



TSA-II **Quick Set Up and Installation Overview**

Before installing the system and software

- 1. The ambient room temperature should be: 18°C 24°C.
- 2. The Windows user must be an administrator to install the software.
- 3. The Windows version must be 7 and up. The software cannot be installed on a Mac operating system.
- 4. Disable any antivirus software during the installation.

System set up - Connectors Panel

- 1. Unpack the box.
- 2. Connect all the accessories according to figure 1, below:

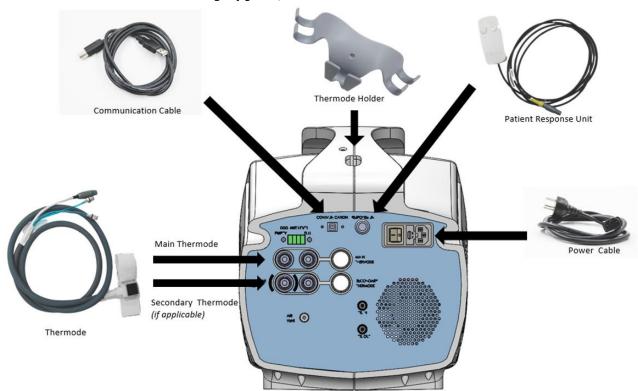


Figure 1: TSA-II Connection Scheme

- 3. Note that the CoVAS unit (if applicable) is connected directly via USB to the computer.
- 4. Additional information regarding system set up can be found in section 3 in the TSA-II Operation Manual (DC 00082- can be found in the software under "Help").



Thermode Holder installation

1. Take the Thermode Holder Fixation and position as shown in the pictures 1 & 2:



Picture 1 Picture 2

2. Position the Thermode Holder in its position, insert the screw (SC and tighten the screw with Philips head Screw Driver as shown in pictures 3 & 4:



Picture 3

Thermode Connections

- 1. For this part, see figure 2 below.
- 2. The Thermode Plug, marked in green (1) is directional. The arrows indicate which side should face upwards. Make sure you hear the "click" after inserting each connector.
- 3. The coolant connectors (2) should be inserted by pushing in the connector, and rotating it all the way clockwise.

Picture 4

- 4. If only one Thermode is used, the Thermode must be connected to the Main Thermode port, on top.
- 5. If there is an additional Thermode, it should be connected to the Secondary Thermode port, on the bottom.
- 6. Make sure that both coolant connectors are connected.

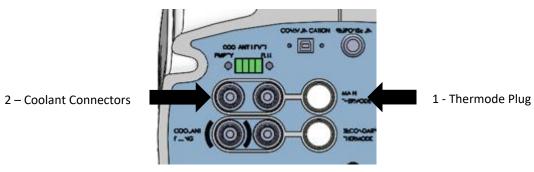


Figure 2: Thermode Connection

Patient Response Unit Connection

- 1. For this part, see *figure 3* below.
- 2. The Patient Response Unit plug is colored yellow. It connects to the yellow port (marked Response Unit) in the system's upper quadrant.
- 3. Please make sure the arrows on the plug are facing up.
- 4. Make sure you hear a "Click" when inserting the plug.
- 5. When not in use, place the Response Unit in the middle of the Thermode Holder.

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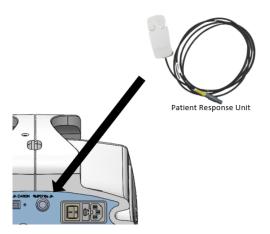


Figure 3: Patient Response Unit Connection



Software Set Up

Software Installation Preparation

- 1. Insert the software USB drive to a USB port.
- 2. Wait for the AutoPlay window to show.
- 3. Click on "Open folder to view files" (see figure 4).

OR

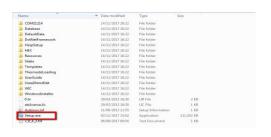
- 1. Click on the link you received.
- 2. Download and unzip the installation files.
- 3. Save the folder locally on your computer.
- 4. Open the folder.



Figure 4: Open the Software folder

Software Installation

- 1. Double click "Setup.exe"
- 2. Click "Next" all the way through (see figure 5)



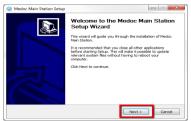




Figure 5: Software installation stages

3. Additional info can be found in section **4.7** in the TSA-II Operation Manual (DC 00082 - can be found in the software under "Help").

TSA-II is now ready for use.

Starting Up

- 1. Before starting always turn the system ON first, and then open the software.
- 2. Start the Medoc Main Station software by double-clicking the icon



3. The Home Screen is displayed showing the devices available under your license. Choose TSA 2 (marked in red see *figure 6*).





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4. When the Login Screen is displayed, enter your user name and password and select "TSA 2" in the "connect to" field. Initial login Username and Password are both "admin" (see *figure 7*).

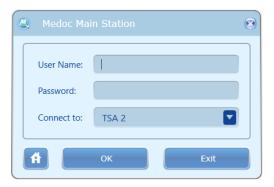


Figure 7: Login Screen

5. Software screen overview:

The software screen is divided into 3 main areas (see figure 8):

- 1. Menu bar consists of dropdown menus with headings: File, View, Settings, Utilities, Help.
- 2. Main toolbar consists of shortcuts to the different views:
 - a. Test Select Test Parameters
 - b. Patients Manage Patient Database
 - c. Programs Manage Program List
 - d. Results View, export or print test results
- 3. Status bar displays important information about the status of the connected device. Status (On-Line/Demo), system state (rest, test, safe), safety status, etc.



Additional information can be found in the TSA 2 Operation Manual (DC 00082 sections 6-10 - can be found in the software under "Help")



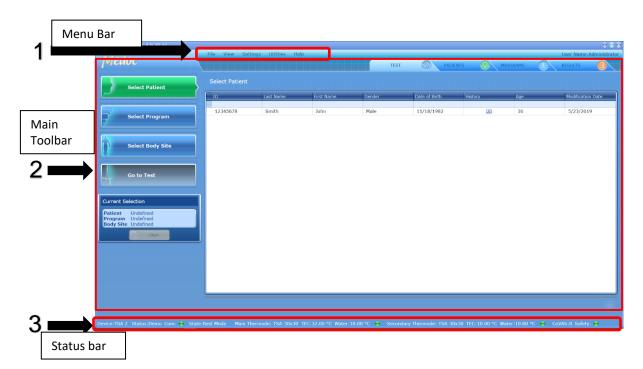


Figure 8: Software Overview



System Maintenance - Filling the Cooling Unit

- Use the "Cooling filling kit AS 00172" to fill the cooling unit.
 The cooling kit contains of 1 syringe and 2 tubes. The first tube <u>without</u> a connector at the end (see *figure 9*) and the second one <u>with</u> a connector at its end (see *figure 10*).
- 2. Connect the syringe to the transparent tube without the connector. Fill the syringe with coolant liquid (see figure 9).



Use only coolant liquid from type Dowtherm SR1 (or other coolant liquid approved by Medoc)



Figure 9: Filling the syringe with coolant liquid

3. Disconnect the tube (without the connector) and switch to the transparent tube with the connector at the end (see *figure 10*).



Figure 10: Syringe with connector



- Connect the connector to the lower left coolant port in the system.
 The Main Thermode should be connected, and the system should be turned ON (see figure 11).
- 5. In case the secondary Thermode is to be used, complete the next steps with the secondary Thermode disconnected. When re-connecting it, check that coolant level is still sufficient.

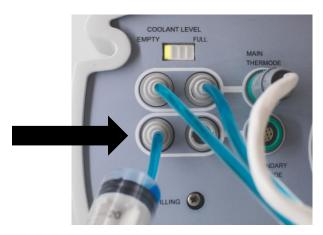


Figure 11: Connecting the syringe to the system

6. Using a Philips head screw driver, open the vent screw, located below the coolant ports. Screw it out 3 turns counter-clockwise. (see *figure 12*)



Figure 12: Air vent screw

- 7. Fill the system slowly with cooling liquid (ONLY) and check the Coolant Level LED lights indicator (located above the Thermode ports).
- 8. As soon as the fourth LED (full) lights up, stop filling the system.



Always allow 15-20 seconds for trapped air in the system to be pumped towards the air vent screw, between pushing the syringe plunger.

- 9. Disconnect the syringe from the system, and keep it for future use.
- 10. Tighten the vent screw back to the system. (3 turns clockwise)
- 11. Important notes:
 - 11.1. It is recommended to fill the system before it reaches the lower indicator (most left of the four LED lights).
 - 11.2. When the coolant level is too low (coolant level empty), safety precautions are activated, and the system will not allow work to continue before filling the system.





System Requirements: 1 GHZ CPU frequency. Windows 7, 8 or 10. 2GB RAM. additional info can be found in section 4.1 in TSA-II Operation Manual (DC 00082- Can be found in the software under "Help")



Do not connect any equipment to the TSA-II system that has not been specifically authorized and approved by Medoc.



Note: Software installation can be performed only by Windows system administrators. Make sure you have the appropriate administrator privileges on your computer, have your system administrator install the software for you.



TSA II fMRI Installation



TSA-II fMRI Thermode and accessories are defined and marked as MR Conditional equipment according to the ASTM F2503–08.



TSA-II fMRI control room cable is defined and marked as MR Unsafe equipment according to the ASTM F2503–08.



WARNING:

Make sure that the Thermode is unblemished in order to prevent potential harm to the test subject.



WARNING:

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



The fMRI TSA-II system was tested in the following MR environments:

Field Strength: 3T and 7T; 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 μT CP

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



The fMRI TSA-II system was tested in the following MR Sequences:

Echo Planer Imaging (EPI) bold (fMRI)

rf_noise and rf_noise spectrum electromagnetic noise interference (Siemens protocol)

2.1. TSA-II system configuration in fMRI mode:

The fMRI TSA-II system includes the following components:



Control room Thermode cable



TSA-II fMRI Thermode

The TSA-II fMRI Thermode incorporates an EMI filter designed to reduce and prevent electromagnetic interference noise from penetrating into the scanner room. The fMRI filter includes:

- Minimal insertion loss: 10MHz/13dB, 100MHz/50dB, and 1GHz/70dB.
- Capacitance: 4000pF
- Non-ferromagnetic filter components



The filters are to be connected via standard 15-pin D-type cutouts in the penetration panel, with the Thermode air tube to be passed through a waveguide of appropriate dimensions (according to the MRI scanner manufacturer design).



Some 15 pin cutouts are slightly smaller than the 15 pin D-Sub filter connector. An adapter is provided to allow for use with such smaller cutouts.

Loosely connected cable connectors or use of conductive tape or braid may lead to interference noise and imaging artifacts.

The fMRI Thermode is "MR Conditional". An extended 13 [m] cable connects between the TSA-II system, which is located outside of the MRI control room, and the Thermode that is located in the MRI room. The part of the Thermode inside the room is 10 [m] long, and the part outside the room is 3 [m] long.



"MR Conditional" means an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

2.2. Installation –MR Filter

1. A penetration panel in the scanner room is the access point for introduction of various equipment into the scanner room. The waveguide (see Figure 13) is used for introducing the coolant tubes of the Thermode, whereas the d-type cutouts are used to connect the signal and power cable to the Thermode.



Figure 13: Typical penetration panel with waveguide tube and 15 pin d-type cutouts (bottom right of the image)

- 2. Connect the system devices according to the following stages:
 - 2.1. Place the TSA-II system in the MRI control room. Leave the TSA-II OFF.
 - 2.2. Place the Thermode on the MRI scanner gantry. It is recommended to place sandbags on the cable to prevent the Thermode from falling off the gantry during installation.
 - 2.3. Orient the cable of the Thermode away from the scanner and run it uncurled along the walls of the room. Minimize any loops in the cable to prevent unwanted electromagnetic interference.
 - 2.4. Connect the 15 pin d-type connector to the panel. An adapter is provided to fit most cutouts. The adapter should be attached to the connector on the scanner side of the penetration panel. Two people may be required to perform these steps, one person on each side of the panel.



- 2.5. Connect the control room side connector to the d-type cutout. Ensure the male/female connectors are firmly attached to each other and to the penetration panel using the connector screws.
- 2.6. Connect TSA-II coolant connectors and electrical connectors to the TSA-II connector panel as with a regular Thermode. See below figures.

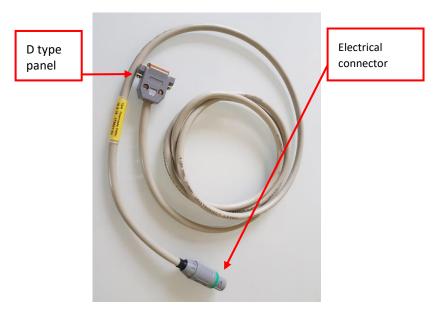


Figure 14: TSA-II fMRI Thermode Control Room part WA 00077

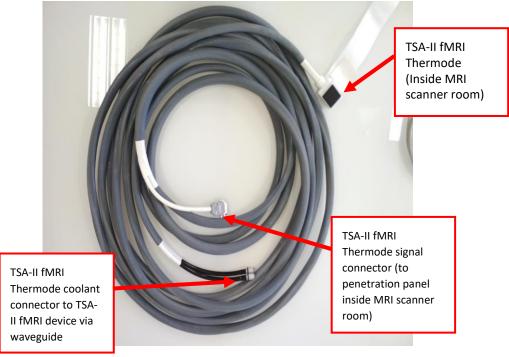


Figure 15: TSA-II fMRI Thermode Shielded room part AS 00178



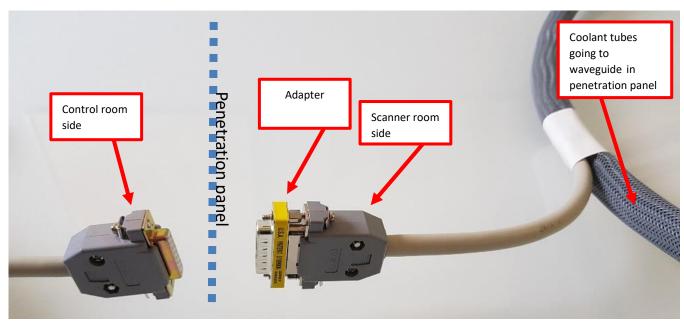


Figure 16: Signal/power cable and adapter connection

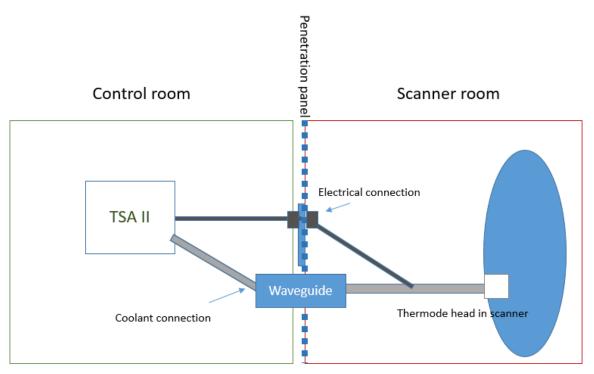


Figure 17: Schematic diagram of connecting fMRI Thermode

- 3. Conduct three phantom tests:
 - 3.1. Conduct the test, when the TSA-II is OFF,
 - 3.2. Conduct the test, when the TSA-II is ON and software is OFF,
 - 3.3. Conduct the test, when the TSA-II and software are ON and software test is running.
- 4. The installation is finished if all three tests are passed successfully.



5. Common Troubleshooting

Thermode Connection

Note that the Thermode liquid connectors need to be inserted <u>all the way</u> in, and rotated clockwise. See below *figure 13* for an example of a correct insertion, and *figures 14* and *15* for examples of incorrect insertion of Thermodes connectors.



Figure 18: Correct connection: connectors are inserted all the way in and rotated all the way clockwise



Figure 19: Wrong coolant connectors' connection should be inserted all the way in



Figure 20: Wrong coolant connectors' connection should be rotated all the way clockwise



Software

In case the software is in Demo mode – how can I re-connect to the system? (see figure 16)

- 1. Make sure that the system is turned ON, and that the communication cable is connected to the computer.
- 2. Go to "Utilities" and click on "Device Recovery".



Figure 21: Device Recovery