Operator's Manual

Orbit and Mandible Coil

Orbit and Mandible Coil
RECEIVE-ONLY COIL

Revision 2 (03/13/2020)

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

Applicable Models:

- 994GE1500
- 994GE1501
- 994GE3000
- 994GE3001

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

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 the sale, distribution, and use by or on the order of a physician.

Type BF Equipment

Class II Equipment

Attention, Consult Accompanying Documents

Ordinary Equipment, Suitable for Continuous Operation

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

©2020 Manufactured by:
ScanMed, LLC
9840 S. 140th St., Suite 8
Omaha, NE 68138 USA
Phone: (402) 934-2650
Fax: (402) 778-9699
www.ScanMed.com

ScanMed®
The Image is Everything

CONTENTS

1.0 INTRODUCTION

Description 1-1

The orbit coil interfaces with the GE 1.5T or 3.0T system and has been designed to collect image data throughout the region of the orbits and optical nerve. This two 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.

Applicable Models 1-2

This manual applies to the following models of the Orbit Coil.

Model	MRI System Compatibility
994GE1500 994GE1501	1.5T GE Signa HD or HDx
994GE3000 994GE3001	3.0T GE Signa HD or HDx

Accessories 1-3

Your coil is supplied with the following accessories.

Quantity	Part Number	Description
1	MSC00015C	22” Velcro Restraint Strap
1	PHA00011F	Phantom Bottle F
1	Xxxxxxxx	Comfort Pad/Head Support

Indications for Use 1-4

The Indications for use are as follows:

The coil family is to be used in conjunction with a 1.5T and 3.0T Magnetic Resonance Scanner, to produce diagnostic images of the orbits and surrounding anatomy, as well as mandible regions that can be interpreted by a trained physician.

The intended use for the device family is to provide MRI antenna sets to facilitate targeting imaging of the orbit region and mandible region, as well as tissue of the brain and face.

2.0 INSTALLATION

Configuration File Installation 2-1

The Orbit Array configuration file will need to be loaded on your MRI scanner before the coil can be used. .

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

3.0 OPERATION

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, head-first into the magnet. The orientation of the coil is such that the cable end of the coil enters the bore first (do not loop the cable to connect to the scanner).

- Orbits: We recommend using the patient support base of the 8 channel head coil and positioning the patient on that head support, or use adequate pillows. If using the head support, run a coil strap (provided) under the support paddle and then position the patient on the paddle using each end of the Velcro straps to secure the coil to the patient's face. If using a pillow, then strap the coil to the patient's face first, then lie them onto the pillow facing upwards.

CAUTION: **Do not over tighten the Velcro strap. Applying too much pressure may cause patient discomfort and skin redness after the coil is removed.**

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.**

Figure 1

LANDMARKING AND IMAGING 3-2

Landmark on the anatomy positioned within the coil volume.

Coil Selection 3-3

Select the coil “Currently Connected” or “SMORBIT” in the coil selection list on the screen.

Operation 3-4

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 4-1

Before running the QA, the phantom bottle must be filled with water. Tap water or distilled / deionized water may be used.

Velcro the coil onto the phantom and use the head coil support paddle if available, otherwise use a pillow to seat the coil in the center of the bore.

CAUTION: **Do not leave the head coil with the head support or any other coil in the magnet before using the orbit coil. Unconnected coils may be damaged.**

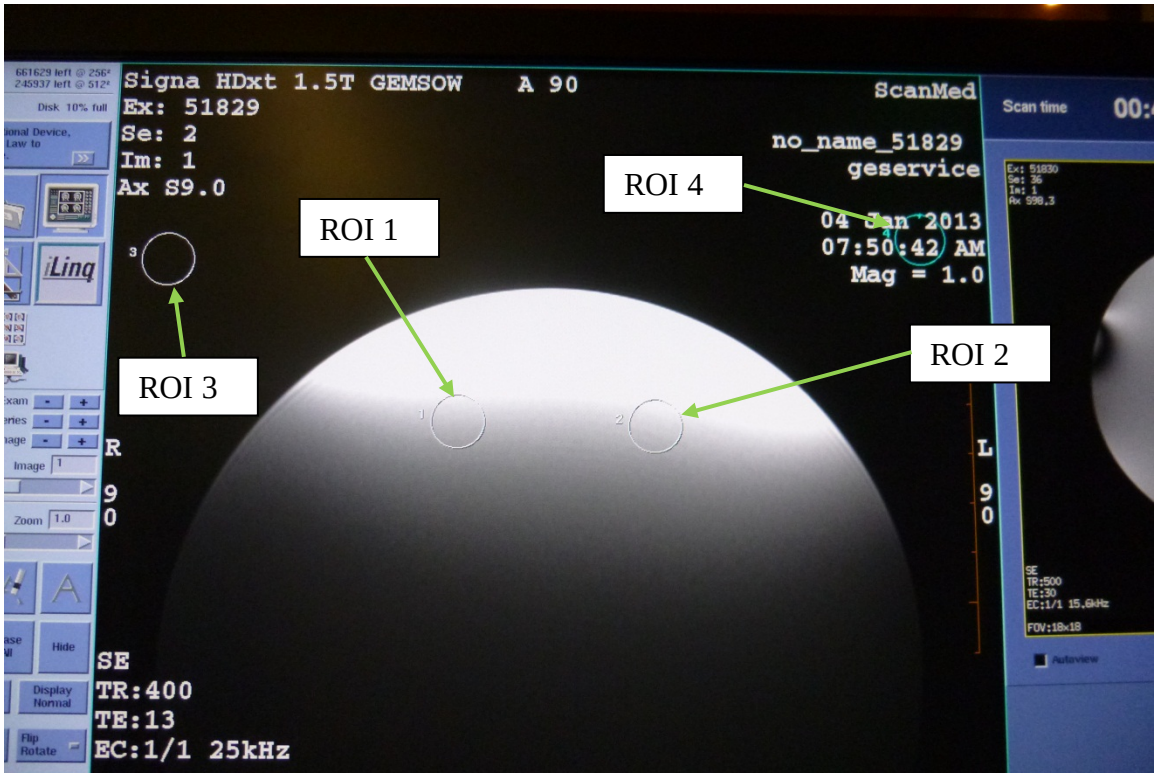
Landmark on the center of the coil and drive the table to isocenter.

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

Scan Protocol	
Scan Plane	Axial
Field of View	25 cm
Pulse Sequence	SE
TR	500
TE	30
# of Slices	1
Slice thickness	5 mm
NEX	1
Matrix Size	256 x 256

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

ROI	Parameter	Value	
1	Signal Mean right		Box A1
2	Signal Mean left		Box A2
3	Standard Deviation		Box B1
4	Standard Deviation		Box B2
	Avg B1, B2		Box B

Table 1: Initial Measurement Values

3) Calculate the SNR by completing Table 2

ROI	Calculation	Calculated Value (SNR Ratio)	Specification Value
1	Box A1 divided by Box B		TBD
2	Box A1 divided by Box B		TBD

Table 2: Initial SNR Values

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 produce a value less than the specification value, call ScanMed™ customer service for further instructions.

5.0 SAFETY

General Safety 5-1

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 5-2

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 5-3

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 5-4

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 5-5

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 6-1

- **QA Test**

  Perform a system quality assurance phantom test as outlined in Section 3 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 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**

  Surface cleaning of the material is the only action allowed. Only the solutions specified below may be used. If the coil is damaged during cleaning, contact ScanMed for repair. This product contains no user replaceable or serviceable parts.

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 6-2

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 “SMORBIT” 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 6-3

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.