IMRIS Interface Extension

for use with Siemens 4 Channel Flex Coil

and 3T on IMRIS scanners

INSTRUCTIONS FOR USE

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1. Intended Use

The 2D and 3D Magnetic Resonance Imaging of the anatomy of head and brain including the brain stem. This device is used in conjunction with a Siemens Medical Systems Large Four Channel Flex Coil and currently available Siemens 3T MAGNETOM systems.

2. Device Description

Package Contents

CP-EXT-22-01	**ClearPoint® Siemens 3T Flex Coil IMRIS Interface** Description: 1.9m Interface Cable with a Flex Array Adapter on one end and an IMRIS Scanner Connector on the other end

Associated Devices:

Siemens 3T 4 Channel Large Flex Coil

3 Tesla MAGNETOM Scanner

3. General Warnings and Precautions

3.1. Explanation of Caution and Warning statements

Warning: Draws attention to a directly or potentially dangerous situation to life and limb.
Caution: Draws attention to a potentially dangerous situation which might lead to medium or slight bodily injury

3.2 Warnings and Precautions

Warning: If this product is not subjected to normal use, various burns and injuries may be caused to the subject, operating staff may be exposed to hazards, or equipment and systems may suffer damage. In conductive materials such as biological tissue the application of strong electromagnetic RF fields may generate levels of current which may cause heating or even burns on the subject.

Warning: The product described in these Instructions for Use does not have its own SAR monitoring system. For this reason the monitoring device of the MR system must not be switched off under any circumstances. This is necessary in order to ensure the safety of the patient, users and devices

Warning: MR scans with cables which have not been connected properly may cause injury to the subject and may damage the transmit parts of the MR system.

Caution: The use of auxiliary equipment, such as physiological monitoring and gating equipment and RF transmit coils, which has not been specifically tested and approved for use in conjunction with the MR environment may result in burns or other injuries to the patient. Even auxiliary devices labeled as MR safe or MR conditional may be capable of causing injury if the manufacturer's instructions, especially with respect to electrically conducting lead positioning, are not followed.

Caution: Operating staff must observe live subjects constantly by means of personal monitoring and/or monitoring with equipment in such a way that in the event of an acute or imminent hazard immediate action can be taken

Caution: The device is not intended to be sterilized.

General Precautions

Handle all components using standard hospital practices.

4. Use Instructions

4.1. General Handling

4.1.1. This product is a sensitive electronic device which has to be handled and used with appropriate care. Therefore avoid any jolts or impacts which might have an effect on the device.

4.1.2. Before every use of this product make sure that the connecting cable and plug contacts are intact. If defects are discovered, the product must not be put into operation.

4.1.3. QA checks of the Interface cable and flex coil should be performed with an appropriate phantom periodically or when troubleshooting. See Attachment I for instructions on set-up and performance of the QA check.

4.1.4. The product does not give any fault warnings of its own, therefore, operating staff must:

4.1.4.1. Observe fault warnings given by the MR device.

4.1.4.2. Visually monitor patients/animals constantly during the examination.

4.1.4.3. Check operation of the product. If any unexpected examination results or device indications should occur or if any artifacts should appear on images notify ClearPoint Neuro.

4.2. General Safety

The product is labeled MR Conditional as it contains metal and is used during MR scanning. The product is safe to use in 3T MR environments when undamaged and used per the provided instructions.

In conductive materials such as biological tissue the application of strong electromagnetic RF fields may generate levels of current which may cause heating or even burns on the subject.

The table below lists potential special risks and appropriate remedial action by way of example. The faults are only typical and the list does not claim to be exhaustive!

Causes of heating and burns:	Avoidance of hazard:
Electrically conductive materials in the working area of the transmit coil, e.g. keys, coins, wristwatches, metal objects on clothing, cardiac pacemaker.	Inform/check the subject, remove any metal objects.
Use of medical products (medicinal products) in transdermal patches.	Remove these patches.
Skin-to-skin contact between different parts of the body may create a closed radio-frequency loop.	Check/correct the subject's position/posture.
Moist clothing.	Only allow dry clothing.
Impermissible positioning of the subject making contact with the surface of the transmit coil.	Make sure there is sufficient distance between the subject and surface of the coil.

Contact between the subject and the RF cable, laying the cable too near to the transmit coil.	Check/correct the arrangement of the RF cables.
Loops in the Interface Cable, RF cables or ECG leads.	Avoid/unravel any loops which have developed when laying the cables / leads.
Use of ECG electrodes and leads not approved for MR scanning.	Only use accessories which have been approved or provided by the manufacturer of the MR device.
Use of ECG electrodes and leads that are classified as MR conditional.	Read and carefully follow the instructions for use of the respective MR conditional ECG electrodes.
Scans on patients under sedation and unconscious patients who are unable to notice partial warming and report it to the examiner.	Constantly monitor patients under sedation and unconscious patients.
Devices, (receive) coils and cables which have been approved for joint use but are not connected up during operation of the transmit coil.	Remove any unconnected devices and/or coils during the scan.

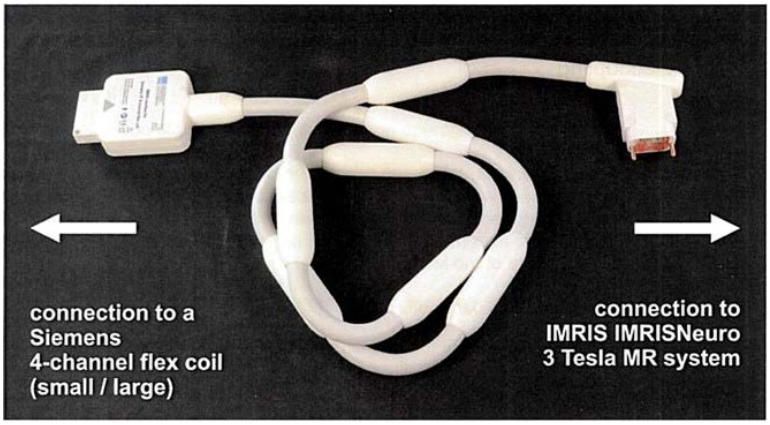
4.3. Connecting the Interface and Flex Coil

4.3.1. This product does not need dedicated coil files.

4.3.2. Before the product can be used in combination with a Siemens 4-channel Flex Coil on an IMRIS Neuro 3 Tesla MR system check that the coil files for the Siemens Large 4-channel Flex Coil(s) have been installed and successfully tested on the MR system.

4.3.3. Only make the electrical connection to the MR system **after** the installation of the coil files(s) is ensured.

4.3.4. The interface is connected to the IMRIS MR system via an appropriate Siemens 6-channel Rx connector. It also incorporates a 4-channel receive connection socket for making connection to a Siemens Large 4-channel Flex Coil. The Siemens Large 4-channel Flex Coil is connected to the interface as depicted below.



4.3.5. Check all connections before commencing scans.

4.3.6. The MR system will identify the coil on its display after the connection.

4.3.7. Confirm there are no loops in the coil, particularly under patient sterile drapes.

4.4. Device Cleaning

4.4.1. The device is not intended to be sterilized.

4.4.2. A moistened cloth can be used to clean the product using commercially available cleaning and disinfection solutions (e.g. alcohol-based}. Do not use aldehyde or phenolic-based disinfectants. Do not use any rough or abrasive detergents.

4.4.3. Although the electronic circuitry is protected against moisture, liquids should not be allowed to get into the device. Do not immerse the device.

4.4.4. It is recommended that any auxiliary devices used be cleaned directly after use and check to make sure that all their components are intact.

4.4.5. Disposal of Equipment: Send the Device to ClearPoint Neuro for disposal.

ATTACHMENT I: Q.A. Scan Method and Parameters for Obtaining Scans for SNR Comparisons

1.0 **MRI Scan Protocol:**

Listed below is a typical scan protocol that can be used for QA testing. '2D spin echo' is a fairly generic sequence that is available on all scanner types. TR and TE values will differ slightly between scanner types due to differences in hardware and software. Long TR and short TE times are selected in order to ensure complete relaxation of the signal from the water phantom. In order to ensure repeatability of SNR measurements it is **critical** that QA images are acquired using identical scan protocols.

Pulse Sequence	-	2D Spin Echo
Slice Orientation	-	Axial
Number of slices	-	1
Field of View	-	300mm
Slice Thickness	-	5 mm
TR	-	1000 msec
TE	-	12 msec
Flip Angle	-	90^0
Matrix Size	-	256*256
Averages	-	1
Receiver Bandwidth	-	130 Hz
Filter	-	None

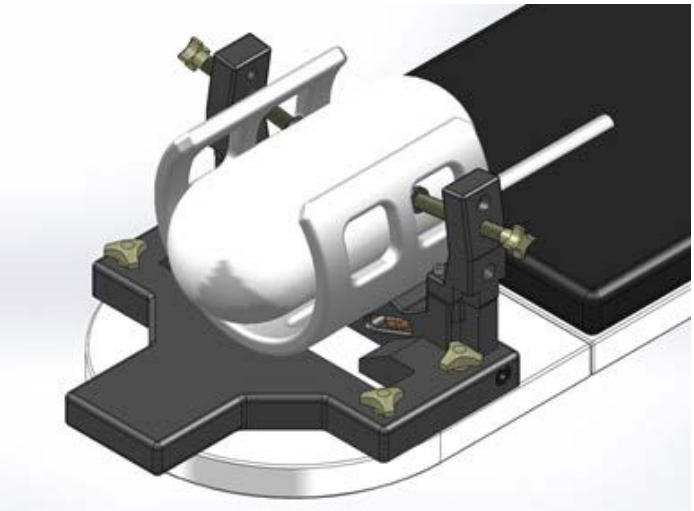
2.0 QA Imaging Setup:

Phantom and coil setup is described for the IMRIS scanner and Siemens 4 channel Large Flex Coil with CLPT Interface Cable. Coil and phantom, typically a cylindrical phantom, need to be placed in a manner that closely mimics the setup with a patient. Also, the setup needs to be repeatable such that the coil and phantom are located in a similar position each time.

Coil Setup

Remove all coils including the spine coil off the MRI table.

Connect the CLPT Interface cable to the Siemens Large 4 Channel Flex Coil. Place the flex coil and Head Fixation Frame assembly on the IMRIS surgical table. Attach the base securely to the surgical table. Connect the coil plug to the face of the scanner. Check the display on the face of the scanner and ensure that the coil is recognized.



Acquire images as per scan protocol.

3.0 Image analysis

Figure 1

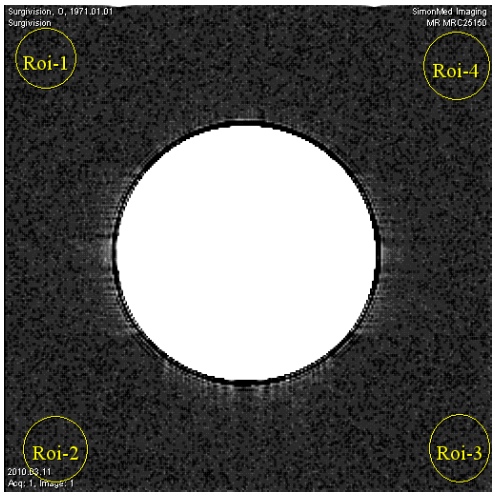


Figure 2

Analyze the combined image from all the channels by measuring mean pixel intensity in a circular measurement region of interest (MROI) as shown in Figure 1. Radius of the MROI is approximately 7 cm or the area is 308 cm^2. The size of the MROI must be adjusted depending on the size of phantom. It is recommended that it should cover at least 80% of the phantom cross section image.

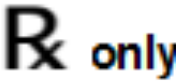
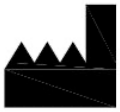
Adjust the window and level of the combined image down such that background pixels become visible. Measure back ground noise in four corners of the image as shown in Figure 2. Noise is measured by determining the standard deviation of pixel intensity within the MROI. Radius of the noise MROI is set at approximately 2 cm or the area is 25 cm^2. Ensure that the noise MROI are not located in regions of any imaging artifacts. Again it is important that for proper comparison nearly identical in size from one QA test to another.

Calculate signal to noise ratio (SNR) of the combined image using following equations:

$$\boldsymbol{Average\ Noise\ SD = \frac{Noise\ SD1 + Noise\ SD2 + Noise\ SD3 + Noise\ SD4}{4}}$$

$$\boldsymbol{Noise = \frac{Average\ Noise\ SD}{0.66}}$$

$$\boldsymbol{SNR = \frac{Signal\ Mean}{Noise}}$$

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	MR Conditional		Non sterile
	Consult instructions for use		Prescription only use
	Batch code		Keep away from sunlight
	Catalogue number		Keep dry
	Date of manufacture		Manufacturer
	Do not use if the product sterilization barrier or its packaging is compromised		

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