

Preparation and Use of the Pathway System in fMRI setting

PLEASE NOTE: this document is not intended to replace the Pathway Technical Reference and Technical Reference service manuals, which provide further detail of importance.

1. The purpose of this document is two-fold:

1. To assist you in the preparation of your facilities for use of the Pathway fMRI System in the scanner and to prepare the best configuration recommended for the fMRI Pathway in the scanner.
2. To provide special instruction and tips on how to handle and work with the pathway system under fMRI conditions in order to optimize results.

2. recommended steps to follow in order to have a successful installation of the pathway system in MRI:

1. Receiving the system - Follow the instructions on the box to uncrate/roll the Pathway out of its shipping crate. Refer to User Manual for instructions on setting up the Pathway h/w (i.e., attaching Thermodes, filling cooling reservoir, etc.)
2. General guidance and training on operating the system and software – run by the local Medoc representative / Distributor
3. Receipt and review of this document with partnering scanner personnel relative to system setup and behavior in the scanner and behavior under MRI conditions
4. Contacting Medoc technical support team by for a conference call to advise the optimal configuration/setup of the system in the control room/scanner; including tips on understanding how to handle the system under MR conditions (see appendix C with information form to be send to Medoc).
5. Prior to initiation of the actual research study, coordination with Medoc technical team to run a remote pilot session in order to run the protocol using a phantom and a demo subject. In such a session, Medoc engineer is conferencing via phone line and remote control of customer's PC/Pathway System.
6. Utilizing Medoc support via remote sessions in your initial scans to practice the protocol and understand the best way to stimulate during MR scanning.

3. Receiving the system and basic training:

1. The pathway system arrives ready to use, other than some simple device connections and filling of the cooling system reservoir with coolant ("DowTherm", initial supply furnished with system). These steps can normally be easily accomplished by customer and/or in conjunction with guidance by Medoc distributor/representative.

2. Coordinate with your Medoc distributor / representative to run basic training on the system h/w and s/w setup and operation. This may entail remote installation of the Pathway Main Station operating software prior to any physical visit of distributor/representative for training.
3. It is very important to understand how to best prepare for use and handling of the system before entering the MR for scanning. This document and Medoc's technical support team (via remote/conference support) will assist you in this process.

4. Before entering the MRI for the first time, please take care to address the following steps and guidelines:

1. Contact Medoc technical support team and send us the scanner room diagram to determine the best configuration and location of the Pathway system. Please note and advise your Pathway serial number on this and all email communications.

Contact information:

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2. Locating and installing the Pathway Filter in the MRI penetration panel (see appendix A)

5. Conference call with Medoc technical support team (with researcher and MR technician)

1. Introduction of Medoc technical support team/capabilities and customer's team, including MR technician support contacts
2. General discussion of Pathway use under MR conditions.
3. Recommendation on the best configuration of the system in the MRI and limitations.

6. Main guidelines for Operating Pathway System under MR Conditions:

1. PATHWAY unit should be located in the scanner control room
2. PATHWAY operating PC should be located inside the scanner control room
3. The MR filters should be located in a penetration panel going into the faraday cage (if no penetration panel is available make sure to ground the filter to the MRI faraday cage)
4. Thermodes should be connected to the fMRI filters and grounded to the faraday cage during stimulation under MR scan to help reduce artifacts on the system and MR image
5. Thermal stimulation with ATS Thermode should be more that **30-40cm and up** from imaging FOV (field of view) during stimulation under MR scan.
6. Thermal stimulation with CHEPS Thermode should be more that **40-50cm and up** from imaging FOV during stimulation under MR scan.
7. Pathway fMRI Thermode must not be moved while delivering stimulation.
8. fMRI Thermode cable should be spread out along the scanned bedside and not rolled by the scanner.

9. Pathway fMRI Thermode movement inside MR environment must be performed very slowly to reduce effect of electrical noise resulting from movement of conductor in powerful magnetic field.
Fast movement of the Thermode during stimulation done by the subject while the scanner is running can generate false alarms on the Pathway system.

7. Appendix A: Installation – CHEPS MR Filter

1. Complete the setup and installation procedure as described for a regular PATHWAY system, according to the System Block diagram below.
2. Connect the system devices according to the following stages:
 - 2.1 Connect the PATHWAY system so it would be placed in the MRI control room, while the Thermode itself is placed in the MRI room, as shown in the diagram:

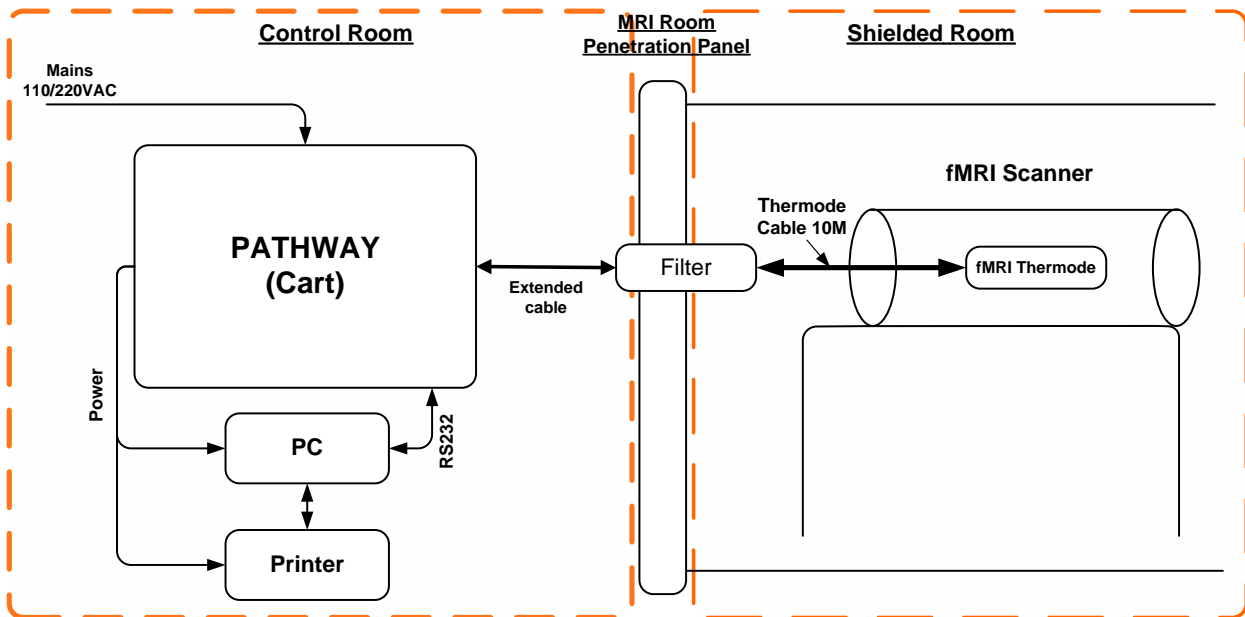


Figure 1: System Block diagram

- 2.2 Make sure your laptop, PATHWAY unit and printer (optional) are all OFF.
- 2.3 Install the fMRI filter according to the following instructions:
 - 2.3.1 Install the filter on your MRI room penetration panel. You can use 4 screws that join the two main aluminum parts of the filter.
 - 2.3.2 The fMRI Thermode connectors should be placed inside the fMRI room. All the other devices' connectors should be placed outside of the fMRI room.

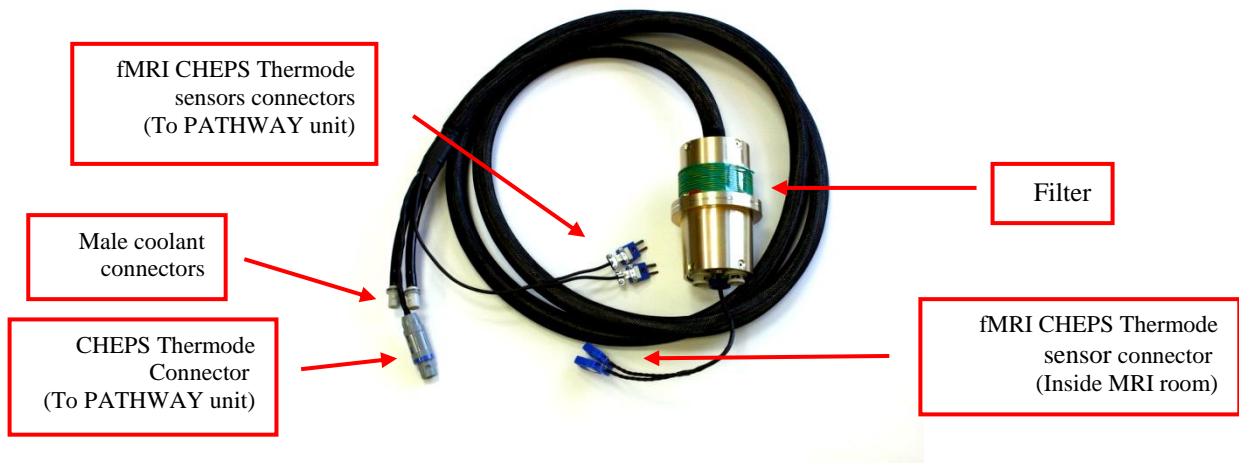


Figure 2: fMRI CHEPS filter

2.4 Connect the coolant tubes connectors to the PATHWAY front panel that fits the Thermode you are using.

2.4.1 Coolant tubes unit connectors (gray connectors).

2.4.2 fMRI CHEPS Thermode sensor connectors (pair of blue connectors).

2.4.3 fMRI Thermode main plug connector (gray plug).

2.4.4 Hollow passage for COVAS and Response unit accessories. Note: This is not the passage for the emergency button. You must transfer the emergency button to the fMRI room through another passage.

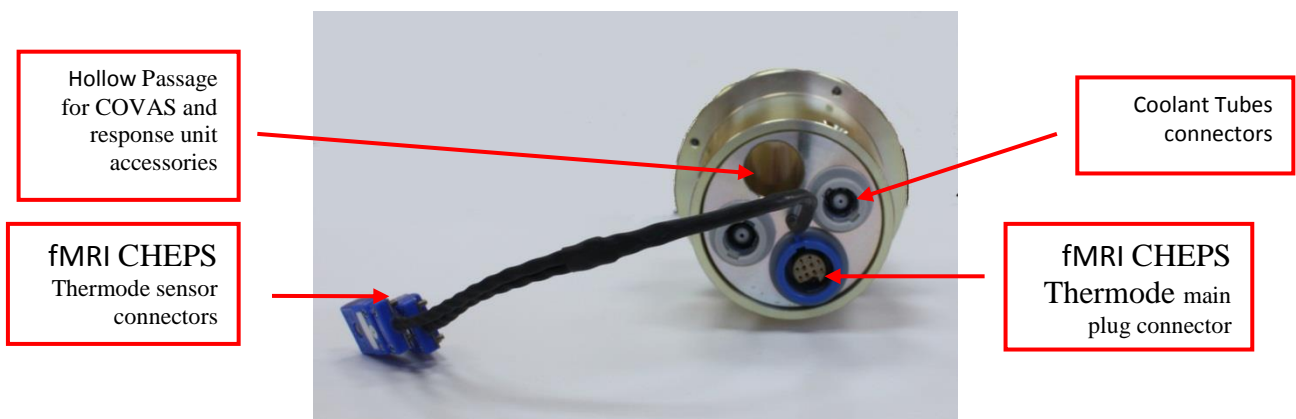


Figure 3: CHEPS fMRI filter front view

2.5 Connect the printer cable to the laptop.

2.6 Connect the main power cord to the PATHWAY system.

2.7 Connect the required devices and accessories, as described in Pathway operation manual section

3. Conduct a Grounding conductivity test: using DVM measure resistance between the ground pin of the power cord, fMRI filter body and ground pin of fMRI penetration panel. The measured resistance must be less than 0.150 Ohm.

4. It is highly recommended to Conduct three phantom tests:

4.1 Conduct the test, when the Pathway is OFF,

- 4.2 Conduct the test, when the Pathway is ON and software is OFF,
- 4.3 Conduct the test, when the Pathway and software are ON and software test is running.
5. The installation is finished if all three tests are passed successfully.







The SIP/SOPs (signal input and outputs) must be connected to medical grade safety approved equipment for Canada and the United States, by a recognized certification agency, which is connected to the common protective earth of the system.





8. Appendix B : System components and MR Classification



The following list of accessories can be purchased from Medoc, and are listed with their Catalogue numbers, which should be quoted when ordering a specific accessory.

CHEPS:






Description	Cat. No.	Classification	
MRI Conditional CHEPS Thermode	AS 00253		
EMI Filter for MRI CHEPS Thermode	AS 00249		

ATS:




Description	Cat. No.	Classification	
MRI Conditional ATS Thermode 30x30mm Thermode.	AS 00251		
MRI Conditional ATS	AS 00252		

EMI Filter for MRI ATS Thermode	AS 00254		
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Accessories:

Description	Cat. No.	Classification	
CoVAS – Computerized Visual Analog Scale for MRI	AS 00248		
MRI Conditional Response Unit	AS 00244		
MRI Conditional Panic Button	AS 00246		

MR Classification Labeling:

	MR-Unsafe
	MR Conditional
	MR Safe

Appendix C

Definitions and safety considerations

1. The PATHWAY unit was tested and validated inside fMRI scanners and is in use worldwide under MR conditions include fMRI and MEG scanners.

2. PATHWAY was tested by Medoc inside 3T GE and Siemens scanners and was found to be safe for use, according to FDA regulations, and performs according to system specifications as specified in the system's manuals.
3. PATHWAY MR conditional Thermodes (CHEPS and ATS) were tested under various conditions and imaging sequences and were found to perform according to specification and have **no effect or minor effect on imaging**.
4. PATHWAY MS conditional accessories (Patient Response Unit, CoVAS and Emergency Button) were tested under various conditions and imaging sequences and were found to perform according to specification and have **no effect or minor effect on imaging**.

Tested sequences:

1. Fast Spin Echo (FSE) T1
1. Fast Spin Echo (FSE) T2
2. Spoiled Gradient Echo
3. Echo Planer Imaging (EPI) bold (fMRI)
4. Gradient Echo



PATHWAY Thermode and accessories are defined and marked as MR Conditional equipment according to the ASTM F2503-08.



The fMRI PATHWAY system was tested in the following MR environments:

Field Strength: 3T; Max. Spatial gradient: 72 mT/m

Max. dB/dt: 346 T/m/s; RF Fields: max. power 35KW pep;

TX bandwidth: 800kHz; RX bandwidth: 500Hz-1MHz; maximal RF field strength: 24,7 μ T CP

SAR: whole body 4 W/kg, head 3.2 W/Kg

9. Appendix C : General information about the customer MRI Site:

Customer: (Institution, department etc):

Technical contact person (email, Phone):

MRI Technical contact person:

MR-scanner Model:

Size of field of view:

How is the floor layout? (Please attach a sketch drawing)

The most important things in this drawing are the location of:

- MR penetration panel
- fMRI PC
- Mains supply outlets
- Where you want the fMRI equipment to be placed inside the scanner room

Floor plan sketch: