Operator's Manual

Elbow Array Coil with HDx Connector

ELBOW ARRAY
RECEIVE-ONLY COIL
HDx CONNECTOR

OM308GE02H-R4 (08/18/2020)

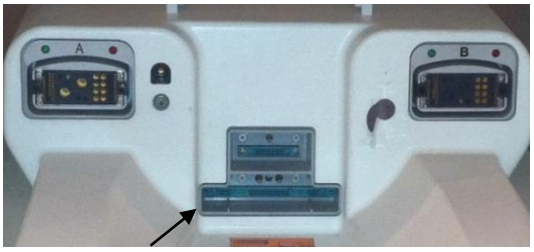
ONLY FOR USE WITH GENERAL ELECTRIC
1.5 or 3.0 TESLA 8-CHANNEL HD & HDx SYSTEMS

Applicable Models:

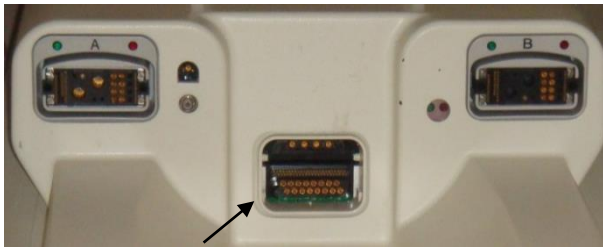
308GE1500H	308GE3000H
308GE1501†	308GE3001†
308GE1501H	308GE3001H

†Older coil model numbers with HDx Connector

Note: This coil is for use on systems with no Legacy Connector interface. If your scanner does have the Legacy Connector port, this coil will not work. Please call (402) 934-2650 for an exchange.



Legacy Port 1.5T System



Legacy Port 3.0T System

Manufactured by:
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Omaha, NE 68138 USA
Phone: (402) 934-2650
Fax: (402) 778-9699
www.scanmed.com

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

Signa, Excite System, and the GE logo are registered trademarks of the General Electric 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 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.

	Attention, Consult Accompanying Documents
	Type BF Equipment
	Class II Equipment
	For use on specified field strength
	Dispose of the coil by returning to manufacturer or via facility equipped to handle electronic products.
	Ordinary Equipment, Suitable for Continuous Operation
	Part Number and Revision
	Serial Number
	Date of Manufacture

NOTICE:

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 101.1 kPa

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1.0 INTRODUCTION

Description

The Elbow Coil interfaces with the GE 1.5T or 3.0T MRI systems and has been designed to collect image data throughout the region of the elbow or wrist and hand depending upon relative patient and coil size. This 8-channel design incorporates a set of unique antenna elements whose geometry has been optimized to image this anatomy. The design is “recognized” as a receive-only coil on the GE Signa® system. The coil form geometry has been formed to facilitate close coupling of the imaging coil's region-of-sensitivity to the anatomy of interest.

Indications For Use

The indications for use for this coil are as follows.

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

Applicable Models

This manual applies to the following models of the Elbow Array Coil:

Model	MRI System Compatibility (Only systems without legacy connector interface)
308GE1500H	1.5T GE Signa HD or HDx
308GE1501	1.5T GE Signa HD or HDx
308GE1501H	1.5T GE Signa HD or HDx
308GE3000H	3.0T GE Signa HD or HDx
308GE3001	3.0T GE Signa HD or HDx
308GE3001H	3.0T GE Signa HD or HDx

Accessories

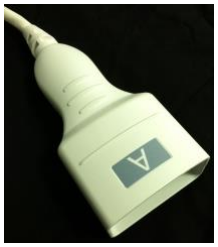
Your coil is supplied with the following accessories.

Quantity	Part Number	Description
1	PHA00011D	Phantom Size D

2.0 INSTALLATION

System Applicability

This coil is supplied with an HDx connector:



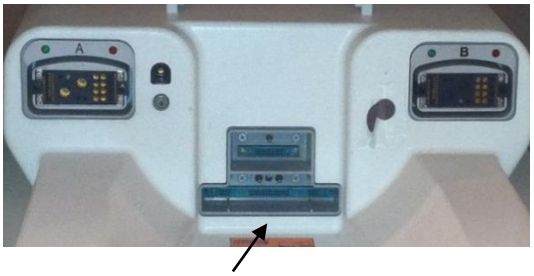
HDx Connector

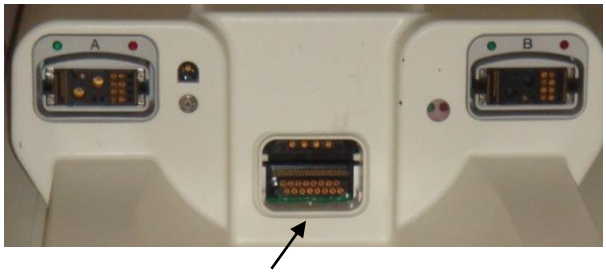
This coil will only work on systems which do not have a Legacy Connector Port. If your MRI system does have a Legacy Connector Port, this coil will not work. Please contact ScanMed® Customer Service for a replacement at (402) 934-2650.

Legacy Port 1.5T System

Legacy Port 3.0T System

Note: This coil is for use on systems with no Legacy Connector interface. If your scanner does have the Legacy Connector port, this coil will not work. Please call (402) 934-2650 for an exchange.





Configuration File Installation

The Elbow Array Coil will be recognized under currently connected as an 8 Ch torso coil (8US TORSOPA) or an 8 Ch brain coil (8HRBrain).

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.

The patient should be in the supine position, feet-first into the magnet. The orientation of the coil is such that the cable end of the coil enters the bore first (do not loop the cable to connect to the scanner).

- Elbows: Place the elbow into the coil and rest the arm and the coil against the patient. Use the MRI table positioning straps to hold the coil in place.

- Wrist & Hands: Place the wrist/hand into the coil and rest the arm and the coil against the patient and Velcro in place using the MRI table positioning straps.

NOTE: Using the coil on the forearm of a patient with a bent elbow such that the coil runs laterally to the bore is not recommended. The image quality will be substantially degraded.

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

Select the coil “Currently Connected” and mode “8US TORSOPA” or “8HRBrain” in the coil selection list on the screen.

Operation

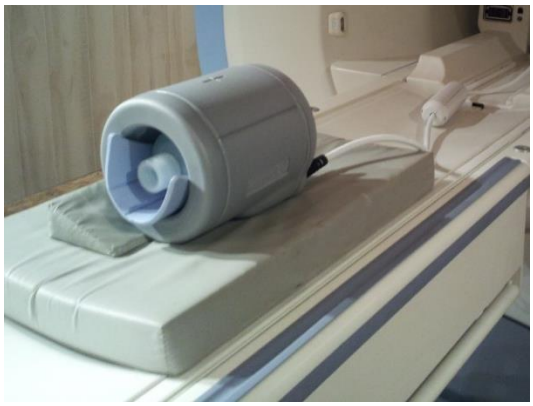
Note that the coil will provide imaging data throughout the entire length of the coil with proper coil selection. This coil is compatible with the common ASSET, PURE, and SCIC type sequences.

4.0 QUALITY ASSURANCE

Quality Assurance Procedures

Before running the QA, the phantom bottle must be filled. The phantom kit supplied with your coil includes bottle(s) which must be filled with water. Either tap water or distilled / deionized water may be used.

Place the phantom in the coil. Position the coil on a pad, if necessary, to center the coil in the bore. Landmark on the center of the coil and drive the table to isocenter.

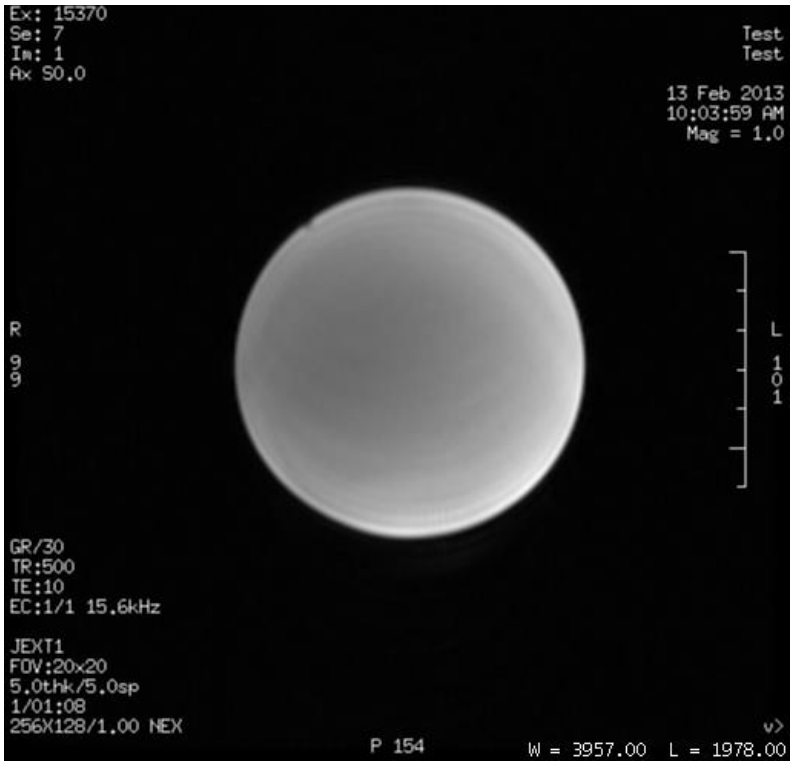


Run an axial sequence through the center of the bottle using the following parameters.

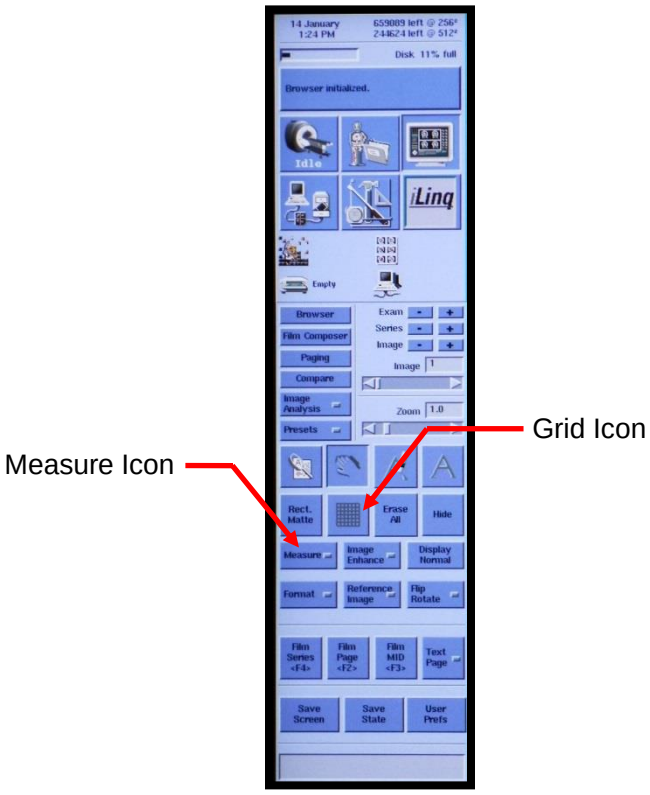
Scan Protocol	
Coil Mode	8US TORSOPA or 8HRBrain
Scan Plane	Axial
Field of View	20 cm
Pulse Sequence Family	Gradient Echo
Pulse Sequence	GRE
TR	500
TE	10
FA	30
# of Slices	1
Slice thickness	5 mm
NEX	1
Matrix Size	256 x 128
Bandwidth	15.63 KHz
Frequency Direction	L-R

After the acquisition, perform the following steps.

1) Review the image for any dark bands or dead zones. The image should be similar to the image below.



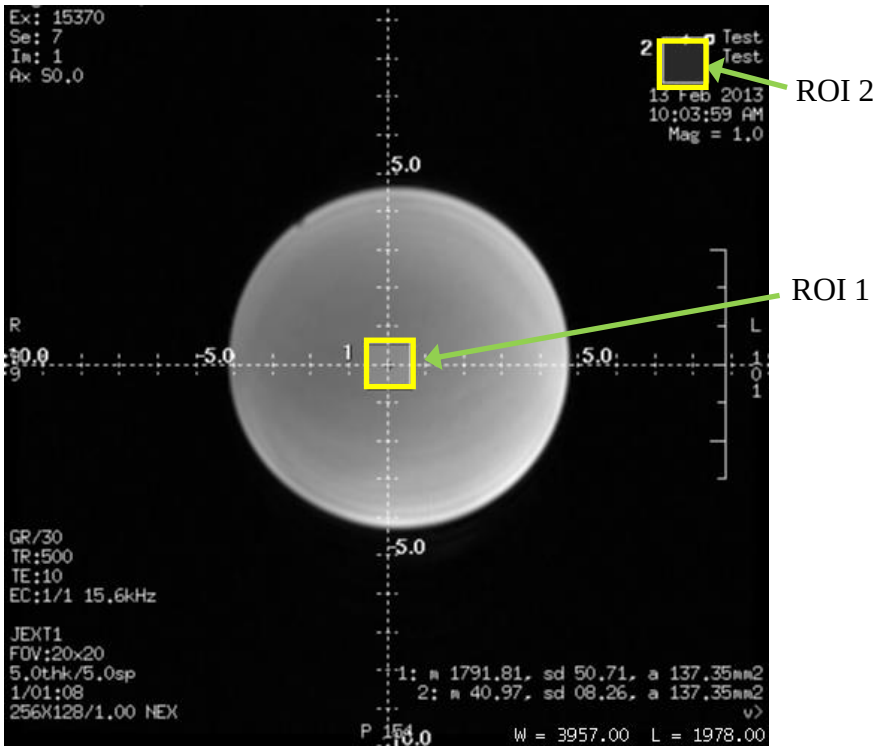
2) Turn on the image grid. To do this, click on the Grid Icon from among the viewer tools icons.



3) Position two measurement regions on the image. Click on the Measure icon and select a rectangular measurement area. Do this 2 times, so that 2 measurement areas are placed on the screen.

4) Move the 2 measurement regions so that they are approximately in the following locations on the grid:

   - Area 1 at center of phantom
   - Area 2 in the upper right corner of the screen.



5) Click on each Measurement Area. Measurements will be shown at the bottom of the screen for each Measurement Area, where:
    - **m** is the Signal Mean within that measurement area
    - **sd** is the Signal Standard Deviation within that measurement area.

6) Position two ROI's on the image as shown above. Record the information on Table 1.

ROI	Parameter	Value	
1	Signal Mean (m)		Box A
2	Standard Deviation (sd)		Box B

Table 1: Initial Measurement Values

7) Calculate the SNR by completing Table 2

ROI	Calculation	Calculated Value (SNR Ratio)
1	Box A divided by Box B	T1=

Table 2: Initial SNR Value

Periodic QA Checks	SNR	Percent Deviation From Initial Measurement
Date	ROI 1	ROI1/T1

Table 3: Periodic QA test results.

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 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.

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.**

WARNING: **No modification of this equipment is allowed.**

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. Do not open the coil.**

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® Customer Service department for assistance. Call (402) 934-2650.

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 housing 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

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.
- Cidex/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® to arrange for service/repair.

ScanMed® Customer Service
9840 South 140th Street, Suite 8
Omaha, NE 68138 USA
Phone: (402) 934-2650
Fax: (402) 778-9699
www.scanmed.com
Available: Monday – Friday, 7:30 AM to 5:30 PM CT

Receiving No Signal

Problem: No signal received during scanning.

Solutions:

1. Verify that you have selected the “currently connected” and mode “8US TORSOPA” or “8HRBrain” coil from the coil selection list.

2. Verify that the cable is correctly connected to the system. The coil cable should be connected to the coil port.

3. 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 this coil. Contact ScanMed® for assistance.

Image Quality

Problem: The SNR percentage obtained in the periodic quality assurance check is not greater than the specified values, 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® at (402) 934-2650.

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.