
IMRIS
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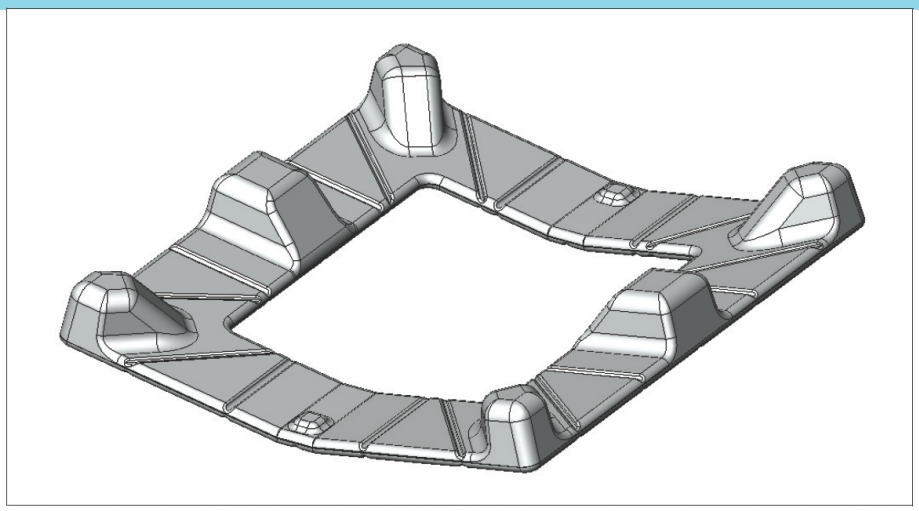
IMRIS Inc.
100-1370 Sony Place
Winnipeg, Manitoba, R3T 1N5
Canada
IMRIS® InSitu™ Coil, Open
3T, Large, Case of 5
REF 114893
QTY 5
LOT 2014081550
IMRIS, Inc.
5101 Shady Oak Road
Minnetonka, MN 55343 U.S.A
www.imris.com
Do Not Use
If Package is Damaged
Do Not
Reuse
Not Made With
Natural Rubber Latex
Do Not
Resterilize
Refer to
Instructions
Rx ONLY
STERILE EO
Sterilized Using
Ethylene Oxide
2019-08
Use by
CAUTION: Coil is surface sterile only.
Damage to the coil surface (e.g. puncturing) will compromise sterility.
CMP Code# C18002
Label Part No. 117396-000 Rev. -

IMRIS InSitu™ Coil, Open, 1.5T, Large

Applications Manual



IMRIS
DEERFIELD IMAGING

CE 0120

Manufacturer's notes:

This product bears a CE marking in accordance with the provisions of regulation 93/42/EEC of June14, 1993 for medical products.

Legal Manufacturer

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EC REP

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℞ ONLY

The IMRIS InSitu™ Coil, Open, 1.5T, Large is intended for use by or on the order of a physician. CAUTION: Federal law (U.S.A.) restricts this device to sale, distribution, and use by or on the order of a physician.

Copyright

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Technical Support

Our Customer Support staff can be reached at the following toll-free numbers:

North America - 866-475-0525
International - 00-800-0019-2021

Customer orders: orders@imris.com

Reporting to IMRIS

Please report to IMRIS all issues or problems relating to the performance characteristics or safety of IMRIS® Surgical Theatre system. In addition, any incidents involving serious injury or death, where IMRIS equipment may have caused or contributed to the injury or death, must be reported to IMRIS.

Email problem reports to: customersupport@imris.com

Acronyms and Abbreviations

CT	Computed Tomography
HFD	Head Fixation Device
MR	Magnetic Resonance
OR	Operating Room

Warning, Caution and Note Statements

The following conventions are used for Warning, Caution and Note statements in this document:

Warning: A warning statement emphasizes dangerous procedures, practices, etc., which could result in serious personal injury or death if not followed correctly.

Caution: A caution statement emphasizes procedures, practices, etc., which could result in damage to or destruction of equipment if not followed correctly.

Note: A note statement highlights procedures, events, practices, etc., which are desirable or essential to efficient operations.

Table of Contents

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Introduction

The IMRIS InSitu™ Coil, 1.5T, is used as a general purpose intraoperative coil for cranial imaging applications in the IMRIS Surgical Theatre. The InSitu Coil is provided as a single-use, sterile disposable product intended for use with a single patient during a single procedure, including any preparatory scans such as the pre-op QA scan.

The InSitu Coil is a receive-only flexible phased array coil. It has two elements and is intended for use with an HC150 Intraoperative Flexible Coil in order to enable parallel imaging and optimal image quality.

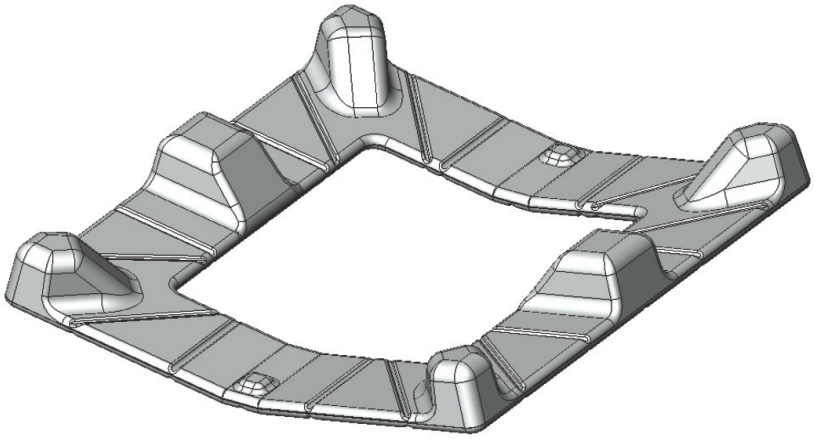


Figure 1: IMRIS InSitu Coil, 1.5T

This manual supplements the operator manual for the HC150 Intraoperative Flexible Coil. Refer to the operator manual for the Horseshoe Headrest for instructions on how to assemble the InSitu Coil to the Horseshoe Headrest.

General Safety Information

In case of damage, contact IMRIS Customer Support.

Indications for Use

IMRIS InSitu Coil 1.5T is intended for use with the IMRIS (Siemens MAGNETOM) 1.5T MRI Systems as an imaging device for clinical procedures.

IMRIS InSitu Coils produce images of the head and upper C-spine internal structures.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis and therapy options.

Notes to Users

This manual provides instructions on the safe and effective use of the IMRIS InSitu Coil, 1.5T in the intraoperative MR environment. It is important that the user has a complete understanding of the entire MR system, as well as the safety precautions and emergency procedures described in the operating manuals for those systems.

Coil Sterility

The InSitu Coil is sterilized using an ethylene oxide sterilization method and is intended for single-use only. Do not re-sterilize.

IMRIS will not be responsible for a coil that is re-sterilized, nor accept for credit or exchange a sterile package that has been opened but not used. As long as the packaging is not opened or damaged, the product is sterile.

Warning: The InSitu Coil is supplied sterile for single-use only and must not be re-used or re-sterilized for use with more than one patient. Re-use may cause cross-contamination and infection. Attempts to re-sterilize will damage the product and diminish performance.

The coil is surface sterile only. Damage to the coil surface, i.e. puncturing, will compromise sterility.

Operator Responsibility

IMRIS does not accept responsibility for the safety, reliability and performance of the InSitu Coil if it is not used in accordance with the instructions, procedures and warnings in this manual.

Warning: Improper usage or usage not conforming to the instructions contained in this manual, may result in serious injuries or death to the patient or the user, and/or damage other equipment.

Warning: Transmissible Spongiform Encephalopathies (TSEs) can be transmitted to other patients, users and third parties. If the patient is suspected of having a TSE, adequate measures must be taken to prevent possible transmission. Any equipment in contact with a suspected TSE case cannot be reused with any other patient and should be properly discarded.

Inspecting Before Use

Inspect the InSitu Coil before use, and do not use a coil with any of the following conditions:

- The sterile packaging has become wet, opened, or damaged. The coil will not be sterile if the packaging is torn or punctured.
- The coil itself is damaged, torn, or punctured. The coil is surface sterile only.
- The coil is past the expiration date shown on the package.

If the coil appears damaged and/or does not function properly, contact IMRIS Customer Support for a returned materials authorization and remove the coil from service.

Handling and Storage of the InSitu Coil

Store the coil in a clean, dry location at 10 to 38°C (55 to 100°F).

Handle the coil with great care, using the following guidelines when handling and storing the coil:

- Do not compress, bend, twist, or stretch the coils when handling. Damage to the internal electronics will result from these actions
- Do not place heavy objects on top of the coils.
- Do not immerse the coils in fluid at any time.

Disposing of the InSitu Coil

Dispose of the coil according to hospital procedures, following all regulations governing the disposal of electronic devices.

Quality Assurance

IMRIS recommends a 1900 ml bottle phantom be scanned daily in the OR prior to use, following the protocol specified in Setting up the QA Scan on page 10. Regular quality assurance testing ensures consistent system and coil performance. The QA procedures not only ensure consistent system performance, they identify potential problems.

Refer to the appropriate section of the *Systems Manual MAGNETOM Operating Instructions* for the complete description of the quality assurance procedures with specific Siemens coils and information on the phantoms.

Setting up the QA Scan

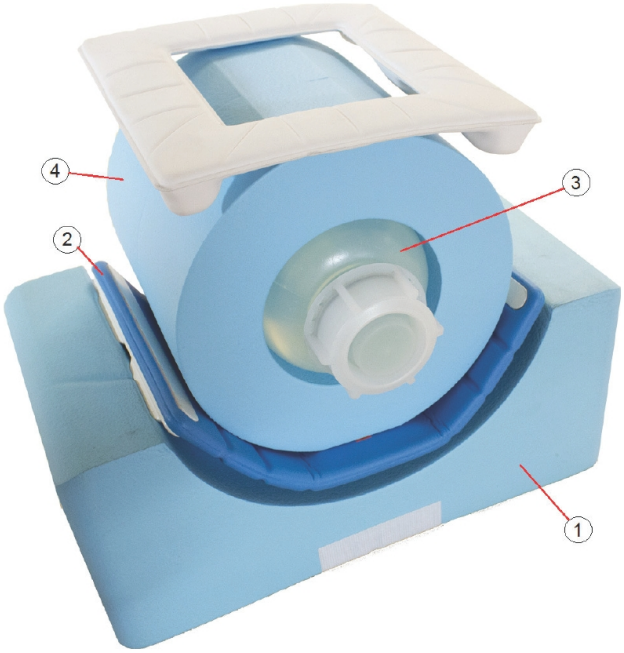
The QA scan for the IMRIS InSitu Coil is completed using the upper HC150 Intraoperative Flex Coil and a InSitu Coil still packed in the sterile packaging.

IMRIS recommends a QA scan using the InSitu Coil and upper HC150 Intraoperative Flex Coil on the table headrest prior to the surgical case. The QA procedures for the InSitu Coil require a precise setup on either the operating room table or the neurosurgical tabletop with the following:

- Operating room table or the Neurosurgical Tabletop, with head rest
- Head support cushion
- Siemens 1900 ml plastic bottle phantom

Setting up Both Coils and the Phantom

1. Install the headrest on the table top. Refer to the appropriate table operator manual for further information.
2. Place the head support cushion (Figure 2, Item 1) on the table headrest and center it in the left-right direction.



Item	Description	Item	Description
1	Head support cushion	3	1900 ml phantom
2	Intraoperative flexible coil	4	Phantom holder

Figure 2: QA Setup

3. Place the upper Intraoperative Flexible Coil (Figure 2, Item 2) inside the head support cushion. Make sure the center of the coil is in line with the center of the head support cushion.
4. Make sure the coil and head support cushion are positioned on the table headrest so that the embossed cross on the coil is located 18 cm (7 in) from the front edge of the table. This position will ensure the coils are located at isocenter.
5. Position the 1900 ml phantom (Figure 2, Item 3) into the phantom holder (Figure 2, Item 4).
6. Place the phantom and the holder on top of the upper Intraoperative Flexible Coil. Make sure the center of the phantom is in line with the center of the coil.
7. Place the InSitu Coil, still within the sterile packaging, on top of the phantom holder and ensure the center of the coil is in line with the center of the phantom.

Caution: Do not puncture or tear the packaging for the InSitu Coil. The coil will no longer be sterile if the packaging is damaged.

Note: The packaging of the InSitu Coil is not shown for clarity in the QA setup shown in Figure 2. The packaging will not affect the quality of the QA scan.

8. Secure the QA setup to the table headrest, for example with straps or surgical tape.

Running the QA Scan with the IMRIS InSitu Coil and Upper HC150 Coil

1. Run the shim batch file for the imaging room. Refer to the magnet operator manual for specific instructions.
2. Register the QA patient.
3. Position the coil/phantom assembly (Figure 2)
4. Bring the magnet into the room and allow it to stop at the PSCP. Refer to the magnet mover operator manual for procedures to move the magnet
5. Make sure the coils are centered vertically in the magnet bore before moving the magnet into place.
6. Move the magnet into the final imaging position.
7. Turn off the magnet mover pendant, fluorescent room lights, and all other equipment in the room. Ensure that all doors, except the large RF doors, are closed.
8. Select the Siemens SN sequence by clicking the Exam Explorer icon at the right side of the bottom of the user interface. The SN sequence is located at SequenceRegion –> SiemensSequences -> Defaultprotocols.

9. Set the FOV to 200 mm on the parameter card (FOV phase 100%).
10. Select the upper HC150 Intraoperative Flex Coil.

Note: Refer to the Siemens *Syngo* MR software help files to setup the scan parameters.

11. Click the Apply button to start the scan.

Calculating the Signal to Noise Ratio

1. Select “Viewing” from the task card tabs at the right of the screen.
2. Select the “Rectangle” tool.
3. Draw an ROI approximately 7 x 7 pixels in size at the center of the phantom.

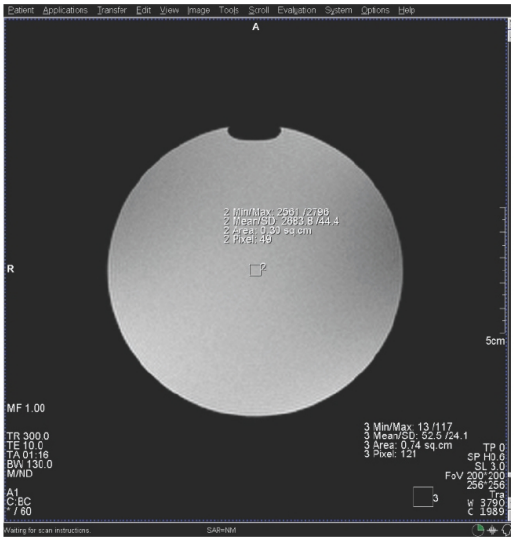


Figure 3: SNR ROI Selection Example

4. Record the mean signal intensity, S, in this ROI.
5. Adjust the window level of the images so that potential imaging artifacts (ghosting, noise lines, etc.) if any, become visible.
6. Draw an ROI approximately 11 x 11 pixels in size in the signal and artifact free region of the image (usually the lowest standard deviation of the noise area).
7. Record the value of the standard deviation (SD) in this ROI.
8. Calculate the signal-to-noise ratio using SNR = $S_{phantom}/SD_{noise}$.
9. The calculated value for both coils should be >85.

10. Record the value of the SNR in the system logbook, or other location as directed by the system manager, e.g. MR Technologist.

Troubleshooting QA

If the QA scan cannot be completed, perform any or all of the following checks and rerun the scan.

1. Recheck the phantom and table positions.
2. Reboot the system.
3. Contact Customer Support for further assistance with the daily QA scan.

Note: If the quality measurement results are outside specifications, the phantom fluid may have moved inside the phantom. Measurement phantoms have to be positioned for at least three minutes at rest on the phantom holder.

Clinical Use

When used clinically, the InSitu Coil, 1.5T is held in place with the Lower Coil Support attached to the Horseshoe Headrest. Refer to the Operator Manual, Horseshoe Headrest for further detail.

The upper HC150 Intraoperative Flexible Coil is placed on top of the draped and cocooned patient. Refer to the Operator Manual, HC150 Intraoperative Flexible Coil for further detail.

Positioning the Patient for Scanning

The patient's head must be positioned in the center of the ROI for imaging, approximately 18 cm (7 in) from the end of the table.

Note: The center of the coils must be in the center of the examination ROI and in the magnet isocenter. Locating the anatomy outside the 18 cm (7 in) region may produce a poor image.

Selecting the Top Intraoperative Flex Coil

Select the top Intraoperative Flex Coil during scanning with the IMRIS InSitu Coil. No further intervention is required, or allowed.

Sequence Parameter Setting

The IMRIS InSitu Coil, 1.5T requires precise adjustments using the system parameter cards to produce high quality images with no distortion.

Parallel Imaging

Parallel imaging with an acceleration factor of 2 may be applied with R>>L and A>>P phase encoding directions only. Parallel imaging is not available in the H>>F phase encoding direction. Parallel imaging may also be used in 3D image volumes acquired in the sagittal plane with an A>>P phase encoding direction.

Additional Information

Technical Description

General	2-element coil with an opening for surgical procedures (coil has no pre-amplifiers). Coil must be used with an upper HC150 Intraoperative Flexible Coil
Type	1.5T receive only disposable coil
Coverage	Head and upper C-spine
Tune/Match	No coil tuning required
Dimensions L×W×H	248 mm x 235 mm x 30 mm (9.76 in x 9.25 in x 1.18 in)
Weight	62 g (2.18 oz)
Preamp	No pre-amplifier
Safety	Passive decoupling and RF fuse are incorporated into each element.
Cable and Interface	No cables on these coils
Equipment Type	Class II Equipment, Type B applied part.

Symbols Used on IMRIS Medical Device

Symbol	Description and Usage
SN	SERIAL NUMBER Manufacturer's serial number
REF	CATALOG NUMBER Manufacturer's catalog or reference number
	MANUFACTURER Name and address of the equipment manufacturer
	DATE OF MANUFACTURE Date of manufacture
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY Manufacturer's authorized representative in the European Community with regards to regulatory matters
	CONSULT INSTRUCTIONS FOR USE Directs user to detailed operating instructions applicable when using the product
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS Directs user to detailed safety warnings applicable when using the product
	WARNING Identifies a general warning
MR	MR SAFE Identifies equipment and supplies that pose no known hazards in all MR environments.
	DAMAGED PACKAGING Directs the user not to use the product if the packaging is damaged.
	DO NOT REUSE Identifies products intended for single use only.
LATEX	CONTAINS NO LATEX Identifies products which contain no latex rubber.
Rx ONLY	PRESCRIPTION ONLY Identifies products which are only available through a physician's prescription. U.S. federal law restricts these devices to sale by or on the order of a physician or properly licensed practitioner.
	CLASS II ELECTRICAL DEVICE Identifies a Class II or double insulated electrical appliance which has been designed in such a way that it does not require a safety connection to electrical earth

Symbol	Description and Usage
	TYPE B APPLIED PART Identifies the level of protection against electric shock, including leakage currents, of a component. Type B Applied parts are generally not conductive and can be immediately released from the patient
	STERILIZED WITH ETHYLENE OXIDE Identifies products that have been sterilized using ethylene oxide gas sterilization method.
	USE BY DATE The date that accompanies this symbol indicates the final date the contents can be used.

IMRIS Surgical Theatre

Toll Free Customer Support:
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International - 00-800-0019-2021
www.imris.com

T300346-000 Rev D

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Change History

Rev	CC#/ECO	Description of Change	Date	Approved
–	ECO 1911	Initial release	2014-Apr-10	E. Heinz
A	ECO 2186	Converted to FrameMaker template including new covers and front-matter (standardized), added tables of call-outs below image in figures and new standardized symbol definitions (also added serial number symbol); changed page cross-refs to include Heading as well as page number; cross-ref to items in Figures and put Figure citation before the Item number citation, updated copyright from IMRIS, Inc. to Deerfield Imaging, Inc.	2015-Nov-06	A. Machovec
B	ECO 2267	Update to copyright and branding information.	2016-Mar-21	D. Schneeberg
C	ECO 2318	Included CE Marking on inside cover.	2016-Jun-29	D. Schneeberg
D	ECO 2451	Change in European Authorized Representative address.	2017-June-02	B. Vought