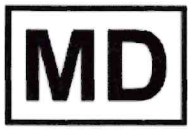
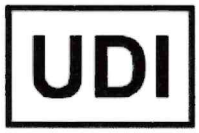
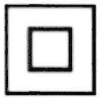
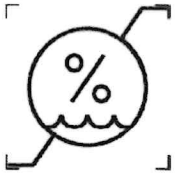
	Non-pyrogenic. Indicates this *medical device* is non-pyrogenic.
	*Medical device.* Indicates this item is a *medical device*.
	Unique Device Identifier. (Optional) Indicates that this medical device has Unique Device Identifier information.
	Waste in electrical and electronic equipment.
	Type BF equipment.
	Class II *medical device.*
95%  15%	Relative humidity of 15% to 95% (non-condensing)

Table of Contents

1.0 INTRODUCTION

Description

The shoulder/knee array interfaces with the G.E. 1.5T or 3.0T Signa® system and has been designed to collect image data throughout the region of the elbow, shoulder, knee, or ankle/foot depending upon patient and coil size. This multi-channel design incorporates a set of unique antenna elements whose geometry has been optimized to image this anatomy. The coil form geometry has been formed to facilitate close coupling of the imaging coil's region-of-sensitivity to the anatomy of interest. The coil assembly comes with Velcro straps to comfortably place and secure the patient onto the coil assembly.

Applicable Models

This manual applies to the following models of the Shoulder/Knee Array Coil.

Model	MRI System Compatibility
208GE1500	1.5T GE Signa HD or HDx
208GE1501	1.5T GE Signa HD or HDx
208GE3000	3.0T GE Signa HD or HDx
208GE3001	3.0T GE Signa HD or HDx
209GE1500	1.5T GE Signa HD or HDx
209GE1501	1.5T GE Signa HD or HDx
209GE3000	3.0T GE Signa HD or HDx
209GE3001	3.0T GE Signa HD or HDx

2.0 INSTALLATION

The Shoulder/Knee Array configuration file will need to be loaded on your MRI scanner before the coil can be used. Please refer to the supplied Installation Manual.

If you require assistance, ScanMed™ personnel will be glad to provide telephone support for the installation process.

3.0 OPERATION

Setup

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

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

For lower extremity imaging the patient should be in the supine position, feet-first into the magnet. Position the coil so that the cable exit is pointed into the magnet. The coil should always be operated with as tight of closure as possible. Simply wrap the coil about the elbow or lower extremity and Velcro snugly in place using the supplied short Velcro straps.

For upper extremity imaging, the patient should be in the supine position, head first. The coil is positioned about the shoulder or arm, and Velcro closed as snugly as possible using the supplied Velcro straps. The longer Velcro straps are sized to wrap entirely around the patient's torso and hold the coil in place. Position the coil so that the cable exit is pointed into the magnet.

The coil may be positioned about the patient's extremities in any manner in which it may be closed, provided that the anatomy is positioned parallel with the bore.

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

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

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

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

Landmarking and Imaging

Landmark on the anatomy positioned within the coil volume.

Coil Selection

The coil will be automatically recognized by the scanner.

Size	Model	Diameter	Length
Medium	208GExxxx	110 mm	210 mm
Large	209GExxxx	180 mm	210 mm

Operation

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

4.0 QUALITY ASSURANCE

Quality Assurance Procedures

Select a phantom to fill the volume of the coil. Perform an initial QA of the coil assembly. Run a standard T1-weighted sequence such as TR 500, TE 20, 5 mm coronal slice, with a 30 cm FOV. After the acquisition, record signal means (ROIs inside phantom) and noise standard deviations (ROIs outside phantom), as shown below.

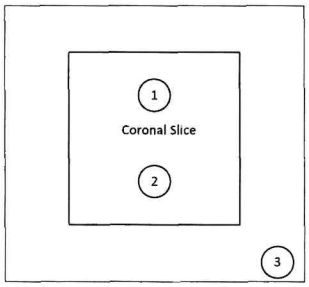
Divide the ROIs inside the phantoms by the average of the ROIs outside the phantoms in each section. Record these numbers in table 4-2.

Refer back to these numbers and periodically repeat the measurement as a quality assurance test or if you suspect problems with the coil. If QA test results reveal SNR degradation of greater than 15%, call ScanMed™ customer service for further instructions.

Make additional copies of the following data tables as needed.

Initial QA Data

Baseline QA Data			
ROI	**Signal ROI Signal Mean**	**Noise ROI Standard Deviation**	**SNR (Mean/Average SD)**
1			
2			
3			



ROI placement. ROI's 1 and 2 are within the phantom volume, while ROI 3 is outside of the phantom volume.

Data Table for Period QA Checks

	Average SNR value	
Original Install		C

1	2	3
Date	**Average SNR Value**	**Percent Deviation (Column 2 ÷ C)**

5.0 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.

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

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

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

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

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

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

Contraindications and Patient Precautions

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

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

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

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

- A greater than normal potential for cardiac arrest.
- An increased likelihood 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.

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.

Material Safety Information

CAUTION: **This product contains chemicals, including lead, known to the state of California to cause birth defects or other reproductive harm. Wash hands after handling.**

6.0 MAINTENANCE, TROUBLESHOOTING, AND DISPOSAL

Preventative Maintenance and Cleaning

QA Test

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

Storage

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

CAUTION: **Do not store your coil at high temperatures (above room temperature) as damage to the foam may result.**

Inspection

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

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

Cleaning

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

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

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

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

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 (CST), Monday through Friday to arrange for service/repair.

- **ScanMed Customer Service**
  9840 S. 140th St., Suite 8
  Omaha, NE 68138
  Tel: (402) 934-2650
  Fax: (402) 778-9699

Receiving No Signal

Problem: You are scanning and yet receiving no signal.

Solutions: 1. Verify that you are transmitting with the body coil and receiving with the imaging coil.

2. Verify that you have selected the "currently connected" or "JEXT" coil 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 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. The protocol should be identical to the recommended protocols provided.

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

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

4. Verify that the coil is properly positioned.

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

Artifacts

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

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

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

Disposal

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

CAUTION: Dispose of RF coil properly.