Medoc
advanced medical systems

TSA 2

Thermal Sensory Analyzer

Operation Manual

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This device complies with 93/42/EEC MDD and EU 2017/745 MDR

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1. TSA 2 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 10. The software cannot be installed on a Mac operating system.
   Computer requirements:

Safety	Computer must comply with IEC 950 – EN 60950 – UL 60950
Processor	2GHz processor as a minimal requirement, Recommended: Intel Core i3 4xxx or better (avoid low power processors such as Atom, Pentium or Celeron).
Memory	4 GB RAM
Storage	128 GB
USB slots	2 free USB slots
Monitor/Display	13'' (15'' recommended)
Screen Resolution	1366 x 768 pixels, 96 DPI (max. 1920x1080)
Operating System	Windows 10
Other	Microsoft Office 2007 or above (required for viewing results in excel)

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:

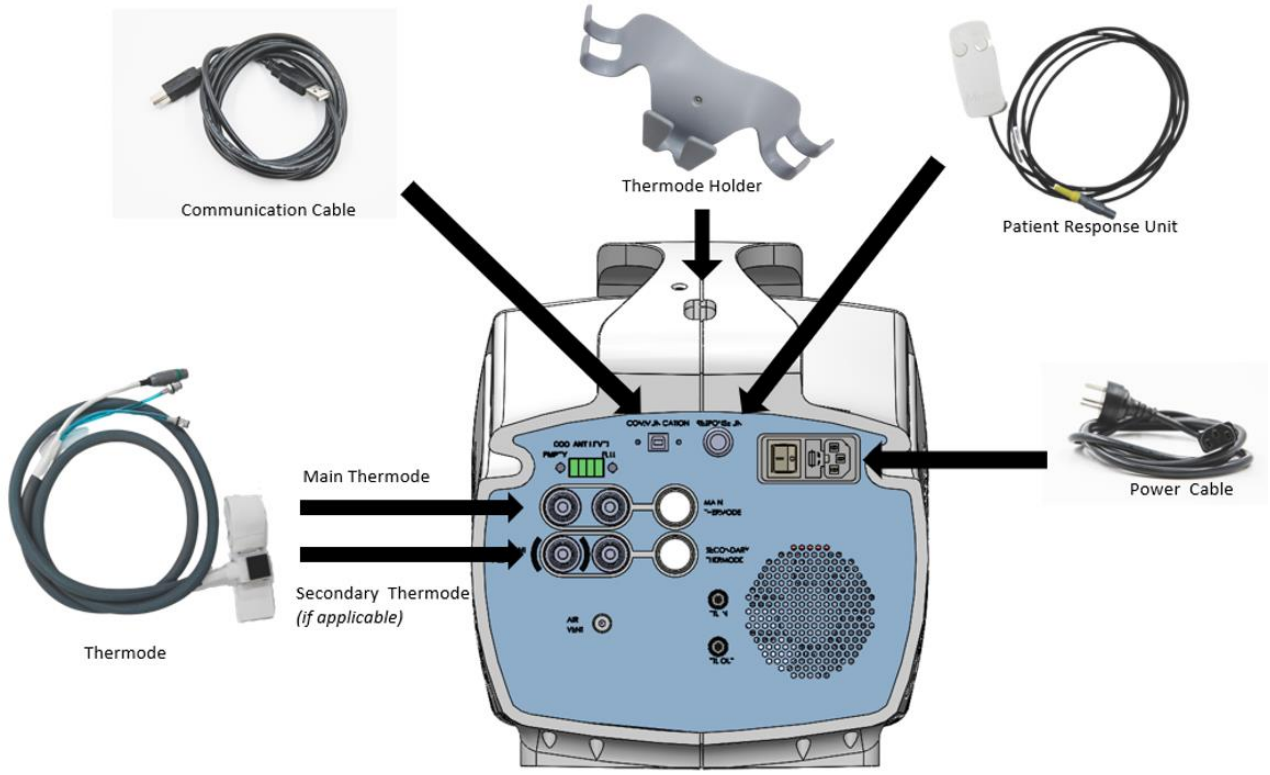


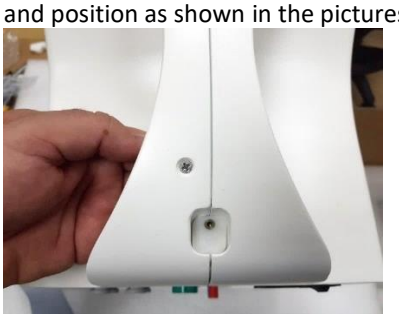
Figure 1: TSA 2 Connection Scheme

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 2 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:

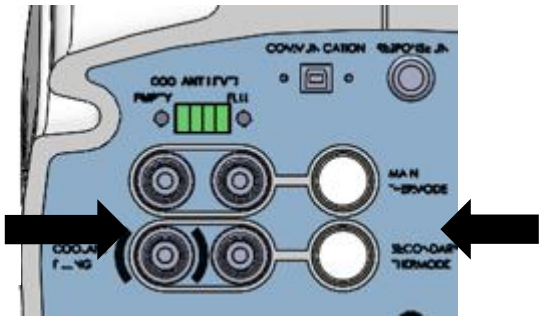
Picture 3

Picture 4

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.
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.

2 – Coolant Connectors



1 - Thermode Plug

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.

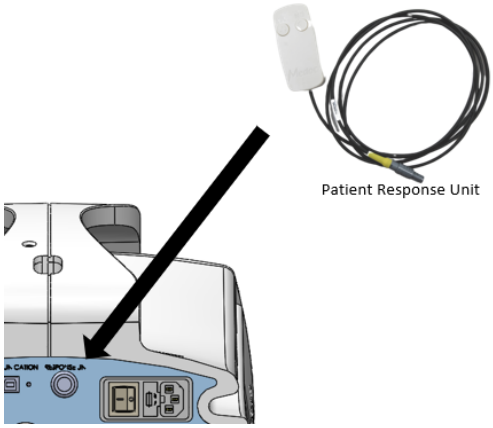


Figure 3 : Patient Response Unit Connection

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.

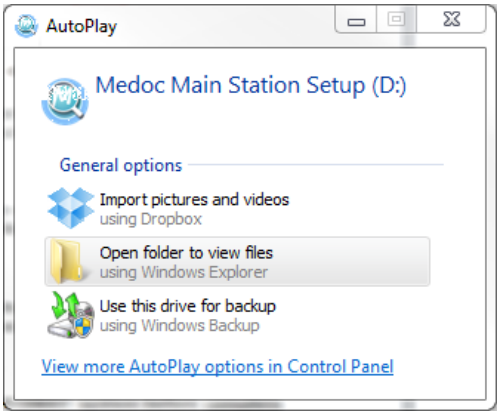


Figure 4: Open the Software folder

Software Installation

1. Double click “Setup.exe”
2. Click “Next” all the way through *(see figure 5)*

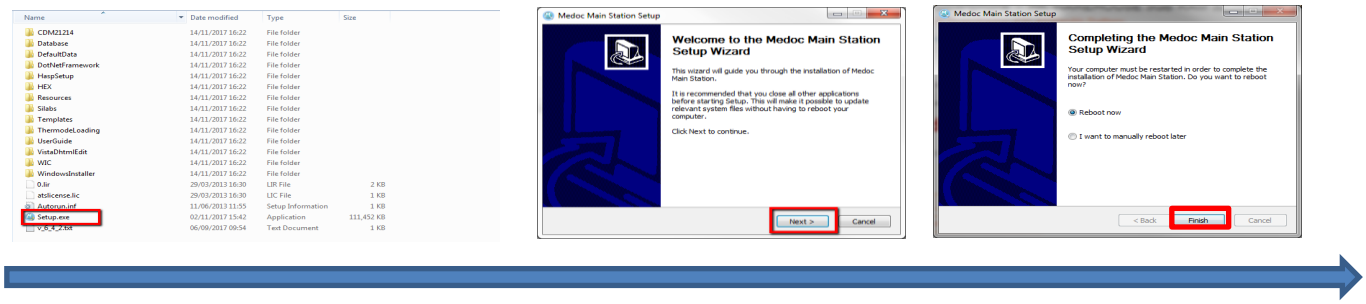


Figure 5: Software installation stages

3 software under “Help”).

TSA 2 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*).

Figure 6: MMS Home Screen

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*).

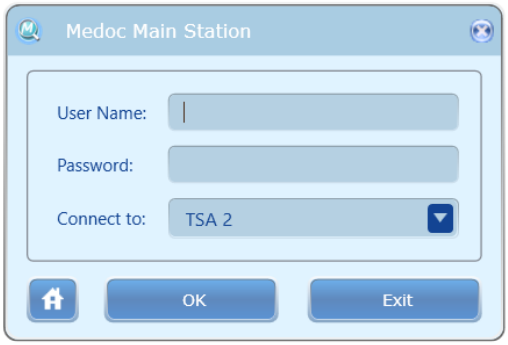


Figure 7: Login Screen

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")

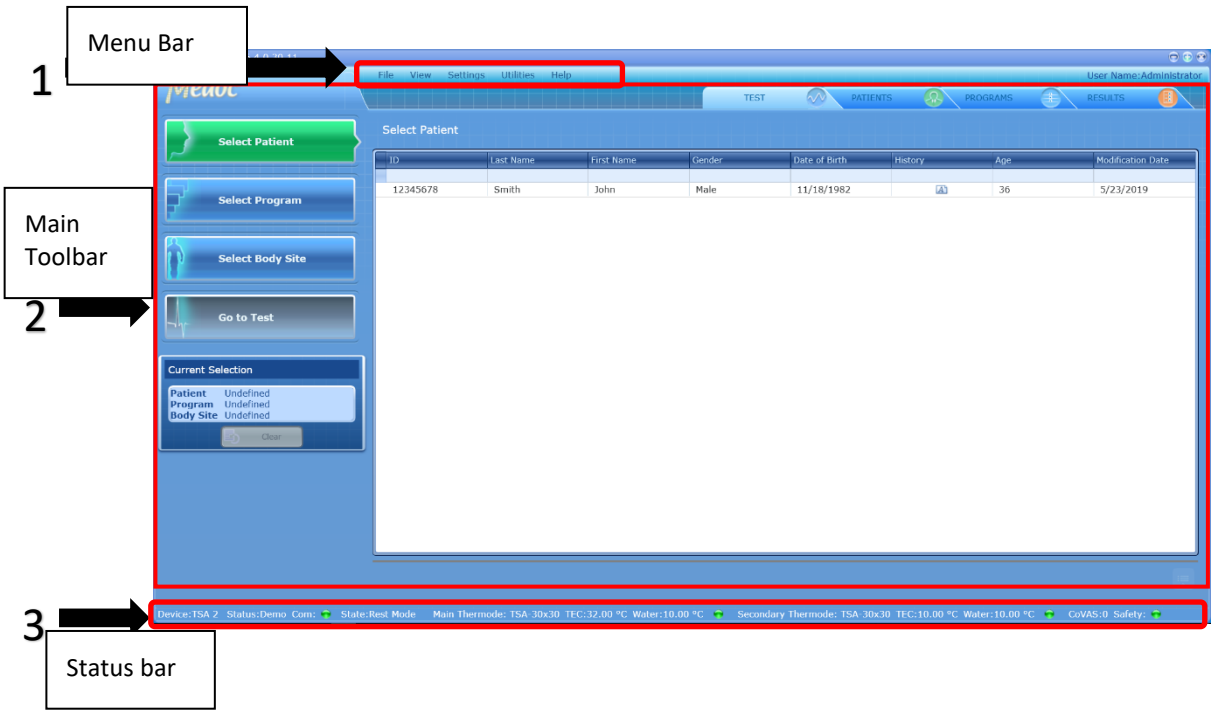


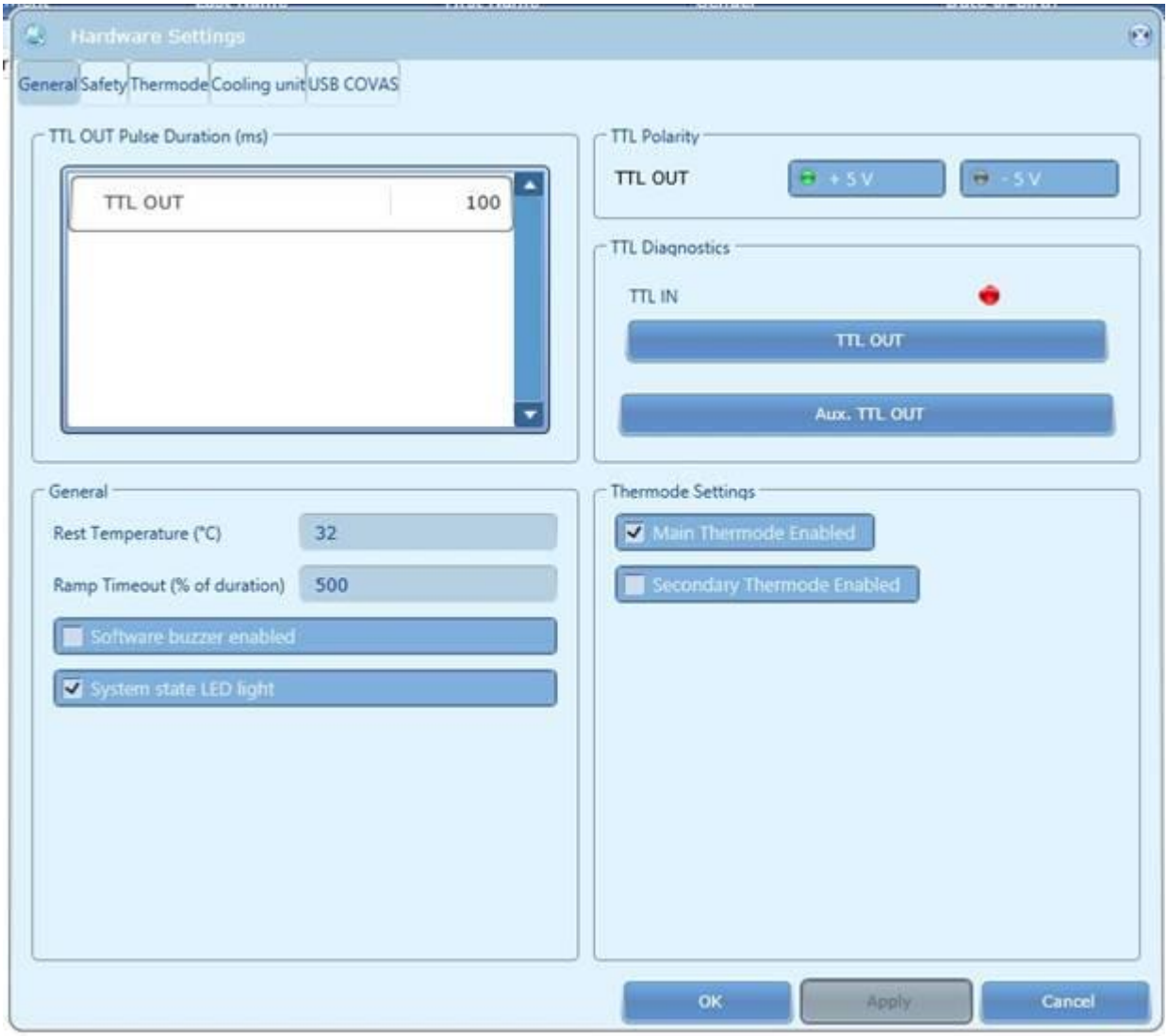
Figure 8: Software Overview

6. Configuring 'Hardware Settings' to match selected thermode(s) - Background

Your TSA 2 System comes with multiple thermode ports, meaning sometimes you may have one thermode connected; and at other times choose to have two thermodes connected (and activated). At times you may have a 30x30mm thermode connected and at other times, a 16x16mm thermode connector; or an fMRI 30x30 connected. Regardless of the configuration you desire, it **is required that you match the thermode(s) that you have connected, with the settings within the MMS software**. Before you use the system for the initial time and when there are any changes to your configuration (ie., thermode or thermodes attached), it is necessary to do the following to enable the use and to load the calibration tables of your specific thermode(s) that are being employed.

Enabling the thermode(s)

To enable your thermode(s), go to SETTINGS >HARDWARE SETTINGS >GENERAL tab



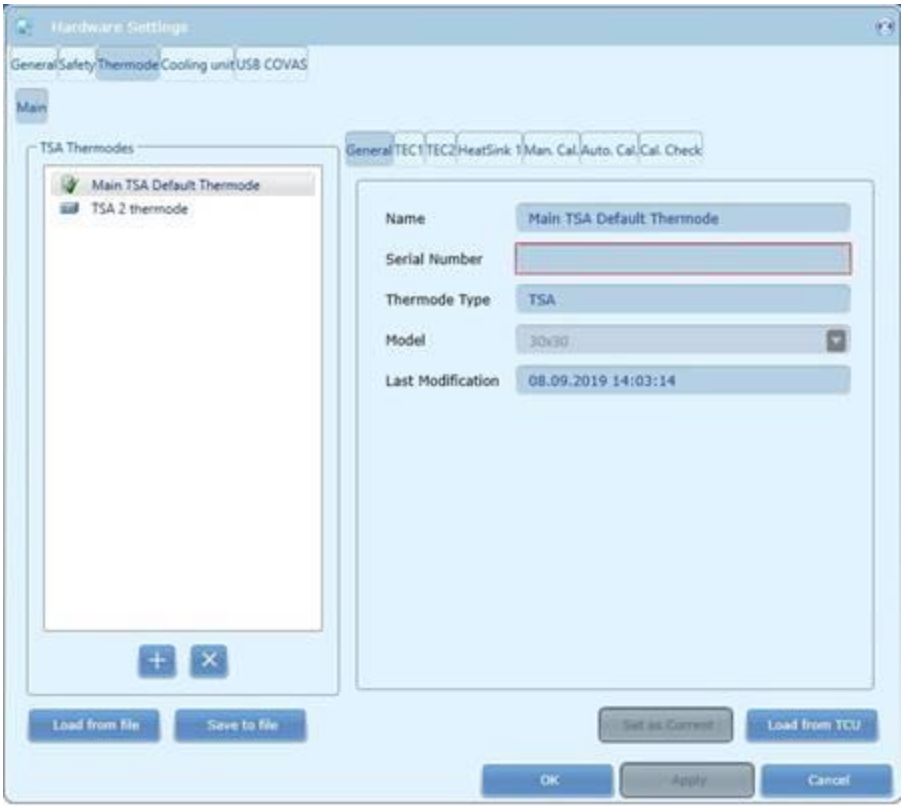
If you have only one (main) thermode attached, select the "Main Thermode Enabled" box. Conversely, if you have attached two thermodes, enable both the "Main" and "Secondary" thermode boxes.

Setting Thermode as Current

Setting Thermode as "current" is used when you wish to load the currently used Thermode parameters, according to Thermode type that is connected to the system.

To set a Thermode as current, perform the following procedure:

1. Go to SETTINGS ◊ HARDWARE SETTINGS ◊ THERMODE tab
2. In the Thermode list on the left side of the screen, select the Thermode you wish to use (attached to the thermode, there is a yellow sticker with thermode serial number)
3. Click the Set as current button
4. Press apply and OK.



The Set as current Thermode has a mark at its left side. This symbol indicates that the parameters loaded to TSA 2 match the selected Thermode.

In case selected Thermode parameters do not match the TSA 2 Thermode parameters, a mark appears to its left, indicating the malfunction.

System Maintenance - Filling the Cooling Unit

1. 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 without a connector at the end (see *figure 9*) and the second one with 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)

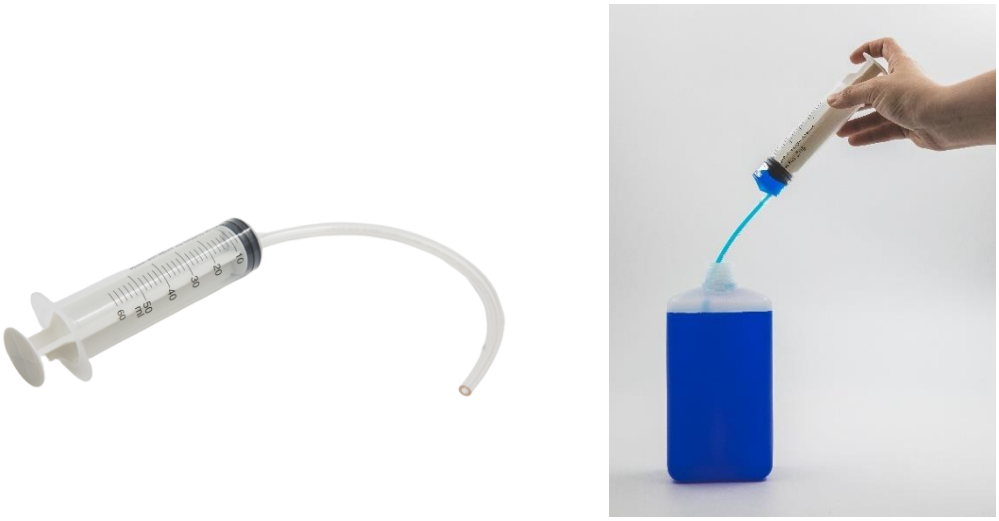


Figure 9: Filling the syringe with coolant liquid

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

4. 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.

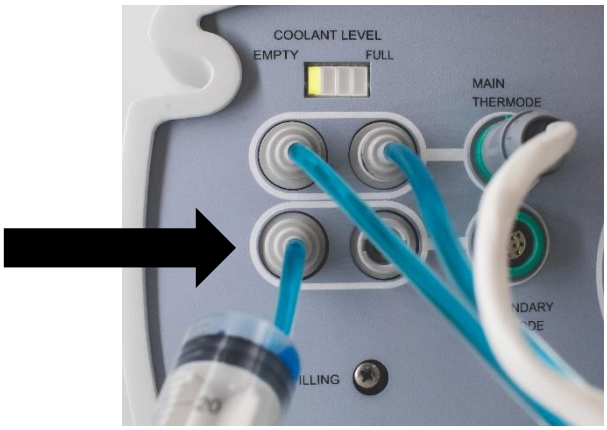


Figure 11: Connecting the syringe to the system

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*)

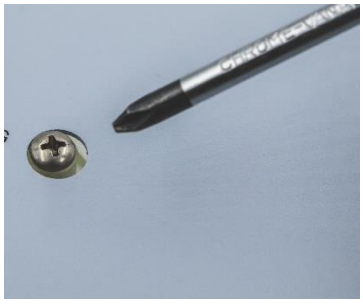


Figure 12: Air vent screw

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

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 2 fMRI Installation

Read the fMRI appendix of this document: Appendix L – fMRI functionality

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.

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 155) 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 2 system in the MRI control room. Leave the TSA 2 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 2 coolant connectors and electrical connectors to the TSA 2 connector panel as with a regular Thermode. See below figures.

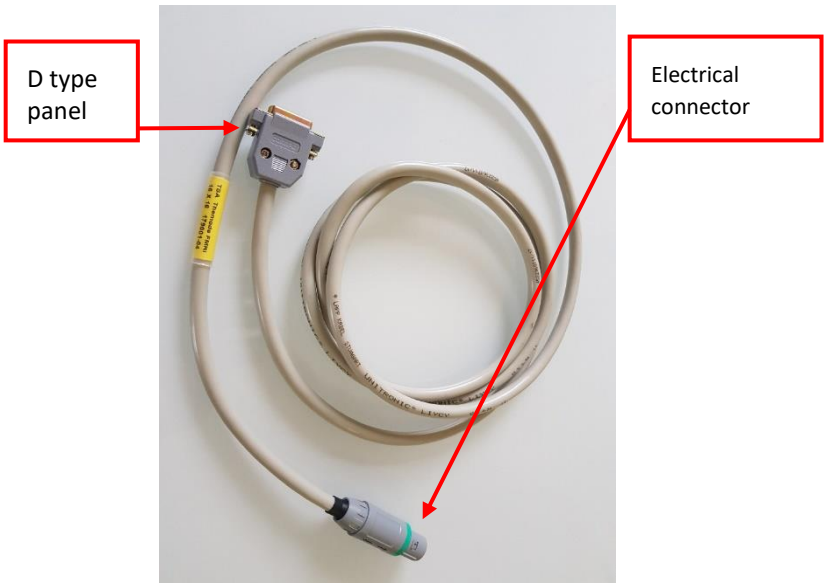


Figure 14: TSA 2 fMRI Thermode Control Room part WA 00077

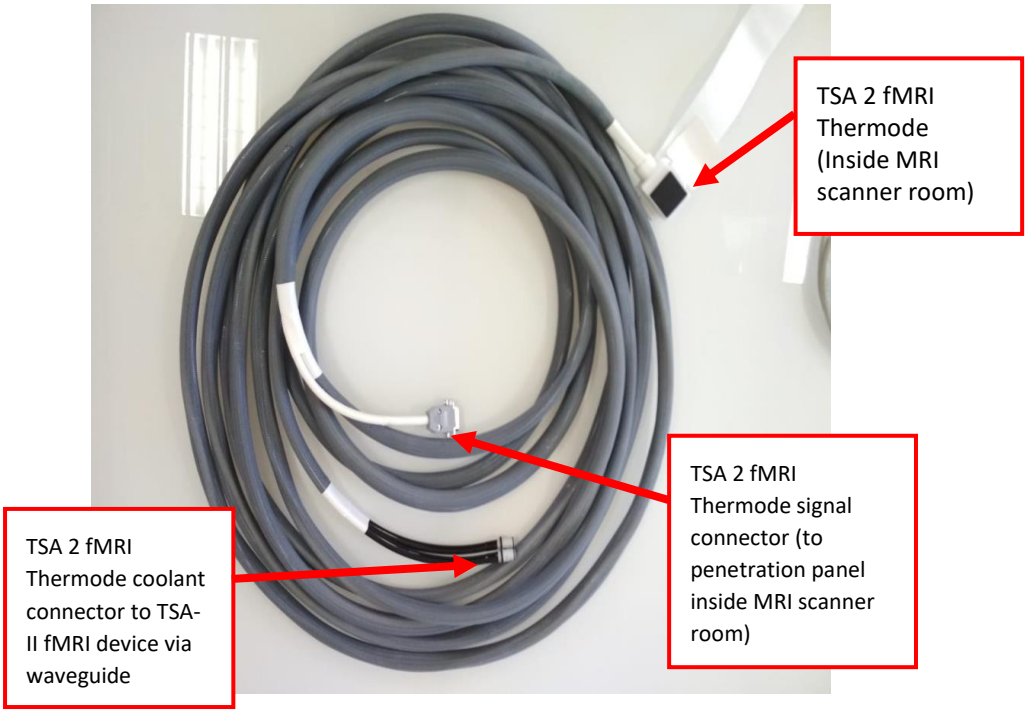


Figure 15: TSA 2 fMRI Thermode Shielded room part AS 00178

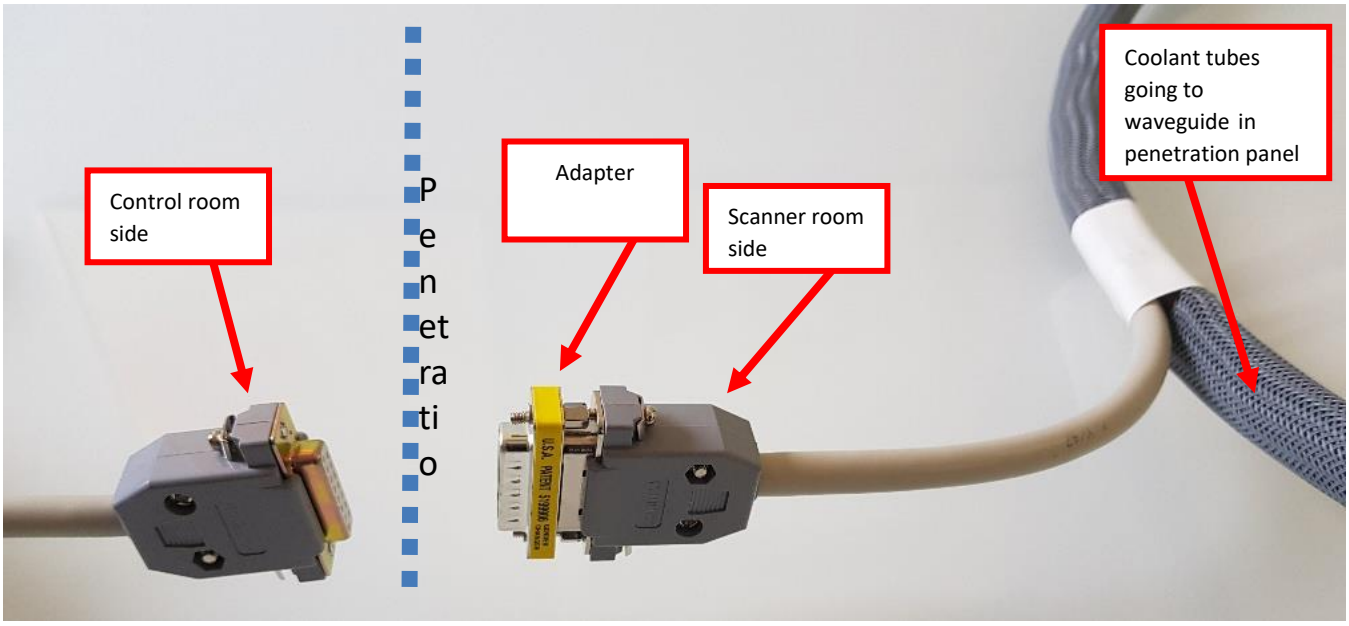


Figure 16: Signal/power cable and adapter connection

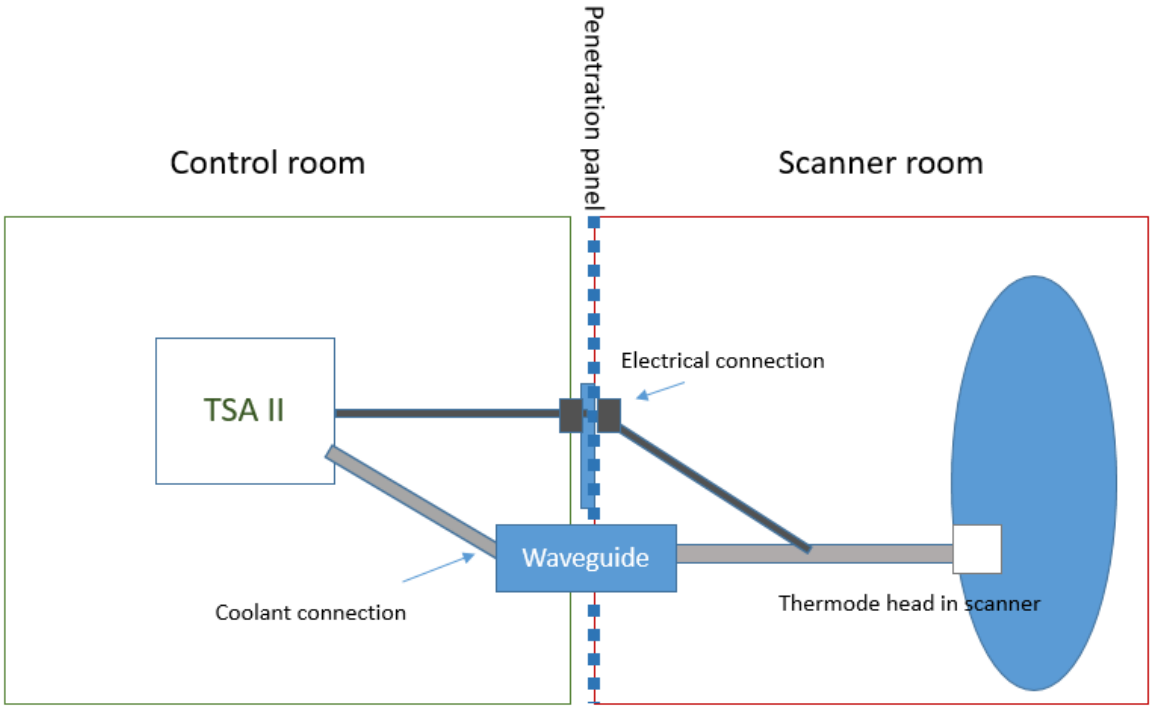


Figure 17 : Schematic diagram of connecting fMRI Thermode

3. Conduct three phantom tests:
   3.1. Conduct the test, when the TSA 2 is OFF,
   3.2. Conduct the test, when the TSA 2 is ON and software is OFF,

3.3. Conduct the test, when the TSA 2 and software are ON and software test is running.

4. The installation is finished if all three tests are passed successfully.

Common Troubleshooting

Thermode Connection

Note that the Thermode liquid connectors need to be inserted all the way 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”.

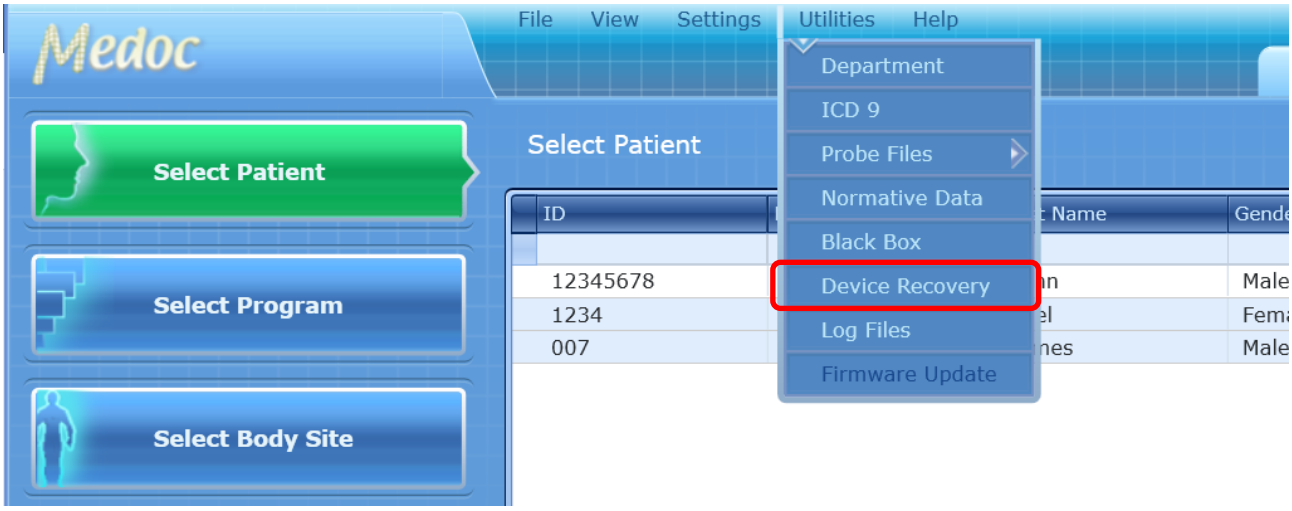


Figure 21: Device Recovery

2. Safety Guidelines and Regulations

Disclaimer

Medoc assumes no liability for use of this document if any unauthorized changes to the content or format have been made. Every care has been taken to ensure the accuracy of the information in this document. However, Medoc assumes no responsibility or liability for errors, inaccuracies, or omissions that may appear in this document. Medoc reserves the right to change the product without further notice to improve reliability, function or design. This manual is provided without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

This manual is written for trained users of Medoc Products. The user includes the body with authority over the equipment and those persons who actually handle the equipment.

Before attempting to work with this equipment, read, understand, note and strictly observe all Warning notices, Cautions and Safety markings on the equipment.

Before attempting to work with this equipment, make sure that this manual and any Release Notes delivered with the software media pack have been thoroughly read and fully understood, paying particular attention to all:

1. Warnings
2. Cautions
3. Notes

4. Important Notices
5. User Notices

2.1 Intended Use

The TSA 2 is a device for quantitative thermo-testing in the context of quantitative sensory testing battery in compliance with Quantitative Sensory Testing (QST) protocols to detect and quantify sensory loss and sensory gain aimed to precisely characterize somatosensory function in patients.

2.2 Target Population, Indications and Contraindications

The TSA 2 can be used on both healthy subjects and patients suffering from wide range of neuropathic, CNS and pain conditions. Minimum age reported in the literature is 6. The indications, populations and body sites are included in, but are not limited to, the attached list of selected examples of past use of the TSA 2 (Appendix N).

The only known contraindication is related to the skin on which the Thermode is applied – it must be used in contact with intact skin only. The Thermode contact surface is intended to be in contact with the patient's skin, not including mucosal membranes or breached or compromised surfaces. In certain applications indirect contact is allowed with mucosal membranes when the thermode contact surface is covered by a protective cover such as a condom (not provided by Medoc).

2.3 Safety and Regulatory Summary

Read and follow all WARNINGS, CAUTIONS and NOTES provided in this manual. To avoid the possibility of injury, damage to your system, or loss of data, always follow these precautions during system operation.

- The TSA 2 system complies with safety requirements for medical electrical systems (based on the IEC 60601-1 standard).
- The TSA 2 system complies with electromagnetic emission levels (based on table 201 in the IEC 60601-1-2 standard).
- The TSA 2 system complies with electromagnetic immunity levels (based on tables 202 and 204 in the IEC 60601-1-2 standard).
- This device complies with 93/42/EEC MDD and with Medical Devices Regulation 2017/745/EU.
- It is recommend keeping a distance of 3 meters between portable and mobile RF communications equipment and the TSA 2 (based on table 206 in the IEC 60601-1-2 standard).

2.4 Safety Requirements

The TSA 2 system can be tested according to IEC 62353 Recurrent test and test after repair of medical electrical equipment.

Do not modify or replace any component of the TSA 2 system.

Connecting or replacing external TSA 2 accessories is allowed.

Keep all liquids away from the TSA 2 system.

Unplug the TSA 2 system if it is not to be used for a long period of time.

Do not block airflow anywhere around the TSA 2 system.

Any safety event that occurred during the use of the device should be reported to Medoc Ltd. and to the competent authority of the country where the user is located.

2.4.1 Warnings

- Only personnel properly trained to operate the TSA 2 system should use this system. A recommended 2-hour training session on the TSA 2 can be used to provide the knowledge and skills required for safe and effective use of the device, and may be provided as a one-time session before first-time use. Users should have at least medium English proficiency and scientific, clinical or technical background. Please contact your local distributor for further information.
- Do not turn on system power until all cables have been properly connected and verified.
- Do not use any electrode paste, gel, or other material on the contact point between the Thermode plate and the skin of the tested subject.
- To reduce the risk of injury, attach the Thermode to the subject only prior to running a test while Medoc Main Station is in Test screen. Remove the Thermode from the subject skin before leaving the Test Screen.
- Connect the Thermode to the patient's skin ONLY during the test; not during system Self-Test, programming or maintenance.
- To reduce the risk of injury while working in MR environment, follow the safety instructions as presented in the relevant section of the TSA 2 Technical Reference Manual
- Connecting any device or accessory that has not been provided by Medoc (except for a Windows-based PC or for third party device TTL synchronization use), to the TSA 2 system is not allowed.
- Using a Thermode without the appropriate calibration table may result in potential harm or injury.
- Using the TSA 2 system not according to instructions may result in potential harm or injury.
- Adverse Reaction: Skin irritation (in addition to pain sensation) beneath the probes has been reported with the use of a stimulator, which was based on similar technology as the TSA 2 device.
- Be aware of potential risk of skin damage caused by wrong parameter combination.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

2.4.2 Cautions

- Proper use of this device depends on careful reading of all instructions and labels.
- Turn OFF system power before connecting or disconnecting any system component(s) or accessories. Otherwise, you may damage the device(s).
- The Thermode is very delicate and can easily be damaged. Therefore, handle with care.
- If you disconnect any cables, take care to reconnect them correctly to prevent damage to the system or components.

- This equipment uses a three-wire power cord with a hospital grade plug (for non-USA applications, the IEC 60601-1-approved plug).
- Inspect the power cord often for fraying or other damage. DO NOT operate the apparatus if the power cord or plug is damaged.
- The computer that is used to operate the TSA 2 system should be used at the user's responsibility, with all cybersecurity measures taken to control user access and authentication, patient and results data protection and general network security.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use caution when using the TSA 2 Thermode on patients with suspected neuropathies as they may be more susceptible to soft tissue or nerve damage at extreme temperatures. Also, patients with neuropathies may not be able to properly discontinue use of the device during prolonged hot or cold stimulation.

2.4.3 Equipment Classification

- Degree of protection against electric shock: Class I
- Type of protection against electric shock: BF
- Type of Operation: Continuous
- Protection against ingress of liquids: Not protected against ingress of liquids
- Ordinary equipment.
- Computer must comply with IEC 950 - EN 60950 - UL 60950.

2.5 System Protection

2.5.1 System IT Security

In order to prevent unauthorized access, upon software start-up, user credentials (unique user name and password) are required in order to enter the software and operate the device.

2.5.2 System Self-Test

Upon start-up the system performs a self-test in which system sensors are being tested. If a malfunction is detected, an appropriate message is displayed and the system cannot operate until that malfunction is resolved.

2.5.3 Temperature Safety Mechanisms

Several safeguard mechanisms have been implemented in the system to safeguard against extreme temperatures and to protect the tested subject and the unit.

Software protection mechanisms include:

- Temperature upper and lower limits – In normal operation, Thermode temperature will always be within these limits.
- Time duration limits – Thermode temperature is limited in duration. If the Thermode temperature maintains a specific temperature (or above) for a longer period of time then specified for that temperature, the system will go into Safe Mode.
- Safe Mode – a protective state of the system in which it is not possible to run tests. In any case of suspected malfunction or if any modification is made to system hardware settings, system will remain in safe mode until a system Self-Test is performed.
- Hardware protection mechanisms include:

- If the Thermode temperature reaches 56°C the system disconnects Thermode voltage and the Thermode is cooled by the coolant flowing through it.

2.6 Equipment Labels, Symbols, Warning Statements and Abbreviations

Table 1: Equipment Labels

Equipment Label	Description
I / O	Power switch ON/OFF
COM	Communications connector.
	Date of Manufacture (YYYY-MM)
	Manufacturer
	Degree of protection against electric shock – Applied Part Type BF.
	Caution
	Consult instructions for use (or electronic instructions for use)
	Mandatory instruction to read instructions for use
	Disposal according to electronic scrap ordinance
EC REP	European Authorized Representative
REF	Catalog Number
CE	CE marking
IPXO	No protection against ingress of water
MD	Medical Device

Equipment Label	Description
	Keep away from sunlight
	Keep dry
70°C 0°C	Storage temperature limits
95% 10%	Humidity limits
1060hpa 500hpa	Atmospheric pressure limits
MR	MR conditional
	Note

Manual edition refers to current version of manufactured system

Medoc reserves the right to change specifications without prior notice, in line with the company policy of constant product improvement

2.7 Electromagnetic Immunity

The TSA 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the TSA 2 should assure that it is used in such an environment.

Declaration – Electromagnetic Immunity			
IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance

Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TSA 2 requires continued operation during power mains interruptions, it is recommended that the TSA 2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Declaration – Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1 Class A	The TSA 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The TSA 2 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

		measures, such as re-orienting or relocating the TSA 2 or shielding the location.

Declaration – Electromagnetic Immunity			
IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Declaration – Electromagnetic Immunity			
IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol:
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	

2.8 Essential Performance

In the case of electromagnetic disturbances, the system will attempt to maintain communication with the MMS software and enable the continuity of the test. If the disturbance does cause communication failure with the PC or affects the system microcontroller, safety mechanisms are activated automatically and the Thermode will be disconnected. An error message will pop up indicating system communication has been lost (see Appendix O – Troubleshooting) and a buzzer will sound. Remove the Thermode from the patient and follow the on-screen instructions to restore communication and perform the self-test.

2.9 Recommended Separation Distance between Portable and Mobile RF Communications Equipment and TSA 2.

The TSA 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TSA 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TSA 2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.10 Technical Data

The table below describes the technical specifications and capabilities of the TSA 2 system. When stated, the term 'Optional' indicates that this specific feature requires an additional license and/or hardware component.

Table 2: TSA 2 Specifications

Parameter	Description
TSA Thermode (probe) active area	30 mm × 30 mm 16 mm × 16 mm 30 mm × 30 mm fMRI 16 mm × 16 mm fMRI Intra oral / clitoral (Ø6mm) CHEPS (24mmX24mm)
Temperature Range	0 – 53 °C (0 - 50°C in Limits). CHEPS range: Limits 0-50°C, Ramp and hold 1-53°C , Pulses 5-55°C Intra oral / clitoral (Ø6mm) range: 0 – 50 °C
Baseline Temperature	10 – 45 °C, programmable
Rate of temperature change - Linear mode	30X30: 0.1 – 13 °C/sec (Range may be lower depending on protocol used) 16X16: Heating 0.1 – 6.5 °C/sec, Cooling 0.1 -3°C/sec (>10°C), 0.1-1.3°C/sec (between 5-10°C), 0.1-0.8°C/sec (<5°C) Ø 6mm: Heating 0.1 - 3°C/sec, Cooling 0.1 -1°C/sec (>10°C), 0.1-0.5°C/sec (between 5-10°C), 0.1-0.3°C/sec (<5°C) CHEPS: Heating 0.1 - 70°C/sec, Cooling 0.1 - 40°C/sec
Stimuli Protocols	Limits Levels TSL search Ramp & Hold Chain Pulses CPM (for dual Thermode configuration)
Stimulus duration at destination temperature	0 – 600 Sec. (limited by protocol and safety cut-off. See below)
Inter-sequence time interval (Time interval between sequences)	0 – 600 Sec., in 0.1 Sec. resolution

Parameter	Description
Intra-sequence time interval (Time interval between stimuli, in one sequence)	0 – 600 Sec., counted onset-to-onset or end-to-onset, in 0.1 Sec. resolution. Optionally, this interval can be randomized within a predetermined range.
Randomize Option	Option to randomize between sequences
Number of stimuli in a program	Each sequence can include up to 100 trials (stimuli). The number of sequences in a program can be more than 100.
Stimuli trigger options	Automatic Manual using keyboard External, via a TTL input (Optional)
Synchronization Options TTL Input	Externally trigger the onset of stimulus Voltage: ±5 V Current: 10 – 15 mA Minimum Duration: 10 msec.
Synchronization Options TTL Output	Can indicate various events during stimuli (depending on protocol used) Voltage: ±5 V Current: 2 mA Duration: 50 – 1000 msec
Sound option (Computer speakers are required – not supplied)	Can indicate various events during stimuli (depending on protocol used)
CoVAS (Optional)	Computerized Visual Analog Scale (CoVAS) enables real-time recording of the subject's pain level, according to the standard VAS procedure.
External Control	Optional control mode, which enables programs to be initiated from an external application or device. External Control can be established via Parallel Port or using TCP/IP network.
Temperature set-point resolution	0.1°C
Temperature display resolution	0.1°C
Temperature repeatability	± 0.15°C
Absolute accuracy	± 0.3°C

Parameter	Description
Ambient temperature	18 – 24°C
Communication with computer	USB
Computer Requirements	See separate specifications
Software Operation System	Windows 10, 64 bit
Database	SQL Server Compact Edition
Software Language	English, German, Chinese
Database capacity	4 GB
Safety	Complies with UL-2601-1:94 and EN-60601-1-1
Safety limitations on Temperature & Duration (as allowed by program)	(1) 52 °C during 0.4 sec. (2) 51 °C during 1 sec. (3) 50 °C during 5 sec. (4) 49 °C during 10 sec. (5) 47 °C during 60 sec. (6) 6 °C during 80 sec. (7) 0 °C during 80 sec.
Dimensions	28.5 cm X 39 cm X 33 cm (W X L X H)
Weight	9 Kg
Operation Voltage	100 – 240 VAC, 50/60Hz, 5A-2.5A.
System Overload Protection	2 × 250 V, 2.5 A SB fuse (for 230 V system). 2 × 125 V, 5 A SB fuse (for 110 V system).
Product life time	10 Years
Thermode life time	3 Years

3. Overview

This Operation Manual for the TSA 2 provides the information you need to install, setup, operate and maintain your TSA 2 unit. Medoc recommends that the first-time user read through the entire Manual before operating the unit.

The TSA 2 is a computerized device designed for both clinical and advanced research applications for the quantitative assessment of peripheral small nerve fiber dysfunctions, and central sensory modulations. It allows to measure sensory thresholds such as the sensation of warmth, cold, heat-induced pain and cold-induced pain.

The thermal sensory thresholds may deviate from the normal range in peripheral nerve dysfunction. Thermal Testing methods permit earlier clinical intervention that may halt nerve damage.

3.1 Medical Background:

Peripheral nerves consist of fibers of variable diameter. The smaller fibers on which the principle of thermal testing is based mediate the sensations of warmth, cold and pain.

Thermal testing allows to quantitatively measure thresholds for warmth, cold, heat-induced pain and cold-induced pain and to compare them to age-matched normal population values. A deviation from the normal range can indicate peripheral or central nervous system dysfunction.

3.2 Principle of Operation:

For thermal testing, a probe, called a "**Thermode"**, is attached to the subject's skin. The system is capable of heating or cooling the Thermode temperature as needed. The Temperature change is achieved by controlling the heat generator inside the Thermode (a Peltier Element) and measuring the output temperature using Thermistors.

Generally, at the onset of a stimulus, an adaptation temperature between 30°C and 32°C is set (within this range, the subject should have neither a warm sensation or a cool sensation). For threshold measurement, temperature will then decrease or increase at a constant rate until a response from the subject or operator is received. Response can be recorded by either using the keyboard (operator or subject) or the Patient Response Unit (subject). The temperature at which the response was noted is saved, and the next cycle of stimuli starts. Test results can be saved, printed as a report or exported for further analysis.

3.3 Thermode

The Thermode is comprised of a Peltier element, with two thermal sensors monitoring the temperature of the contact plate and one sensor monitoring coolant temperature. The surface contacting skin of subjects is made of anodized aluminium. The Thermode can be used for both hot and cold stimuli.

Thermode standard lengths are 2.5m (8.2ft) and 12.5m (41ft) for fMRI versions.

For more detailed specifications of the TSA Thermode please refer to Technical Specifications in section 2.10, page 35.

For a list of available Thermode sizes and types, refer to Table 34: Accessories

3.4 Terminology

The following terms are used throughout the user manual:

Table 3: Terminology

Term	Description
Thermode	The probe which is used to apply the thermal stimulation on the subject's skin.
TEC	Thermo Electric Cooler (TEC), a Peltier element used as the active heat generator in the Thermode.

Term	Description
Cooling Unit	The Cooling Unit is a component within the system which is responsible for refrigerating and circulating the coolant through the system and Thermode.
Rest Temperature	The initial/rest temperature of the Thermode, after system initialization and in between tests. Also referred to as Adaptation Temperature.
Baseline Temperature	The initial temperature the stimulus starts from.
Destination Temperature	The final temperature the stimulus ends with.
Duration Time	Indicates the time the probe will remain at the destination
Trial	Represents one stimulus
Sequence	A set of trials with the same specifications
Test	A set of sequences.
TTL	Transistor to transistor logic - A square wave signal which is commonly used to synchronize between different devices.
Event	A specific occurrence during a test such as the onset of a stimulus, reaching a specific temperature and etc.
LUT	A Look Up Table (LUT) maps one set of values to another. A LUT is used to map between the readings from the temperature sensors to the actual temperature it represents, also referred to as a calibration table.
Firmware	The program embedded on the internal processor of the system

3.5 System Status

- **Online:** Indicates full communication between Medoc Main Station software on your PC and the TSA 2 System. While on-line the TSA 2 system can operate in several different states as listed in the following section.
- **Demo Mode:** This is a demo mode of operation. There is no communication between the software and the TSA 2 system. All tests performed while working in this mode are simulated. No actual thermal stimulation is performed and there is no access to the TSA 2 hardware settings. The Simulator is useful for demonstration, training and for protocol design without executing actual thermal stimulation. It is recommended to turn off the TSA 2 system while working in Simulator mode.

3.6 System States

System State is the active state in which the system is currently operating. System states refer to the **online** status only.

The TSA 2 active states are as follows:

- **Rest Mode**: The TSA 2 system is active and ready to perform a test. The temperature is maintained at a constant value, according to the selected Rest Mode Temperature (by the user). The default value (after a new installation), is 32°C. In this mode, patient, program and result management are possible.

- **Test Run**: The TSA 2 system is running a (predefined) test. The Thermode is active, and the temperature varies according to the active program.
- **Safe Mode**: No output is sent to the Thermode; no test can be activated. The system must perform Self-Test successfully, before continuing work with the system. Thermode temperature is initially set to 25°C upon system startup. If safe mode is engaged due to an error the voltage to the Thermode is cut off and the coolant temperature is conducted to the contact plate. In this mode the subject should not be in contact with the Thermode.
- **Engineering**: During Thermode Calibration the system state is set to Engineering. In this state safety limitations are lowered and it is not allowed to run any actual tests. In this mode the subject should not be in contact with the Thermode.
- **Test Initiation**: The system raises the temperature from Rest Mode temperature to Baseline level. A stabilization test (pre-test) is then performed, to make sure that the temperature is maintained according to the program requirements.
- **Self-Test**: The system performs a Self-Test in order to check whether the connected Thermodes function according to system requirements. During self-test the subject should not be in contact with the Thermode.
- **Black Box**: The system has detected an error and is saving the details in the internal black box logger.

3.7 Application Methods

Detection of **sensory thresholds** depends on subjective data input. Several algorithms for threshold measurement have been developed in order to minimize subjective variation, and make the result as objective as possible.

TSA 2 supports the following methods (indicated as program types):

- **Ramp & Hold**: The temperature of the stimulus is maintained for a predetermined duration.
- **VAS Search:** A set of Ramp & Hold stimuli is emitted, and for each stimulus, the subject is required to report the perceived level of pain. The following stimulus is calculated according to the subject's response.
- **Pulses**: Fast and short duration stimuli.
- **Search**: The temperature of the stimulus rises (or falls) according to the tested subject’s response (using CoVAS or Response Unit), and stops after a predefined period.
- **Limits**: A set of stimuli at a predetermined rate is given, and for each stimulus, the subject is required to stop the stimulus when perceiving the required sensation.
- **Levels**: A set of stimuli is emitted, and for each stimulus, the test subject is required to respond. The following stimulus is calculated according to the tested subject's response.
- **Thermal Sensory Limen (TSL)**: The temperature of the stimulus rises (or falls) according to the test subject's response and stops according to predefined trails.
- **Chain**: This method can chain any of the predefined methods, any number of times, in any order.
- **CPM:** Deliver thermal stimuli using two Thermodes each determined using a separate protocol.

Before applying any of these methods, make sure to read section 7, page 71, on Test Procedure and Management

3.7.1 Ramp & Hold Method

In this method, the temperature rises (or falls) to a predetermined destination, at a predetermined rate, remains there for a predetermined duration and proceeds to the next destination.

There are two main options: Return to Baseline, and Continue to Next Destination.

3.7.1.1 "Return to Baseline" Option

The diagram below shows a general view of the sequence and predefined parameters. For the definition of each parameter, see table 14, page 81

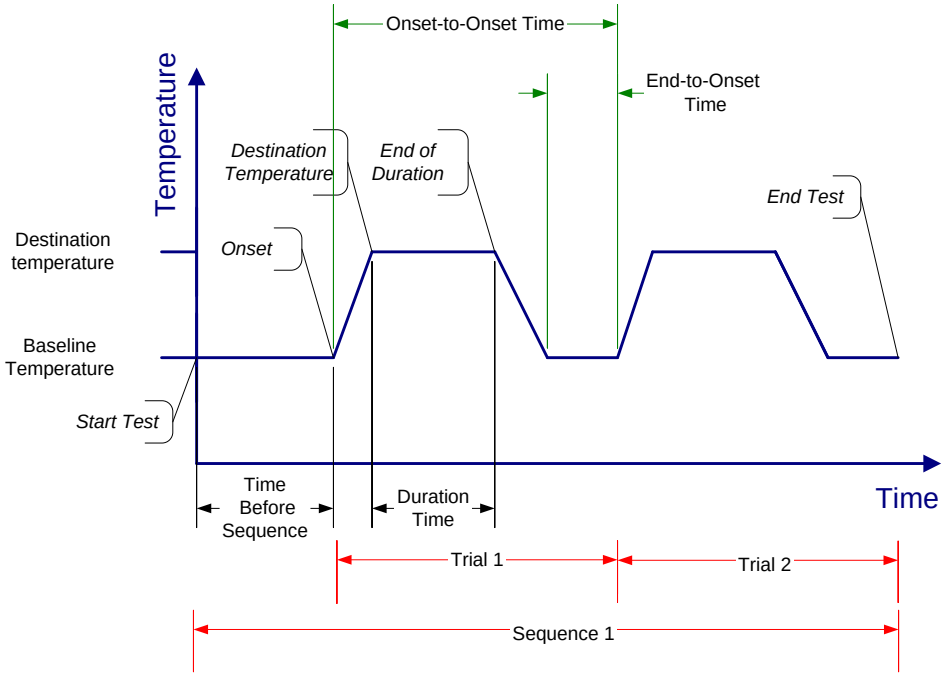


Figure 22: Ramp &Hold Sequence – Return to Baseline

Each sequence consists of a number of similar trials (one trial is also allowed).

1. The start point of each trial is called onset.
   The temperature at this point (the onset point) is the *Baseline Temperature* defined for this sequence.
2. From this point the temperature changes at a predefined rate, until it reaches the predefined *Destination Temperature*.
3. Then, the temperature remains at the destination temperature level for the predefined duration time. The point at the end of the duration time is called end of duration.
   Setting duration time to zero produces peaks.
4. Finally, the temperature returns at the return rate, to the baseline temperature. The temperature remains at this level for a duration that can be specified in one of two ways: as an end-to-onset time or an onset-to-onset time.

At the start of each sequence the temperature should remain at the *Baseline Temperature* level for the time given by the parameter *Time Before Sequence*.

3.7.1.2 "Return to the Next Destination" Option

The temperature at the End of Duration point goes directly to the Destination Temperature of the next sequence when this option is used.

This is available only for sequences consisting of one trial.

See definition of each parameter in table 14, page 81

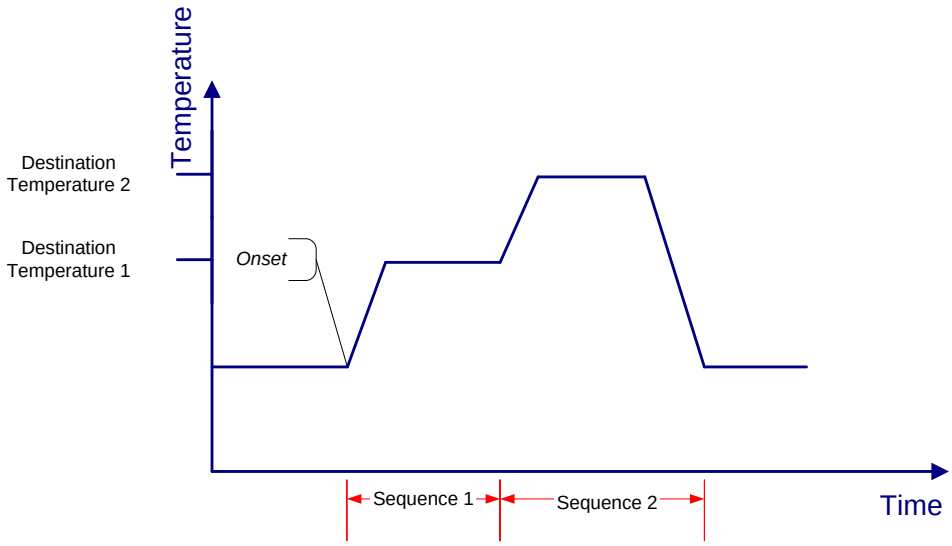


Figure 23: Ramp & Hold Sequence – Return to Next Destination

3.7.2 VAS Search Method

In VAS Search method, first Ramp & Hold stimulus with predefined intensity and duration is given and the subject is asked to estimate the perceived magnitude of pain. The intensity of the next stimulus is set according to the response – increases if the reported pain rating is lower than the desired, decreases if the reported pain rating is higher than the desired. The step size by which the intensity of the next stimulus is changed can be predetermined during program creation or set by the operator during the test. The VAS Search method can be used to individually define what temperature is associated with patient's pain rating.

The temperature associated with the subject individualized rating of pain can be determined in one of two modes – automatic and manual.

In Manual mode only the first stimulus is predefined, the intensity of the next stimulus is set by the operator during the program run using the following window that pops up after each trial:

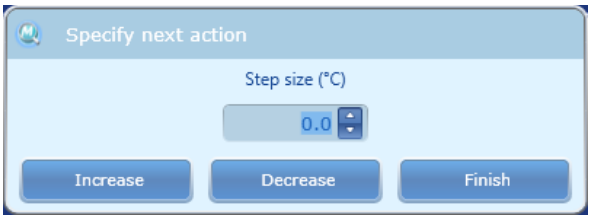


Figure 24: VAS Search – Manual Mode

In this window the user selects if to increase or decrease the destination temperature of the next trial and by how much (determined by the 'Step Size' value). There is also an option to resume the program if the operator decides that the target pain rating was reached.

In Automatic mode the target pain rating and the step size are predetermined during program creation and the temperature of each trial is defined according to these parameters and the subject reported pain rating - increases by the step size value if the reported pain rating is lower than the target and decreases by the step size value if the reported pain rating is higher than the target.

See section 25 for further use of VAS Search in External Control.
See section VAS Search, section 7.6.5, page 85, for full description of program details and parameters.

3.7.3 Pulses Method

When using this method, the temperature rises or falls at the maximal rate, and then returns to a predefined starting point of a new pulse.

There are two main options: Without a Low Destination, or With a Low Destination.

3.7.3.1 Without a Low Destination

The schema below shows a pulses sequence without a low destination.

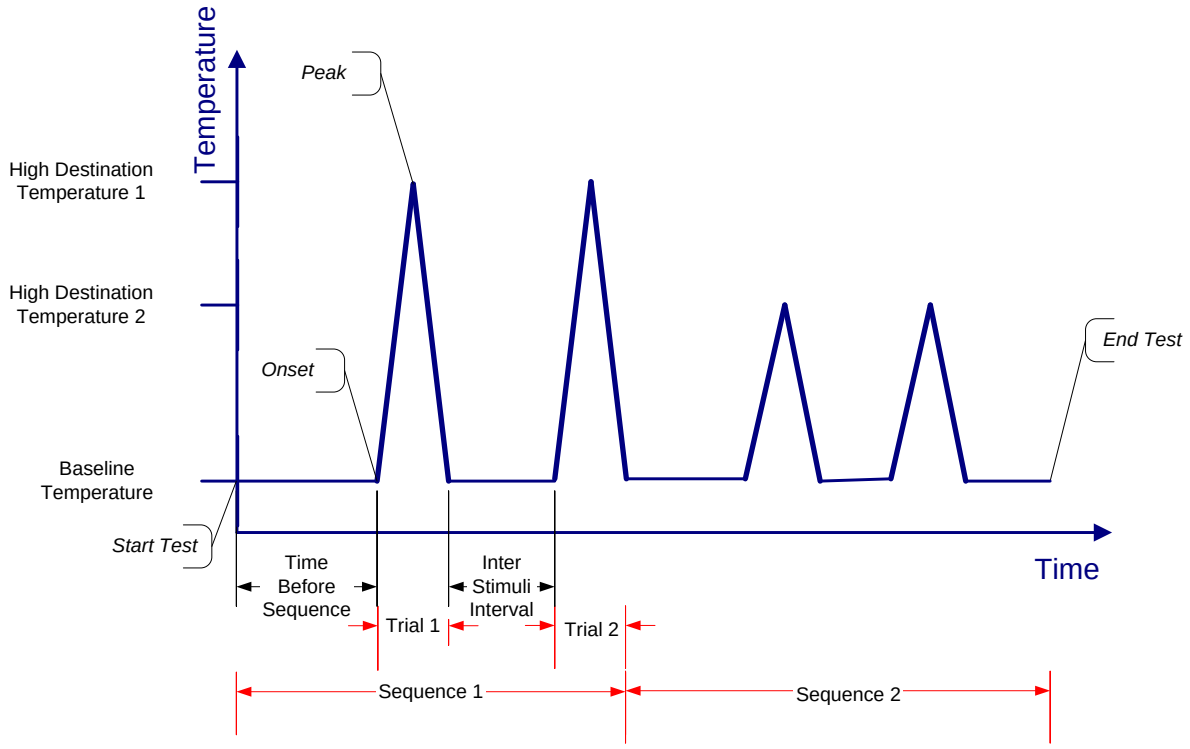


Figure 25: Pulses Sequence – Without Low Destination

Each sequence consists of a number of similar trials (one trial is also allowed).

1. The starting point for each trial is called the *Onset*.
   The temperature at this point is the *Baseline Temperature* defined for the entire sequence.
2. From this point on the Baseline Temperature is maintained until the pulse is created. The temperature at the peak of a pulse is the *High Destination Temperature*.
3. When the High Destination Temperature is reached, the temperature returns to the Baseline Temperature.
4. From here on the Baseline Temperature is maintained until the next pulse is created.

At the start of each sequence the temperature should remain at the Baseline Temperature for the time given by the parameter *Time Before Sequence*.

See section 7.6.6 page 86 for full description of program details and parameters.

3.7.3.2 With a Low Destination

When this option is used, the first pulse in each trial starts at the Baseline Temperature and ends at the Low Destination Temperature. All the following pulses start and end at the Low Destination Temperature. The last pulse in the trial starts at the Low Destination Temperature and ends at the Baseline Temperature.

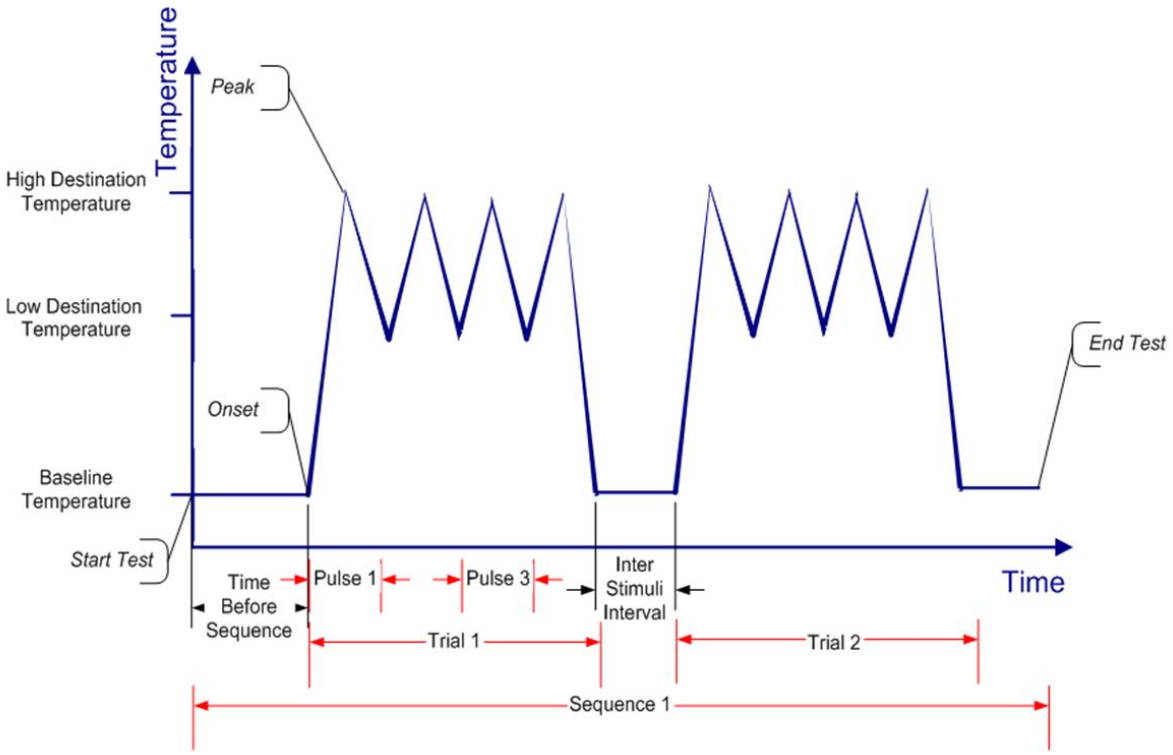


Figure 26: Pulses Sequence – With Low Destination

3.7.4 Search Method

The Search method allows you to map the test subject for pain / sensory threshold.

The Search sequence may start with a defined baseline temperature, or with a ramp from the Baseline Temperature to other destination temperatures. After the temperature has stabilized on the Baseline Temperature (in the first case), or reaches the Destination Temperature (in the second case), the test subject starts to control the temperature changes, by using one of the following input devices:

- Response Unit – Pressing **No** decreases temperature .Pressing **Yes** increases the temperature. The temperature increase and decrease rates are parameters of the sequence. Temperature safety limits are controlled during the test using standard TSA 2 safety procedures.
- CoVAS – The user controls direction and rate of temperature change.

The test subject controls the temperature changes during the time defined for this sequence, after which the temperature returns to the Baseline Temperature.

See section7.6.7 page 88 , for full description of program details and parameters.

3.7.5 Limits Method

The Limits method is the most widely used method for threshold determination, because it requires the shortest test duration of all methods, and it can measure not only pain thresholds, but also non-painful sensory thresholds.
See section7.6.1 page 77 , for full description of program details and parameters.

3.7.6 Levels Method

In the Levels method, stimuli are increased by a predetermined initial step until the first YES response. Stimuli then decreased by one half the initial step until a NO is given. Subsequently, the direction changes according to the response: increase for NO and decrease for YES. The step is halved at every direction change. The test is terminated when the step reaches a small enough size, as pre-determined by the user. Threshold is determined by taking the mean of last YES and the last NO. This is the shortest of all constant stimuli methods.
See section 7.6.2 page 78, for full description of program details and parameters.

3.7.7 Thermal Sensory Limen (TSL)

The TSL method is a reaction time inclusive method in which the stimuli direction changes with every response from the subject. The stimuli continuously alternate between warm and cold sensation for a pre-determined number of trials. The TSL method can be used to determine the area of no thermal sensation by calculating the difference between the means of cold sensation and warm sensation.

See section 7.6.3 page 81, for full description of program details and parameters.

3.7.8 Chain Method

Using this method, you can create a program that includes any other methods, any number of times, in any order.

See section 7.6.8 page 89for full description of program details and parameters.

3.7.9 CPM Method

Using this method you can create a program in which both Thermodes are operated synchronically.

See section 7.6.9 page 92 for full description of program details and parameters.

4. System Components

Figure 27: TSA 2 Side view

4.1 TSA 2 Connector Panel

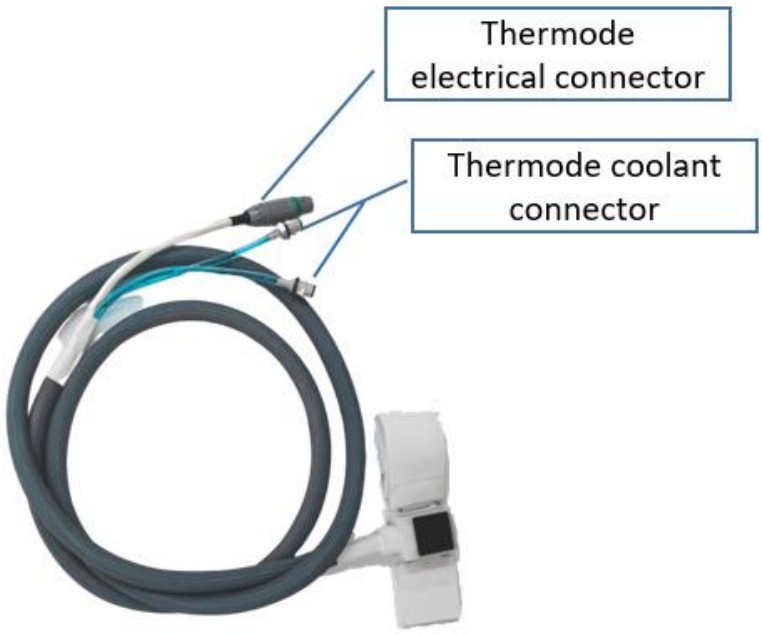
Do not connect any equipment during tested subject examination.

Figure 28: TSA 2 Connection Panel

TSA 2 panel contains the following receptacles and controls:

Not all accessories are supplied in standard configuration.

Table 4: TSA 2 Panel Receptacles

Receptacle	Mate with
Mains cable inlet	Figure 29: Power cable
Main TSA Thermode electrical connection	 **Figure 30: TSA Thermode**
Main TSA Thermode coolant ports	

Receptacle	Mate with
Response Unit Receptacle	**Figure 31: Response Unit**
USB Communication cable connector	**Figure 32 USB Communication cable**
TTL Cable connector	**Figure 33: TTL In or Out Cable (not supplied)**

4.2 Coolant Level Management

4.2.1 **Coolant Level Indication**

Can be found in the upper left side of the back panel.

Figure 34: Coolant level indication

4.2.2 Coolant Filling

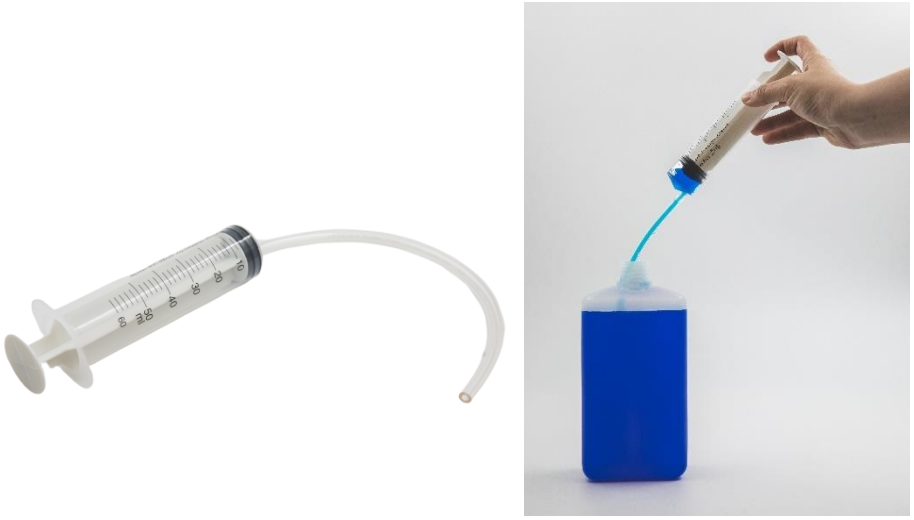


Figure 35: Filling the syringe with coolant liquid

1. Use the AS 00171 to fill the cooling unit. Connect the syringe to the tube without the connector, fill the syringe with coolant liquid

2. Switch the transparent tube to the one with the connector at the end (see figure below)

Figure 36: Syringe and tube with connector

3. Connect the connector to the lower left coolant port in the system.
   Main Thermode should be connected and the system should be turned ON. Note: CHEPS Thermode has two connectors, labelled MAIN and SECONDARY. These should be connected to the respective panel connectors only, i.e. MAIN thermode cable connector to MAIN THERMODE panel connector.
4. In case secondary Thermode is to be used, complete the next steps with secondary Thermode disconnected. Then connect it and check that coolant level is still sufficient

Figure 37: Connecting syringe to system

5. Using a Philips head screw driver, open the vent screw, located below the coolant ports. Unscrew 3 turns.

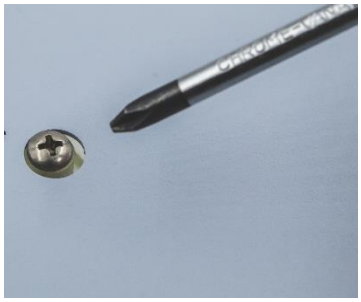


Figure 38: Air vent screw

6. Fill the system **slowly** with cooling liquid (ONLY) and check the Coolant Level LED lights indicator (located above of the Thermode ports).
7. 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.

8. Disconnect the syringe from the system and keep it for future use.
9. Tight the vent screw back to the system. (3 turns clockwise)
10. Important notes:
    - It is recommended to fill the system before it reaches the lower indicator (most left of the four LED lights).
    - When the coolant level may be too low (coolant level empty) – the System will not allow the user to continue working before filling the system. This is to prevent damage to the system.

4.3 Status LED indication

The LED lights on the side of the system provides the user information regarding the system state.

4.3.1 Green

Rest mode and test mode.

Figure 39 : Green light LED

4.3.2 White

Safe mode / during self-test/ when system is not connected to software.

Figure 40: White light LED

4.3.3 Red

Error was triggered- refer to software error messages for further instructions

Figure 41: Red light LED

4.3.4 Turning OFF LED lights

It is possible to turn off the LED light indications. Refer to 11.2.1.3

5. Setup and Installation

The TSA 2 system installation is designed to be simple and fast. Follow the instructions given below for selecting a location, installing and initial setup of the TSA 2 system. Proper installation and operation of the equipment is important for ensuring the safety of the tested subjects.

Complete and verify the entire TSA 2 setup and installation process before using the system.

5.1 Computer Requirements

The requirements below are **minimum** requirements intended to be used as a guideline for selecting a computer to use with Medoc Main Station software.

Table 5: TSA 2 Computer Requirements

Safety	Computer must comply with IEC 950 – EN 60950 – UL 60950
Processor	2GHz processor as a minimal requirement, Recommended: Intel Core i3 4xxx or better (avoid low power processors such as Atom, Pentium or Celeron).
Memory	4 GB RAM
Storage	128 GB
USB slots	2 free USB slots
Monitor/Display	13'' (15'' recommended)
Screen Resolution	1366 x 768 pixels, 96 DPI (max. 1920x1080)
Operating System	Windows 10
Other	Microsoft Office 2007 or above (required for viewing results in excel)

The computer used for Medoc Main Station software should be dedicated for this purpose only. Medoc takes no responsibility for any conflicts which may occur with other programs

For optimal performance disable any other resource heavy programs running on the same computer such as Anti-Virus, Screen Saver, Hibernate Mode, and Network connections.

5.2 Installation USB Content

The installation USB contains the Medoc Main Station setup program and additional features that are required for system normal operation, as detailed below:

1. Medoc Main Station setup program.
2. Software license files.
3. Technical Reference Manual.
4. Technical Reference Service Manual.
5. Remote assistance tools.

The installation USB contains all of the unique system files. Keep it in a safe place. It may be required for restoring the system configuration in case of malfunction and/or service during remote control session by Medoc.

5.3 Setup and Installation Main Steps

The assembly procedure consists of the following steps:

1. Selecting a location for the system. See section 5.4, page 55.
2. Connecting the Thermodes and any additional accessories to the system. See section 5.5, page 55.
3. Connecting the PC and installing Medoc Main Station software. See section 5.6, page 55.
4. Configuring the system.

5.4 Selecting a Location

An appropriate location for the TSA 2 system should meet the following criteria:

1. The room temperature should be kept between 18°C and 24°C (64°F – 75°F).
2. The room humidity range should be kept between 30% – 75%
3. The TSA 2 system should not be placed in a location, which is exposed to direct sunlight or constant vibrations, or close to heaters or air conditioners.
4. The space allocated for the system should allow enough room to perform regular system maintenance procedures.
5. The room in which the system will be located should be quiet, allowing the tested subject to concentrate on the examination with minimum distractions.

5.5 Device Connections

1. Ensure that the PC meets the minimum computer requirements. See section 5.1, page 54
2. Make sure that the PC, TSA 2 unit are all **OFF**.
3. Do not connect the Computer to the TSA 2 before installing Medoc Main Station software (see section 5.6).
4. Connect the system, Thermodes and accessories according to your application.

Note that the coolant tubes are connected properly, and that there are no leaks. Make sure that the electrical connector of the Thermode is secured.

5. Connect the TSA 2 power cord to an AC grounded outlet.

Do not connect any equipment to a TSA 2 system that has not been specifically authorized and approved by Medoc.

5.6 Software Installation

The installation procedure of Medoc Main Station software can only be performed by a user with windows system administrator rights. Without appropriate access rights, the installation procedure may fail.

Users with previously installed versions of Medoc Main Station should review the upgrading instructions.

Depending on the current configuration of the computer, Medoc Main Station installer may require the installation of additional components. The installation procedure may take several minutes.

Disable any antivirus that runs on the PC before installing Medoc Main Station.

Software installation can be performed only by Windows System Administrators only

The following instructions will guide you through the installation procedure:

5.6.1 Installing from a USB drive:

The following instructions will guide you through the installation procedure:

1. Insert the **USB drive** into an available USB port on the computer
2. Wait for the **AutoPlay** window to show:

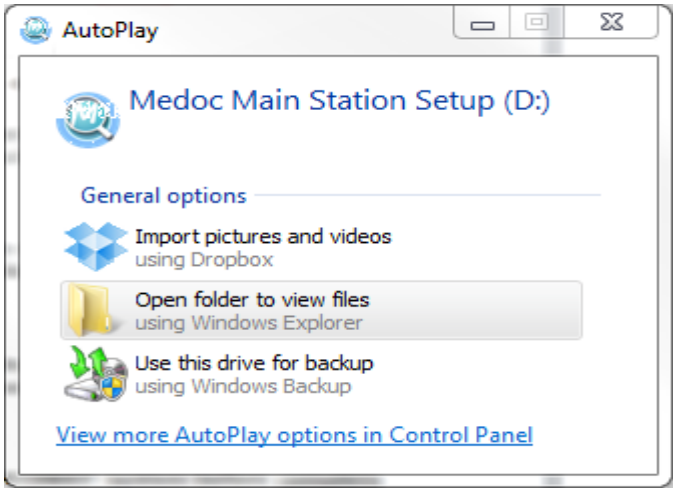
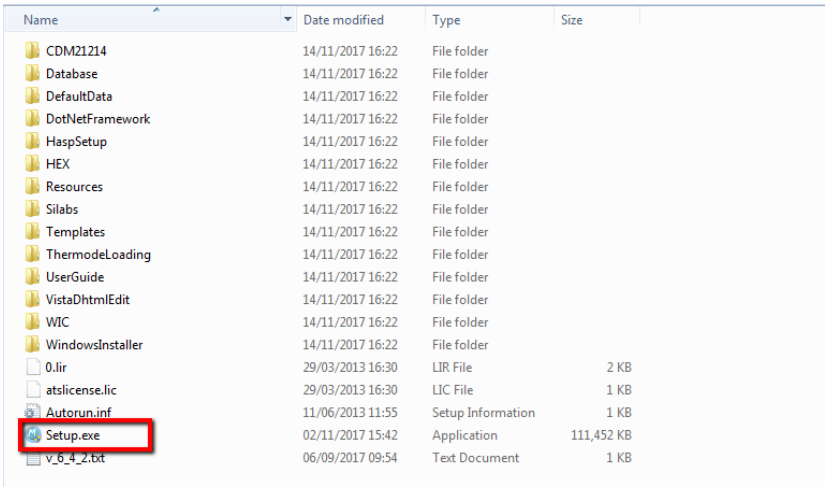


Figure 42: AutoPlay

If the AutoPlay is not displayed, open the USB drive from the Computer folder

3. Select **Open folder to view files**



Name	Date modified	Type	Size
CDM21214	14/11/2017 16:22	File folder	
Database	14/11/2017 16:22	File folder	
DefaultData	14/11/2017 16:22	File folder	
DotNetFramework	14/11/2017 16:22	File folder	
HaspSetup	14/11/2017 16:22	File folder	
HEX	14/11/2017 16:22	File folder	
Resources	14/11/2017 16:22	File folder	
Silabs	14/11/2017 16:22	File folder	
Templates	14/11/2017 16:22	File folder	
ThermodeLoading	14/11/2017 16:22	File folder	
UserGuide	14/11/2017 16:22	File folder	
VistaDhtmlEdit	14/11/2017 16:22	File folder	
WIC	14/11/2017 16:22	File folder	
WindowsInstaller	14/11/2017 16:22	File folder	
0.lir	29/03/2013 16:30	LIR File	2 KB
atslicense.lic	29/03/2013 16:30	LIC File	1 KB
Autorun.inf	11/06/2013 11:55	Setup Information	1 KB
Setup.exe	02/11/2017 15:42	Application	111,452 KB
v_6_4_2.txt	06/09/2017 09:54	Text Document	1 KB

Figure 43: USB Folder Content

4. Double-click **Setup.exe** to start software installation
5. The following screen is displayed:

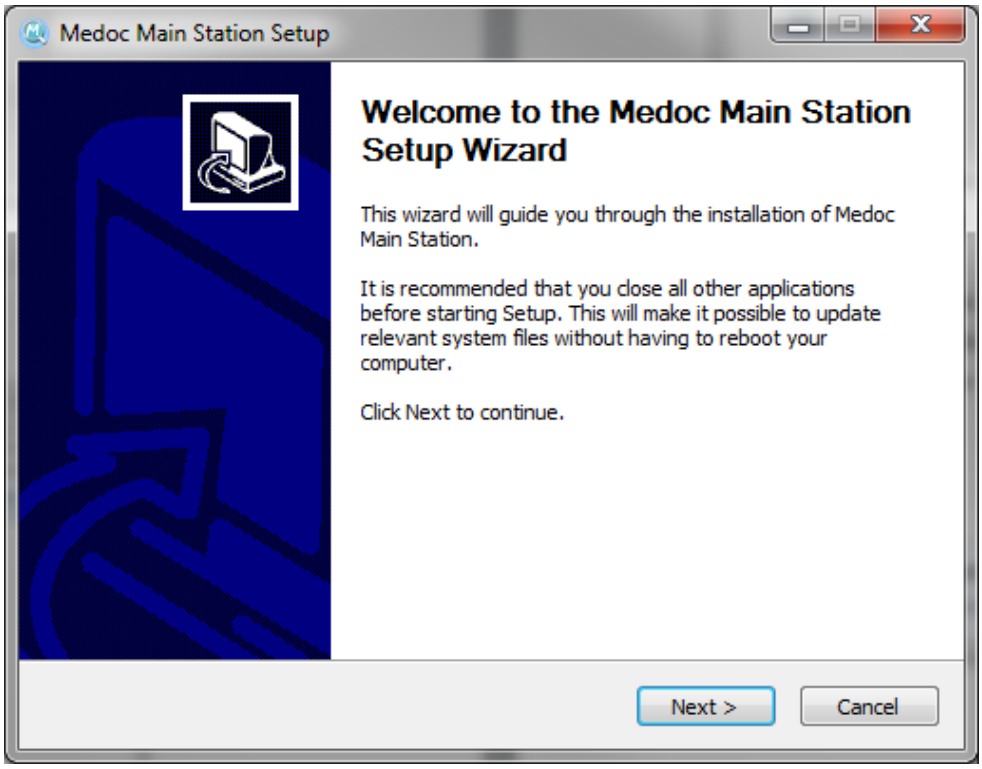


Figure 44: Main Station Installation 1

1. Click **Next** to start the installation.
   The following screen is displayed:

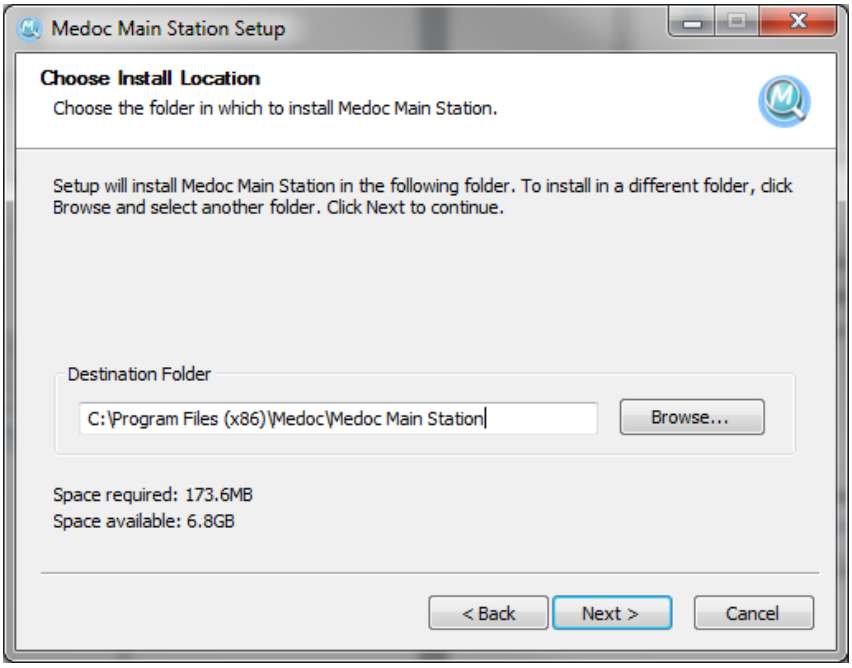


Figure 45: Main Station Installation 2

It is recommended to use the default folder as displayed in the installer

2. Select Medoc Main Station Installation folder and click **Next** to continue.
   The following screen is displayed:

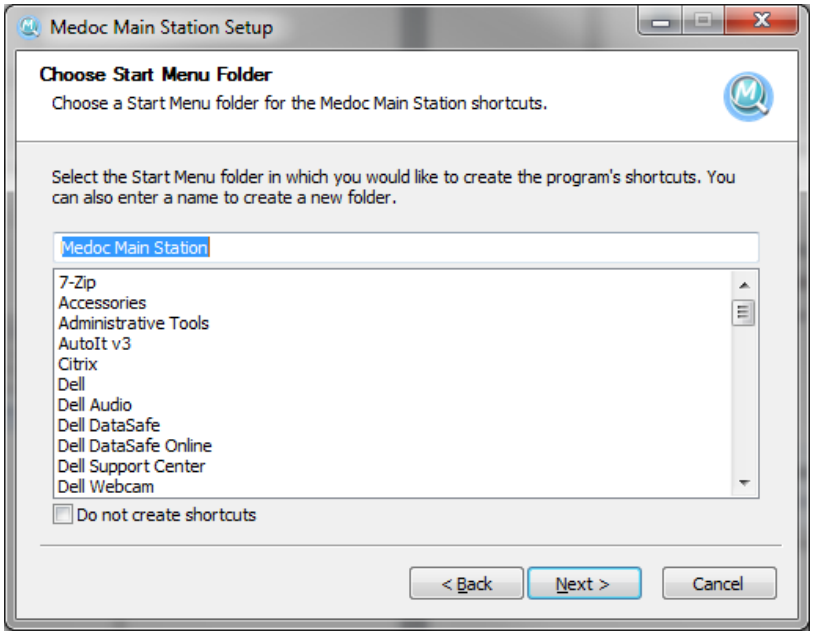


Figure 46: Main Station Installation 3

3. Click **Next** to continue.
   the following screen is displayed:

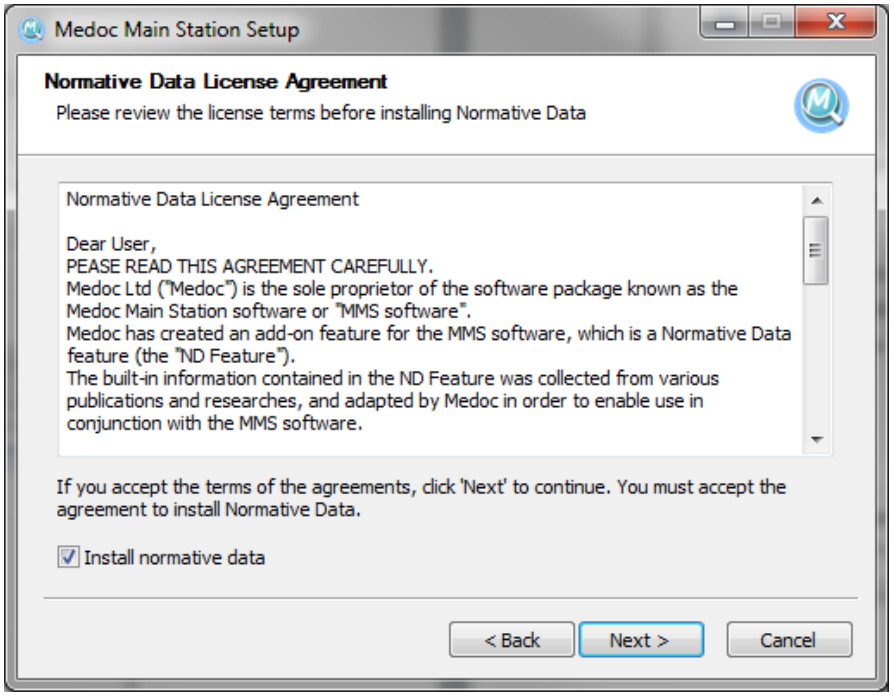


Figure 47: Main Station Installation 4

4. Please review the Normative Data usage license agreement carefully. Click **Next** to continue. The following screen is displayed:

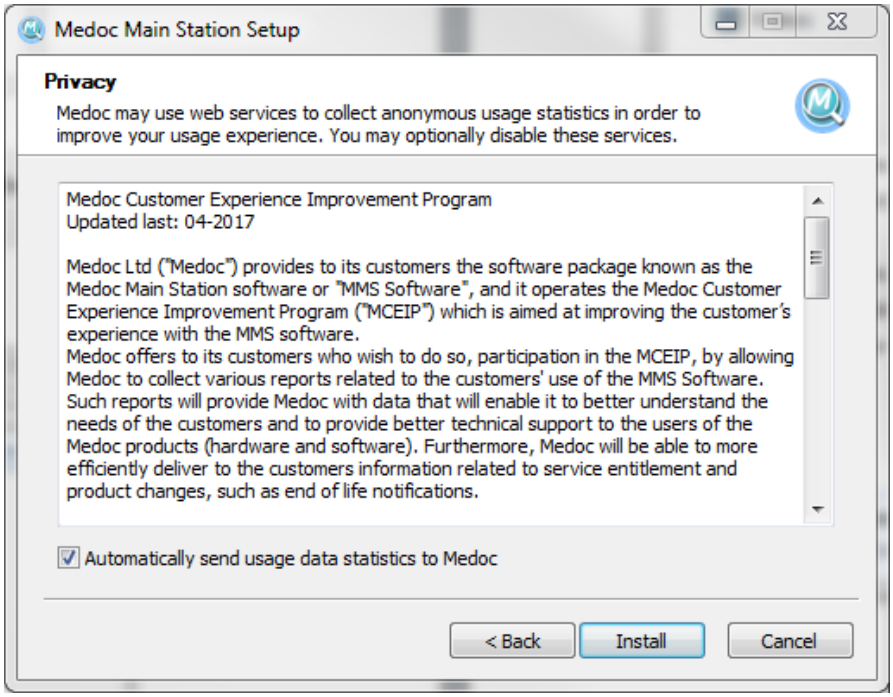


Figure 48: Main Station Installation 5

5. Please review the privacy statement carefully and select the option below. Click **Install** to continue. Installation is now in progress.

6. When the installation is complete the following screen is displayed:

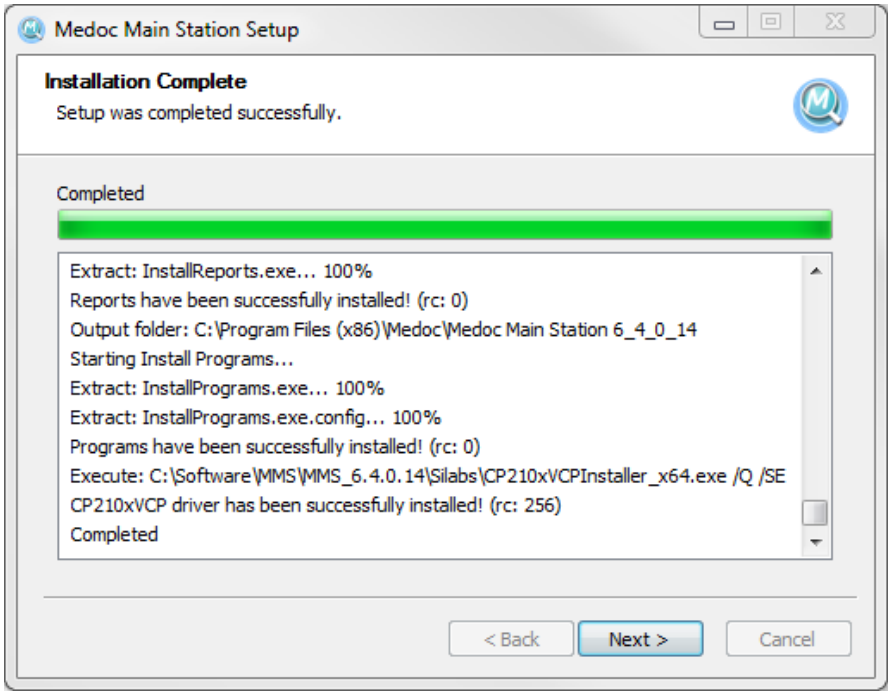


Figure 49: Main Station Installation 6

7. Click **Next** to complete Medoc Main Station Installation.
   The following screen is displayed:

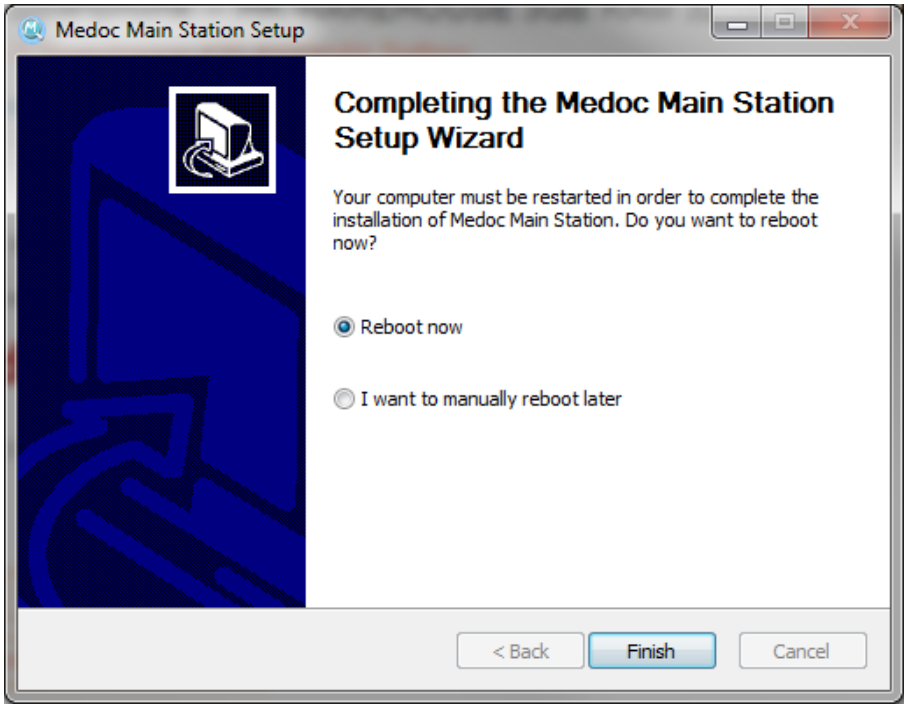


Figure 50: Installation Complete

8. Click **Finish** to close the wizard.
9. **Restart** your Computer.

5.7 Unit Protection

- **Keep all liquids away from the TSA 2 system.**
- **Unplug the power supply of the TSA 2 system from electricity if it is not to be used for a long period of time.**
- **Do not block airflow anywhere around the TSA 2 system and Thermode.**

When all setup and installation procedures have been completed you may start using the system in accordance with the operation instructions in section 5.9.

5.8 Powering up TSA 2 System

Prior to powering up the system, pay extra attention that the Thermode coolant connectors are properly connected.

Make sure that all communication and power cables, accessories and Thermodes are properly connected to the system!

1. **Connect** the system and computer via communication cable to the TSA 2 system.
2. Power up the TSA 2 system by using the main switch
3. Start Medoc Main Station software by double-clicking the icon
4. The Home screen is displayed showing the available devices (license dependent).

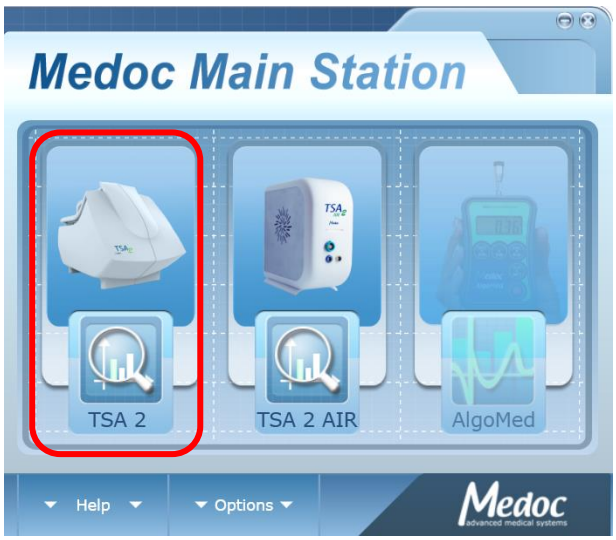


Figure 51: MMS home screen

5. To select TSA 2, click on the TSA 2 image.

6. When the login screen is displayed, enter your user name and password and select "**TSA 2**" in the "**connect to**" field. The administrator user name and password are both “admin”. It is recommended to change the password after first use. See 11.1.6.1.
7. The system and the software are ready for use.

5.9 Firmware Update

TSA 2 Firmware is the embedded software that runs and manages all system processes on the TSA 2 Main Board CPU. The firmware also includes the matching license files required to control the TSA 2 system from your Medoc Main Station instance.

TSA 2 Firmware may need to be updated from time to time. The following section describes the process for updating TSA 2 firmware.

To update the Firmware, without affecting the license files follow the instructions below:

1. Make sure that no program is running.
2. Prepare the firmware file “**TSA2_###.zip**”: it can be found in the installation folder, under the folder “**HEX**” in the install location (see Figure 45: Main Station Installation 2).
3. Make sure all other programs are closed.
4. Firmware update is done via regular communication cable and port.
5. Firmware update can be done via one of these two ways:
6. MMS main screen **Options > TSA 2 firmware update**.

Figure 52: Firmware update via main screen

5.2 Device screen –> Utilities -> “firmware update”

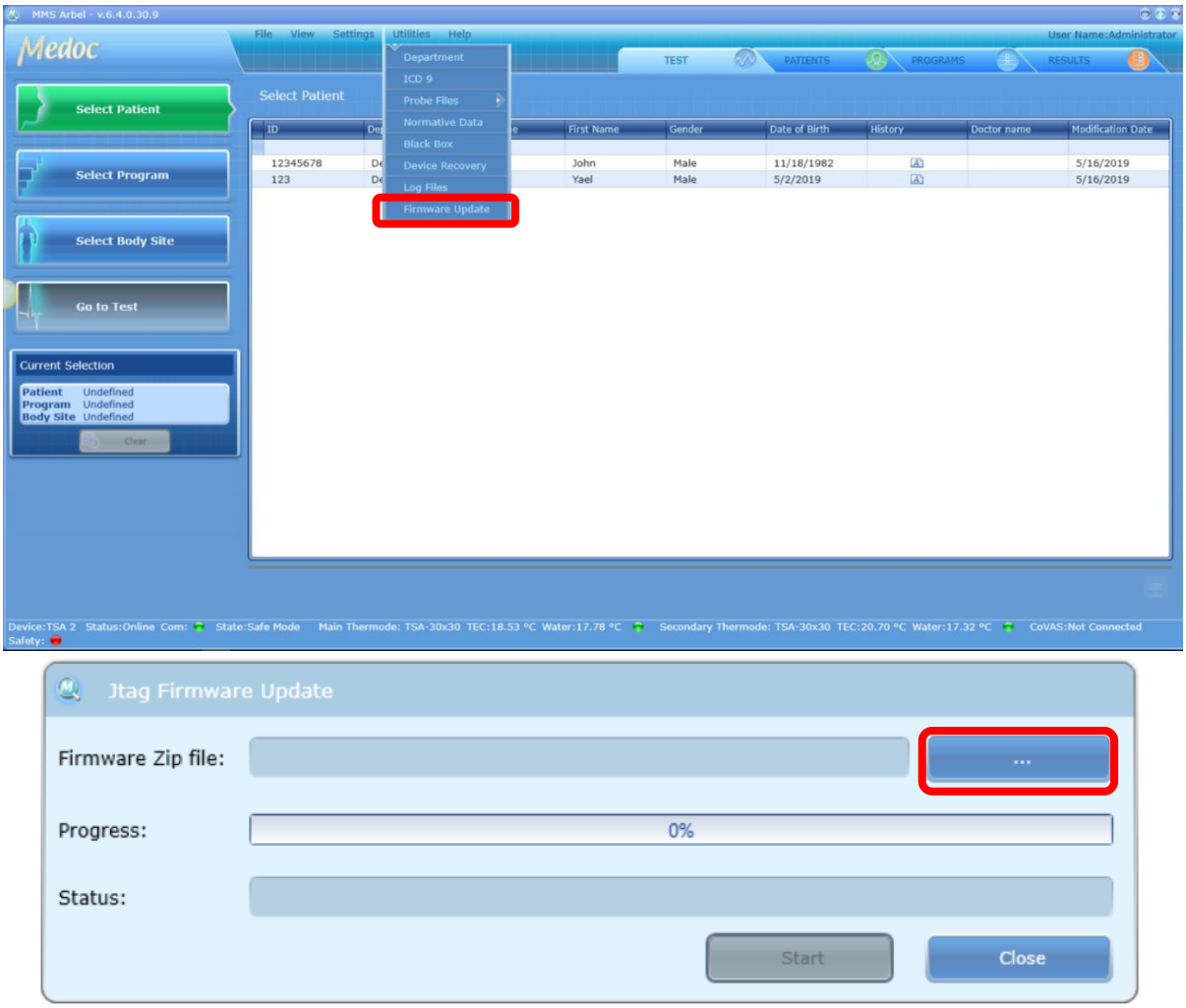
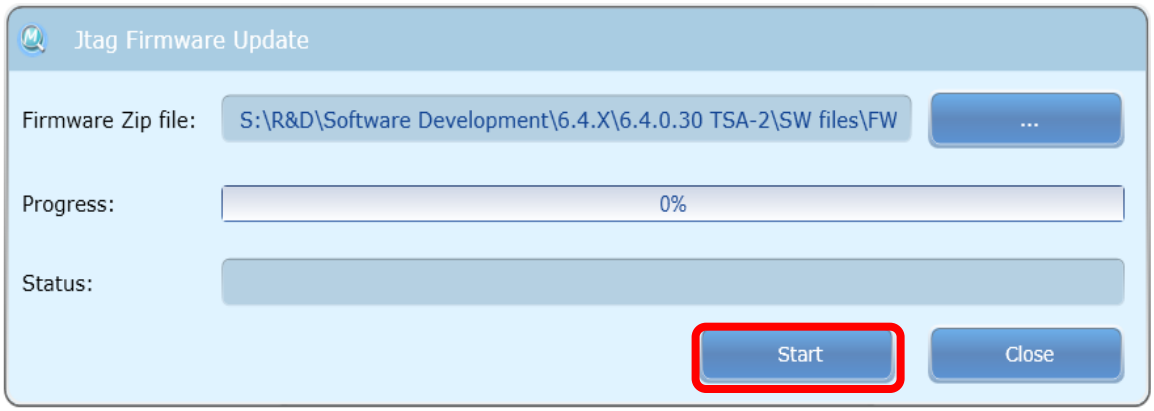


Figure 53: Firmware update – screen 1

7. After clicking one of the options the following window will be presented, click the “…” button and chose the TSA2_###.zip file.

8. Upload the file and click the “**Start**” button, to start the firmware update process



9.

Figure 54: Firmware update – screen 2

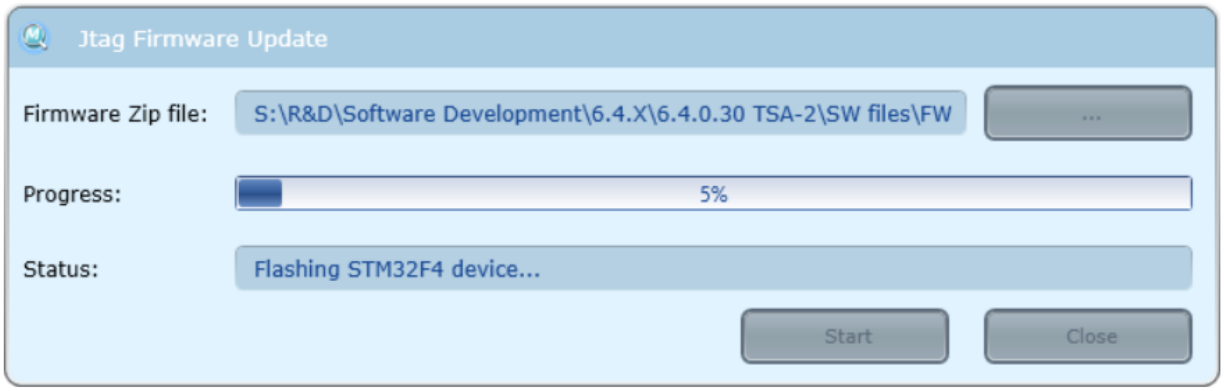


Figure 55: Firmware update – screen 3

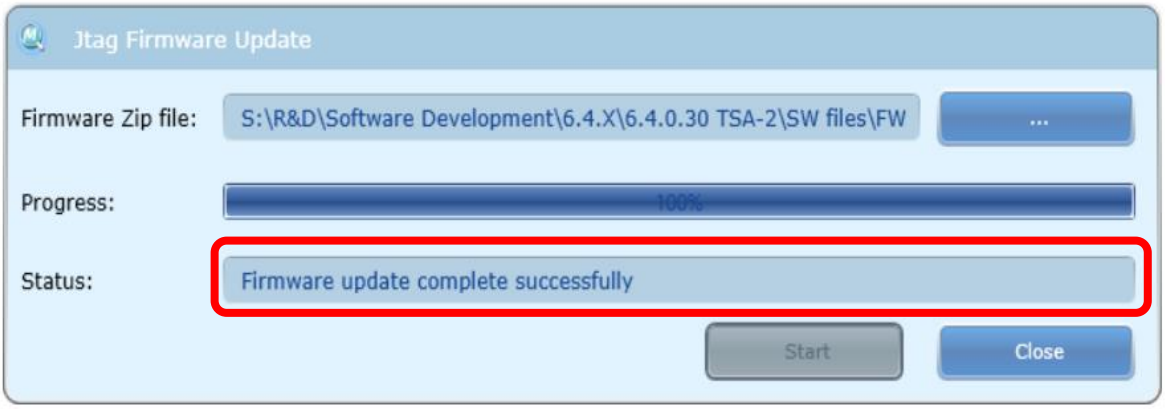


Figure 56: Firmware update – screen 4

10. The process is complete when the status changes to “firmware update complete successfully”
11. Click the button “**Close”**.
12. Close the MMS software.
13. Turn the system **OFF,** wait for a minute and turn the system **“ON”**.
14. Open the MMS software.

6. Operation

The purpose of the following chapters is to specify the TSA 2 applications and to bring in-detail step-by-step instructions for using the system.

This chapter specifies TSA 2 behavior at start up and Medoc Main Station basic components.

6.1 Safety Procedures and System Self-Test

Upon start-up the system performs a self-test in which system sensors are being tested. If a malfunction is detected, an appropriate message is displayed and the system cannot operate until that malfunction is resolved.

Make sure that the Thermode is not attached to human subject before self-test is complete.

Before turning on the TSA 2 system, make sure that the Thermode main plug and coolant connectors are securely connected to the TSA 2 system.

The Thermode should be attached to the subject's skin only when performing a test. Do not attach the Thermode to the subject during system Self-Test, while programming the system or performing maintenance.

6.2 Starting TSA 2

1. Turn **ON** the TSA 2 unit, by using the main power switch located on the unit. See section 3.1 page 37
2. Turn **ON** the computer
3. Start Medoc Main Station software by double-clicking the icon .
4. The Home screen is displayed showing the available devices (license dependent).

Figure 57: Device selection Screen

5. To select TSA 2, click on the TSA 2 image
6. 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*. It is recommended to change the password after initial use (see 11.1.6.1).

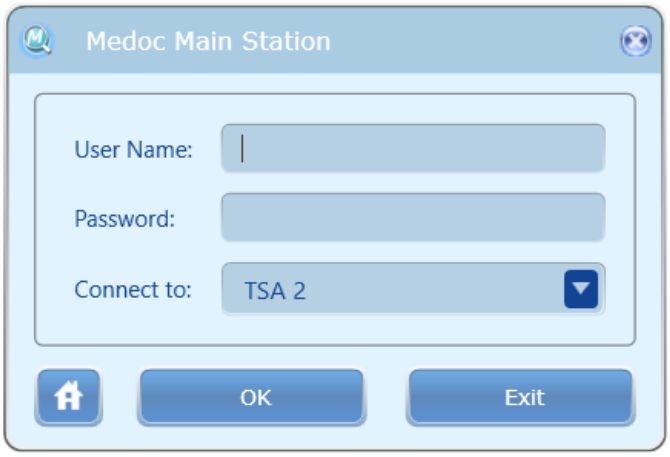


Figure 58: Login Screen

7. While the software is establishing communication with the device the following screen may be displayed:

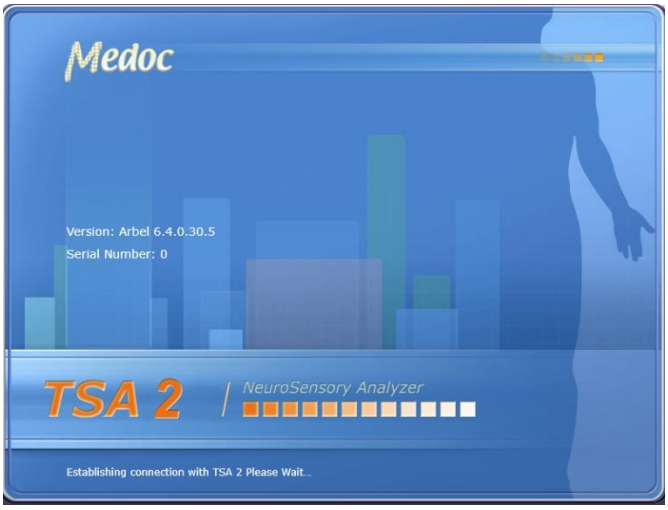


Figure 59: TSA 2 Splash Screen

8. When communication is established, the system will enter SAFE MODE and remain in this state until completing the system Self-Test. Make sure the Thermode is not attached to the Subject and click on OK on the following message:

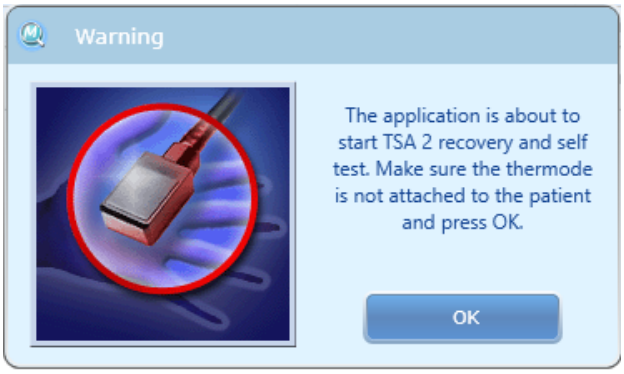


Figure 60: Self-Test Prompt

9. The system will perform a complete self-test of all enabled Thermodes according to your system settings.
10. After the system Self-Test has completed successfully, the system state will change to REST MODE.

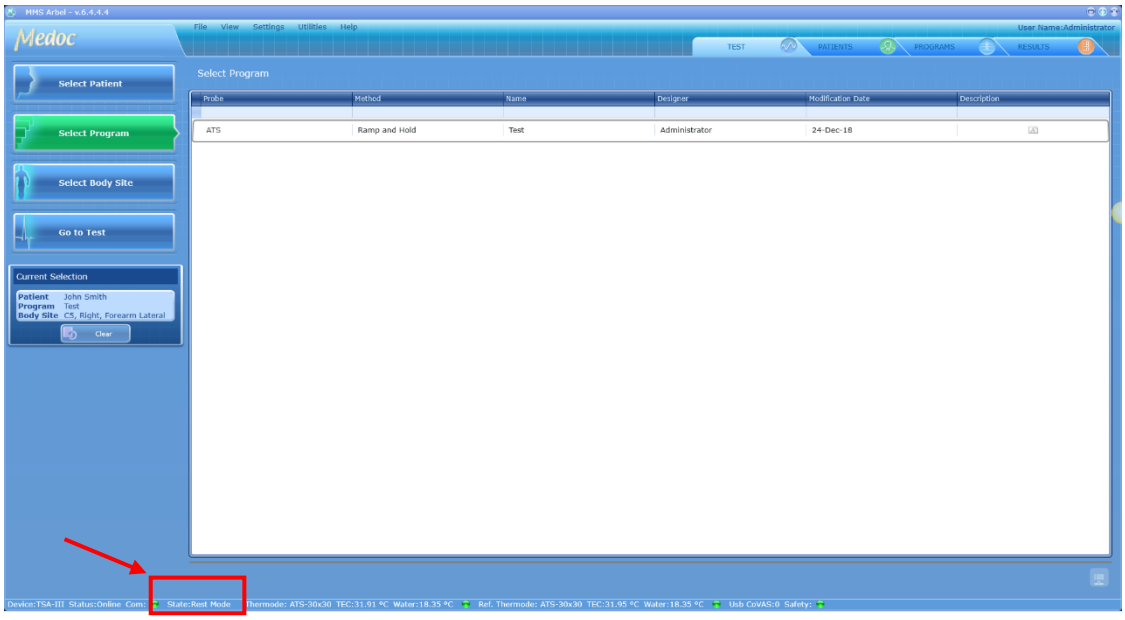


Figure 61: TSA 2 in Rest Mode

6.3 Basic Operation

As soon as the self-test is successfully completed the **TEST** screen is displayed:

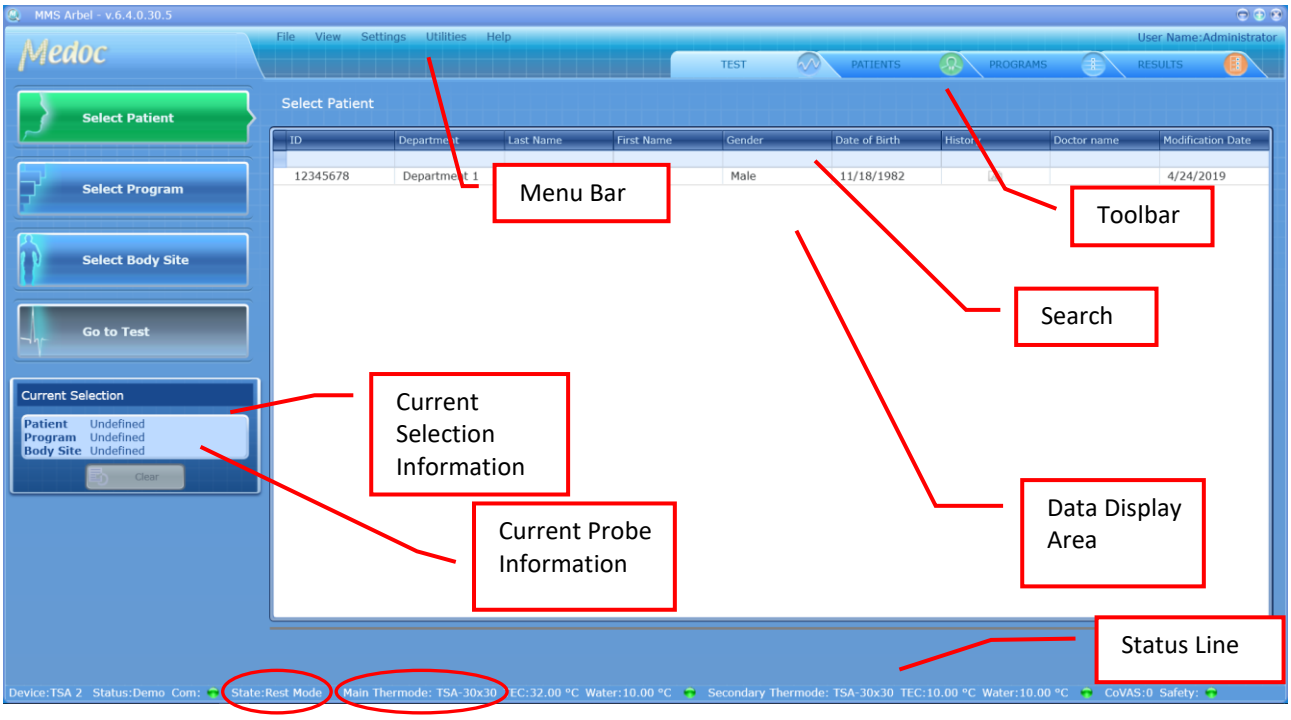


Figure 62: TEST screen – Main Menu

Note that the status line also indicates the type and model of the Thermode currently active (circled in red, above).

The Test screen enables you to select a patient, program and body site before starting the test procedure.

The TEST screen menu consists of the following components:

- Menu Bar – Perform general and software related operations
- Toolbar – Quick access to patient and program editors and saved test results
- Search Row – Filter the data for quick access to patients and programs
- Current Selection Information – Display of current selections made by user
- Current Probe Information – Display of enabled Probes
- Data Display Area – View list of patients, programs or body sites
- Status Line – Continues real-time display of TSA 2 status and Thermode temperature.

- The components are detailed in the following sections.

6.3.1 Menu Bar

The Menu bar consists of the following options:

Table 6: Menu Bar Options

Menu	Option	Description
File	Export	Export selected Patient data, Program parameters or Test Results to *.ats file format. The ***.ats** file format is encoded and can be read only by Medoc software, enabling simple backup, export and import options while maintaining patient confidentiality. For detailed export and import instructions see relevant sections in Patient, Program and Results Management chapters.
	Import	Import Patients, programs and test results saved in *.ats file format. See above description on Export.
	Export to Excel	Export **Tests Results** to MS Excel format, for data analysis.
	Print	Print **Test Results** as a **Report** (enabled in the **Results** screen).
	Logoff	Log off and switch users without exiting the software or shutting down TSA 2.
	Switch Device	Return to Home Screen and select another device or change preferences.
	Exit	Exit Medoc Main Station.
View	Test	Switch to Test Navigator screen to perform and manage tests from the available patient and program library.
	Patients	Switch to Patient Editor screen for managing Patient lists.
	Programs	Switch to Program Editor screen for managing programs and protocols.
	Results	Switch to Results screen to view and manage saved test results.

Menu	Option	Description
Settings	Software settings	Medoc software related configuration and preferences.
	Hardware settings	TSA 2 system and Thermode hardware configuration and management.
	Test settings	Test configuration and display preferences
	Status	Switch from On-Line to Demo Mode
Utilities	Department	Manage Department list
	ICD 9	Manage list of ICD 9 codes
	Probe files	import or export Thermode calibration details
	Normative Data	Normative Data database and Editor.
	Black Box	System logs (populated only in case of suspected error)
	Device Recovery	Manually initiate TSA 2 system Self-Test in case safety was triggered.
	Log Files	Software log files.
	Firmware update	Flashing system Firmware. For additional information refer to TSA 2 service manual.
Help	Operating Manual	Link to the TSA 2 Operation Manual
	Service Manual	Link to the TSA 2 Service Manual
	About …	System and software information including license details
	Service Call	Submit a Service Call via Medoc web site*.
	FAQ	FAQ on Medoc web site*.
*internet connection required		

6.3.2 Toolbar

The Toolbar consists of shortcuts to the different views:

- Test Navigator – Select test parameters
- Patients View – Manage patient database
- Programs – Manage program list
- Results – View, export or print test results

6.3.3 Search Row

The Search Row allows you to filter the displayed data, in order to find the required data quickly. To use the filter, place the cursor in the in-search row, in the column you want to filter by and start typing the beginning of the word.

6.3.4 Current Selection Information

Current selection panel displays the currently selected items. The data may vary depending on the current view. While in test navigator for example, the current selection will show the currently selected patient, program, body site and enabled probe.

6.3.5 Data Display Area

Displays list of data which is relevant to the current screen.

6.3.6 TSA 2 Status Line

The Status bar displays important information about the status of the connected device. If the status line is empty, Medoc Main Station is not connected to any device. When connected to the TSA 2 system, the status line displays the following information as described table 7 below

Table 7: Status line parameters

Information	Description
Device	The device currently in use and connected to Medoc Main Station.
Status	The current status of the system, either Demo or On-Line.
Com	Communication status between the system and the PC. A green indicator is displayed for ON and a red indicator for OFF.
State	The state of the Temperature Control Unit. The following modes are available: Rest, Engineering, Safe and Test run.
Probe (main /secondary)	Indicates the type and model of the Thermode currently **active**.
TEC	Temperature of the Thermode.
Coolant	Temperature of the coolant. When CoVAS is connected and switched on the coolant display is “Not Connected”.
CoVAS	CoVAS state and value (Not Connected / Value)
Safety	Safety status. A green indicator is displayed for OK and a red indicator for Safe Mode activation – in Safe Mode Thermode power is disabled and system remains non-functional, until malfunction is resolved.

7. Test Procedure and Management

Starting a test procedure is only possible from the Test Navigator screen

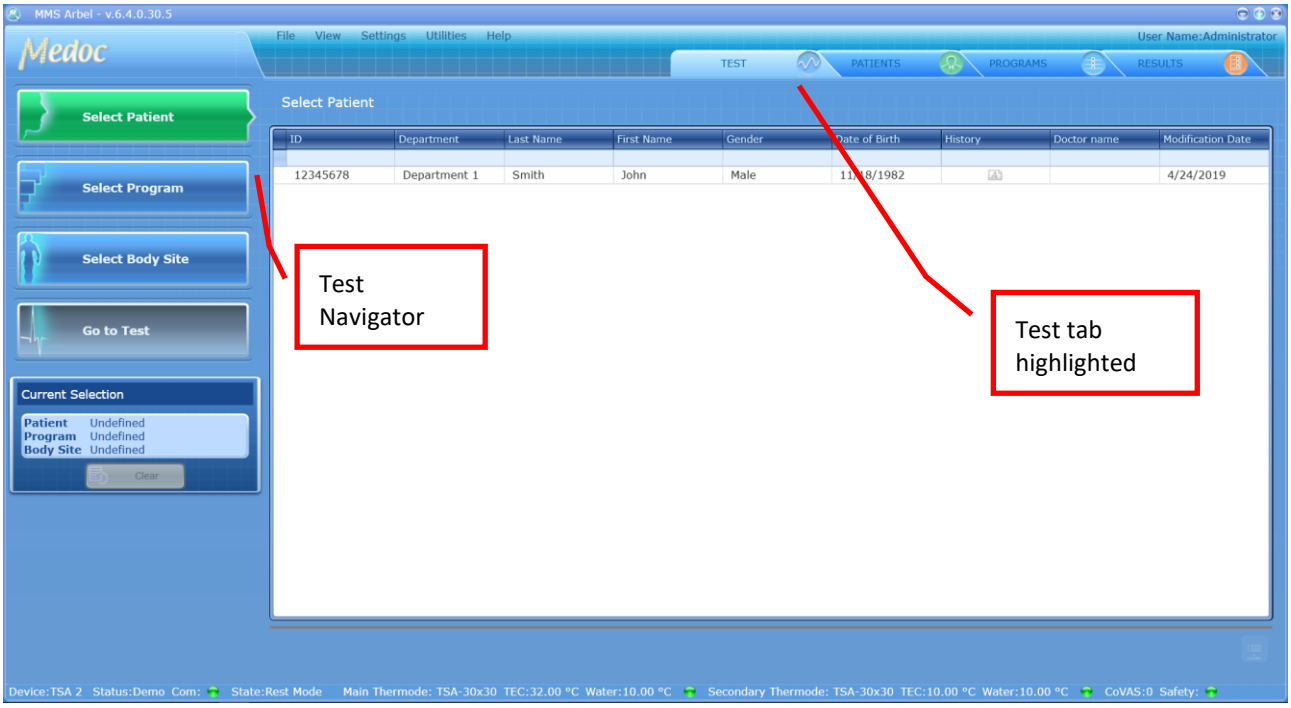


Figure 63: Test Management Main Screen

The stimulation procedure (test) consists of the following main steps:

- **Select Patient** – Select the tested subject's file from the database.
- **Select Program** – Select the relevant program to be used for the test.
- **Select Body Site** – Select the body site and its details for the current test. This step is optional.
- **Apply Stimuli** – Perform the test
- **Save/Print Test Results** –Print test report and/or save test data for future reference (This step is optional).

Make sure you are familiar with the stimulation method before you start with the test procedure

Inform the subjects how to operate the applicable controls, and request them to concentrate on the perceived sensations throughout the full duration of the test.

The stimulation procedure steps are described in detail in the following sections.

7.1 Selecting a Patient

1. Click the **Select Patient** button from the Test Navigator
2. Use the Search Row (see section 6.3.3 above) to filter and sort list in order to find the relevant patient entry.

The Patient List can be sorted according to any of the displayed fields. Click the relevant column header to sort the list.

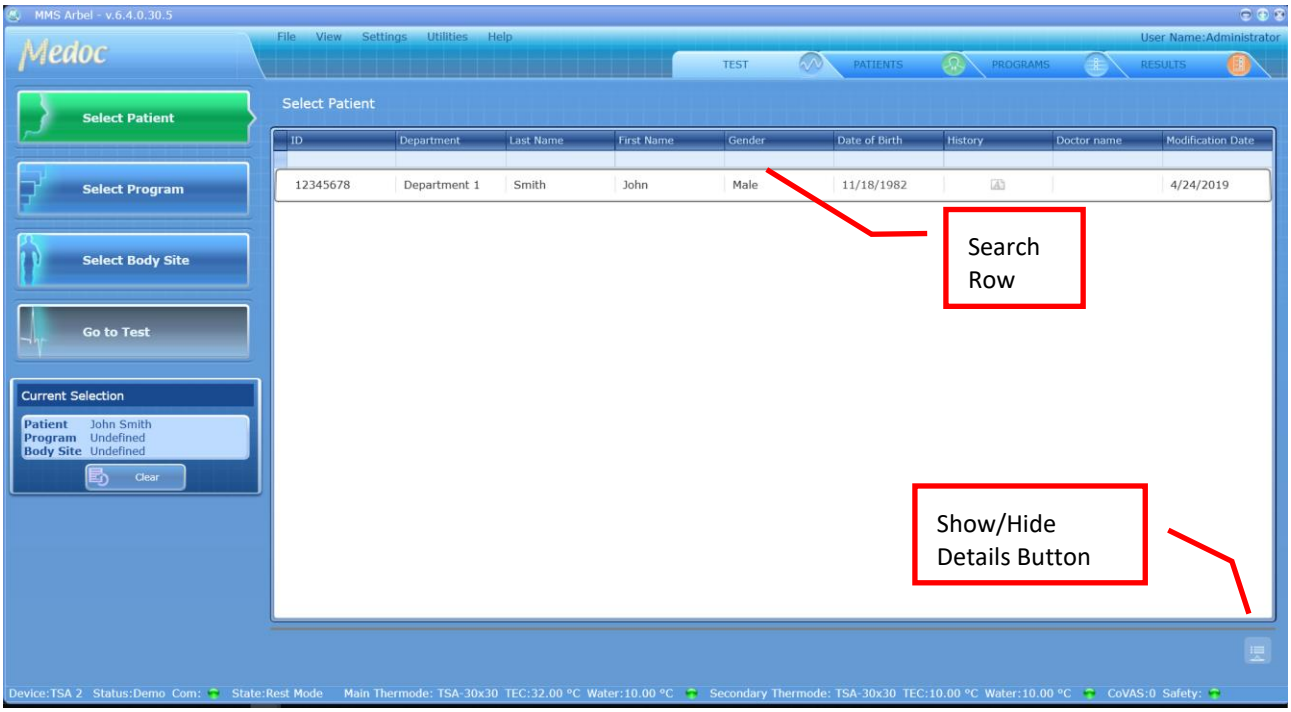


Figure 64: Patient Selection Menu

3. Click the patient entry to select (or double-click to select and move on to the next step). The selected entry will be displayed in the current selection details in the left panel.

4. In order to view patient details, click the **Show Details** button.

5. To hide the details, click the **Hide Details** button to view the patients list only.

Patient details can only be viewed from the Test screen. For editing, refer to Patient Management section in TSA 2 Technical Reference Manual

6. Click the **Clear** button to clear Current Selection details if required.
7. Proceed to the **Selecting a Program** section.

It is not possible to run a test before you select the test subject and program. The "Go to Test" button will remain disabled as long as test details are not complete.

7.2 Selecting a Program

1. Click on the **Select Program** button from the Test Navigator
2. Use the Search Row (see section 6.3.3 above) to filter and sort list in order to find the relevant program entry.

The Patient List can be sorted according to any of the displayed fields. Click the relevant column header to sort the list.

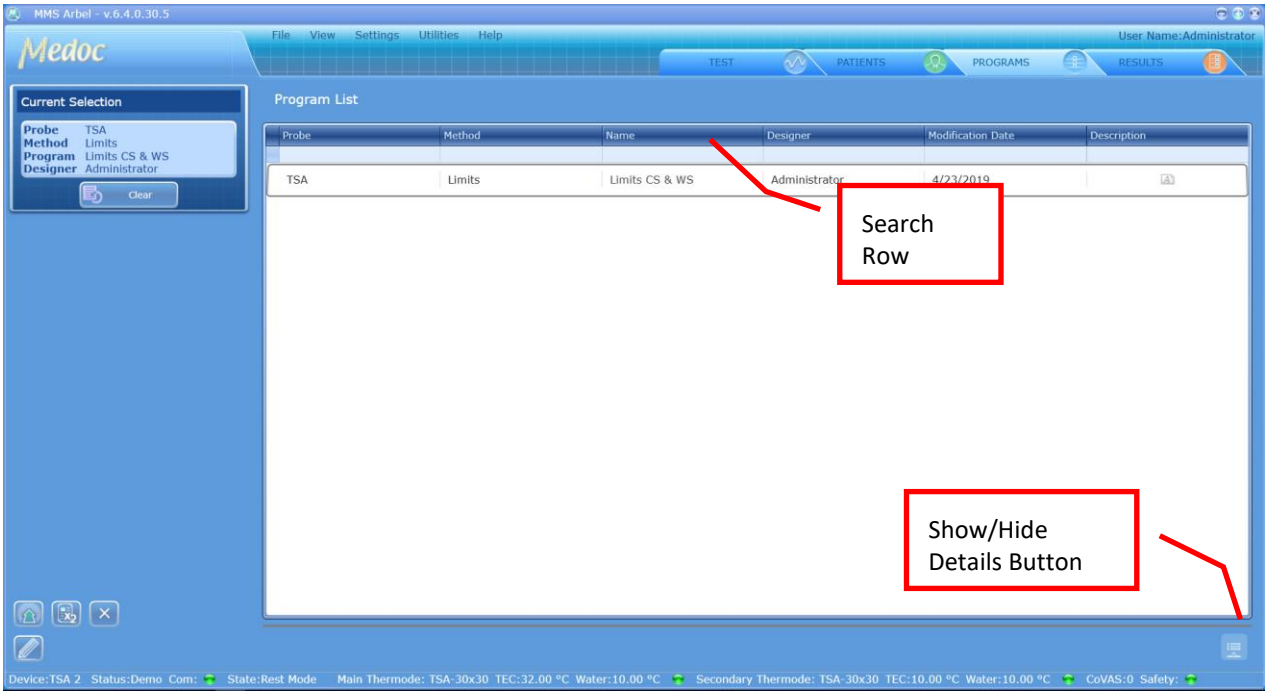


Figure 65: Program Selection Menu

3. Click the program entry to select (or double-click to select and move on to the next step). The selected entry will be displayed in the current selection details in the left panel.
4. In order to view program details, click on the **Show Details** button.

Program details can only be viewed from the Test screen. For editing, refer to Program Management section in TSA 2 Technical Reference Manual

5. The following options are available in the Program Details view:

	Display program details.
	Display program graph preview (selected methods only)
	View test instructions.
	View recent program modification dates.

6. To hide the details, click on the **Hide Details** button to view the program list only.
7. Click on the **Clear** button to clear current selection if required.
8. Proceed to the **Selecting Body Site** section if you want to select site for the specific test, or click on the **Go to Test** in order to run the test without specific body site selection.

It is not possible to run a test before you select the test subject and program. The "Go to Test" button will remain disabled as long as test details are not complete.

7.3 Selecting a Body Site

Selecting a body site for the test is optional. A test can be initiated without selecting a body site.

1. Click on the **Select Body Site** button in the Test Navigator.

Figure 66: Body Site Selection Menu

2. Click on the Dermatome (Dermatomic area) you wish to use in the current test.
   An enlarged view of the selected dermatome and a list of specific sites will be displayed on the right.

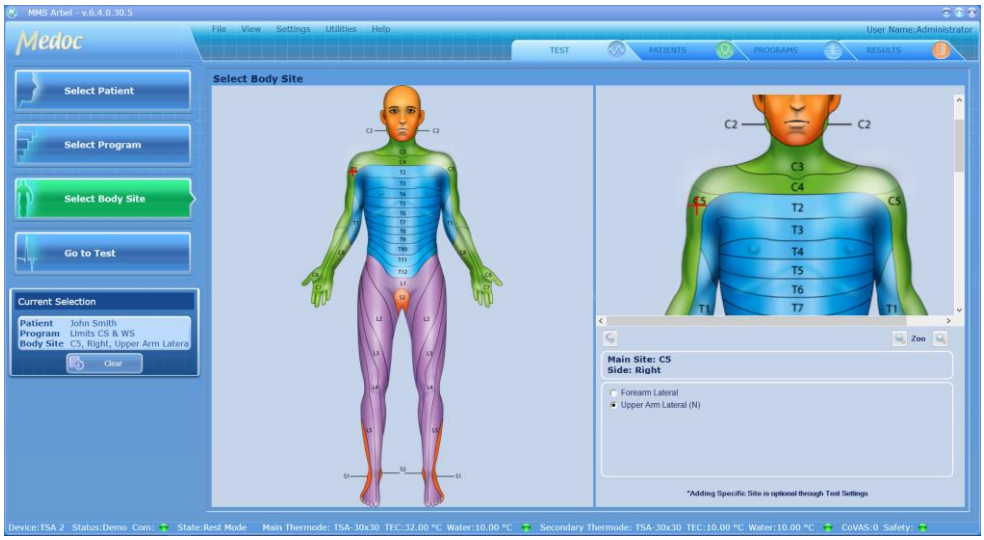


Figure 67: Select Body Site – Specific site selection

3. Use the Zoom In/Out controls for a more precise selection

4. Use the Flip Image control to switch between Anterior / Posterior view

5. Complete the site selection by selecting one of the Specific Sites. The selected site will be displayed in the current test details in the left side bar.

6. Click the "**Go to Test**" button to proceed to the test.

7.4 Running the Test

Make sure you have selected both a Patient and a Program before you try to proceed with an actual test.

1. Click on the **Go to Test** button.
   The following screen is displayed:

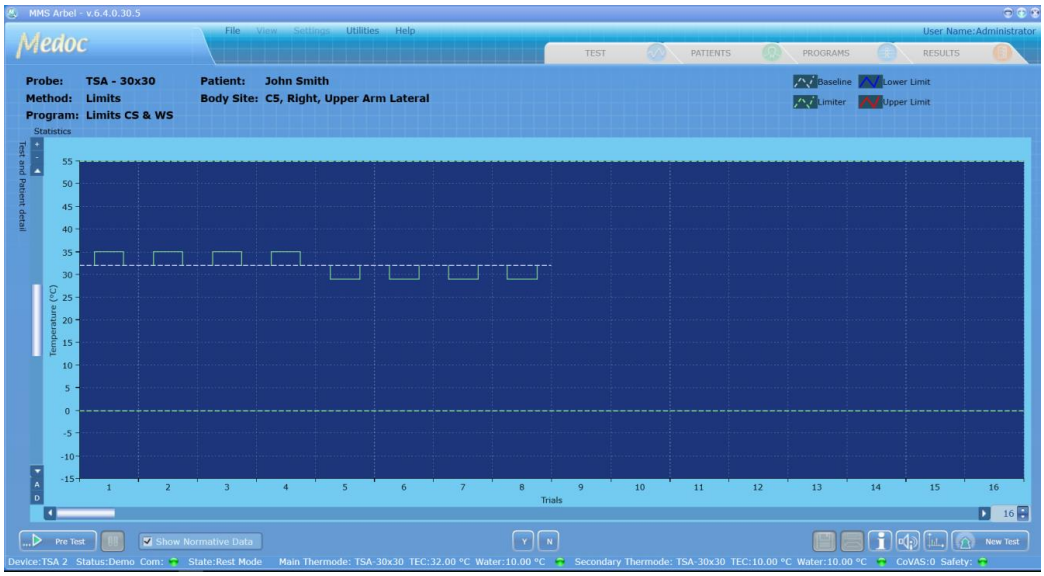


Figure 68: Pre-Test Screen

2. Click on the **Start Pre-test** button

.
   The system performs a short **pre-test**, and stabilizes on the *Baseline* Temperature.

3. After a successful pre-test, the **Pre-test** button is replaced by a **Start** button

.

At this point attach the Thermode to the tested subject.

Caution! DO NOT use any electrode paste, gel or other material on the contact point between the Thermode and the tested subject's skin.

1. **Place the Thermode on the intended stimulation site so that the contact plate makes the best possible contact with the skin, fastening it lightly with the attached strap.**
2. **It is recommended to first fasten the strap around the area to be stimulated and then tighten the strap by pulling it an additional 2 cm before fastening the two ends.**

4. Click on the **Start** button

5. To pause the stimulation, click the **Pause** button

6. To stop the stimulation, click the **Stop** test button

The first click stops the test, and initiates the Finalizing test procedure (accompanied by a message), which saves relevant information in the Black Box in case of an error.
A second click aborts the test immediately.

7. Once a test has finished, it is possible to use the mouse curser to display the exact time, temperature and other available information at any given point.

8. Click on the **Save** button to save test results and stimulation data.

7.4.1 Test and Post-Test Options

Table 8: Test Run Options

	Automatic zoom along the temperature axis. The temperature axis scale expands according to maximum temperature currently displayed on the screen. To reset the automatic zoom, click the button again. Alternatively, change zoom manually by using the **+/-** buttons.
	Reset the zoom to the original (default) scale.
	Change the zoom along the time/trial axis, by changing the value in the spin box at the bottom right of the graph. Use the up/down arrows or type the value in the box.
	Print test results as a report.
	Save the stimulation data.
	Display test instructions for the subject.
	Play audio test instructions for the subject.
 	Return back to the Test Navigator to start a new test. Test results are not saved automatically. Remember to save the test results if needed, before leaving the Test Screen.
	Indicates positive subject response in Limits, Levels, TSL and Search protocols.
	Indicates negative subject response in Limits, Levels, TSL and Search protocols.
	Trigger the next stimulus. Available only when the manual trigger option is selected. The button is enabled only when the system expects a trigger.
	Edit the program locally. The edited parameters are effective only in the specific test and the program parameters are not changed in the data base.

The system will prompt you to save the stimulation data before starting a new test or exiting the current session.

After concluding a stimulation session, always clean the Thermode contact plate using 70% alcohol or alcohol wipes.

Do NOT immerse the Thermode in any kind of liquid or use detergents.

7.4.2 Temperature Graph Display

During the test, the test graph is generated and displayed on the screen. Following is an example:

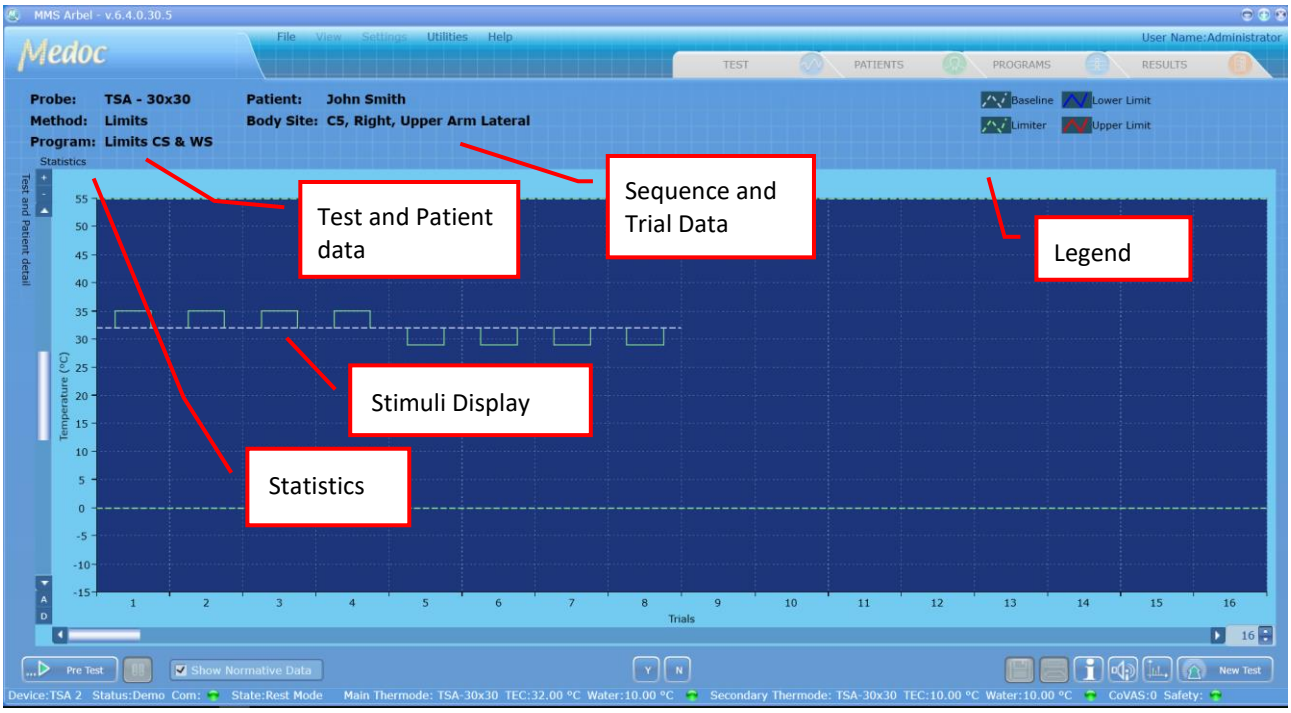


Figure 69: Real-Time Test

The following information is displayed:

- Stimuli display (including CoVAS and events where applicable)
- Current probe and program details.
- Current sequence and trial data
- Legend
- Axes labels: Temperature axis on the left and CoVAS on the right (where applicable)
- Statistics Panel: hidden by default. To view in full click on it. To keep the display permanently open, use the pin icon ( ) on the top right corner. Click again to hide.
- Test and Patient Details Panel: hidden by default. To view in full click on it. To keep the display permanently open, use the pin icon ( ) on the top right corner. Click again to hide.

7.4.3 Test Run Keyboard Shortcuts (Hot Keys)

Keyboard shortcuts (hot keys) are available for several test functions enabling control of the test from the keyboard. Table 9: Hot Keys below describes the available options.

Table 9: Hot Keys

Button	Key	Action
Stop	**S**	Stop (finalize / abort) the test
Pre Test / Start / /	**Spacebar**	Pre-Test / Run Test / Pause / Resume Test.
Y	**Y**	YES (cannot replace the response unit in the Search method).
N	**N**	NO (cannot replace the response unit in the Search method).
	T	Manual Trigger
	Tab	Wrong Sensation (Levels and TSL)
	Delete	**Delete** / **Undelete** trials from **Limits** test. Available only after a test is complete and before it is saved.

8. Program Management

This chapter explains how to create and edit stimulation programs. The specific program parameters for each method will be described in the sections below.

8.1 Program List

The Program screen enables you to manage programs (add, remove, edit etc.).

1. To access the program database, click the **Programs** button in the toolbar. The following screen is displayed:

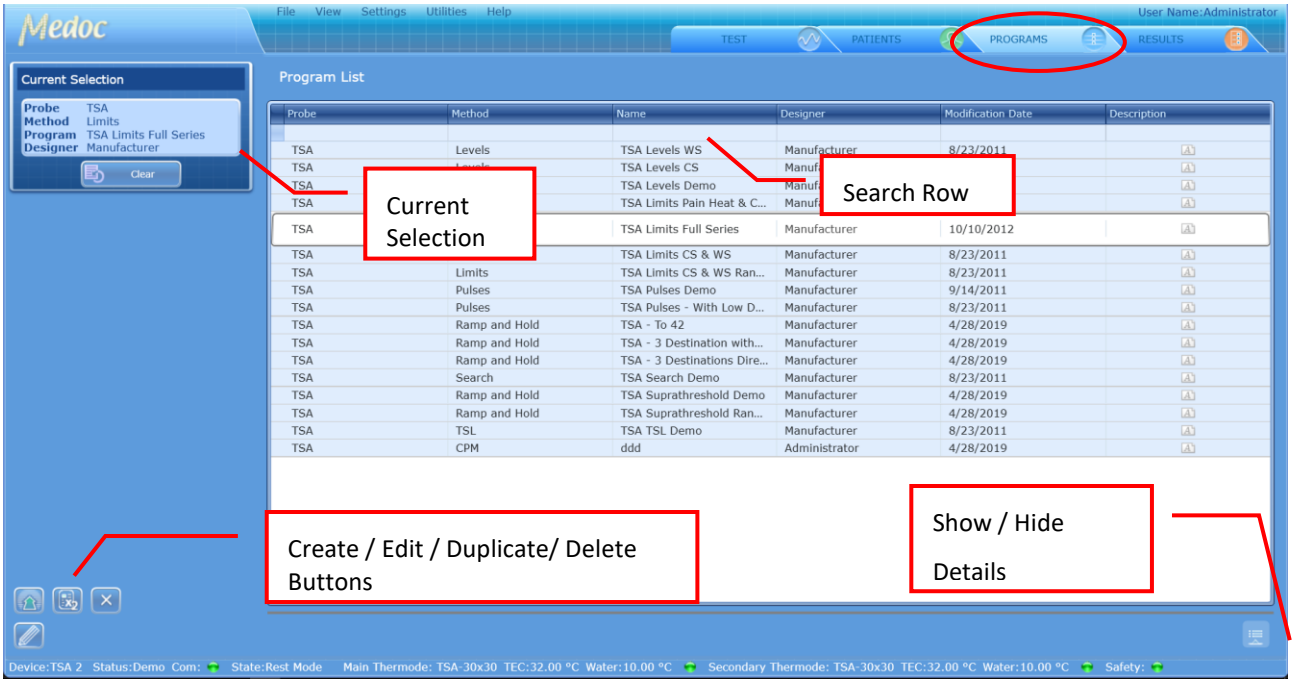


Figure 70: Program Management screen

2. Use the search row to filter the program list
3. The current selection pane shows the details of the currently selected program.
4. The following editing options are available from the Program Management screen:

	Create a new program
	Duplicate selected program
	Delete selected program
	Edit selected program

5. To view program parameters in more detail (without editing) use the Show Details button. To return to program list, click the Hide Details button.

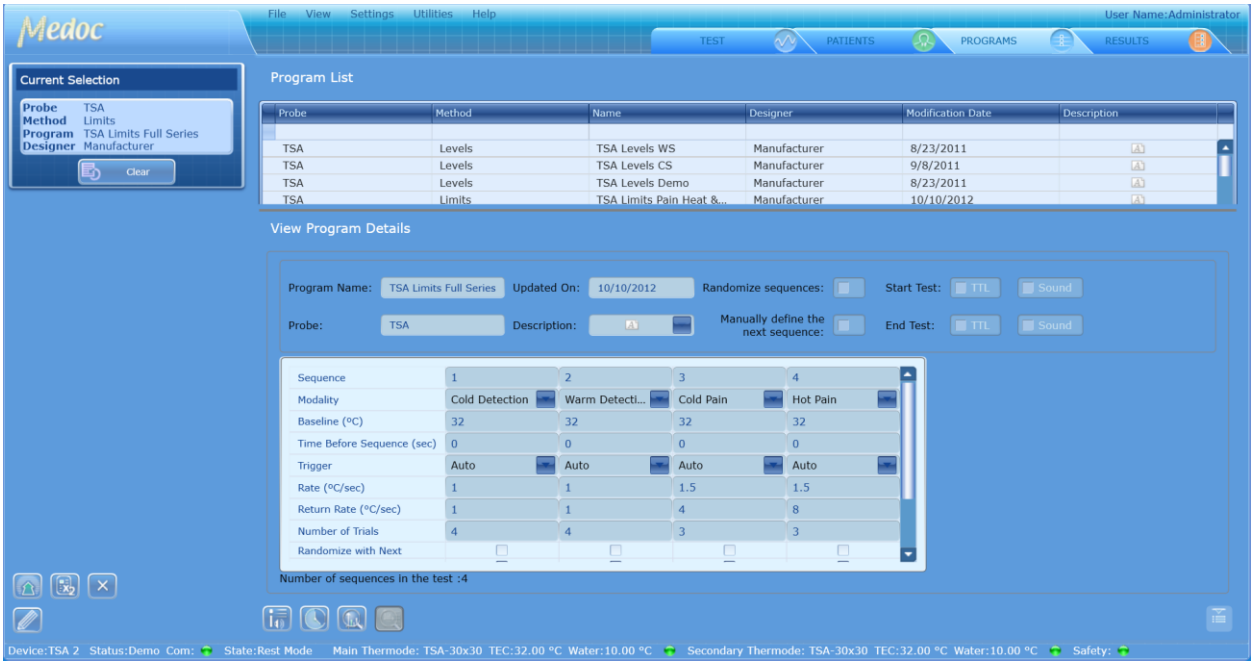


Figure 71: Program Management - Program Preview

6. The following viewing options are available from the Program Editor view:

	Display program details.
	Display program graph preview. Available on selected methods.
	View selected test instructions.
	View recent program modification dates.

Program details cannot be edited from the Program Details view.

8.2 Creating a New Program

To create a new program, perform the following procedure:

1. From the **Programs** screen, click on the Create New Program ( ) button.
   The following dialog is displayed:

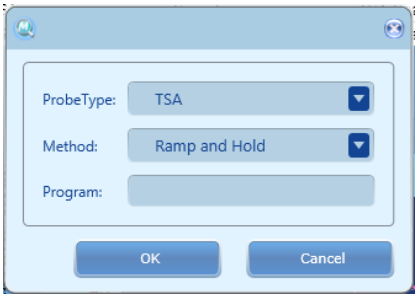


Figure 72: New Program Screen

2. From the **Method** drop-down list, select the required stimulation method
3. Enter a program name and click **OK** to create a new program.
4. Edit the program parameters in the Program Editor, see section 7.5 below.

8.3 Remove a Program

To remove a program from the program list:

From the **Programs** screen, select the program to delete and click on the remove program button

8.4 Duplicate a Program

To duplicate a program from the program list:

From the **Programs** screen, select the program to copy and click on the copy program button

A copy of the selected program will be added to the program list with the suffix "(1)" in the program name.

8.5 Program Editor

When creating or editing a program, the Program Editor screen opens and enables you to modify program parameters.

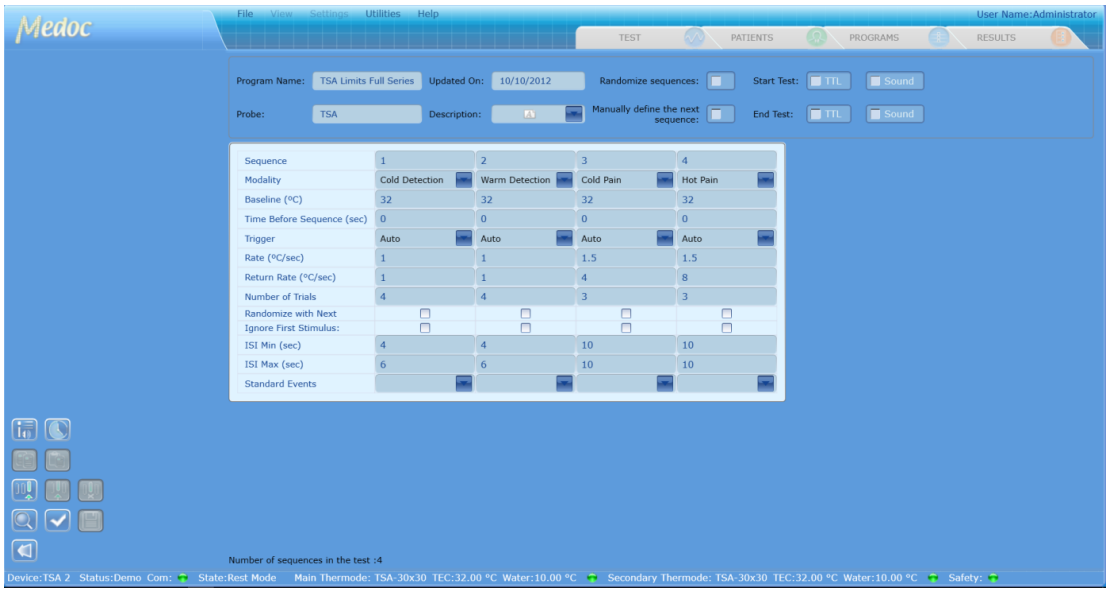


Figure 73: Program Editor Screen

The top part of the program editor displays global details which are available for all methods. The lower part of the program editor displays the specific program parameters according to the selected method. For detailed information about the program parameters, continue to section 7.6

The following program details are available:

Table 10: Program Details

Parameter	Description
Program name	The program name (editable).
Description	Program description. To edit, click the arrow and type free text to describe the program. The description will become active when text is entered.
Updated on	The date program was last edited on (automatic)
Start test / End test	Start / End test events: can be indicated by TTL, sound, or both.

The following options are available from the Program Editor screen:

	View program revision history by version date and username.
	Edit text and audio instructions. Refer to section 10.3.6.2 page 139
	Exit Program Editor screen
	Copy the selected sequence
	Paste the copied sequence
	Add a new sequence at the end of the test
	Add a new sequence after the selected sequence
	Delete the selected sequence
	Preview the test graph
	Check that all program parameters are valid
	Save changes

When adding or editing programs, follow these rules:

1. **Enter meaningful information in the Program Description section of the screen.**
2. **Define all the parameters of a sequence for that sequence to be valid.**
3. **If not all the sequences are displayed, use the horizontal scroll bar to display the ones that are out of sight.**

Missing or incorrect parameters are identified by an icon that flashes next to the relevant field. A short description of the malfunction can be displayed by holding the cursor over the relevant icon.

8.5.1 Next Sequence Definition

In Limits, TSL, Ramp & Hold and Search protocols additional settings are available in the top part of program editor, allowing different options for next sequence definition during the program run:

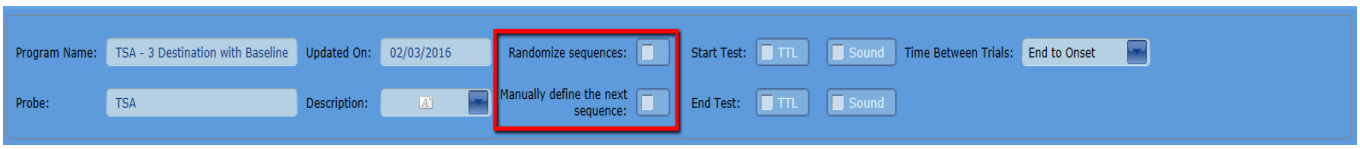


Figure 74: Program Editor Screen – Next Sequence Definition

Two checkboxes are available and unchecked by default:

- **Randomize Sequences:** If this checkbox is checked the sequences order during program run will be randomized
- **Manually define the next sequence:** If this option is selected, the operator will receive the following dialog window at the end of the sequence, allowing them to specify the next sequence they would like to perform:

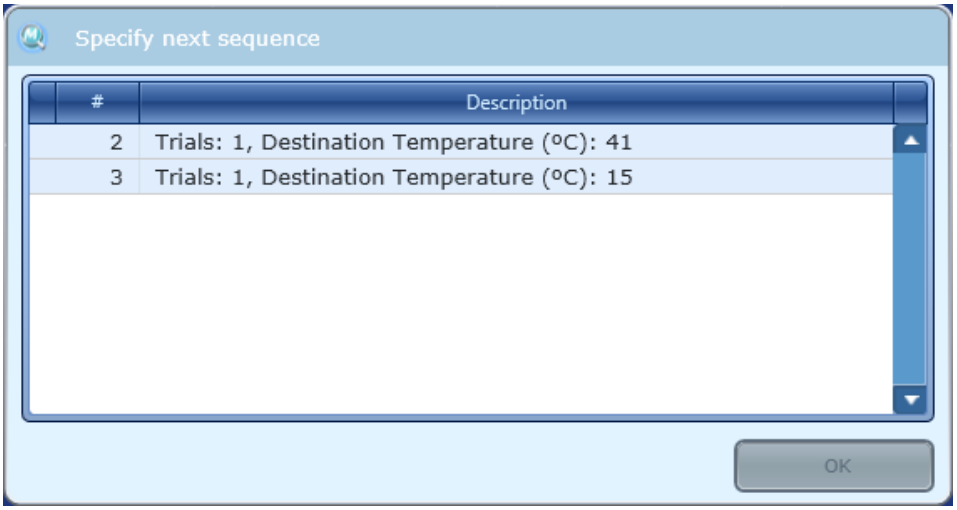


Figure 75: Manual Definition of the Next Sequence

Note: this option is available if the program contains more than 2 sequences; otherwise this option will be disabled.

- If both checkboxes are unchecked the sequences order will be according to their order in program editor (sequence number)

8.6 Program Details

The following sections described the program details for each of the applicable methods.

8.6.1 Limits

In this method, the system generates a number of stimuli of continuously changing intensity. With each stimulus, when the subject perceives a predefined sensation, they manually stop the stimulus. For an additional description of the method refer to section 2.7.5 page 33

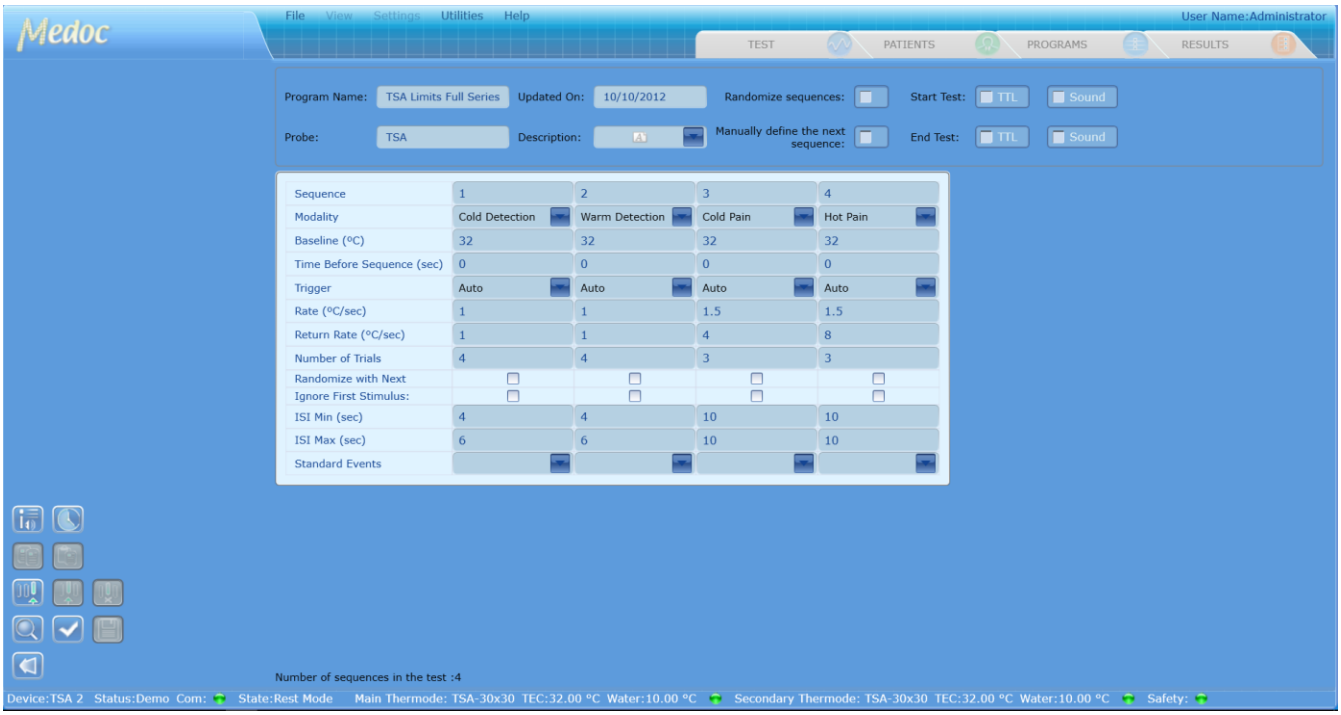


Figure 76: Program Editor – Limits

The table below describes the program parameters available for Limits method:

Table 11: Limits- Program Parameters

Parameter	Description
Modality	Four different types of sensation can be delivered to the subject: Warm sensation; Cold sensation; Hot pain; Cold pain.
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 10°C to 45°C.
Trigger	Trigger mode: • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI).

	• Manual – The operator or an external device must initiate the onset of the stimulus after the defined ISI.
Rate (°C/sec)	Defines the temperature change rate from the baseline temperature until the subject responds. Valid range: 0.1 to 13°C/Sec.
Return Rate (°C/sec)	Defines the temperature change rate when stimulus returns to baseline temperature after the subject has responded. Valid range: 0.1 to 13°C/Sec.
Number of Trials	The number of trials per sequence. Valid range: 1 to 100
Randomize with next	Randomize trials with next sequence
ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
ISI Max (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Standard Events	Different events which can be indicated during the test via TTL or Sound See section 7.7 page 89

8.6.2 Levels

In this method, the system generates a number of stimuli of changing intensity according to the subject response. With each stimulus, the subject receives a stimulation of varying intensity which is determined according to his previous response. Test is terminated after predefined temperature step size and number of alternations is achieved. For a detailed explanation, refer to section 3.7.6 page 46.

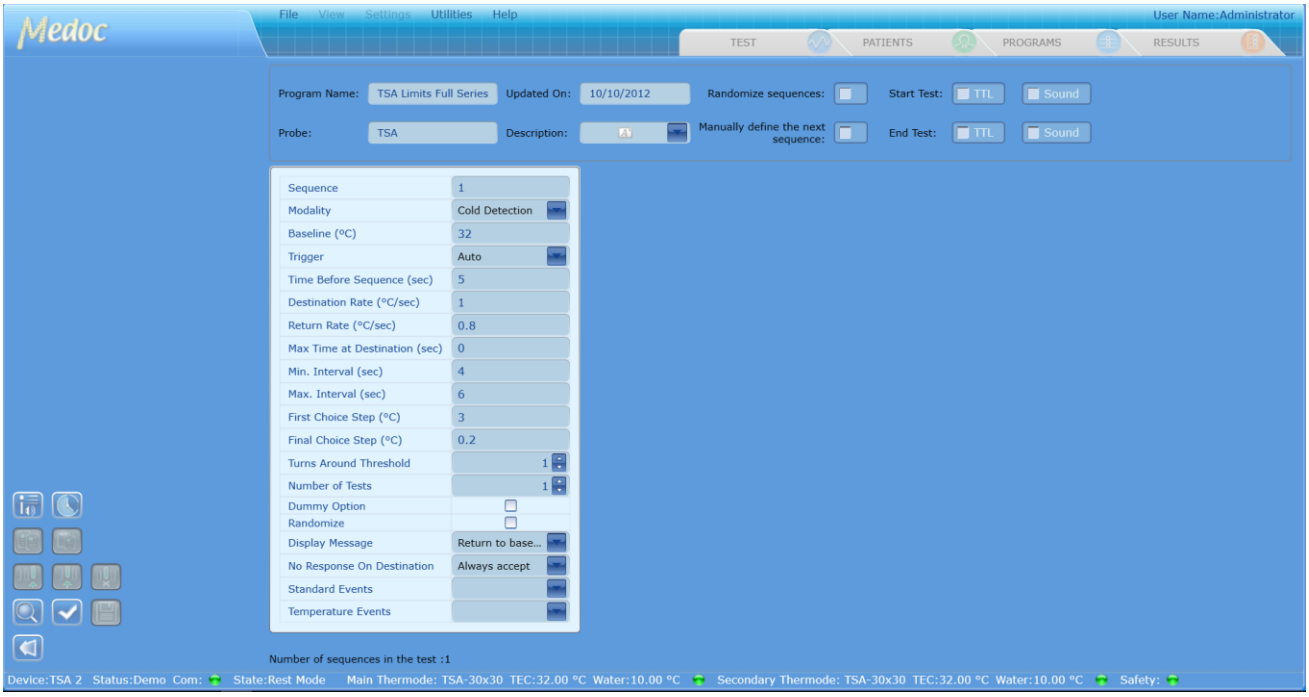


Figure 77: Program Editor – Levels

The table below describes the program parameters available for the levels method:

Table 12: Levels - Program Parameters

Parameter	Description
Modality	Two different types of sensation can be delivered to the subject: Warm Sensation and Cold Sensation.
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 20°C to 45°C.
Trigger	Trigger mode: • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). • Manual – The operator will initiate the onset of the stimulus after the defined ISI. • External – The onset of the stimulus will be initiated by an external system via TTL in (see Technical Specifications)
Time Before Sequence (sec)	The time interval before the first trial. Valid range: 0 to 600 (sec).
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. Valid range: 0.1 to 13°C/Sec
Return Rate (°C/sec)	Defines the temperature change rate from destination back to baseline temperature. Valid range: 0.1 to 13°C/Sec.
Max. Time at Destination (sec)	Defines the maximum duration for Thermode temperature to remain at destination temperature before returning to baseline. If subject's response is 'YES' – the temperature will immediately return to baseline. If subject's response is 'NO' – the temperature will remain at destination for the maximum duration as specified. Valid range: 0 to 600 (sec). May be limited by safety limitations.
Min. Interval (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
Max. Interval (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
First Choice Step (°C)	The initial step size that is used until the first 'YES' response is given. Valid range: 0.2 to 5 °C
Final Choice Step (°C)	The smallest step size that is used in the final Turns Around Threshold. Valid range: 0.1 to 2 °C
Turns Around Threshold	The number of turns (alternating 'YES' and 'NO' responses) at the Final Choice Step which is required to complete the test. Valid range: 1 to 10.
Number of Tests	The number of repetitions for entire test. Valid range: 1 to 5.
Dummy Option	Randomized dummy trials where no actual stimulus is given to increase test reliability. Frequency of dummy trials is randomized with an average of 10% of all trials.
Randomize	Randomize between trials of several tests.

Parameter	Description
Display Message	Define when message to respond is displayed: • **Destination** – Display message upon reaching destination temperature • **Return to Baseline** – Display message after temperature returns to baseline.
No Response on Destination	Define program behavior if subject responds after the **Maximum Time at Destination** is over. Relevant only if **Maximum Time at Destination** is larger than 0 and **Display Message** is set to *Destination*. • **Always Accept** – Accept subject's response and continue the test • **Always Repeat** – Ignore subject's response and repeat the same trial again • **Manually Select** – Manually select whether the response should be accepted (press 'A') or ignored (press 'I').
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.7 page 89
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.8 page 95

8.6.3 Thermal Sensory Limen (TSL)

In this method, the system generates warm sensation and cold sensation stimuli, alternating according to the subject response. The stimuli direction changes after each subject response. For a method explanation, refer to section 3.7.7, page 46.

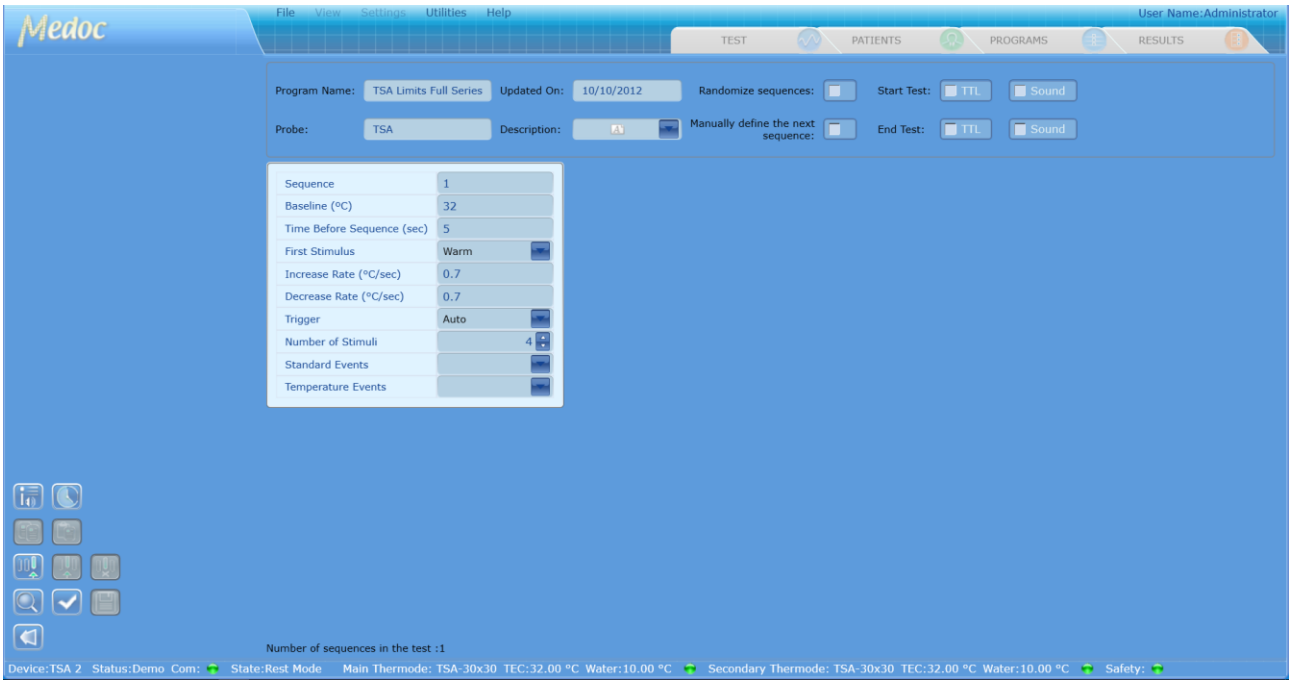


Figure 78: Program Editor – TSL

The table below describes the program parameters available for the TSL method:

Table 13: TSL- Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 20°C to 45°C.
Time Before Sequence (sec)	The time interval before the first trial. Valid range: 0 to 600 (sec).
First stimulus	Define direction of first stimulus: warm or cold
Increase Rate (°C/sec)	Defines the temperature change rate for increasing temperature. Valid range: 0.1 to 13°C/sec.
Decrease Rate (°C/sec)	Defines the temperature change rate for decreasing temperature. Valid range: 0.1 to 13°C/sec.
Number of stimuli	Number of stimuli until the test ends (each subject response is counted as one stimulus.
Trigger	Trigger mode: • Automatic – the stimuli will start automatically • Manual – The operator will initiate the onset of the stimuli • External – The onset of the stimuli will be initiated by an external system via TTL in (see Technical Specifications)
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.7 page 89
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.8 page 95

8.6.4 Ramp & Hold

In this method, the temperature rises (or falls) to a predetermined destination, at a predetermined rate, remains there for a predetermined duration, and returns to the next destination. Patient estimation of perceived magnitude of sensation is recorded for each stimulus. For a method explanation, refer to section 2.7.1 page 29

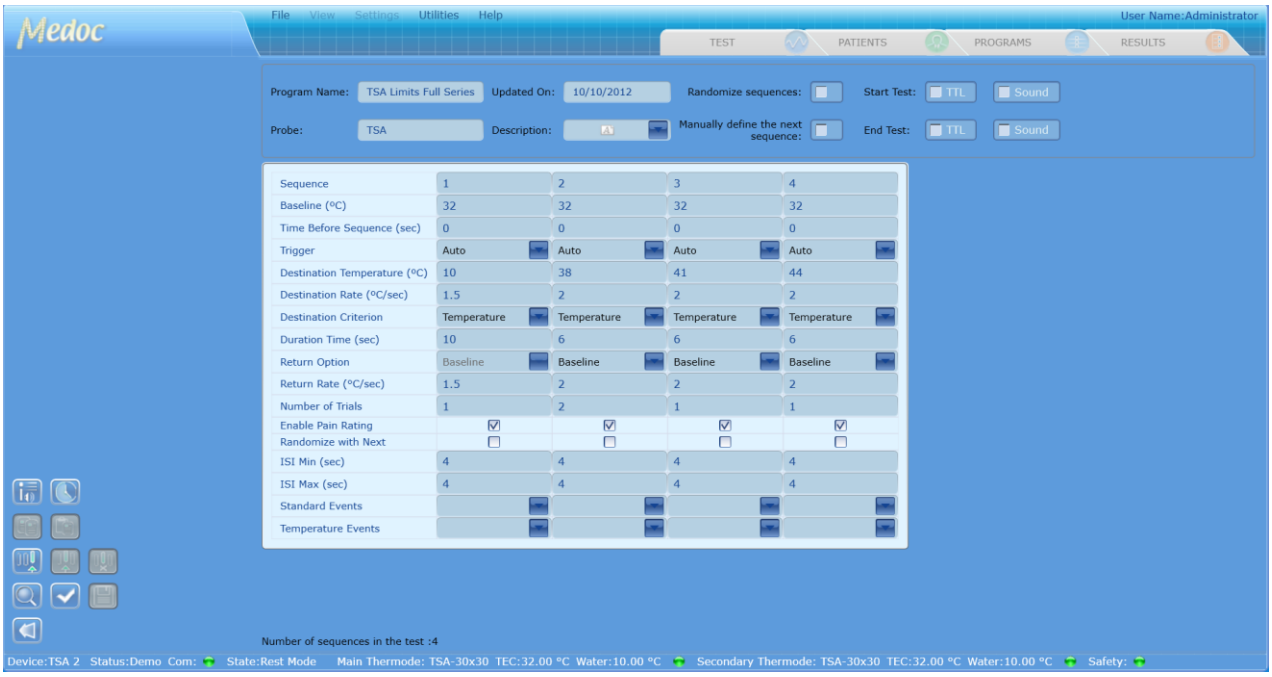


Figure 79: Program Editor – Ramp & Hold

The table below describes the program parameters available for the Ramp & Hold method:

Table 14: Ramp & Hold- Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 20°C to 40°C.
Trigger	Trigger mode: • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). • Manual – The operator will initiate the onset of the stimulus after the defined ISI. • External – The onset of the stimulus will be initiated by an external system via TTL in (see Technical Specifications)
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. Valid range: 0.1 to 13°C/Sec
Number of Trials	The number of trials per sequence. Valid range: 1 to 100
Destination Temperature (°C)	Defines the destination temperature for all trials in the current sequence. Valid range is limited by safety limitations and depends on the duration time.
Duration Time (sec)	Defines the duration for Thermode temperature to remain at destination temperature before returning to baseline. Valid range: 0 to 600 (sec)
ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
ISI Max (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.7 page 89
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.8 page 95

8.6.4.1 Pain Rating

Enables advanced options for monitoring Patient Response: customized range for numerical pain rating scale, multiple ratings per trial.

Pain Rating Parameters Configuration

Pain rating is available only for Ramp & Hold program.

Advanced parameters available with pain rating license can be configured while creating or editing any Ramp & Hold program.

The following options can be configured:

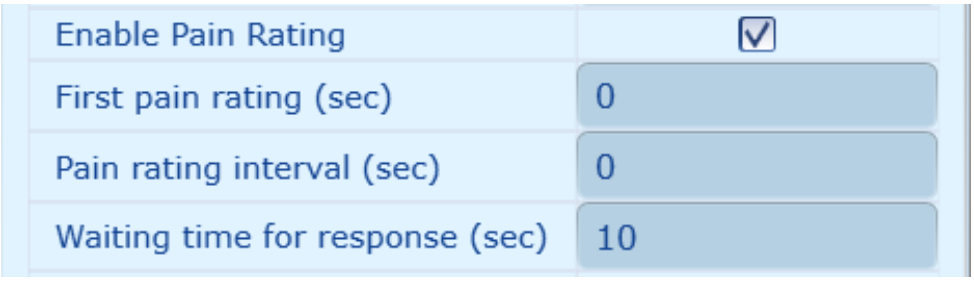


Figure 80: Pain Rating Options

Parameter	Description
Enable Pain Rating checkbox	When checked enables pain rating patient response.
First pain rating (sec)	Time of the first pain rating. Default value is "0", meaning that the first pain rating will occur at the moment the destination temperature is reached.
Pain rating interval (sec)	Interval between pain ratings. Default value is "0", meaning there will be only one pain rating in trial, at time determined by first pain rating parameter value
Waiting time for response	Time for which the pain rating dialog will remain on the screen waiting for user to respond.

Note: The amount of paint ratings in trial is determined by combination of first pain rating, pain rating interval and duration time parameters value. For example, if the duration time of the trial is 20 sec, first pain rating value is 5 sec and pain rating interval value is 5 sec, there will be 4 pain ratings in the trial - 5, 10, 15 and 20 sec after reaching the destination temperature.

In addition, **Pain rating limits** can be configured from Test Configuration tab in Settings>Test Settings window:

Figure 81: Test Setting – Pain Rating Limits

8.6.5 VAS Search

In this method, the temperature of the first stimulus rises (or falls) to a predetermined destination, at a predetermined rate, remains there for a predetermined duration, and returns to baseline. Patient estimation of perceived magnitude of sensation is recorded for the first stimulus. The intensity of the next stimulus is determined by patient response being higher or lower than the desired pain rating. For a method explanation, refer to VAS Search Method, page 29

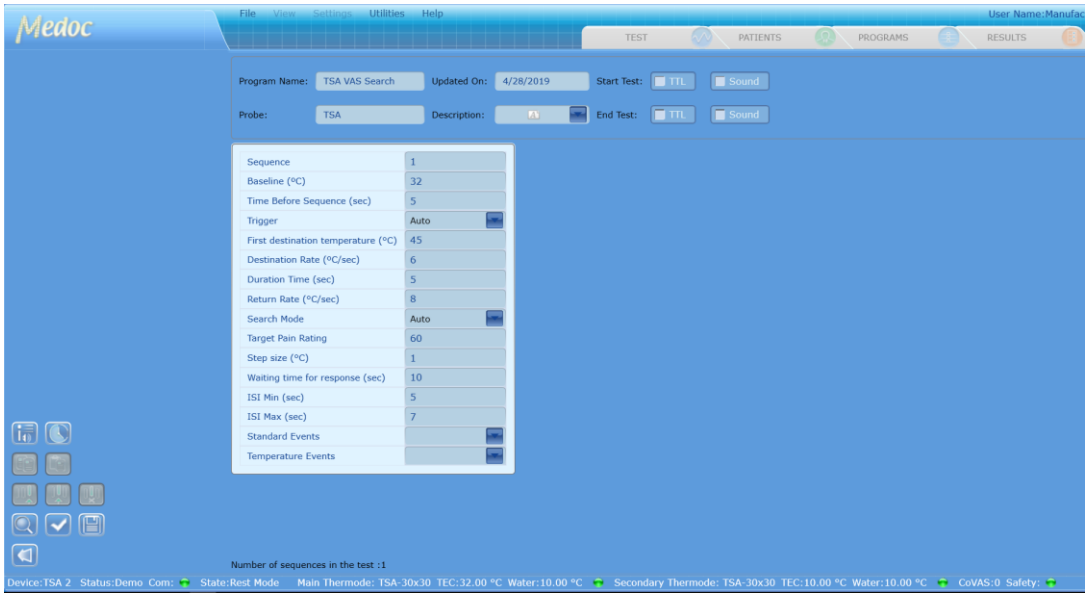


Figure 82: Program Editor – VAS Search

The table below describes the program parameters available for the VAS Search method:

Table 15: VAS Search Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 20°C to 40°C.
Trigger	Trigger mode: • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). • Manual – The operator will initiate the onset of the stimulus after the defined ISI.
First destination temperature (°C)	Defines the destination temperature for the first trial. Valid range is limited by safety limitations and depends on the duration time.
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. Valid range: 0.1 to 13°C/Sec
Duration Time (sec)	Defines the duration for Thermode temperature to remain at destination temperature before returning to baseline. Valid range: 0 to 600 (sec)
Return Rate	Defines the temperature change rate from the destination to baseline temperature. Valid range: 0.1 to 13°C/Sec
Search Mode	Search mode: • Automatic – starting from the second trial, the stimulus parameters will be defined automatically by the predetermined target pain rating and step size. • Manual – At the end of each trial the user will define the destination temperature of the next trial, until the desired pain rating is reached. The user also decides when to finish the program (i.e. when the desired pain rating is achieved). In manual mode the 'Target Pain Rating' and 'Step size' parameters become dimmed.
Target Pain Rating	Relevant for Automatic search mode only. Defines the pain rating that needs to be reached. If the actual pain rating of the current trial is lower than 'Target Pain Rating' value, the temperature of the next trial will increase by the Step Size (see below) and vice versa. Valid range: 1 - 100
Step Size (°C)	Relevant for Automatic search mode only. Determines the step size by which the temperature will increase/ decrease in every new trial. The direction of the temperature change will depend on the difference between the target and the actual pain ratings (see above in 'Target Pain Rating' description) Valid range: 0.1 – 10 (°C)
Waiting time for response (sec)	Time for which the pain rating dialog will remain on the screen waiting for user to respond.

Parameter	Description
ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
ISI Max (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.7 page 89
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.8 page 95

8.6.6 Pulses

In this method, the temperature rises or falls at a very rapid rate, and then returns to a predefined starting point of a new pulse. For an example graph and an explanation of the method, refer to section 2.7.3 page 31

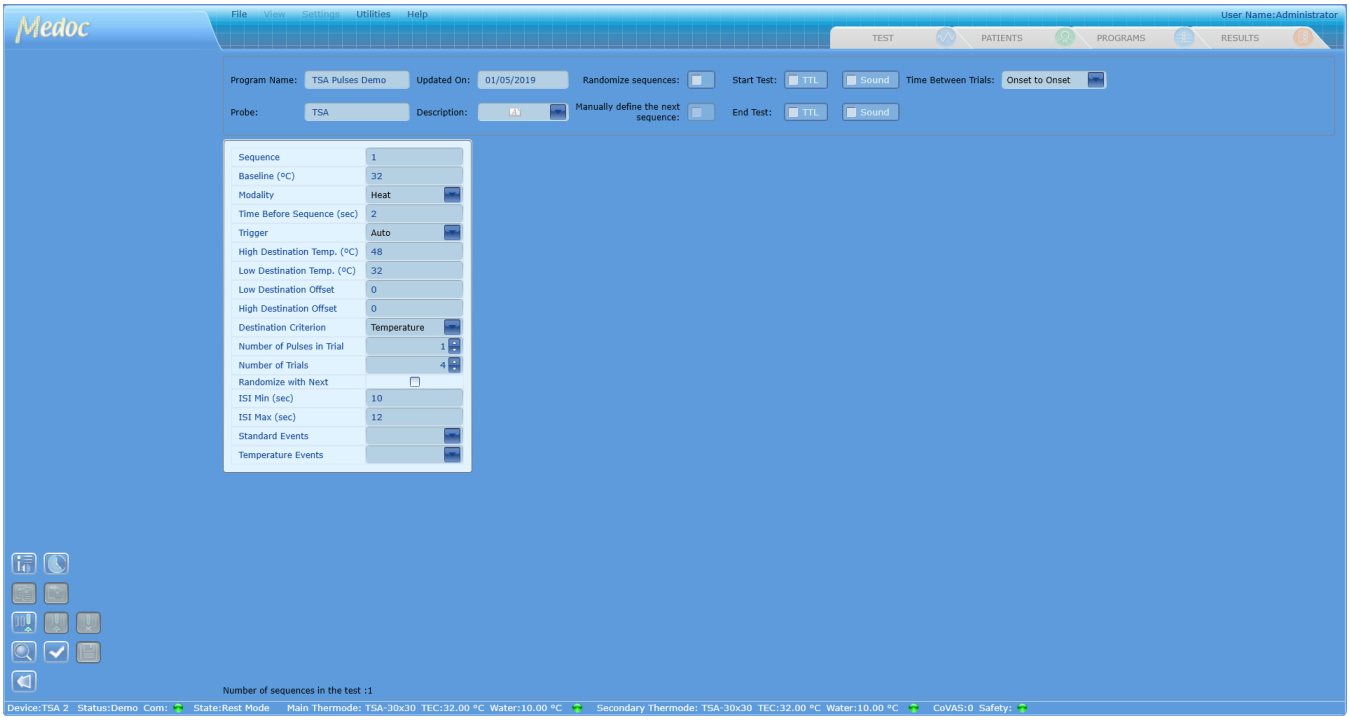


Figure 83: Program Menu – Pulses

The table below describes the program parameters available for Pulses method:

Table 16: Pulses – Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. 10°C – 45°C
Modality	Either hot pulses or cold pulses modalities
Time before sequence (sec)	The time interval before the first trial. Valid range: 0 to 600 (sec).
Trigger	Trigger mode: • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). • Manual – The operator must initiate the onset of the stimulus after the defined ISI (using the manual trigger, keyboard shortcuts or TTL-IN)
High destination temp (°C)	Defines the high destination temperature for all trials in the current sequence. Valid range is limited by safety limitations and depends on the duration time.
Low destination temp (°C)	Defines the low destination temperature. Relevant if there is more than one pulse per trial.
Offset (°C)	The Offset is used to control the overshoot of the Thermode temperature when it reaches the destination temperature. To determine the offset required, run the program with different values until you are satisfied with the results. Note that increasing the offset will reduce the overshoot and decreasing the offset will increase the overshoot. Valid Range: 0 – 10 (default is 2). The software will display a warning if the offset parameter is set to be lower than then the default. The default offset can be set in the Test Settings.
Destination criterion	Temperature: The system recognizes that it has reached the target temperature, by monitoring the temperature. Time: The system recognizes that it has reached the target temperature, by referring to the theoretical time that is required to reach the destination temperature according to the selected rate.
Number of pulses in trial	Number of pulses, between high and low destinations, in a trial (until temperature returns to baseline). Valid Range: 1 to 100
Number of Trials	The number of trials per sequence. Valid range: 1 to 999
Randomize with next	Randomize trials with next sequence
ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
ISI Max (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.7 page 89

Parameter	Description
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.8 page 95

8.6.7 Search

In this method, the intensity of the stimulus changes according to the patient's response. Using the response unit or CoVAS the patient can control whether the temperature will increase or decrease and to what extent. For an example graph and an explanation of the method, refer to section 2.7.4 page 32

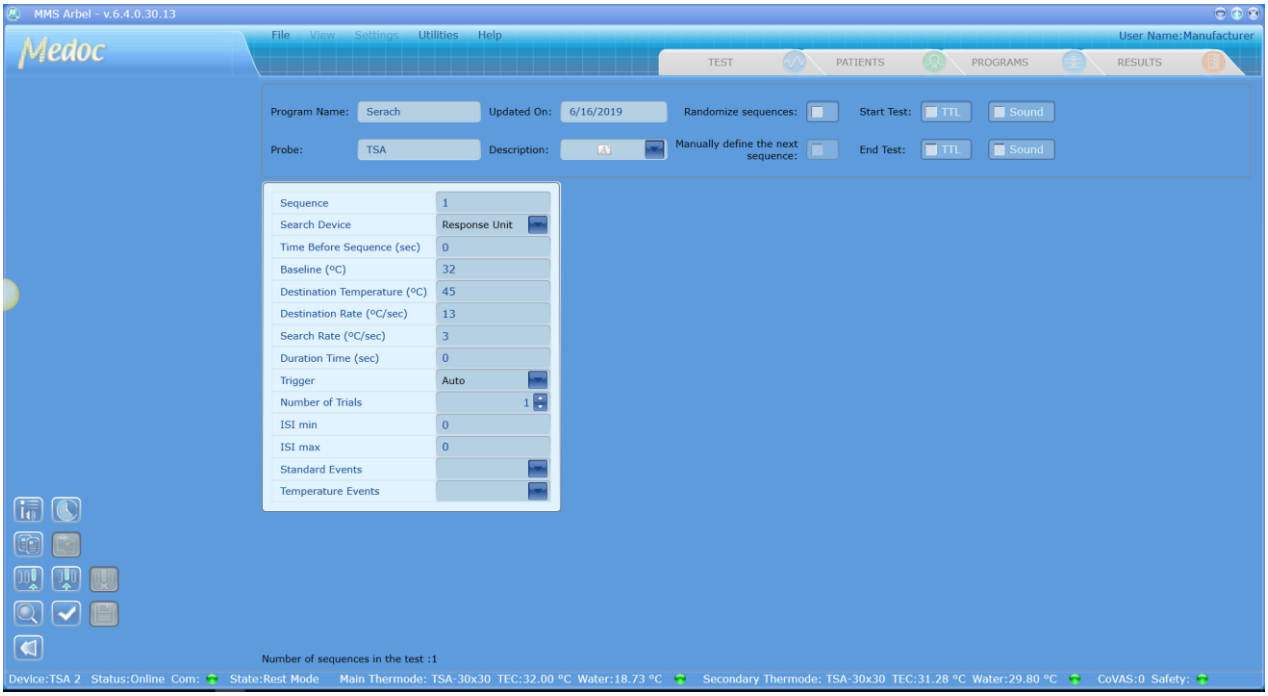


Figure 84: Program Menu – Search

The table below describes the program parameters available for Search method:

Table 17: Search - Program Parameters

Parameter	Description
Search Device	Specify the device which will be used to control the temperature: CoVAS or Response Unit
Time before sequence (sec)	The time interval before the first trial. Valid range: 0 to 600 (sec).
Baseline (°C)	Temperature from which each new stimulation sequence begins. 10°C – 45°C
Destination Temperature (°C)	Defines the destination temperature before the search starts. Valid range is limited by safety limitations and depends on the duration time.

Parameter	Description
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. 0.1 to 13°C/Sec
Search Rate (°C/sec)	Defines the temperature change rate during the search period.
Duration Time (sec)	Defines the duration of the search period. Valid range: 1 to 600
Number of Trials	The number of trials per sequence. Valid range: 1 to 100
ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
ISI Max (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.7 page 89
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.8 page 95

8.6.8 Chain Program Option

The purpose of the Chain Method is to chain several programs one after the other. The result is a master program which runs the selected programs continuously, each program repeated by the number of cycles defined and in order according to the indexed list.

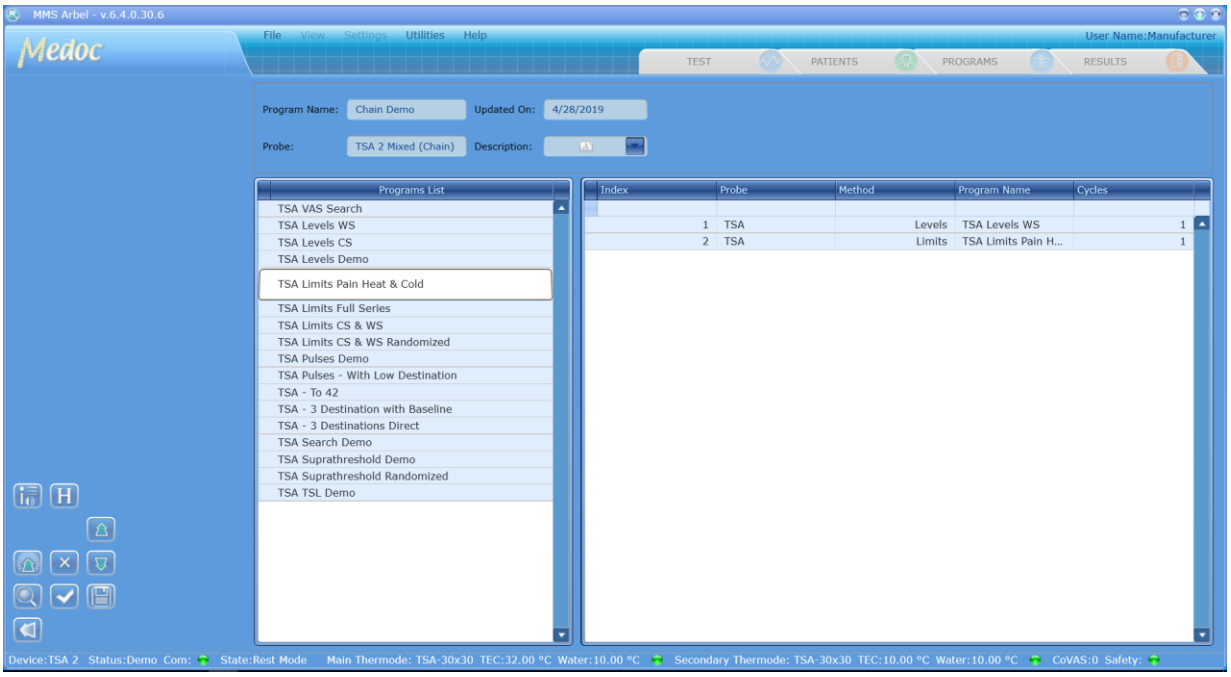


Figure 85, a program list is present for the user to choose from, when constructing the master program.

Each sub-program is defined by the following factors:

Table 18: Chain sub program parameters

Parameter	Description
Probe	The probe to be used in that specific sub-program.
Method	The method to be used in that specific sub-program.
Program name	A meaningful name for the specific sub-program.
Cycles	The number of cycles to be executed in that specific sub-test.

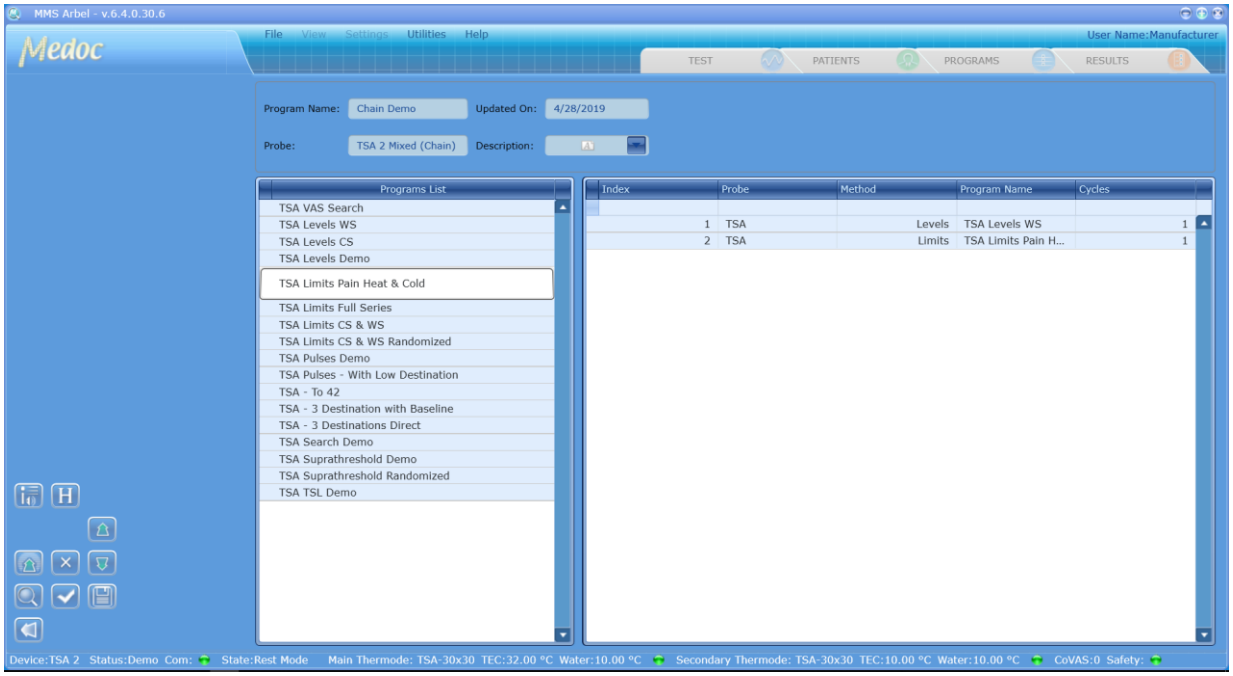


Figure 85: Program Chain

The program menu varies according to the probe, and the method of stimuli intended for use, as shown on the left side of the screen.

The parameters available for program creation at this stage are as follows:

Table 18: Chain Protocol - Program Details

Column	Description
Program name	The program name (editable).
Probe	The Thermode type used with this program.
Description	Under Description, click the arrow ; then type free text to describe the program. The Description icon is indicated as active ( ).
Update on	The date on which the latest changes were made and saved.

Table 19: Program Table

Parameter	Description
Program list	A list of the available programs.

Index	The serial number of the chained program. The serial number indicates the execution order of the programs.
Probe	The Thermode type to be used in the chained program.
Method	Test method of the chained program.
Program name	Name of the chained program.
Cycles	Number of times the chained program is to be performed. To change the value, type the new one, or use the Up/Down arrows.

The following additional functions are available:

- Adds the program selected from the Program List to the chained list, below the selected program in the chained program list.
- Deletes the selected program from the chained program list.
- Moves the selected program up the index (up the list).
- Moves the selected program down the index (down the list).

8.6.9 CPM (Conditional Pain Modulation)

Note: “CPM” is interchangeable with “dual Thermode” throughout this document.

Note: CPM is not available in dCHEPS mode.

To set up a CPM protocol, start first by creating separate programs for the Test Stimuli and Conditioning Stimuli.

When creating programs for the Thermodes in a CPM protocol follow the guideline below:

- The program for the conditioning stimuli must have a “Ramp and Hold” or limits Method.
- Consider the different time intervals built-in the programs (Inter-Stimulus-Interval (ISI) and Time before Sequence) or set the Trigger option to Manual to enable synchronization between Thermodes.

Once you have created the programs for the Test Thermode and the Conditioning Thermode, create a protocol of type “CPM”. The following screen will be presented to you:

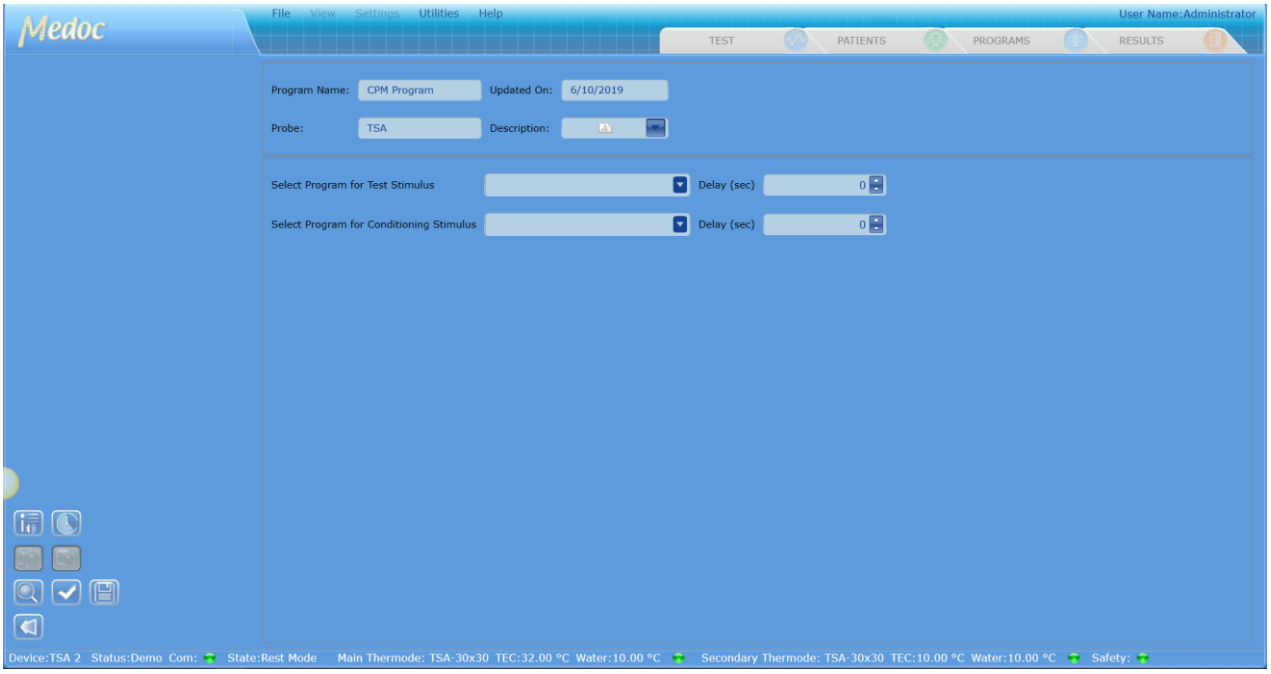


Figure 86: CPM Program Editor

Select the programs for the Test Stimulus and the Conditioning Stimulus from the drop-down lists.

8.6.9.1 Types of conditioning stimulus

In CPM configuration the available program types for conditioning stimuli are Ramp & Hold, Limits and TSL programs. The conditioning stimulus can be combined with test stimulus represented by any available program type (Ramp & Hold, Limits, Levels, TSL etc.).

Note: if Limits program is selected as a conditioning stimulus, test stimulus can be represented by Limits program only.

In case both test and conditioning stimuli are set to be Limits programs, the 'Delay' parameter in CPM program editor is disabled.

If both test and conditioning stimuli are selected to be Limits they should be set following the below rules:

- Both Limits programs should have similar destination and return rates.
- Both Limits programs should have similar 'time before sequence' and ISI parameters.

In case Limits is selected for both condition and test stimuli, stopping the test stimuli with response unit/keyboard/ mouse will also stop the condition stimulus and both tests will return to the baseline and proceed to the next trial.

8.7 Standard Events

Standard Events are pre-defined events that occur during the test such as the onset of a stimulus or reaching the destination temperature. Events can be marked by a TTL and/ or sound:

1. TTL Trigger – TSA 2 can send a TTL signal which can be used for synchronization with external systems.
2. Sound – a sound can be played from the computer (speakers are required) when a certain event occurs. This can be used as a cue for the subject to perform a certain task.
3. Every event is also marked on the screen during the test by an asterisk (*).

For other event types see:

Temperature Events section 7.8
User Defined Events section 11.3.2

8.7.1 TTL Setup

TSA 2 can send two types of TTL signals:

1. 1-bit TTL is sent from the front panel TTL Out BNC connector (see TSA 2 front panel connection in section 3.1 page 36
2. TTL events are recorded in the results graph and also can be outputted via the external control feature. See Appendix K

The polarity of the TTL can be configured in TSA 2 hardware settings. Refer to section 10.2.1 page 125 for further details.

The technical specifications of the TTL output are detailed in section 1.6 page 23

8.7.2 Standard Event Configuration

1-bit TTL signals are sent only if the standard event is configured in the program

To configure standard events in the required program, follow the steps detailed below:

1. From the **Programs** screen, select the program you want to configure standard events for and double click to open the program editor or click on the edit program button
2. From the list of parameters, select the Standard Events option

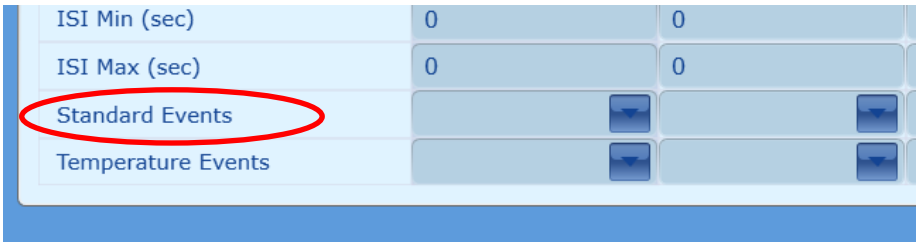


Figure 87: Standard Events in Program Editor

3. Click the arrow on the left to open the standard event editor.

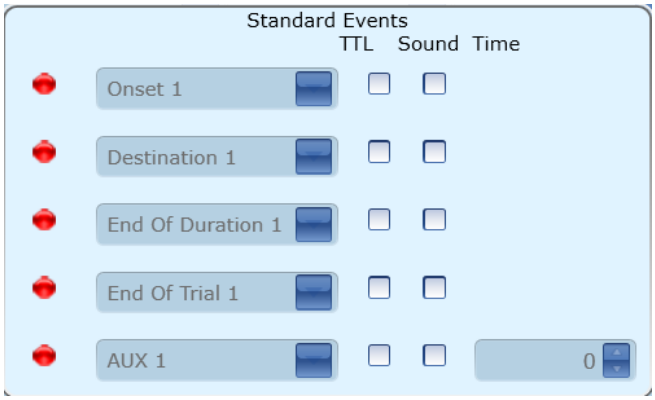


Figure 88: Standard Event Editor

For each event that you want to configure mark the TTL and/or the Sound column to activate. Once the event is activated, you can use the drop-down list to select a different event type.

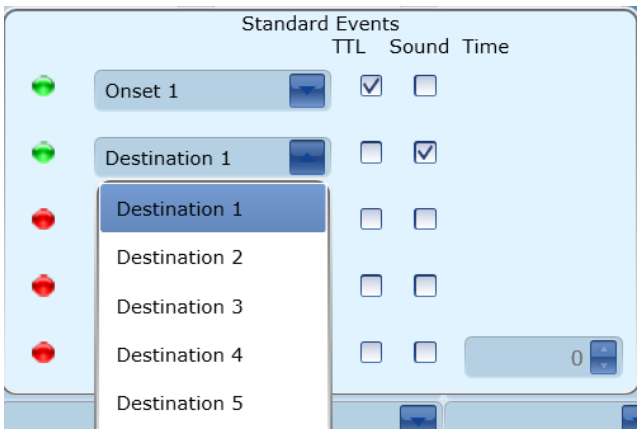


Figure 89: Standard Event Configuration

4. To configure an auxiliary event (time-based event) select the last row with event type 'AUX'. In the time column enter the time when the event should be sent (counted in seconds from the onset of each trial in the selected sequence)
5. Click anywhere on the screen to close the Standard Events dialog.
6. The available standard events vary according to the test method. For a list of the available standard events according to the program type continue to the following section.

8.7.3 List of Standard Events according to Program Type

The available standard events according to program type are detailed in the table below:

Table 20: List of standard events according to program type

Program Method	Standard Events	Description
Ramp and Hold	**Onset**	The start of each trial in the sequence
	Destination	Thermode temperature reached target temperature
	End of Duration	End of duration at target temperature

Program Method	Standard Events	Description
	AUX	Time based event timed from the onset
Limits	**Onset**	The start of each trial in the sequence
Levels	**Onset**	The start of each trial in the sequence
	Destination	Thermode temperature reached target temperature
	End of Duration	End of duration at target temperature
	AUX	Time based event timed from the onset
TSL	**Destination**	Subject response was detected
Pulses	**Onset**	The start of each trial in the sequence
	Peak	The highest temperature recorded in a pulse. Peak detection is performed in real time, therefore there is a 50 [msec] delay between the occurrence of the peak and the display of the TTL on screen.
	AUX	Time based event timed from the onset

8.8 Temperature Events

Temperature Events are events that occur when the Thermode temperature reaches a specific temperature as defined during program setup. Up to 5 different temperature events can be specified per sequence. The temperature events can be marked by a TTL and/or sound. Please refer to the section for a more detailed explanation on TTL setup. Temperature events are also marked on the screen during the test by a dot (●).

For other event types see:

Standard Events section 7.7

User Defined Events section 11.3.2

8.8.1 Temperature Event Configuration

To configure temperature events in the required program, follow the steps detailed below:

1. From the **Programs** screen, select the program you want to configure standard events for and double click to open the program editor or click on the edit program button
2. From the list of parameters, select the Temperature Event option
3.

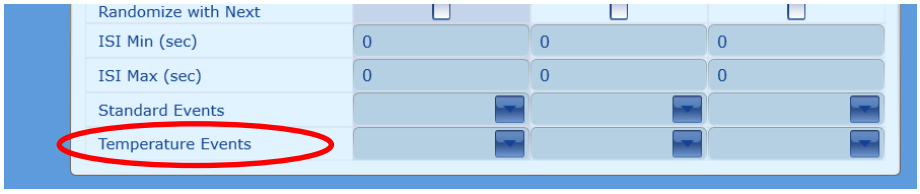


Figure 90: Temperature Events in Program Editor

4. Click the arrow on the left to open the temperature event editor.

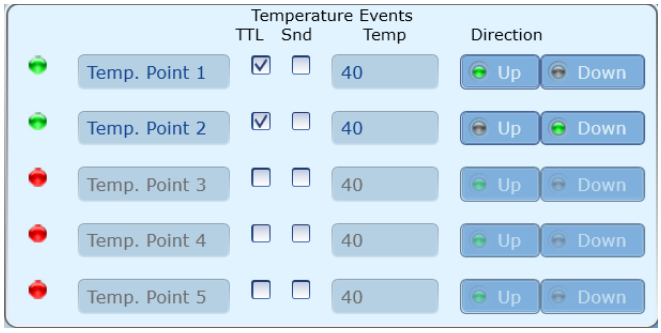


Figure 91: Temperature Event Editor

For each event that you want to configure mark the TTL and/or the Sound column to activate. Once the event is activated, you can specify the temperature and direction (temperature increase or decrease) in which the event should occur.

5. Click anywhere on the screen to close the Standard Events dialog.

8.9 Test Instructions

Test instructions can be assigned to any program as a text file (to be read out loud by the operator) and/or as an audio file which can be played before starting the test. The test instructions can be edited globally for all programs of the same method (see section 11.3.5), or separately for each program.

This section describes how to edit the test instruction for a specific program:

1. From the **Programs** screen, select the program you want to configure standard events for and double click to open the program editor or click on the edit program button

2. From program editing options on the left, click on the edit test instructions button

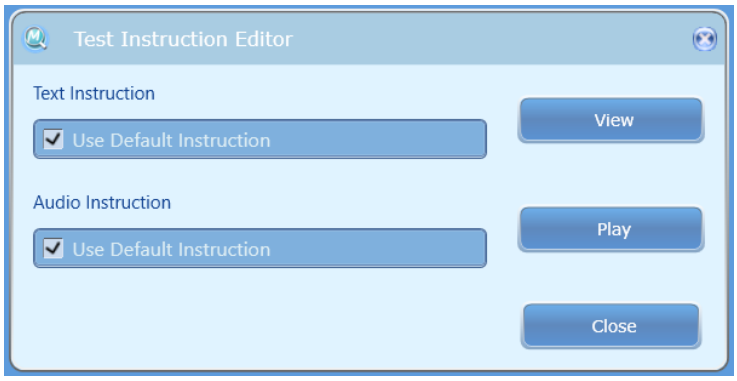


Figure 92: Test Instructions Editor

3. To edit the text instructions:

   3.1. Unselect the relevant **Use Default Instruction** checkbox

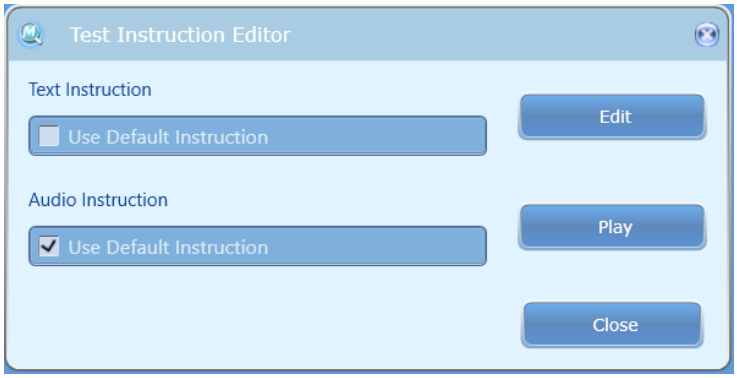


Figure 93: Edit Text

3.2. Click on the **Edit** button to open a rich text editor. Edit the text instructions and save them (see also section 11.3.5.1)

4. To replace the audio instructions:

4.1. Deselect the relevant **Use default instruction** checkbox.

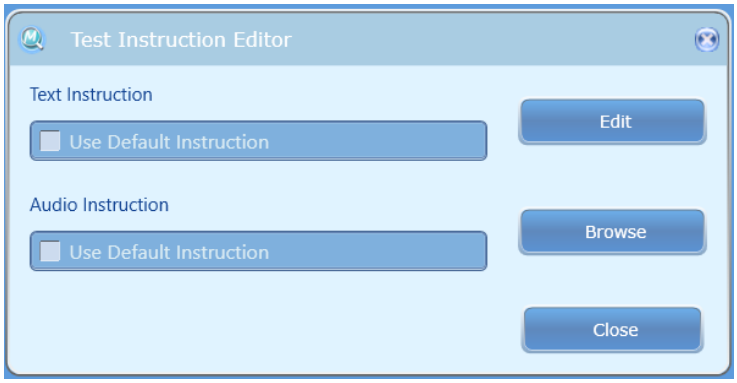


Figure 94: Replace Audio Instructions

4.2. Click on the **Browse** button and select an audio file to use as the audio instructions (see also section 11.3.5.2)

8.10 Import / Export Programs

Programs from the program list can be exported and saved for backup or imported into another TSA 2 system. The export format uses a secure and unique format that can be accessed by Medoc Main Station software only.

Importing and/or exporting program data from different software versions may result in compatibility errors and loss of data. Check database compatibility before proceeding.

8.10.1 **Export Programs**

In order to export programs, follow the procedure below:

1. Open the program list in the **Programs** screen.
2. Select the programs to export. Multiple selection is possible by holding down the **Shift** or **Ctrl** buttons on the keyboard

3. From the menu bar select **File** and then **Export**.
4. Enter a file name for the exported programs and select the save location.
5. Click the **Save** button.
   The selected programs are saved to the selected location under the selected name.

8.10.2 Import Programs

In order to import programs, follow the procedure below:

1. From the menu bar select **File** and then **Import**
2. Browse to the location of the saved programs and select the file to import
3. Click on the **Open** button. The programs will be added to the program list.

8.10.3 Solving Conflicts When Importing Programs

Medoc Main Station identifies any possible conflicts between existing programs and imported programs. In case of conflict (e.g. programs have the same name) it is possible to manually select how to handle the import. The following options are available:

1. Use Local – keep the existing program and ignore the imported program
2. Use Import – overwrite the existing program with the imported program
3. Keep Both – import the program and save under a different name.

9. Patient Management

This Chapter explains how to add and edit patient record

9.1 Patients List

The Patients screen enables you to manage the patient list.

1. To access the patient database, click the **Patients** button in the toolbar. The following screen is displayed:

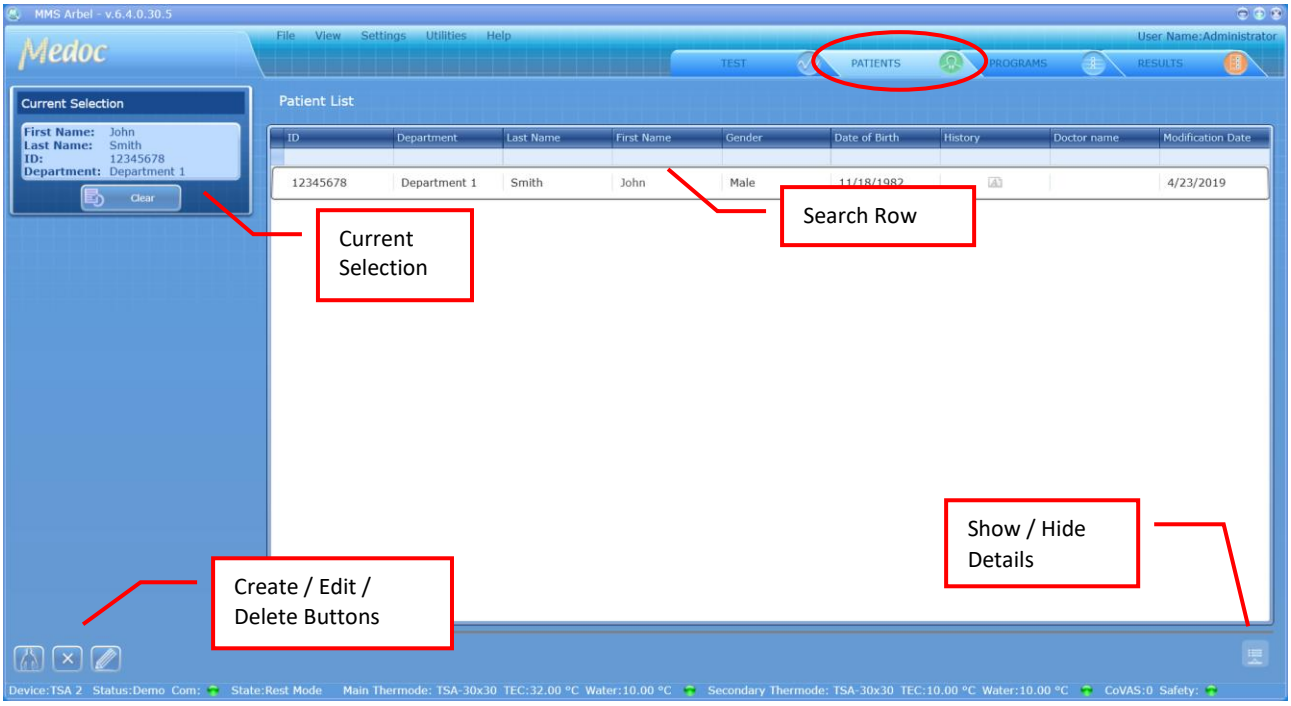


Figure 95: Patients List

2. Use the search row to filter the patient list.
3. The current selection pane shows the details of the currently selected patient.
4. The following options are available in the Patient Management screen:

	Create a new patient
	Delete selected patient details.
	Edit selected patient details

Deleting Patient Records also removes all associated test results!

5. To view patient details in more detail (without editing) use the Show Details button. To return to patient list, click on the Hide Details button.

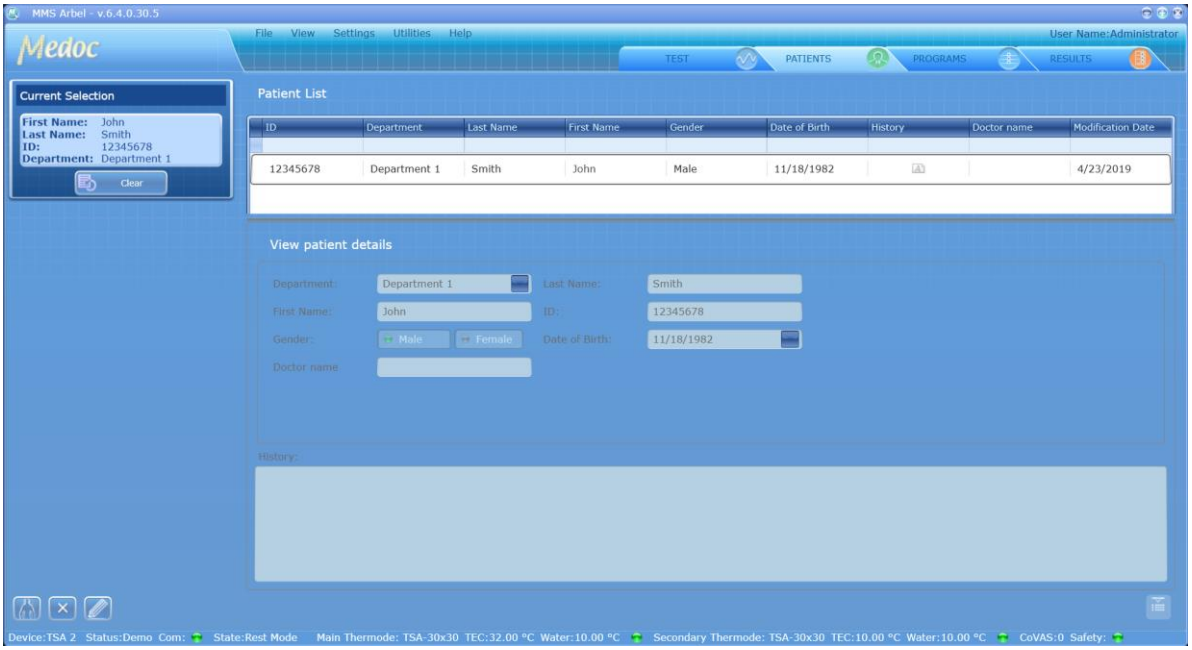


Figure 96: Patient Management – Patient Details Preview

Patient details cannot be edited from the Patient Details view.

9.2 Adding a New Patient

To add a patient to the patients list:

15. From the Patients screen, click on the Add New Patient button
    The **Patient Editor** screen is displayed:

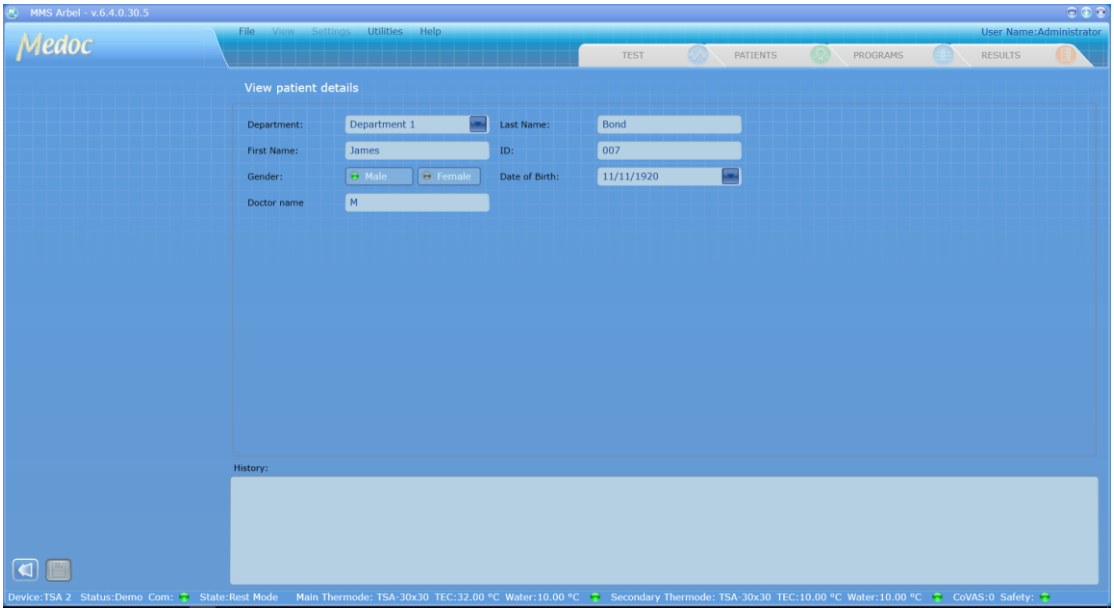


Figure 97: Patients Editor Screen

16. Insert all the relevant patient data.

Missing or incorrect parameters are highlighted by an icon next to the relevant field. A short description of the problem is displayed when holding the cursor over the relevant icon.

17. To add or edit the available departments see section 8.5 page 102

18. Click the **Save** button

19. To return to the patient list click on the return button

The available patient fields can be customized. For further information, refer to section 11.1.4.

9.3 Remove a Patient

To remove a patient from the patient list:

From the **Patient** screen, select the patient to delete and click on the remove patient button

Note that deleting a patient from the list also removes all the corresponding test results!

9.4 Edit Patient Details

To edit a patient from the patient list:

From the **Patient** screen, select and double click the patient record to edit or click on the edit patient button

9.5 Add / Edit Departments

The department list can be managed from the utility menu. It is possible to add, edit or remove departments as needed. It is not possible to remove a department if there are patients associated with it.

Department management is enabled according to the authorization level of the current user. For further information, refer to section 11.1.6

1. From the menu bar select **Utilities** and then **Department**.
   The *Edit departments* menu is displayed:

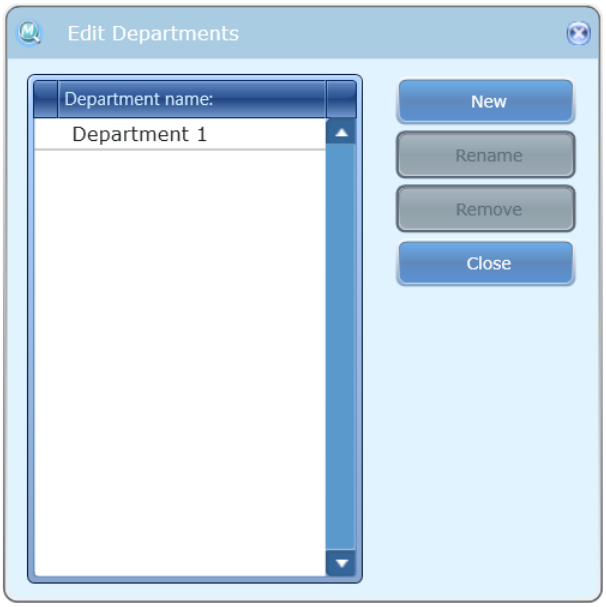


Figure 98: Edit Department Menu

2. To add a new department, click the **New** button; then, type the department name.
3. To rename a department, select the required department; then click the **Rename** button.
4. To remove a department, select the required department; then click the **Remove** button. At the prompt click the **OK** button.
5. To close the dialog, click the **Close** button.

9.6 Import / Export Patient Records

Patient details can be exported and saved for backup or imported into another TSA 2 system. The export format uses a secure and unique format that can be accessed by Medoc Main Station software only.

Importing and / or exporting patient data between different software versions may result in compatibility errors and loss of data. Check database compatibility before proceeding.

9.6.1 Export Patient Records

In order to export programs, follow the procedure below:

1. Open the patient list in the **Patients** screen.
2. Select the patient records to export. Multiple selection is possible by holding down the **Shift** or **Ctrl** buttons on the keyboard
3. From the menu bar select **File** and then **Export**.
4. Enter a file name for the exported patient records and select the save location.
5. Click the **Save** button.
   The selected patient records are saved to the selected location under the selected name.

9.6.2 Import Patient Records

In order to import patient records, follow the procedure below:

1. From the menu bar select **File** and then **Import**
2. Browse to the location of the saved patient records and select the file to import
3. Click on the **Open** button. The patient records will be added to the patient list.

9.6.3 Solving Conflicts When Importing Patient Records

Medoc Main Station identifies any possible conflicts between existing patient records and imported patient records. In case of conflict (e.g. patients with same unique ID) it is possible to manually select how to handle the import. The following options are available:

1. Use Local – keep the existing patient record and ignore the imported one
2. Use Import – overwrite the existing patient record with the imported one
3. Keep Both – edit the conflicting field in the imported patient record and keep both records. The “keep both” option only becomes available if the conflict no longer exists.

10. Results Management

This chapter explains how to view, export and print reports from saved test results.

10.1 Results List

The Results screen displays the list of saved test results.

1. To access the results database, click the **Results** button in the toolbar. The following screen is displayed:

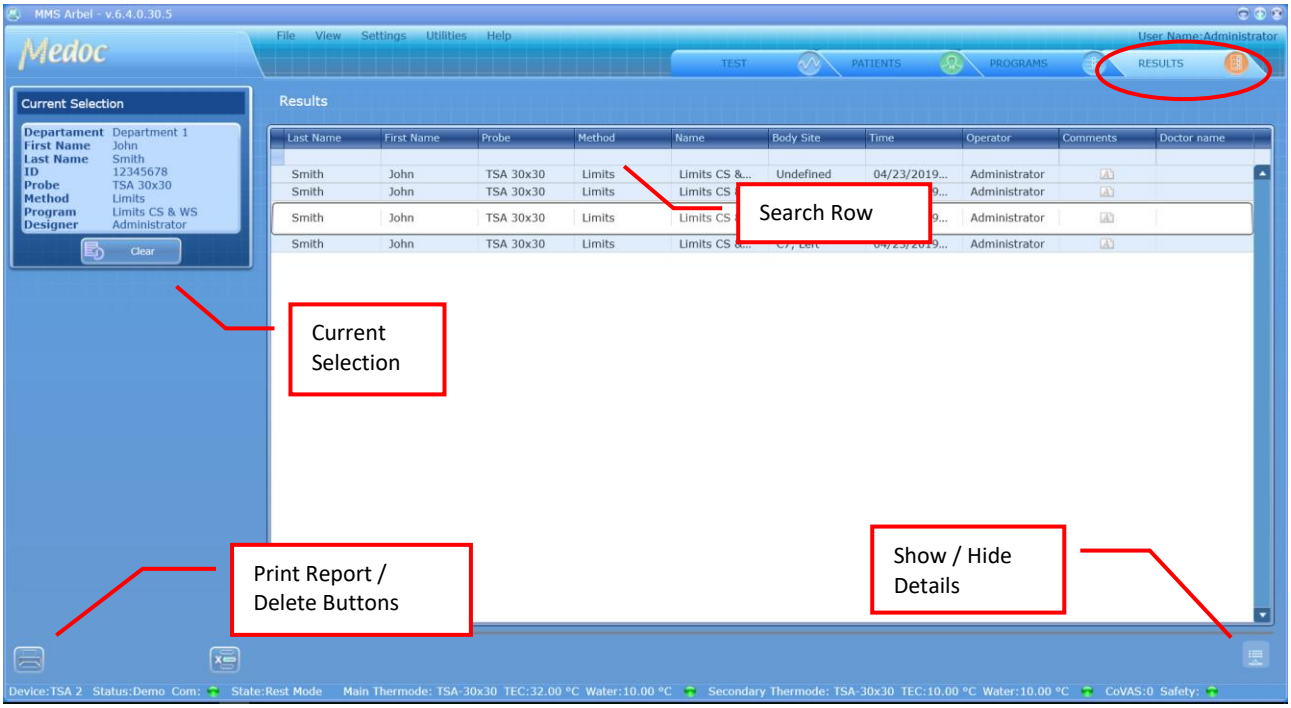


Figure 99: Results List

2. Use the search row to filter the list of results.
3. The current selection pane shows the details of the currently selected test result.
4. The following options are available in the results management screen:

	Print test results as a report
	Delete selected test result

5. To view a test results in more detail, select the relevant row in the list and click on the Show Details button. To return to result list, click on the Hide Details button.

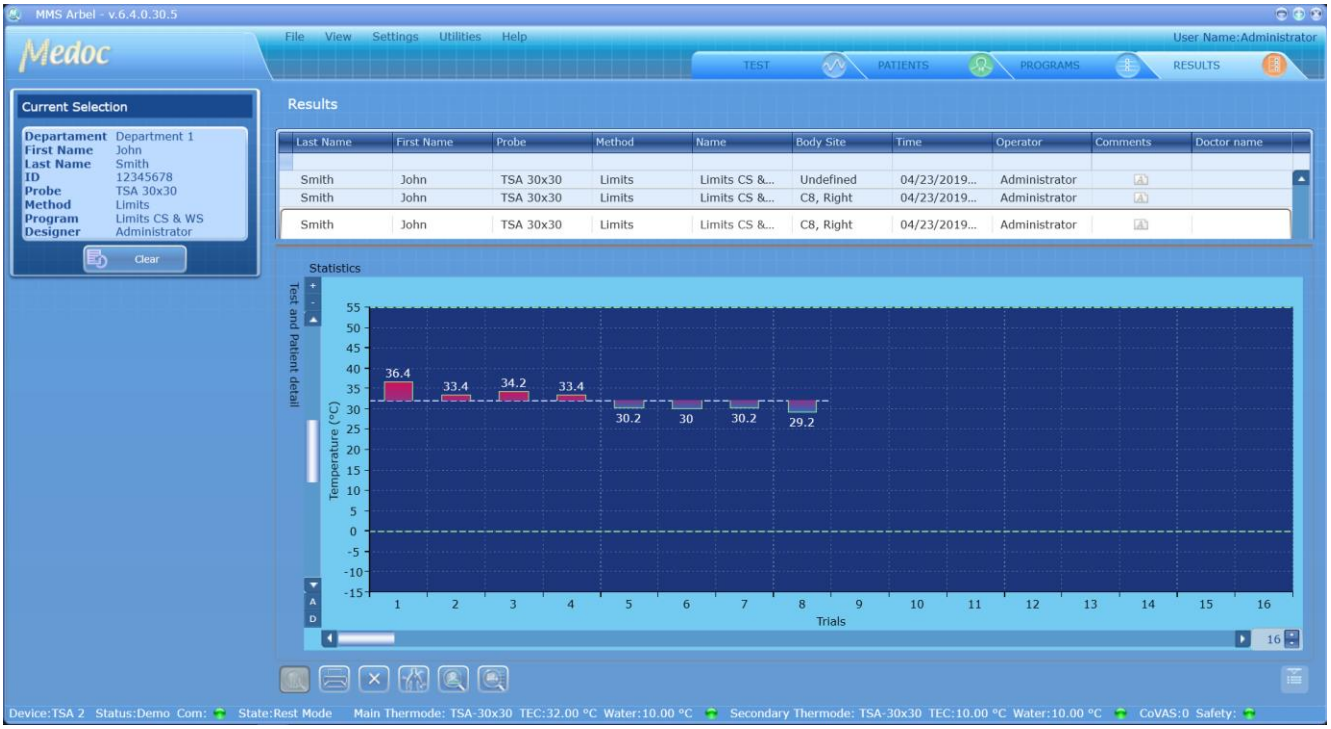


Figure 100: Result Preview Display

The following options are available from the detailed test result view:

	Display details of program used in selected test results
	Display Patient Details
	Display Body Site.
	Delete Selected Test Results
	Print Test Results as a Report
	Display Test Results
checkbox	Show / Hide Normative data display (if applicable)
checkbox	Show / Hide CoVAS data (if applicable)

10.2 Import / Export Results

Test Results can be exported and saved for backup, further analysis or to import to another TSA 2 system. Test results can be exported using the default export format which is secure and can only be accessed by Medoc Main Station software. Alternatively, results can be exported to an excel file for further analysis.

Importing and/or exporting test results between different software versions may result in compatibility errors and loss of data. Check database compatibility before proceeding.

10.2.1 **Export Test Results**

In order to export test results, follow the procedure below:

1. Open the result list in the **Results** screen.
2. Select the test result to export. Multiple selection is possible by holding down the **Shift** or **Ctrl** buttons on the keyboard
3. From the menu bar select **File** and then **Export**.
4. Enter a file name for the exported test results and select the save location.
5. Click the **Save** button.
   The selected test results are saved to the selected location under the selected name.

10.2.2 Export Test Results to Excel

In order to export test Results to MS excel format follow the procedure below:

1. Open the results list in the **Results** screen.
2. Select the test result to export. Multiple selection is possible by holding down the **Shift** or **Ctrl** buttons on the keyboard. Each test result will be exported as a separate file.
3. From the menu bar select **File** and then **Export to Excel**
4. Select the save location and click **OK** to save.
5. Click the Save button.
   The selected results are saved to the selected location.

The name of each result file is automatically generated according to the patient name, date, and time of test. Chain results are exported to a new folder containing a separate file for each sub-program of the chain program.

The Excel File Structure:

The excel file includes the following sheets (content may change depending on test method):

1. Description – Patient and test information.
2. Data – All test data organized in a data table including Thermode temperature, events (when response unit button is pressed, triggers, standard events and etc.), CoVAS and any other data if available.
3. Results – Summary of results depending on test method.

	A	B	C
1	**Summery**		
2	**Department**	Department 1	
3	**Patient**	Smith, John	
4	**ID**	12345678	
5	**Probe**	CHEPS	
6	**Model**	Standard	
7	**Method**	Pulses	
8	**Program**	A-delta (CHEPS)	
9	**Start time**	03/11/2006 14:23	
10	**End time**	03/11/2006 14:23	
11	**Patient Details**		
12	**Department**	Department 1	
13	**Last Name**	Smith	
14	**First Name**	John	
15	**ID**	12345678	
16	**Sex**	Male	
17	**Date of Birth**	24/11/2005	
18	**Program Details**		
19	**Program Name**	A-delta (CHEPS)	
20	**Probe**	CHEPS	
21	**Description**	20 Fast pulses to 51 at 70 degrees/sec for activation of A-delta fibers.	
22	**Updated on**	03/11/2006 14:23	
23			
24			
25			
26			
27			

Description / Data

Figure 101: Description Sheet Example

	A	B	C	D	E	F
1	**Timestamp [msec]**	**Heater [C]**	**Tec [C]**	**Water [C]**	**COVAS**	**Baseline [C]**
2	0			10	0	
3	20	32	10	10	0	
4	40	32	10	10	0	
5	60	32	10	10	0	
6	80	32	10	10	0	
7	100	32	10	10	0	
8	120	32	10	10	0	
9	140	32	10	10	0	
10	160	32	10	10	0	
11	180	32	10	10	0	
12	200	32	10	10	0	
13	220	32	10	10	0	
14	240	32	10	10	0	
15	260	32	10	10	0	
16	280	32	10	10	0	
17	300	32	10	10	0	
18	320	32	10	10	0	
19	340	32	10	10	0	
20	360	32	10	10	0	
21	380	32	10	10	0	
22	400	32	10	10	0	
23	420	32	10	10	0	
24	440	32	10	10	0	
25	460	32	10	10	0	
26	480	32	10	10	0	
27	500	32	10	10	0	
28	520	32	10	10	0	
29	540	32	10	10	0	
30	560	32	10	10	0	

Description / Data

Figure 102: Data Sheet Example

10.2.3 Import Test Results

In order to import test results, follow the procedure below:

1. From the menu bar select **File** and then **Import**
2. Browse to the location of the saved test results and select the file to import
3. Click on the **Open** button. The results will be added to the test results list.

10.2.4 Solving Conflicts When Importing Test Programs

Medoc Main Station identifies any possible conflicts between existing test results and imported test results. In case of conflict (e.g. patient and/or program already exist in the database, with saved test results for the patient) it is possible to manually select how to handle the import. The following options are available:

1. Use Local – keep the existing test results and ignore the imported test results
2. Use Import – overwrite the existing program with the imported test results
3. Keep Both – Edit the conflicting fields of the patient or program data and keep both test results.

10.3 Generate Test Reports

Medoc Main Station has a powerful Analysis and Report Generator that can be customized as needed.

In order to print test results, follow the next steps:

1. Open the result list in the **Results** screen
2. Select one or more test results to generate reports from.
3. Click on the **Print** button

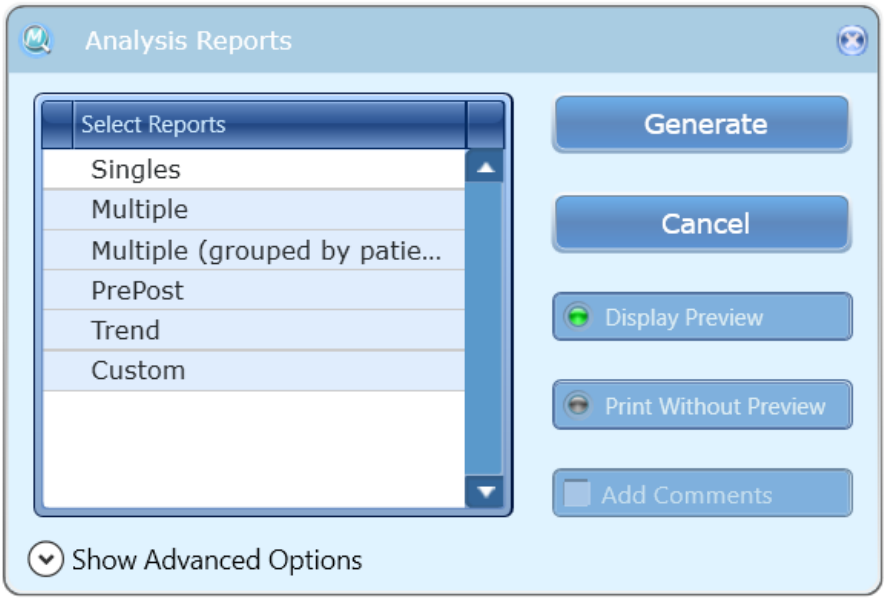


Figure 103: Analysis Reports Dialog

4. Select the type of report to print. The available report types depend on the selected results. See section 9.3.1 details about report types.
5. Select print preview option:
   5.1. Display preview (default) – opens report in viewer. The report can be exported in various formats (.pdf, .jpg and etc.) or printed.
   5.2. Print without preview – report will be sent directly to the default printer specified on your computer.
6. Select whether or not to add comments to the report
7. Click on the **Generate** button to preview / print report.
8. Advanced Options: the advanced options enable you to configure the results which will be displayed in the report. The following options are available:

Table 21: Report Advanced Options

Parameter	Description
Number of Trials	Specify number of trials to display (relevant only for trial-based programs such as Limits or Levels)
Start Time	Specify start time of test (relevant only for time-based programs such as Ramp and Hold or Pulses)
End Time	Specify end time of test
Min. Value.	Specify minimum temperature to display on graph
Max. Value.	Specify maximum temperature to display on graph

10.3.1 Analysis Report Types

There are a number of different report templates which can be used to generate a report from the selected test results. The available report template depends on specific parameters of the selected report.

Report templates can be edited and customized according to specific needs. For further information refer to section 9.3.2.

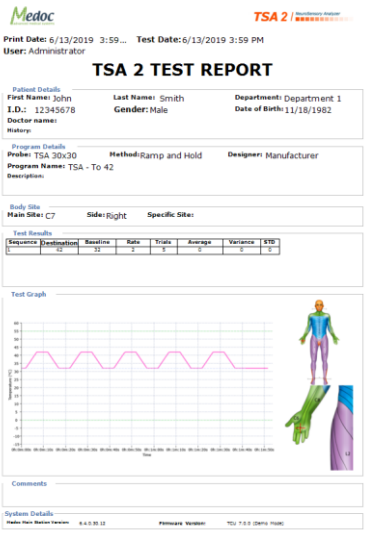
The following templates are available:

Table 22: Built-in Report Templates

Report Type	Description	Restrictions
Singles	Simple report which displays the selected test results. One report will be generated for each test results.	None
Multiple / Multiple grouped by Patient	A Statistic summary of results from more than one test.	Test Methods: TSL, Levels, Limits Selection of 2 or more result files
Bilateral	Compares test statistics for both sides (left and right) of the same body site for the same patient.	Test Methods: TSL, Levels, Limits Selection of 2 result files Identical Test Subject Identical Test Program Identical Main and Specific body site Opposite body site sides
Site to Site	Compares test statistics for two different body sites of the same patient.	Test Methods: TSL, Levels, Limits Selection of 2 result files Identical Test Subject Identical Test Program Different Main and / or Specific Site

Report Type	Description	Restrictions
Pre / Post	Compares test statistics from two separate tests performed at different times for the same patient.	Test Method: TSL, Levels, Limits Selection of 2 result files Identical Test Subject Identical Test Program Identical Body Site
Trend	Displays a trend graph from results of more than one test.	Test Method: TSL, Levels, Limits Selection of at least two test result files Identical Test Subject Identical Test Program Identical Body Site
Pain Rating	Displays the selected test results and the results of pain rating patient report.	Test Method: Ramp and Hold with Pain Rating option enabled.
Custom	Custom report with custom analysis and restrictions.	Varies according to report analysis. Contact Medoc Service for further details.

10.3.2 **Examples of Reports Types**



Medoc TSA 2

Print Date: 6/13/2019 3:59... Test Date: 6/13/2019 3:59 PM
User: Administrator

TSA 2 TEST REPORT

Patient Details
First Name: John Last Name: Smith Department: Department 1
I.D.: 12345678 Gender: Male Date of Birth: 11/18/1982
Doctor name:
History:

Program Details
Probe: TSA 30x30 Method: Ramp and Hold Designer: Manufacturer
Program Name: TSA - To 42
Description:

Body Site
Main Site: C7 Side: Right Specific Site:

Test Results

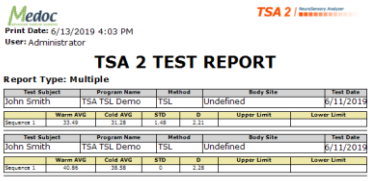
Sequence	Destination	Baseline	Rate	Trials	Average	Variance	STD
1	42	32	2	5	0	0	0

Test Graph

Comments

System Details

Figure 104: Singles Report



Medoc TSA 2

Print Date: 6/13/2019 4:03 PM
User: Administrator

TSA 2 TEST REPORT

Report Type: Multiple

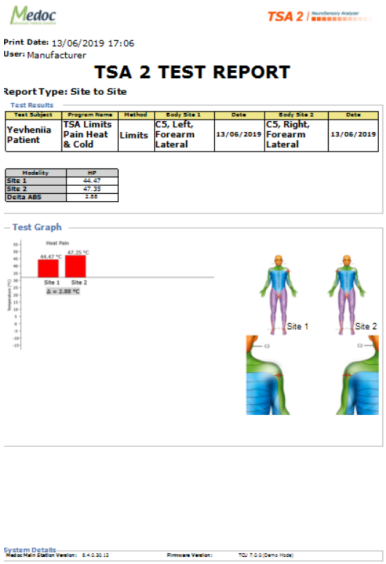
Test Subject	Program Name	Method	Body Site	Test Date
John Smith	TSA TSL Demo	TSL	Undefined	6/11/2019

	Warm AVG	Cold AVG	STD	D	Upper Limit	Lower Limit
Sequence 1	33.49	31.28	1.48	2.21		

Test Subject	Program Name	Method	Body Site	Test Date
John Smith	TSA TSL Demo	TSL	Undefined	6/11/2019

	Warm AVG	Cold AVG	STD	D	Upper Limit	Lower Limit
Sequence 1	40.86	38.58	0	2.28		

Figure 105: Multiple Report



Medoc TSA 2

Print Date: 13/06/2019 17:06
User: Manufacturer

TSA 2 TEST REPORT

Report Type: Site to Site

Test Results

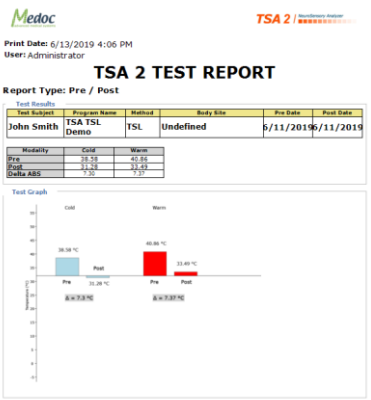
Test Subject	Program Name	Method	Body Site 1	Date	Body Site 2	Date
Yevheniia Patient	TSA Limits Pain Heat & Cold	Limits	C5, Left, Forearm Lateral	13/06/2019	C5, Right, Forearm Lateral	13/06/2019

Modality	HP
Site 1	44.47
Site 2	47.35
Delta ABS	2.88

Test Graph

System Details

Figure 106: Site to Site Report



Medoc TSA 2

Print Date: 6/13/2019 4:06 PM
User: Administrator

TSA 2 TEST REPORT

Report Type: Pre / Post

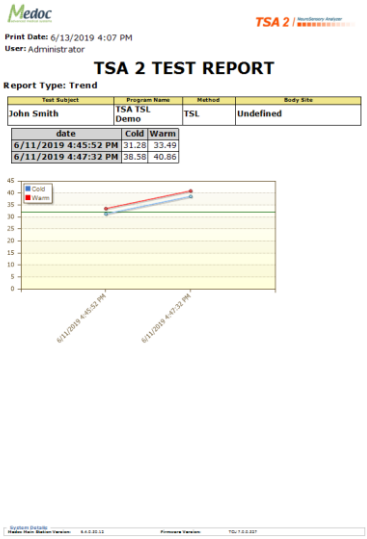
Test Results

Test Subject	Program Name	Method	Body Site	Pre Date	Post Date
John Smith	TSA TSL Demo	TSL	Undefined	6/11/2019	6/11/2019

Modality	Cold	Warm
Pre	38.58	40.86
Post	31.28	33.49
Delta ABS	7.30	7.37

Test Graph

Figure 107: Pre / Post Report



Medoc TSA 2

Print Date: 6/13/2019 4:07 PM
User: Administrator

TSA 2 TEST REPORT

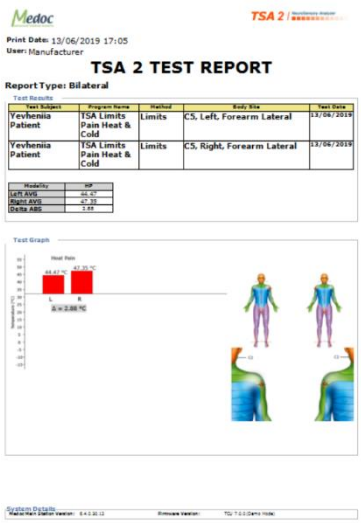
Report Type: Trend

Test Subject	Program Name	Method	Body Site
John Smith	TSA TSL Demo	TSL	Undefined

date	Cold	Warm
6/11/2019 4:45:52 PM	31.28	33.49
6/11/2019 4:47:32 PM	38.58	40.86

Figure 108: Trend Report

Figure 109: Bilateral Report



Medoc TSA 2

Print Date: 13/06/2019 17:05
User: Manufacturer

TSA 2 TEST REPORT

Report Type: Bilateral

Test Results

Test Subject	Program Name	Method	Body Site	Test Date
Yevheniia Patient	TSA Limits Pain Heat & Cold	Limits	C5, Left, Forearm Lateral	13/06/2019
Yevheniia Patient	TSA Limits Pain Heat & Cold	Limits	C5, Right, Forearm Lateral	13/06/2019

Modality	HP
Left AVG	44.47
Right AVG	47.35
Delta ABS	1.88

Test Graph

Medoc TSA 2

Print Date: 6/13/2019 4:39 PM
User: Administrator
Test Date: 6/13/2019 4:39 PM

TSA 2 TEST REPORT

Patient Details
First Name: John
Last Name: Smith
Department: Department 1
I.D.: 12345678
Gender: Male
Date of Birth: 11/18/1982
Doctor name:
History:

Program Details
Probe: TSA 30x30
Method: Ramp and Hold
Designer: Administrator
Program Name: 1
Description:

Body Site
Main Site: T1
Side: Right
Specific Site: Upper Arm Medial

Test Results

Sequence	Destination	Baseline	Rate	Trials	Average	Variance	STD
1	50	32	6	3	50	100	10

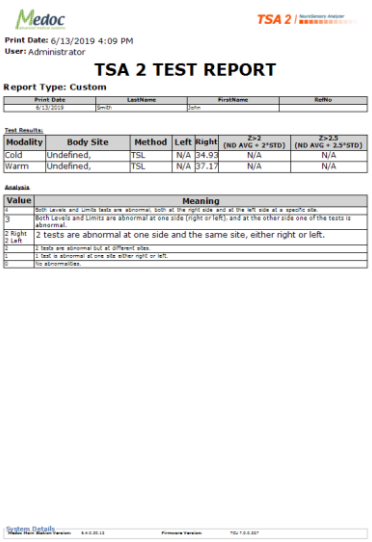
Pain rating

Sequence	Trial	Destination	Rating
1	1	45	50
1	2	45	60
1	3	45	40

Comments

System Details

Figure 110: Pain Rating Report



Medoc TSA 2

Print Date: 6/13/2019 4:09 PM
User: Administrator

TSA 2 TEST REPORT

Report Type: Custom

Print Date	LastName	FirstName	RefNo
6/13/2019	Smith	John	

Test Results:

Modality	Body Site	Method	Left	Right	Z>2 (ND AVG + 2*STD)	Z>2.5 (ND AVG + 2.5*STD)
Cold	Undefined,	TSL	N/A	34.93	N/A	N/A
Warm	Undefined,	TSL	N/A	37.17	N/A	N/A

Analysis

Value	Meaning
4	Both Levels and Limits tests are abnormal, both at the right side and at the left side at a specific site.
3	Both Levels and Limits are abnormal at one side (right or left), and at the other side one of the tests is abnormal.
2 Right 2 Left	2 tests are abnormal at one side and the same site, either right or left.
1	1 tests are abnormal but at different sites.
1	1 test is abnormal at one side either right or left.
0	No abnormalities.

System Details

Figure 111: Custom Report

11. System Settings

This chapter describes the available system settings options.

The available system configuration options depend on the user authorization level (see section 11.1.6)

11.1 Software Settings

The Software Settings menu includes communication setup, user interface and preferences and user management (authorization levels).

To access the software settings options, from the top menu bar, select **Settings** and then **Software Settings**.

Figure 112: Open Software Settings

11.1.1 Communication

Connect, disconnect, and configure communication settings between the system and software.

To access communication settings: from the top menu bar, select **Settings** and then **Software Settings**. In the Software Settings window that opens, select the **Communication** tab. The following window is displayed:

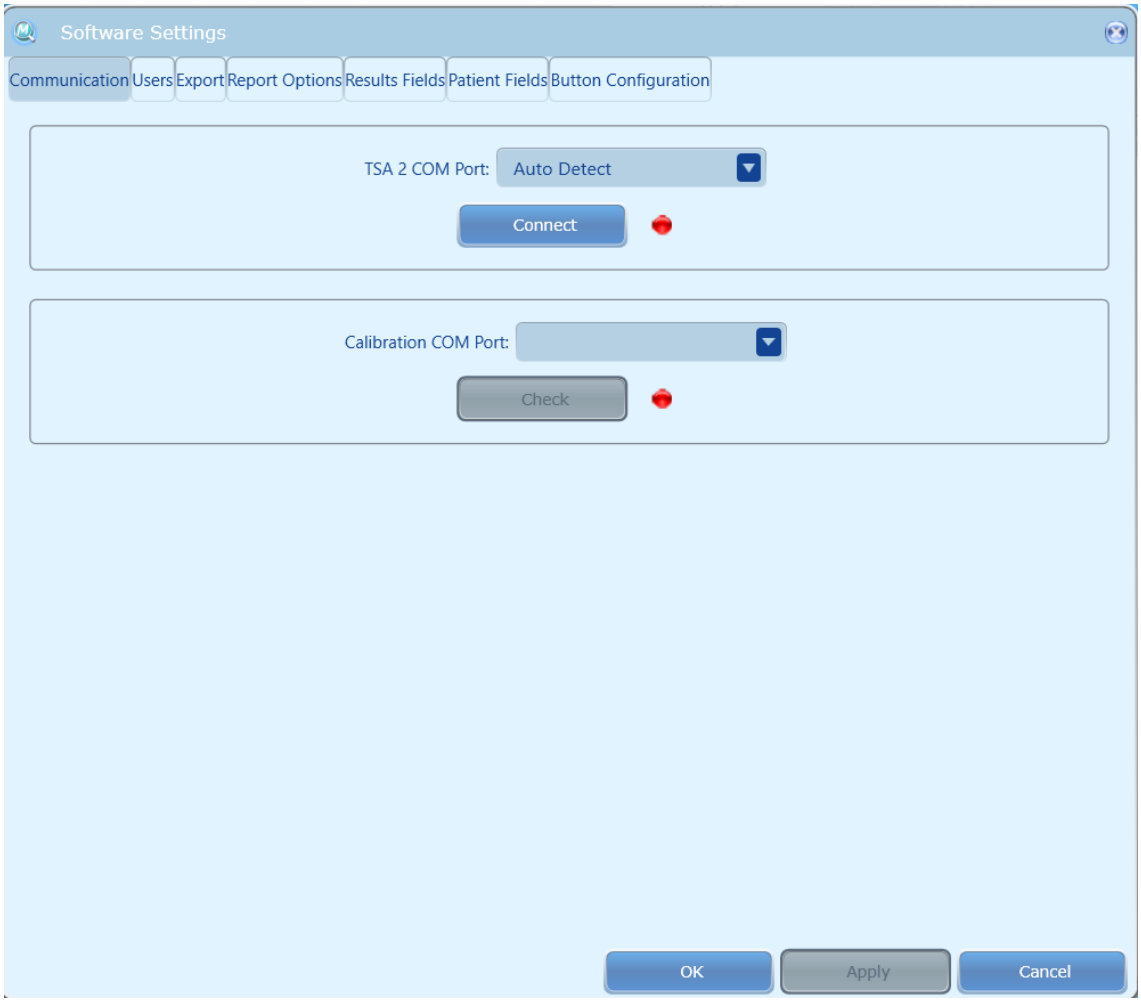


Figure 113: Communication Tab

Set up Communication with TSA 2

1. Select the COM port from the TSA 2 COM Port list:
   1.1. Auto Detect – automatically scan all available ports
   1.2. COM "X" – select the specific COM port TSA 2 is connected to. Select this option if you already know the Port number or the "Auto Detect" option has failed.
   1.3. Simulator – Work in Demo Mode. Medoc Main Station will NOT be connected to the TSA 2 system.
2. Click the connect button to establish communication

Set up communication with Thermometer (for calibration only)

This option only checks which port the thermometer is connected to. Communication is established only when the calibration procedure is started (see Technical Reference Service Manual for more information about the calibration procedure).

11.1.2 Report Options

Configure the appearance of test reports and customized report templates.

To access Report Options: from the top menu bar, select **Settings** and then **Software Settings**. In the Software Settings window that opens, select the **Report Options** tab.

The following screen is displayed:

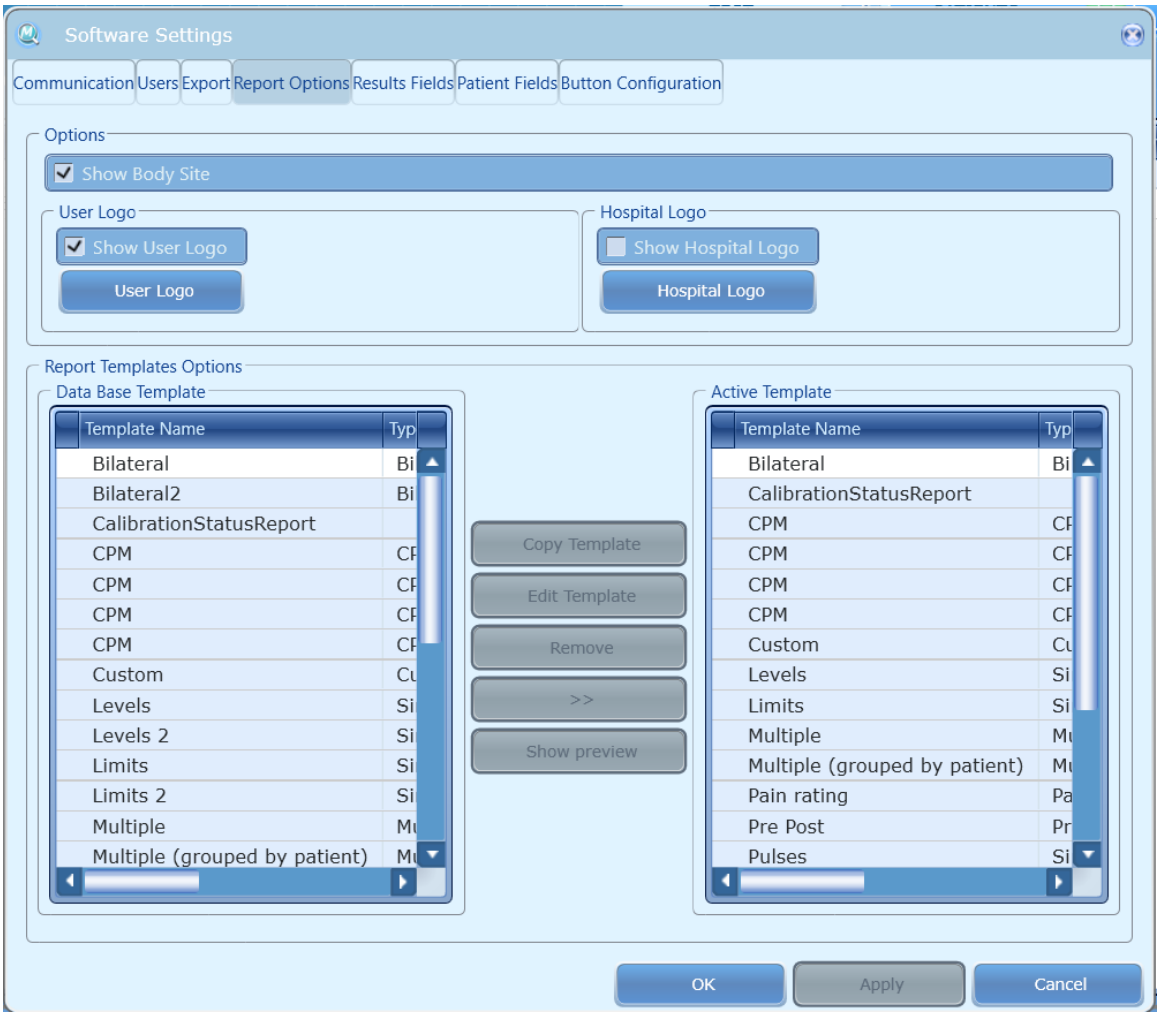


Figure 114: Report Options Tab

General Options

1. Show body site – show / hide body site image in the report. Check or uncheck the checkbox on the left and click the Apply button to save changes.
2. User Logo – Add institution logo to reports. To add a user logo:
   2.1. Click the User Logo button
   2.2. Select the picture to upload.
   2.3. To remove the user logo, unselect the Show User Logo checkbox. Click the Apply button to save the changes.
3. Hospital Logo – Add Hospital logo to reports. To add a Hospital logo:
   3.1. Click the Hospital Logo button
   3.2. Select the picture to upload.
   3.3. To remove the Hospital logo, unselect the Show Hospital Logo checkbox. Click the Apply button to save the changes.
4. To remove the user logo, unselect the Show User Logo checkbox. Click the Apply button to save the changes.
5. Show preview – enables to see preview for each report type

11.1.2.1 Report Templates

Each test method has a unique report template which is used to generate the **Singles** report option. In addition, there are templates for the comparative reports such as **Pre-Post**, **Trend**, **Multiple** and etc. The following section explains how to apply a customized report template.

The templates have the following properties: Template Name, Report Type, Applicable Test Methods, and Custom (whether or not the report is a customized report).

The report templates are separated into two lists:

1. Database Templates – List of templates saved in the database. The database can have more than one template per Report type and/or Method
2. Active Templates – List of currently active templates used to generate test reports. There can only be one active template for each Report Type and Method.

Add a Customized Report Template to the Database:

1. From the list of database templates in the bottom left panel of the report generator window, select the template you want to base the customized template on.
2. Click the **Copy Template** button to create a copy of the template.
3. Name the copied template
4. Select the copied template and click the **Edit Template** button
5. The report editor will open
6. Make the required changes in the template. Alternatively, to import and pre-made report template, from the top menu of the report editor, select file, then open report and open the report template to import
7. Close the editor after (there is no need to save the template, the changes are automatically saved in the database)

Replace an Active Template with a customized Template:

1. Select the required template from the database templates and click the “Move Right” button

   >>

2. The template will be copied to the Active templates list and replace the current active template for the same Report Type and Method.

Editing a report template requires some basic programming skills and knowledge of the database structure. Contact Medoc Support for further assistance if needed.

The built-in report templates cannot be edited. To create a customized template based on a pre-existing template, create a copy of the template and edit the copy.

11.1.3 Results Fields

Configure the fields that will be visible in the results table. The available fields include patient data, program data and test information.

To access Results Field settings: from the top menu bar, select **Settings** and then **Software Settings**. In the Software Settings window that opens, select the **Results Fields** tab. The Following screen is displayed:

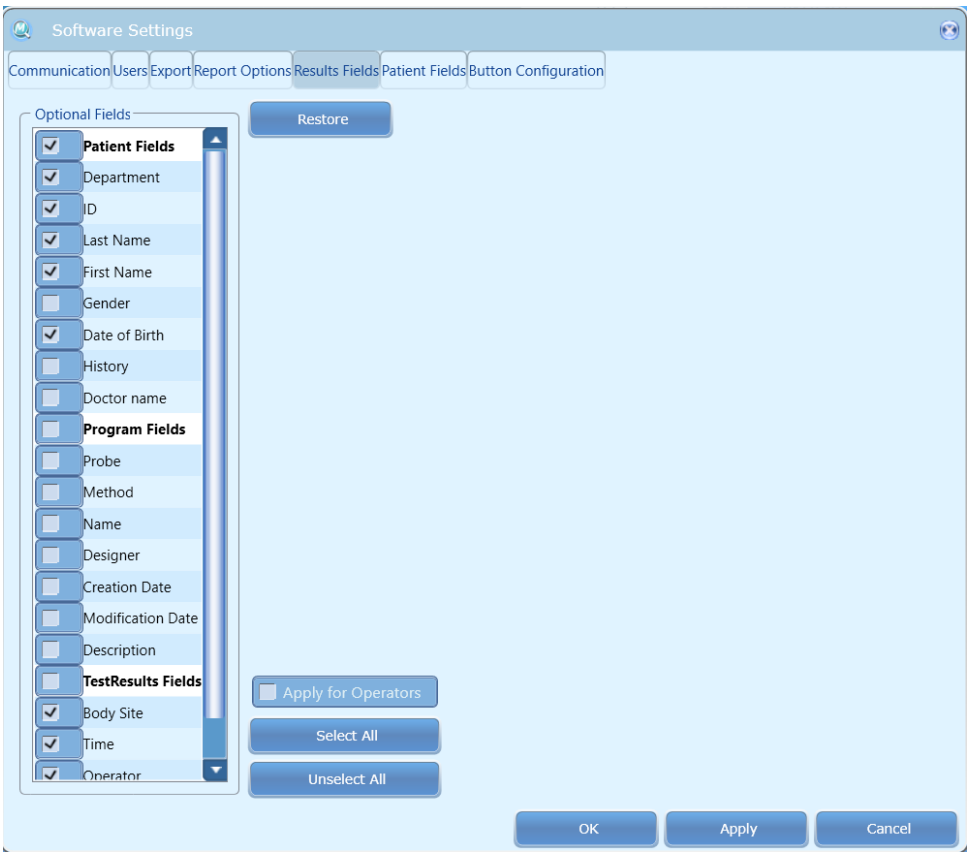


Figure 115: Results Fields Tab

1. To add fields to the Results Table, select the required fields from the Optional Fields List on the left and click the Apply button

To restore the default results field settings, click the Restore button

11.1.4 Patient Fields

Configure the available fields for patient records and determine which fields will be displayed in the patient list. The fields can be configured separately per user (see section 10.1.6).

To access Patient Field settings: from the top menu bar, select **Settings** and then **Software Settings**. In the Software Settings window that opens, select the **Patient Fields** tab. The following window is displayed:

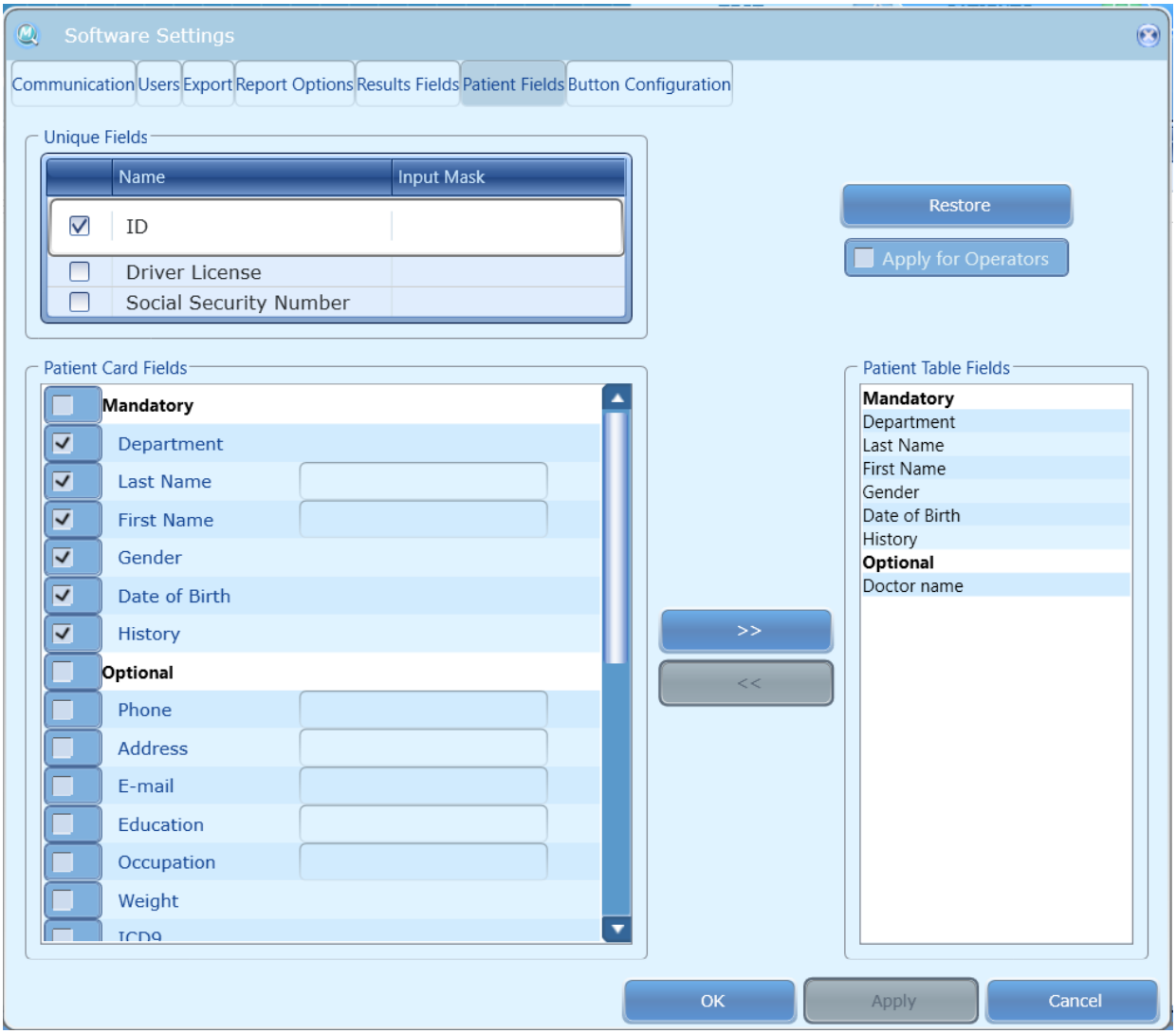


Figure 116: Patient Fields Configuration Screen

The available options are described in the table below:

Table 23: Patient Fields

Parameter	Description
Unique Fields	Used for conclusive patient identification (more than one can be selected). These fields must be unique per patient. Two or more patients cannot have the same value in a unique field.
Patient Card Fields	Fields that appear in the patient editor when creating or editing patient records. To add or remove fields from the patient records select or unselect the check boxes on the left respectively. 1. Mandatory fields – used for patient identification and cannot be deleted (unselected) 2. Optional fields – commonly used fields (can be edited) 3. User Defined fields – customizable fields
Patient Table Fields	Fields that appear in the patient list (table). Only fields which appear in the patient card can also be displayed in the list. 1. To add fields from the patient card to the patient table select the fields from the patient card list and click the Move Right button >> 2. To remove fields from the patient table, select the fields from the patient table list and click the Move Left button <<

To apply changes to the Patient Field Settings, click the Apply button Apply

To restore the default Patient Field Settings, click the Restore button Restore

11.1.5 Button Configuration

Configure the behavior of the “New Test” button at the end of a test.

The New Test button closes the Test Screen and return to the Test Navigator. By default, it does not clear the selected Patient, Program or Body site. It is possible to configure the button to clear all or part of the above selections.

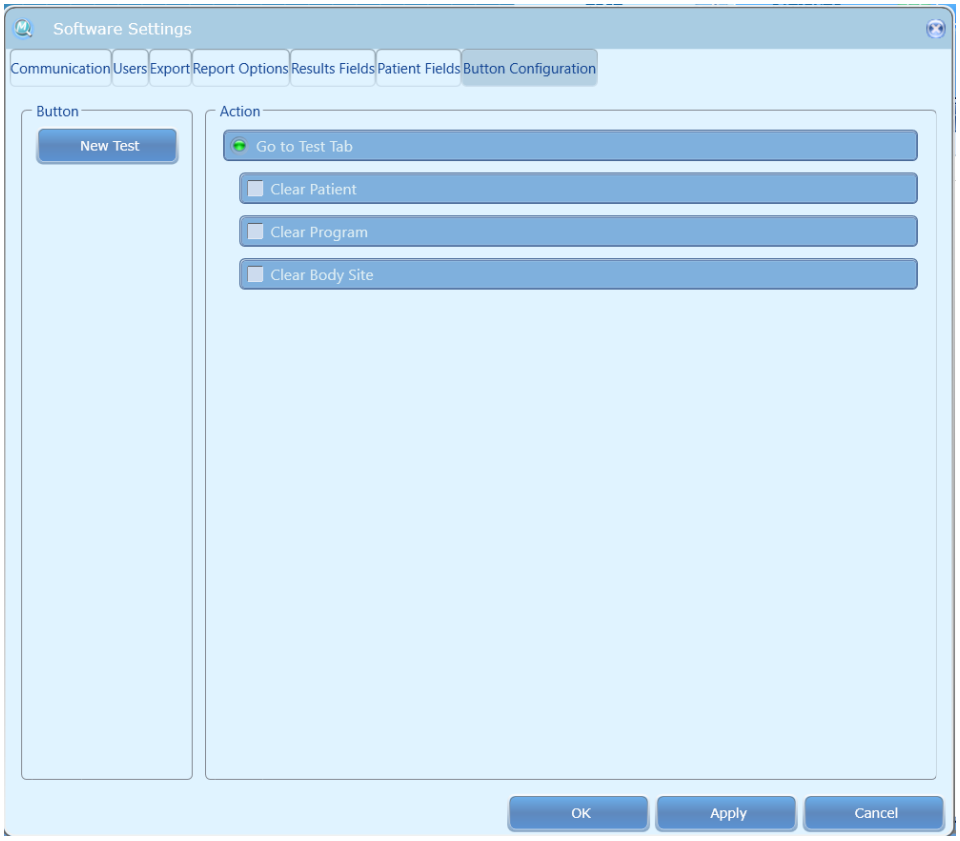


Figure 117: Buttons Configuration Tab

To access Button Configuration option: from the top menu bar, select **Settings** and then **Software Settings**. In the Software Settings window that opens, select the **Button Configurations** tab.

Select which actions should be taken when the **New Test** button is pressed and click the **Apply** button to save the changes.

11.1.6 Users

User management enables you manage and restrict the access of specific users to certain features of the software. For example, restrict a test operator from accidently deleting patient records.

There are four available authorization levels: Software Administrator; Biomedical Engineer; Medical Supervisor and Operator.

See Table 24: Authorization Parameters for a list of the main functions allowed or restricted according for each user level.

To access the User Management Configuration option: from the top menu bar, select **Settings** and then **Software Settings**. In the Software Settings window that opens, select the **Users** tab.

11.1.6.1 Add/Remove Users

1. Click the add user button at the bottom of the user list.
2. Enter the relevant information, according to the table below.
3. From the **Change role** drop-down menu, select the required authorization level.

4. If you want to change the user's authorization level, select the required user from the list; then from the **Change role** drop-down menu, choose the required authorization level.
5. Click the **Apply** button to save changes.
6. To remove a user from an authorization list, click the remove button.

The following table describes the fields for creating a new user:

Table 24: Authorization Parameters

Parameter	Description
User Name	User name used to log on to the Main Station and differentiate from other users.
Last Name / First Name	The users full name
Change Role	Select the authorization level for the user
New Password	Set a password for the user to use when logging on to the Main Station
Confirm Password	Password confirmation field.

A user cannot create new users with an authorization level higher than his/her own authorization level.

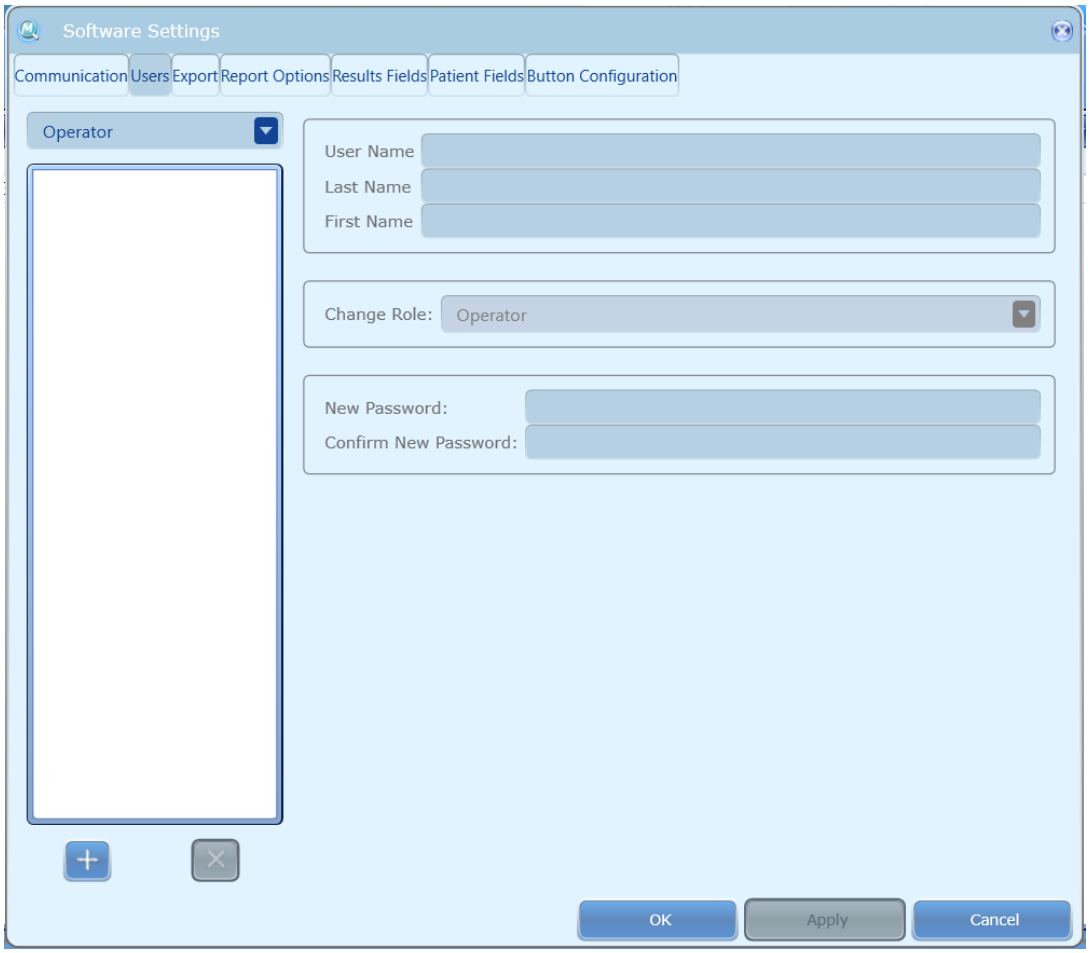


Figure 118: User Authorization Software Settings

11.1.6.2 Allowed functions according to authorization level

The following table lists the main functions and operations available in Medoc Main Station software and specifies which functions are available for each user authorization level.

Table 25: Functions according to authorization level

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
Patient	Add Patient	√	√	√	√
	Edit Patient	√	√	√	√
	Delete Patient	√	✗	√	X
	Add Department	√	√	√	√
	Delete Department	√	✗	√	✗
	Rename Department	√	✗	√	✗

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
Programs	Add Program	√	√	√	✗
	Edit Program	√	√	√	✗
	Delete Program	√	√	√	✗
	Duplicate Program	√	√	√	✗
	Program Preview	√	√	√	√
Results	View Graph	√	√	√	√
	View Program Details	√	√	√	√
	Delete	√	✗	√	✗
Test	View Patient Details	√	√	√	√
	View Program Details	√	√	√	√
	Clear	√	√	√	√
	Go to Test…	√	√	√	√
Tool bar - File	Export	√	√	√	√
	Import	√	√	√	√
	Export to Excel	√	√	√	√
	Print	√	√	√	√
	Log Off	√	√	√	√
	Exit	√	√	√	√
Tool bar - View	Test	√	√	√	√
	Patient	√	√	√	√
	Programs	√	√	√	√
	Results	√	√	√	√
Tool bar - Settings	**Software Settings**				
	communication				
	Connect/Disconnect	√	√	√	√
	Change COM	√	√	√	√
	Patient's fields				

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	View	√	√	√	√
	Edit	√	√	√	X
	Results fields				
	View	√	√	√	√
	Edit	√	√	√	X
	Report options				
	View	√	√	√	√
	Edit	√	√	√	X
	Buttons configuration				
	View	√	√	√	√
	Edit	√	√	√	X
	Authorization				
	View	√	√	√	√
	Add	√	√	√	X
	Edit	√	√	√	X
	Delete	√	√	√	X
	Hardware Settings				
	General				
	View	√	√	√	√
	TTL out Pulses duration (msec)	√	√	√	X
	TTL Polarity	√	√	√	X
	TTL Diagnostic	√	√	√	√
	Enable Thermode	√	√	√	X
	Rest Mode temp.	√	√	√	X
	% duration …	√	√	√	X
	Safety				
	View	√	√	√	√

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	Edit	✗	✗	✗	✗
	Thermode				
	View	√	√	√	√
	General	√	√	√	✗
	Edit LUT tables	√	√	✗	✗
	Manual calibration	√	√	√	✗
	Automatic calibration	√	√	√	√
	CoVas (calibration)	√	√	√	
	View	√	√	√	√
	Calibrate	√	√	√	√
	Test settings				
	Test configuration				
	View	√	√	√	√
	Edit	√	√	√	✗
	4-bit TTL configuration (disabled)				
	View	√	√	√	√
	Edit	√	√	√	✗
	Instruction Configuration				
	View	√	√	√	√
	Edit	√	√	√	✗
	Sound Configuration				
	View	√	√	√	√
	Edit	√	√	√	√
	Body Sites				
	View	√	√	√	√

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	Edit	√	√	√	X
	Events Marker				
	View	√	√	√	√
	Edit	√	√	√	X
	language	√	√	√	√
	status				
	Demo	√	√	√	√
	On-line	√	√	√	√
Tool bar - Utilities	**Test Instructions**	√	√	√	√
	Department				
	View	√	√	√	√
	Edit	√	√	√	X
	Normative data				
	View	√	√	√	√
	Edit	√	√	√	X
	Delete	√	√	√	X
	Import/Export	√	√	√	X
	Black Box				
	Software				
	View	√	√	√	√
	Export	√	√	√	√
	Hardware Settings				
	View	√	√	√	√
	Export	√	√	√	√
	Device Recovery	√	√	√	X
	Automatic Calibration	√	√	√	√
	Calibration Check	√	√	√	√

11.2 Hardware Settings

The Hardware Settings menu includes all hardware configurations including TTL IN/OUT configuration, Thermode Calibration and CoVAS configuration.

To access the hardware settings options, from the top menu bar, select Settings and then Hardware Settings. The TSA 2 needs to be **ON** and **connected** to the computer in order to access the hardware settings menu.

Figure 119: Open Hardware Settings

11.2.1 General Hardware Configurations

Configure TTL polarity and duration, Enable Thermodes and other general hardware settings.

To access general hardware settings: from the top menu bar, select **Settings** and then **Hardware Settings**. In the Hardware Settings window that opens, select the **General** tab. The following window is displayed:

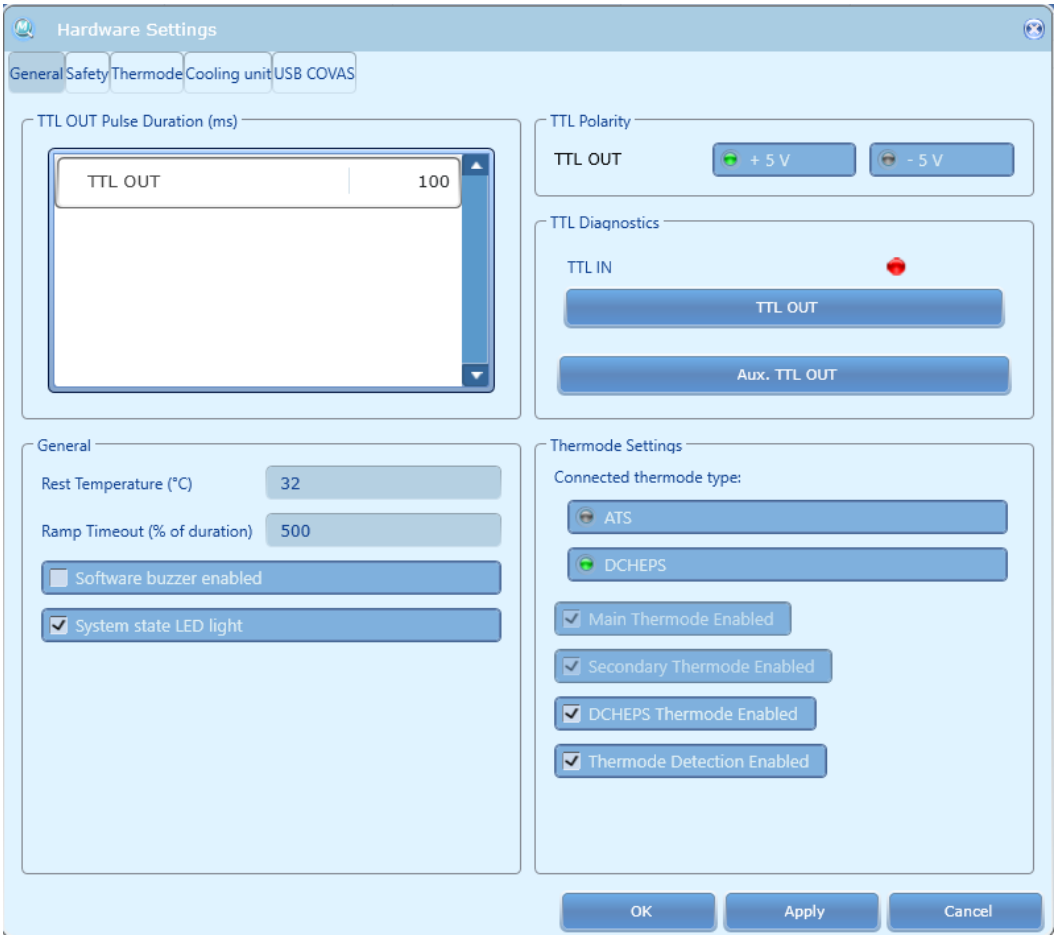


Figure 120: HW Settings - General Tab

11.2.1.1 TTL Configuration

1. **TTL Pulse Duration:**
   1.1. Configure the duration of the TTL OUT (1-bit) and Auxiliary TTL OUT. The allowed range is: 50 – 1000 msec.
2. **TTL Polarity:**
   2.1. **TTL OUT:** Configure the Polarity of TTL OUT pulse: 5V or (-)5V. For 5V: The TTL is 0V when Idle and 5V when triggered. For (-)5V: The TTL is 5V when Idle and 0V when triggered.
   2.2. TTL IN: The polarity of the TTL IN does not need to be configured. TSA 2 will automatically detect if it is 5V or (-)5V.
3. **TTL Diagnostics:** Manually generate a TTL OUT (1-bit), an Auxiliary TTL word to test the configuration. To test TTL-IN setup, send a TTL to the system and check of the TTL-IN indicator turns on.

*Click the Apply button to apply changes.

11.2.1.2 General Hardware Configurations:

Rest Temperature – The temperature of the Thermode when the system is in Rest Mode (not running a test or in Safe Mode). The allowed range is 20-40 °C.

Warning! The parameters described below effect the performance of the Thermodes. Medoc recommends not to change the default values unless you are absolutely sure it is required

Ramp Timeout (% of duration) - If Ramp temperature continues to be detected beyond this setting, an error message is displayed. The test is not aborted. Default value is 200%.

Peak Detection Delay (samples) – peak detection is used when a standard event of type 'peak' is used. This parameter can be adjusted if the timing of the event and the actual peak are not synchronized. The default value is 30.

Dynamic Factor–this parameter is currently not in use.

Software Buzzer Enabled – the software buzzer informs the system operator of an occurrence that requires his or her attention by sounding an alert sound (computer speakers are required). This safety measures enables the operator to be aware of the system status even while not observing the screen. To enable or disable this option, select or unselect the checkbox. Default option is enabled.

System state LED light- the LED light informs the system operator on the system state (see 3.3) To enable or disable this option, select or unselect the checkbox and click "Apply".
Default option is enabled.

11.2.2 Safety

The safety limits and parameters can be viewed from Safety tab in the hardware settings menu. Safety parameters include the limits on duration of stimulus according to temperature, self-test parameters and parameters for the safety tab displaying the software temperature time limitations which are allowed according to the program safety regulations. In addition, is presents a list of the self-tested parts, and built-in test (BIT) parameters.

The values in this tab can only be read, and cannot be edited.

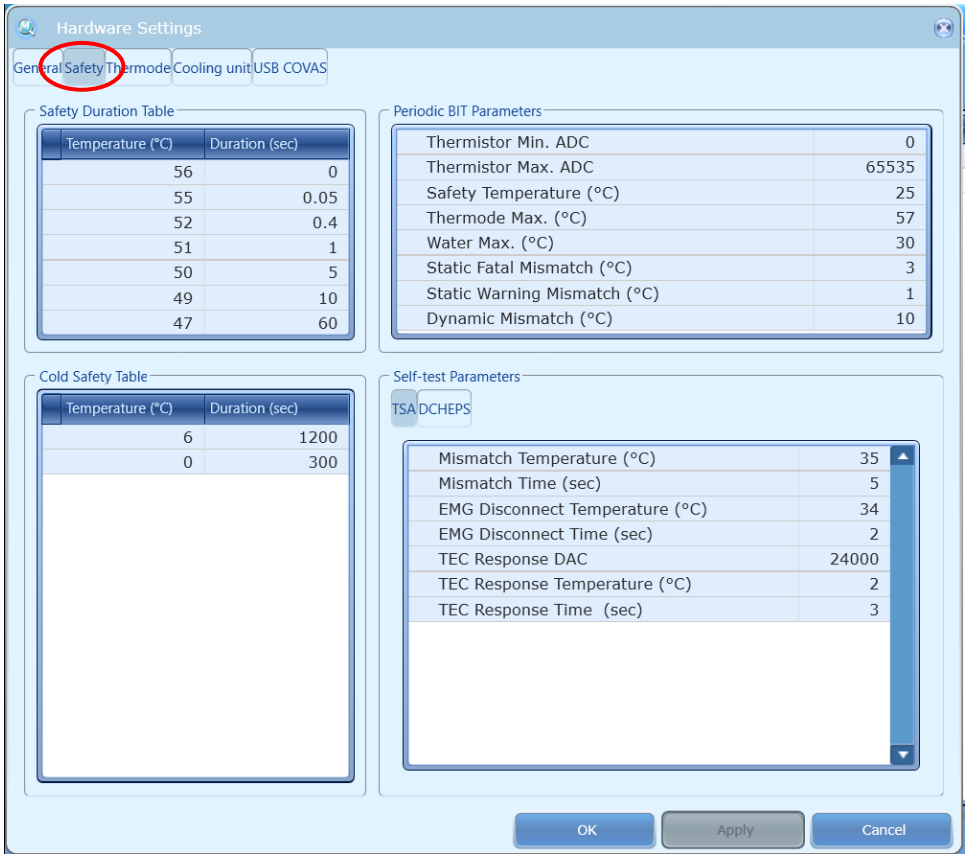


Figure 121: Hardware Settings – Safety Tab

11.2.3 Thermode

All Thermode management actions including adding or removing Thermode information and calibration data can be performed from the Thermode tab in Hardware Settings. ATS and dCHEPS modes provide access to the respective Thermode types per the Thermode mode. Refer to the Thermode Management and Thermode Calibration sections in the Service Manual for further instructions.

Figure 122: Hardware Settings – Thermode Tab for each of ATS and dCHEPS modes

11.2.4 **CoVAS Calibration**

Calibrating the CoVAS ensures the CoVAS range 0 to 100 corresponds with the left most and right most point of the slider, respectively.

Calibrate the CoVAS before the first time it is used

<u>The CoVAS should be calibrated when:</u>

- It is used for the first time

- Software or firmware are re-installed

To Calibrate the CoVAS:

1. From the Settings menu, select the Hardware Settings option.
   Select the **CoVAS** tab. The following screen is displayed:

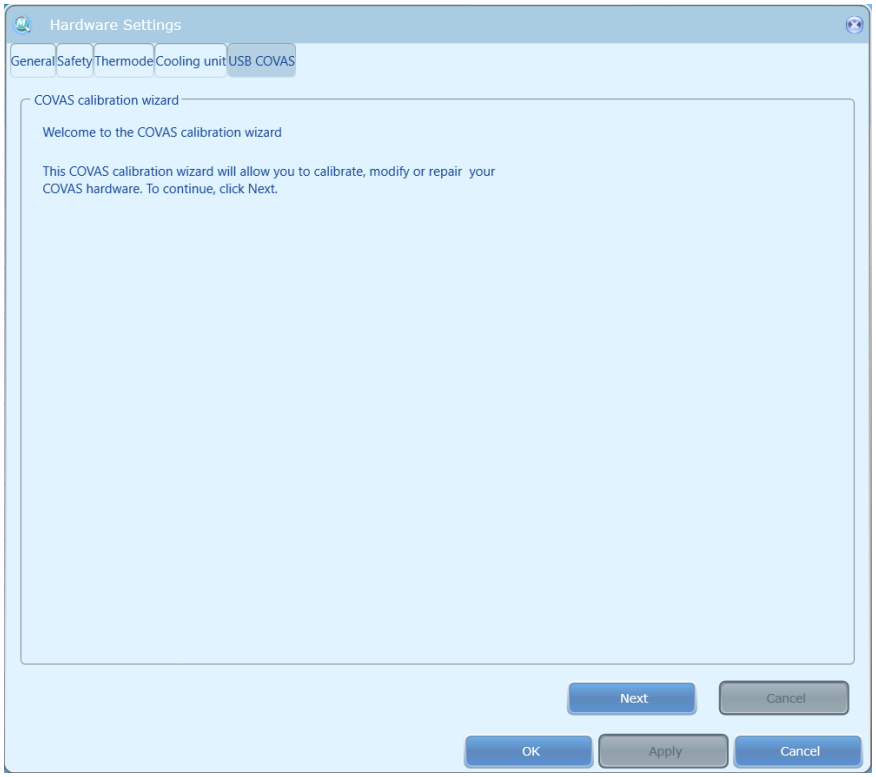


Figure 123: Hardware Settings - CoVas Calibration

2. Click the **Next** button and follow the instructions shown on screen (a short version is given here)
3. Move the **CoVAS** slider all the way to the left and click the **Next** button.
4. Move the **CoVAS** slider all the way to the right and click the **Next** button.
5. Click **Next** to save the calibration results.
6. Click the **Finish** button to complete the calibrating process; then click OK.

11.3 Test Settings

The Test Settings menu includes settings and preferences which affect how the tests are performed and displayed.

To access the test settings options, from the top menu bar, select **Settings** and then **Test Settings**. See Figure 125: Test Configuration Settings.

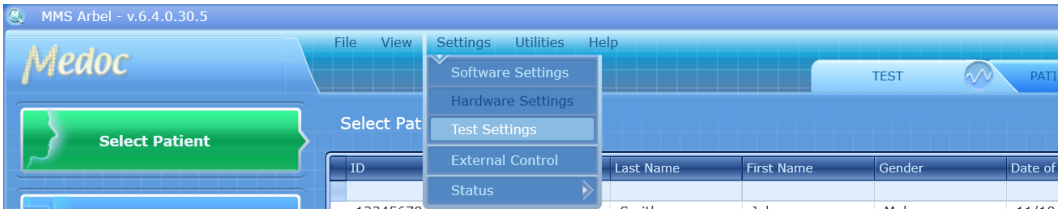


Figure 124: Accessing test settings

The following settings can be accessed from the Test Settings menu:

Test display– change how the test is performed and displayed

Event Marker – configure the F2-F10 keys for marking events

Event Sounds – configure the sounds used for the different standard events

Body Sites – customize list of body sites.

Test Instructions – modify text and audio test instructions for the different program types

11.3.1 Test Configuration

Control test behavior and appearance.

To access the Test Configuration settings: from the top menu bar, select **Settings** and then **Test Settings**. In the Test Settings window that opens, select the **Test Configuration** tab. The following window is displayed:

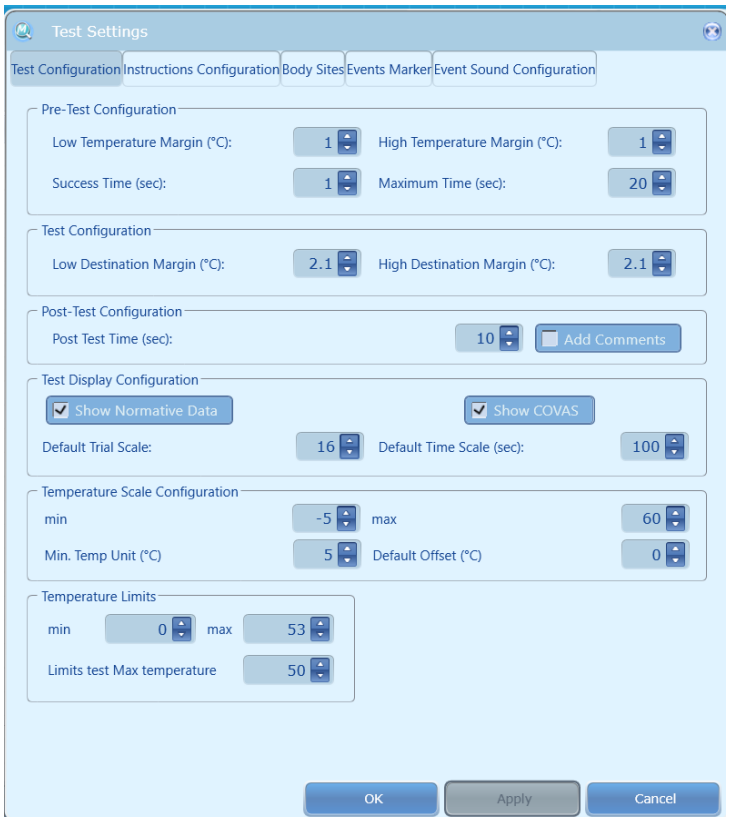


Figure 125: Test Configuration Settings

The following options are available:

11.3.1.1 Pre-Test Settings

Table 26: Pre-Test Parameters

Parameter	Description
Low Temperature Margin	The bottom margin for a stabilized temperature allowed for a successful pre-test.
High Temperature Margin	The top margin for a stabilized temperature allowed for a successful pre-test.
Success Time	The stabilized temperature duration, required to render a successful pre-test.
Maximum Time	The maximal time allowed for stabilizing trials (during the pre-test sequence).

11.3.1.2 Test Configuration

Table 27: Test Configuration Parameters

Parameter	Description
Low Destination Margin	The bottom margin, above which the system declares that it has ascended a high destination temperature.
High Destination Margin	The top margin, below which the system declares that it has descended to a low destination.

11.3.1.3 Post Test Configuration

Table 28: Post-Test Parameters

Parameter	Description
Post-Test Time	Post-test temperature stabilization is required by safety standards. This setup is used to add time for post-test monitoring.
Add Comments	When the Add Comments option is checked, a dialog box for adding comments to the test open when a test end. These comments will be displayed in the final report.
Save Automatically	When Save Automatically option is checked, results will be saved automatically at the end of each test.

11.3.1.4 Test Display Configuration

Table 29: Test Display Configuration

Parameter	Description
Show CoVAS	When checked, the CoVAS output graph is displayed, with the stimulation output graph by default. Can also be changed per test, from the Test View screen.
Show Normative Data	When checked, the Normative Data information graph is displayed, with the stimulation output graph by default. Can also be changed per test, from the Test View screen.
Default Trial Scale	Sets the trial scale of the output graph while using the Limits method. Can also be changed per test, in any Test View screen.
Default Time Scale	Sets the time scale of the output graph. Can also be changed per test, in any Test View screen.

11.3.1.5 Temperature Scale Configuration

Table 30: Temperature Scale Configuration

Parameter	Description
Temperature Scale Range	Sets the default limits for the test graph.
Minimum Temp Unit	Sets the minimum resolution of the grid
Default Offset	Sets the default offset temperature for using pulses method. A lower value than the default one results with a warning when validating pulses program.

11.3.1.6 Temperature Limits

Table 31: Temperature Limits

Parameter	Description
Temperature Limits	Sets the minimum and maximum temperature that is allowed during a test. This parameter does not replace the safety limitation of the TSA 2. It allows limiting the stimulus temperature to a specific range, according to unique requirements. In case the temperature violates the temperature limits, the following actions are taken by the TSA 2 system: Limits protocol: stimulus is terminated and temperature returns to baseline temperature, and then continues to the next trial. The terminated trial is marked with an asterisk. The terminated trial will be taken into consideration when calculating test statistics. Search protocol: the temperature does not exceed the allowed range, according to the temperature limiter. In case search temperature exceeds the allowed range, the test switches to the “pause” status and settles on the baseline temperature, until it is resumed. Temperature limiter is marked with an asterisk upon violation of the allowed range.

Parameter	Description
	Ramp & Hold Protocol: upon verifying a program the test parameters are checked according to the current temperature limiter. In case a temperature limit of a test parameter is violated, an error message indicating the violated parameter is displayed. Pulses Protocol: upon verifying a program, the test parameters are checked according to the current temperature limiter. In case a temperature limit of a test parameter is violated, an error message indicating the violated parameter is displayed.

11.3.2 Event Marker

Configure the keyboard keys, manual trigger button or patient response unit to mark events during a test.

To access Event Marker Configuration: from the top menu bar, select **Settings** and then **Test Settings**. In the Test Settings windows that opens, select the **Event Marker** tab. The following window is displayed:

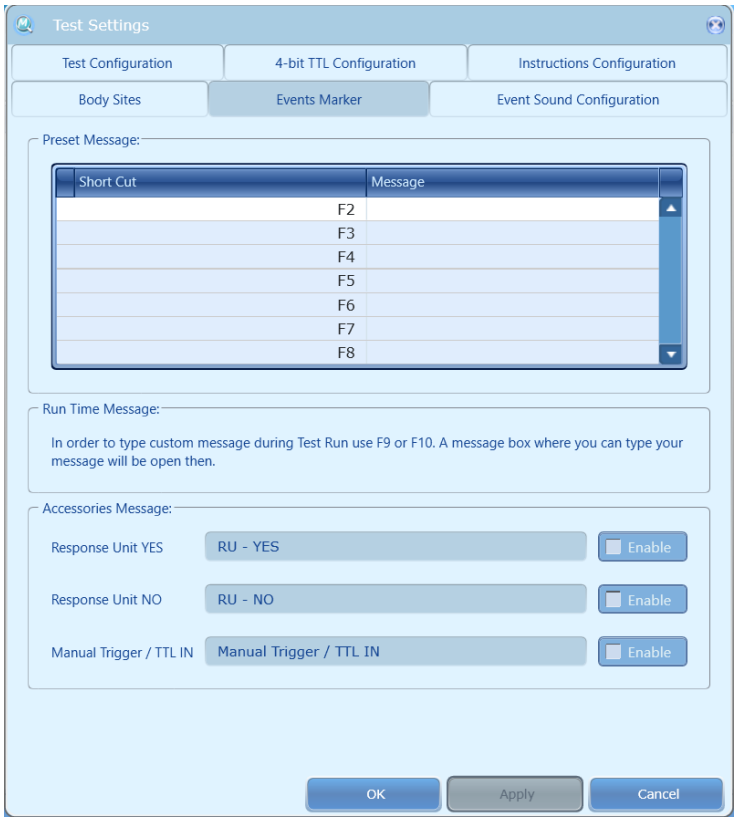


Figure 126: Event Marker

The Event Marker options enable you to mark specific events by adding messages that will be displayed during the test. The events are also saved with the test results and can be viewed in exported excel file.

There are three types of messages that can be added:

1. **Preset Messages** – F2 to F8 keys are used to mark an event and display a preset message during the test. To edit the present message, click the cell in the Message column beside the relevant key. Preset messages may contain Numbers, Letters and Symbols.

2. **Run Time Messages** – F9 or F10 keys are used to mark an event and display a message box for entering free text during the test. Press one of these keys and type the message in the dialog box. Use **Shift+Enter** to begin a new line when typing the message and **Enter** to save the message.
3. **Accessories Messages** - Change the text displayed when the patient response unit is pressed and/or the manual trigger is used. This option can be used in methods such as Ramp and Hold to indicate different sensations felt by the subject, for example.

11.3.3 Event Sound Configuration

Configure the sounds which will be played if a sound event is defined in a test.

To access the Event Sound Configuration settings: from the top menu bar, select Settings and then **Test Settings**. In the Test Settings window that opens, select the **Event Sound Configuration** tab. The following window is displayed:

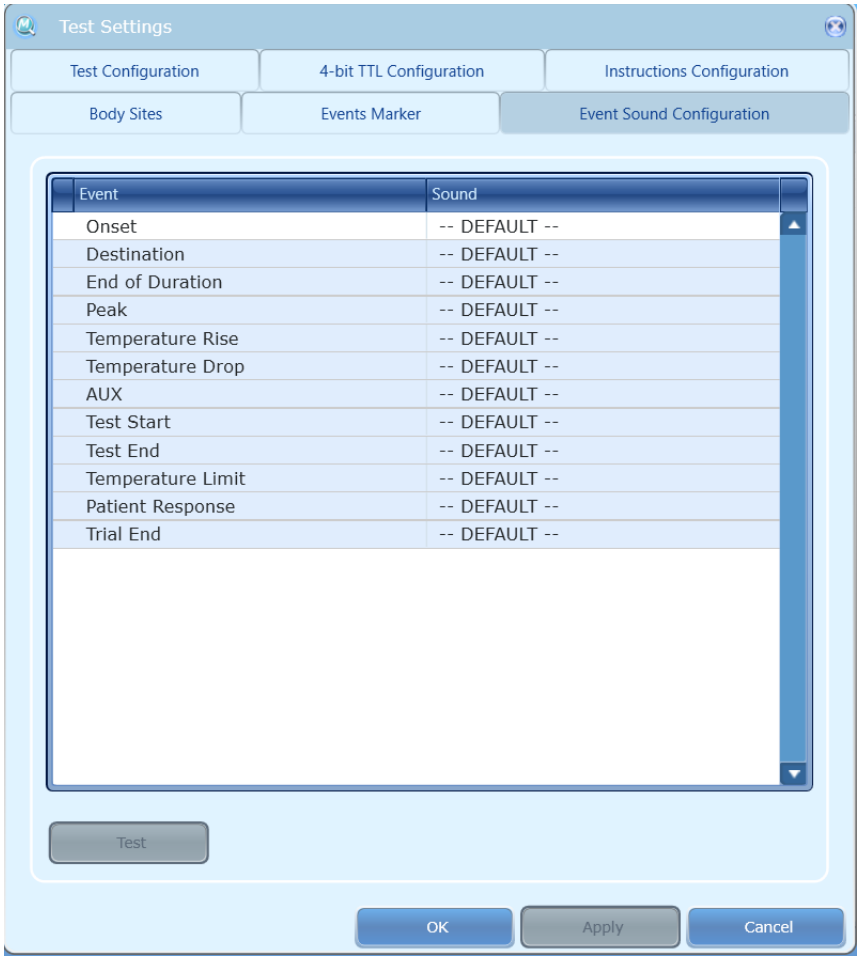


Figure 127: Event Sound Configuration

To change the sound for an event:

1. Click the cell in the right column of the event

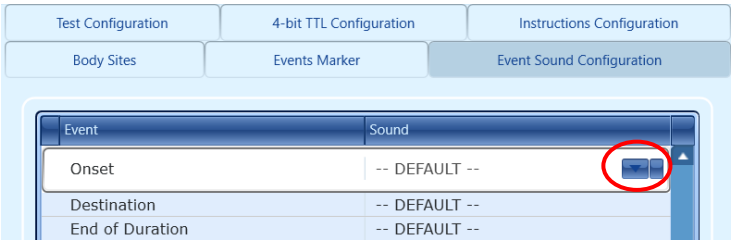


Figure 128: Change event sound

2. Click the arrow to view a list of available sounds from Medoc Main Station sound library or click the blank button to add your own.
3. Click the **Test** button to listen to the selected sound effect.

11.3.4 Body Site Editor

Customize the list body sites to select from when running a test.

To access the Body Sites editor: from the top menu bar, select **Settings** and then **Test Settings**. In the Test Settings window that opens, select the **Body Sites** tab. The following window is displayed:

Figure 129: Body Sites Editor

The Manufacturer Body Sites table lists the complete list of body sites (Dermatomic areas) available by default. The user Body Sites lists all body sites added by the user.

A body site is defined by the following parameters:

- Main Site – the dermatome area (C1…C8; T1…T12; L1…L5; S1…S5)
- Side – left or right
- Secondary Site – detailed description of the site (upper arm medial, leg anterior and etc.)
- Normative Data – a 'read-only' parameter which specifies whether the specific body site has normative data assigned to it. The parameter is changed automatically if normative data exists or is added for the site.

The following operations are available:

- **Export or import a list of body sites**– The list of body sites can be exported or imported from a excel file. To see the required configuration of the excel file required for import, export the manufacturer body sites list and use the same format. The user body site list can also be exported and important as an *.ats file for backup.
- **Hide body sites from list** – a hidden body site will not appear in the list when starting a test.
- **Add or remove body sites from the list of User Body Sites** – add, edit or remove body sites as needed to the user body sites list. User body sites will appear together with the manufacturer body sites for selection before performing a test.

11.3.5 Text and Audio Test Instructions

Edit the default text and audio test instructions which apply to each program type.

To access Test Instructions settings: from the top menu bar, select **Settings** and then **Test Settings**. In the Test Settings window that opens, select the **Instructions Configuration** tab. The following window is displayed:

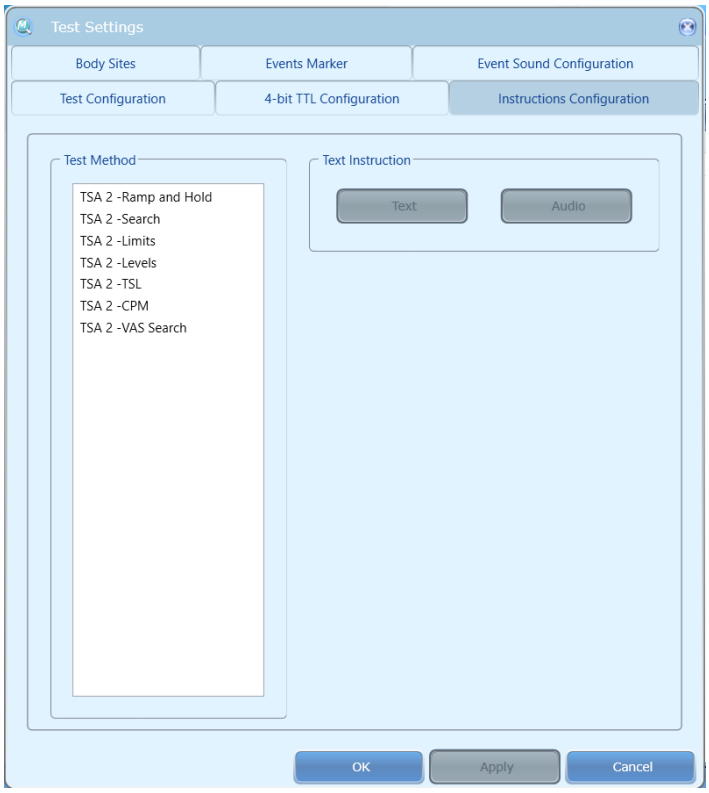


Figure 130: Instructions Configuration

11.3.5.1 Text Instructions

To edit the default text instructions for a test method:

Select the test method from the list on the left and click the **Text** button on the right. Edit the text in the test editor and save before closing the editor.

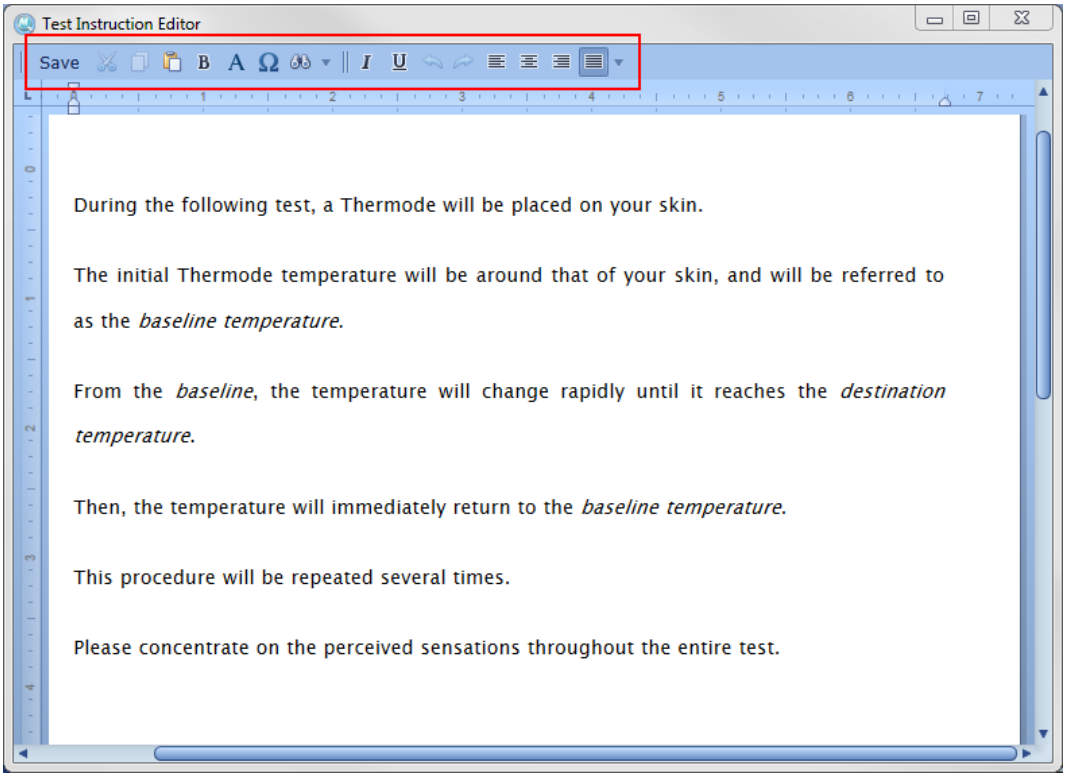


Figure 131: Test Instructions Editor

11.3.5.2 Audio Instructions

To add or change the default audio instructions for a test method:

To add audio instructions:

- Create an audio file of the instructions in one of the following formats:
  WAV, WMA, MP3
- Select the test method from the list on the left and click the **Audio** button on the right.
- Select the audio file and click open. The following dialog will open:

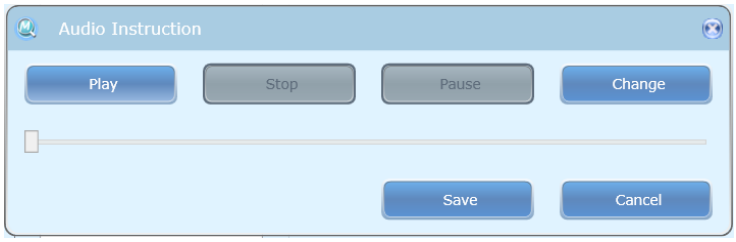


Figure 132:Audio Save Button

- Click the **Save** button.

To change existing audio instructions:

1. Select the test method from the list on the left and click the **Audio** button on the right.
2. Click Change to select a new audio file.

12. Thermode Management

This section explains how to conduct Thermode management actions such as creating new Thermode, loading and saving Thermode files, deleting Thermode and naming Thermode.

12.1 Managing Thermode

In order to manage Thermode activity, perform the following instructions:

1. Start the Medoc Main Station, and make sure that communication is established with TSA 2.
2. Go to **Settings→Hardware Settings→Thermode** tab.
   The following screen is displayed:

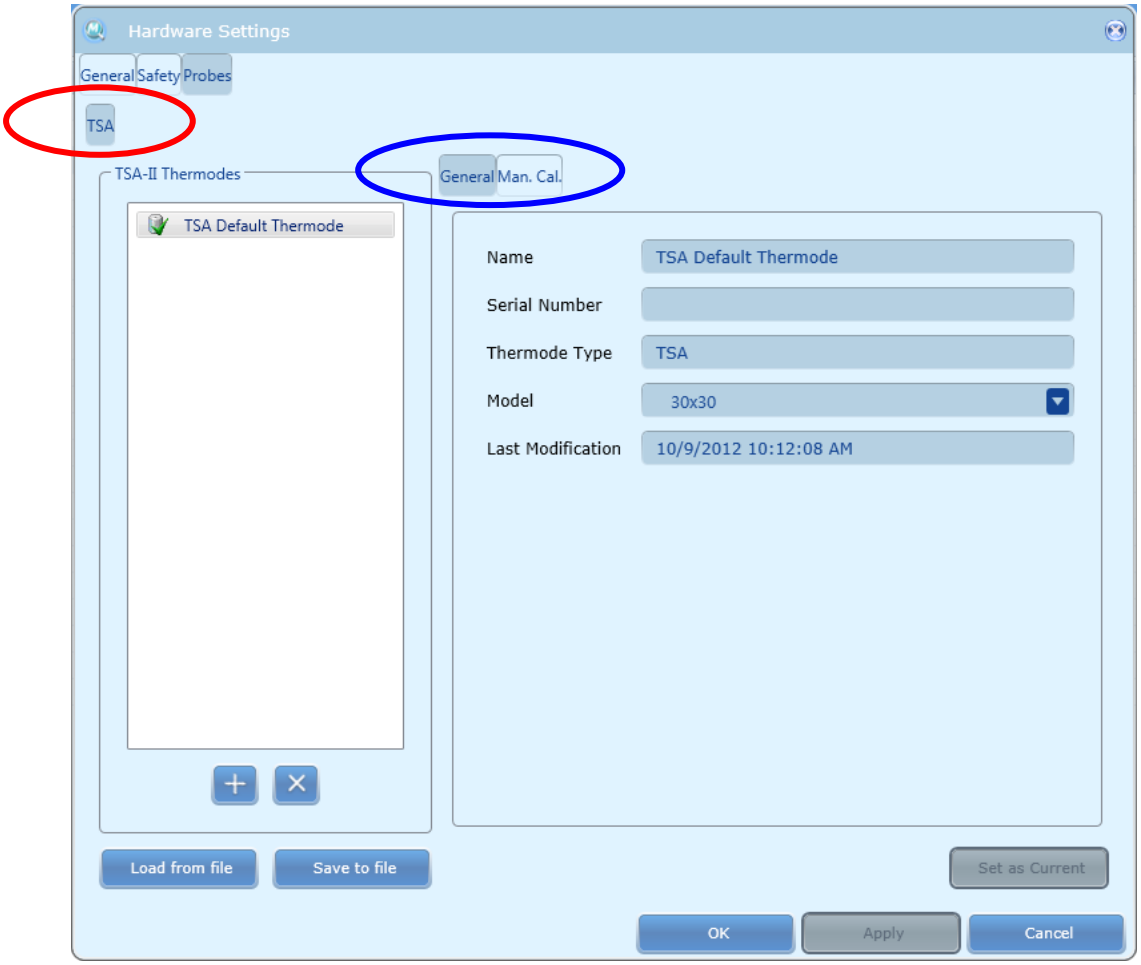


Figure 133: Hardware Settings – Thermode

a. To view and edit Thermode properties, use the tabs at the lower side of the screen (blue mark).

b. To perform Thermode calibration, refer to Appendix M – Calibration for a detailed explanation of the calibration procedure.

The Thermode list on the left side of the screen contains all the Thermodes saved in the Data Base.

The following functions are available under the General tab:

Table 32: General Tab Options

	Description
	Creates a new Thermode in the database.
	Deletes the Thermode from the database. It is not possible to delete a Thermode, when it is the only one in the list.
Load from file	Enables to load a saved Thermode (.thr) file from a selected location.
Save in file	Enables to save a Thermode (.thr) file to a selected location under selected name. Medoc recommends naming Thermodes with significant names.
Set as current	Loads the selected Thermode parameters.
Apply	Accepts the last changes that were made manually.
Cancel	Aborts changes, and exit the Hardware settings menu.

12.1.1 Creating new Thermode

Creating a new Thermode is required when a new Thermode model is in use.

To create a new Thermode, perform the following procedure:

1. Enter the Thermode management screen.
2. Select the required Thermode type.
3. Click the **Create New Thermode** button.
   The Select Model window is displayed.

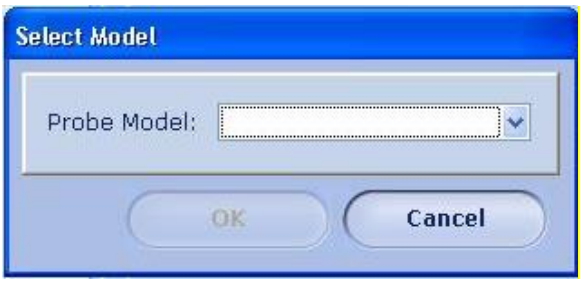


Figure 134: Select Thermode Model Dialog

4. From the drop-down list, select the required Thermode type.
   The following types are available in ATS mode:
   4.1. 30x30mm
   4.2. 16x16mm
   4.3. Intra oral

   CHEPS Thermode is available in dCHEPS mode.

5. Click the **OK** button.

6. Fill in the Thermode details: Name and Serial Number.
7. Click **Apply.**

Please note that once a Thermode is created, its type cannot be edited.

12.1.2 Delete a Thermode

Deleting Thermode is required when old Thermode is out of use.

To delete a Thermode, perform the following procedure:

1. Enter the Thermode management screen.
2. In the Thermode list on the left side of the screen, select the Thermode you wish to delete.
3. Click the **Delete Thermode** button.
4. At the prompt, confirm your action.

12.1.3 Saving Thermode file

Saving Thermode file is required in order to backup Thermode files or in case you wish to send the Thermode parameters that you use to another TSA 2 user. Thermode are saved into **.thr** files that can be read by Medoc Main Station only.

To save a Thermode file, perform the following procedure:

1. Enter the Thermode management screen.
2. In the Thermode list on the left side of the screen, select the Thermode you wish to save.
3. Click the **Save in file** button.
4. Browse to the location in which you wish to save the Thermode file.
5. Type a meaningful name (Thermode type, size, serial number) for the Thermode you wish to load, and click the **Save** button.

12.1.4 Load Thermode file

Loading Thermode file is required when restoring Thermode table from a backup file. The Thermode file contains of all Thermode data. Thermode files are **.thr** files, and can be read by Medoc Main Station only.

To load a Thermode file, perform the following procedure:

1. Enter the Thermode management screen.
2. Click the **Load from file** button.
3. Browse to the Thermode file you wish to load.
4. Select the Thermode file, and click the **Open** button.

12.1.5 Setting Thermode as Current

Setting Thermode as current is used when you wish to load the currently used Thermode parameters, according to Thermode type that is connected to the TSA 2 system.

To set a Thermode as current, perform the following procedure:

1. Enter the Thermode management screen.
2. In the Thermode list on the left side of the screen, select the Thermode you wish to use.
3. Click the **Set as current** button.

The Set as current Thermode has a mark at its left side. This symbol indicates that the parameters loaded to TSA 2 match the selected Thermode.

In case selected Thermode parameters do not match the TSA 2 Thermode parameters, a mark appears to its left. Positioning the cursor over the mark provides a floating message indicating the reason for the warning.

12.2 Thermode Properties

All Thermode properties can be displayed from the Thermode tab. Thermode parameters can vary according to the Thermode sensors type.

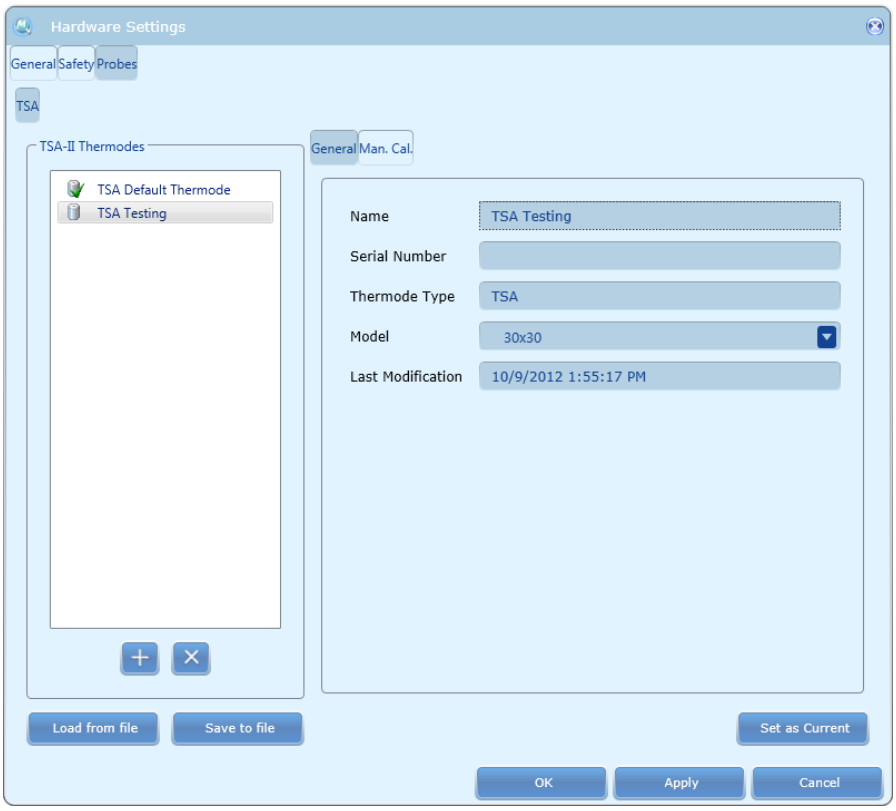


Figure 135: Thermode properties

12.2.1 General

The General tab displays the Thermode identification details.

Table 33: Thermode Identification Details

	Description
Name	The Thermode name, according to user selection. It is advisable to use meaningful names.
Serial Number	The Thermode serial number.
Thermode Type	The selected Thermode type (TSA).
Model	The Thermode model, according to selection.
Last Modification	The date when the Thermode properties were last updated.

13. System Information and Logs

System information includes license information, software and firmware version numbers, supported Thermodes or probes, software and hardware logs, and computer information. Some or all of the system information may be required by Medoc for troubleshooting or service.

13.1 View System Information

To view the license information, software and firmware versions, and supported Thermodes: From the top menu bar select **Help** and then **About…**

Alternatively, information about all your systems can be viewed from the **Options** Menu in the Opening screen.

Software log files and system black-box can be accessed from the top menu bar **Utilities** option. Software logs record all software operations at all times and can be accessed from the **Log Files** option in the Utilities menu. Hardware logs (black-box) are recorded only in case a safety or hardware error has occurred. The logs include important information about the hardware status immediately before and after the error occurred. The black box logs can be accessed from the **Black Box** option in the utilities menu.

13.2 Retrieve Full System Information

In order to retrieve full system information if required for service:

From the top menu bar select **Help** and then **About…**

In the window that opens click the **Sys info** button, select a location to save the file and click **Ok**. A sys info file will be created in the selected save location. Send this file to your Medoc service representative if required.

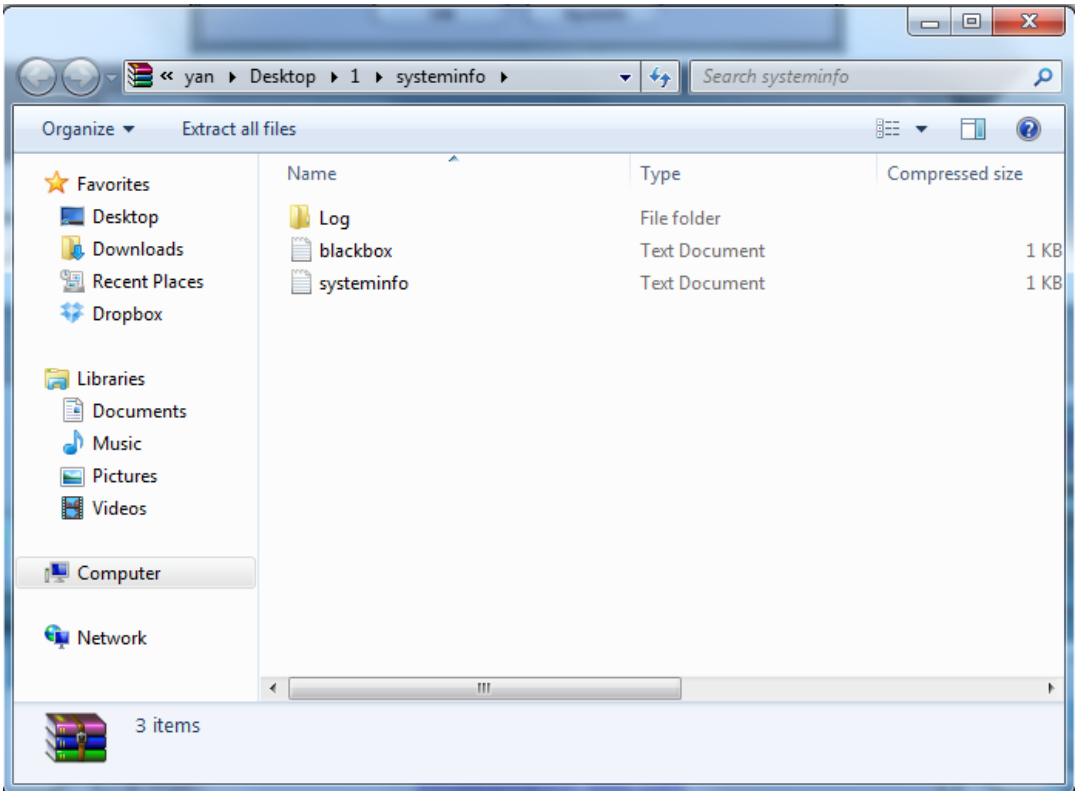


Figure 136: Sysinfo File Sample

14. Accessories

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.

Table 34: Accessories

Description	Cat. No.	
TSA 2 Thermode Standard 30mm x 30mm This is the standard thermal probe, which is capable of heating the skin. Used on large body sites.	AS 00176	

Description	Cat. No.	
TSA 2 Thermode – 16mm x16mm This is the thermal probe, which is capable of heating the skin.	AS 00177	
TSA 2 Thermode 30 mm × 30 mm fMRI The Thermode is MRI Conditional, made of non-magnetic / low magnetic components. The Thermode has an extended cable length of 12.5 meters to allow the required distance between the device, which is located outside the MRI room and the active side of the Thermode attached to the subject. This option requires the use of an EMI filter, for preventing magnetic and RF noises in an MRI environment, which may be caused by the Thermode. Includes d-type adapter and control room cable	AS 00178	

Description	Cat. No.	
TSA 2 Thermode 16 mm × 16 mm fMRI The Thermode is MRI Conditional, made of non-magnetic / low magnetic components. The Thermode has an extended cable length of 12.5 meters to allow the required distance between the device, which is located outside the MRI room and the active side of the Thermode attached to the subject. This option requires the use of an EMI filter, for preventing magnetic and RF noises in an MRI environment, which may be caused by the Thermode.	AS 00179	
TSA 2 Thermode Intra oral / clitoral)	AS 00185	
TSA 2 Thermode CHEPS	AS 00420	

Description	Cat. No.	
TSA 2 Thermode CHEPS fMRI The Thermode is MRI Conditional, made of non-magnetic / low magnetic components. The Thermode has an extended cable length of 12.5 meters to allow the required distance between the device, which is located outside the MRI room and the active side of the Thermode attached to the subject. This option requires the use of an EMI filter, for preventing magnetic and RF noises in an MRI environment, which may be caused by the Thermode. **Includes d-type adapter and control room cable**	AS 00421	
Standard Strap - 39 cm (15.3") The standard strap is used for securing the Thermode to the hand.	AS 00004	
Response Unit This unit enables the tested subject to respond to the stimuli by pressing one of two buttons. Depending on the selected test, the tested subject feedback signal terminates any process or causes the test to continue following a Yes/No response.	AS 00243	
Computerized Visual Analog Scale (CoVAS) The CoVAS can be used to record a continuous pain rating during a test.	AS 00213	

Description	Cat. No.	
Thermode Calibration Kit This kit is used for checking and calibrating the Thermodes of the TSA 2 which can be a requirement of certain grant-funded research/study protocols. See the service manual for operation details. The calibration kit includes fixation jigs for each thermode (ordered separately), thermal compound, USB cable. See **27**Appendix M – Calibration for the list of component options.	AS 00187	
Coolant filling kit **Includes one syringe, one tube with connector (for filling TSA 2 coolant system) and one tube without connector (for filling syringe)**	AS 00171	
Coolant fluid 1L pack of 4 bottles	GP 00406	

fMRI Thermodes are defined and marked as MR Conditional equipment according to the ASTM F2503–08.

Please see Appendix L – fMRI functionality for more details.

15. Appendix A – Normative Data

Medoc Main Station includes a built-in database of Normative Data which has been collected from various studies. In addition, you can add your own normative data to the database by using the User Normative Data table. Normative data is categorized by Thermode size, age group, gender, program type, body sites and various other parameters depending on the source. Normative Data can be displayed in real-time during the test, or be viewed later with the test results or in the report. Normative data is only displayed if normative data exists for the selected body site, program parameters, and patient age and gender. The following parameters need to be matched between the current selection and normative data for it to be displayed:

- Patient age and gender
- Program Method, modality, baseline temperature and rate
- Body site (main site, side and specific site)

New normative data can be added to the Normative Data database. If there are matching parameters (according to the criteria above) between normative data added by the user and the normative data provided by the manufacturer, the former will be used.

Please note that the use of the built-in Normative Data is subject to the terms and conditions specified in the Normative Data license agreement.

15.1 Normative Data License Agreement

Use of the built-in normative data is subject to the terms and conditions as stated below.

PEASE READ THIS AGREEMENT CAREFULLY.

Medoc Ltd ("Medoc") is the sole proprietor of the software package known as the Medoc Main Station software or "MMS software".

Medoc has created an add-on feature for the MMS software, which is a Normative Data feature (the "ND Feature").

The built-in information contained in the ND Feature was collected from various publications and researches, and adapted by Medoc in order to enable use in conjunction with the MMS software.

You are welcome to use the ND Feature, but you may do so only in accordance with, and subject to, the following provisions. Use of the ND Feature by you means that you accept all the terms and conditions of this agreement, including all limitations. You further agree that this agreement is enforceable like any written, mutually negotiated agreement signed by you.

If you do not agree to any of the provisions of this agreement, please do not use the ND Feature.

Should you decide to install and use the ND Feature, you may do so under the following conditions:

1. Medoc is not responsible or liable for, and does not guarantee or underwrite, the accuracy, completeness or applicability of the information contained in the Normative Data.
2. Medoc is not responsible or liable for the use you make of the ND Feature, nor is it liable for your conclusions from such use.
3. Medoc is not responsible or liable for any clinical diagnostics reached or treatment given based on the Normative Data.
4. Any use of the ND Feature and the information contained therein is at the user's sole responsibility and liability.

Should you have any questions regarding the ND Feature or this agreement, please contact Medoc Ltd. at info@medoc-web.com

15.2 Normative Data Editor

The Normative Data editor allows you to select the Normative Data source and to add your own customized normative data.

To open the Normative Data editor, select **Utilities** from the top menu bar, and then select **Normative Data**. The following screen is displayed:

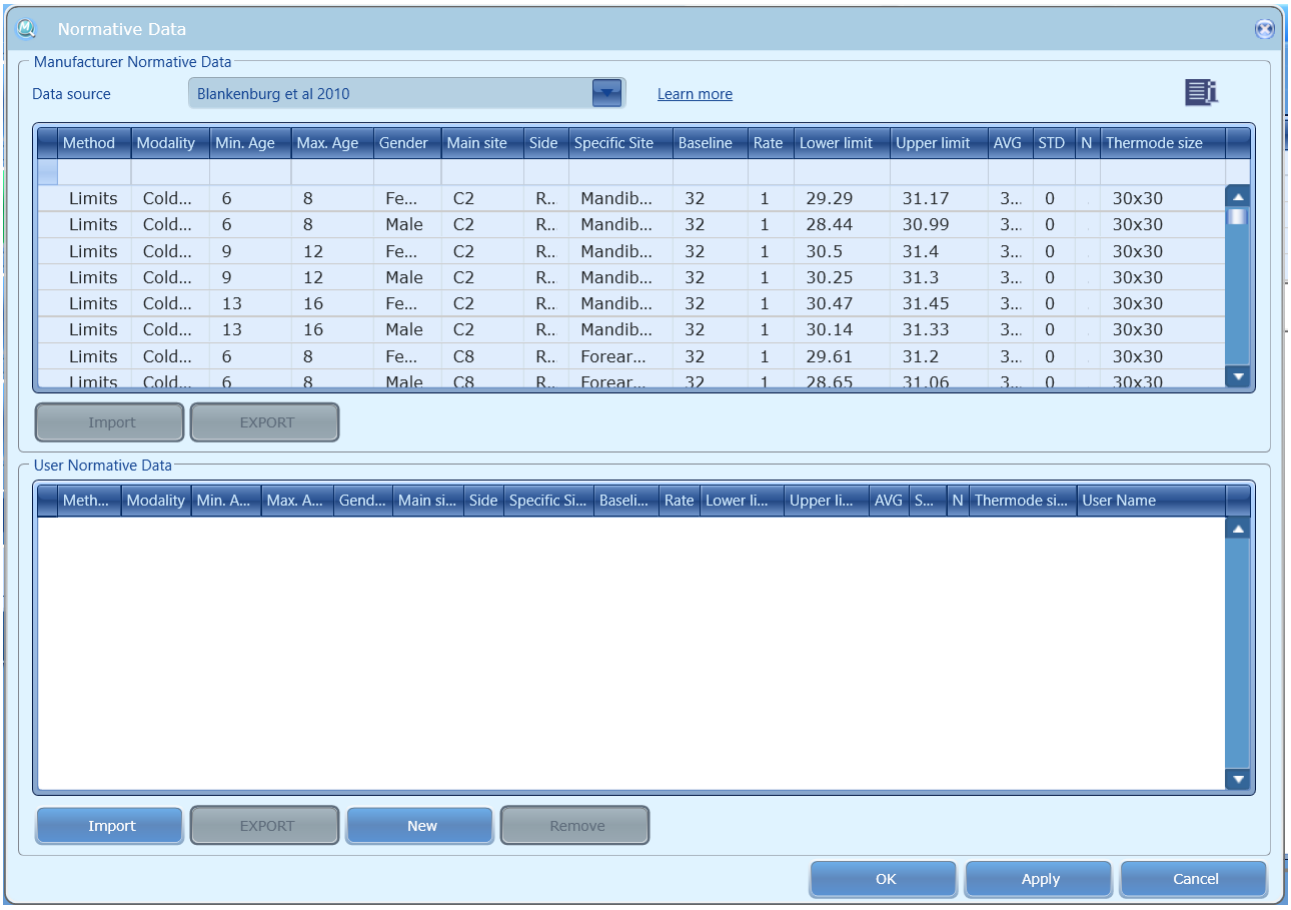


Figure 137: Normative Data Editor Screen

The Normative Data Editor screen is divided into two sections:

1. Manufacturer Normative Data
2. User Normative Data

The Manufacturer Normative Data table is a 'read-only' table. The data cannot be edited or modified. If needed, you can export the data, modify it and upload it again as User Normative Data. To add customized normative data, use the User Normative Data table.

Normative data includes the following parameters:

Table 35: Normative Data Fields

Parameter	Description	Mandatory
Method	The test method (Limits, Levels, …)	✓
Modality	The test modality (Cold Detection Threshold, Warm Detection, …)	✓
Minimum Age	Lower limit of age for which this Normative Data is applicable	✓
Maximum Age	Upper limit of age for which this Normative Data is applicable	✓
Gender	The gender that this Normative Data is applicable	✓
Main Site	The dermatome that was used to collect the normative data.	✓

Parameter	Description	Mandatory
Side	The anatomic side that was used to collect normative data.	
Specific Site	The specific body site that was used to collect the normative data.	
Baseline	The Baseline Temperature	✓
Rate	The temperature change rate	✓
N	The number of subjects which the normative data statistics is based on.	
AVG	The average threshold of the subjects that were tested to collect the specified normative data.	See note below
STD	The standard deviation of the threshold of a sample subject who was tested to collect the specified normative data.	See note below
Upper Limit	The upper limit as calculated from the normative data. Upper Limit = AVG + 2xSTD.	See note below
Lower Limit	The lower limit as calculated from the normative data. Lower Limit = AVG – 2xSTD.	See note below
Thermode Size	Thermode size used to collect this Normative Data (30x30, 16x16, …)	

Note: In order to apply the normative data to test results, it is necessary to provide the upper limit for Warm Detection Threshold and Heat Pain or the lower limit for Cold Detection Threshold and Cold Pain. However, if these parameters are left blank, the software will calculate them from the average and standard deviation. In this case of course, the average and standard deviation must be provided instead.

The following operations are available:

- **Export or Import a List of Normative Data** – The list of normative data can be exported or imported from a excel file. To see the required configuration of the excel file required for import, export the manufacturer normative data list and use the same format. The user normative data list can also be exported and important as an *.ats file for backup.
- **Add or Remove Data from the List of User Normative Data**

1. Click the **New** button to add a new row to the User Normative Data table
2. Enter the details for the normative data (for information about the specific parameters see table 33 above)
3. Click the **New** button to add more rows or **Apply** to save and apply the new data.

15.3 Selecting Normative Data Source

The built-in Normative Data includes several normative data tables from different sources. Each Normative Data table is usually based on a different publication. The normative data tables may differ in age groups, body sites and even in normative values for same gender, age group and body site. Before using the built-in normative data select the source of the data which best fit your application.

To select a Normative Data table following the instructions below:

1. Open the Normative Data editor: select **Utilities** from the top menu bar, and then select **Normative Data**.
2. Click the arrow to right of the data source name. A list will open displaying the list of available sources.

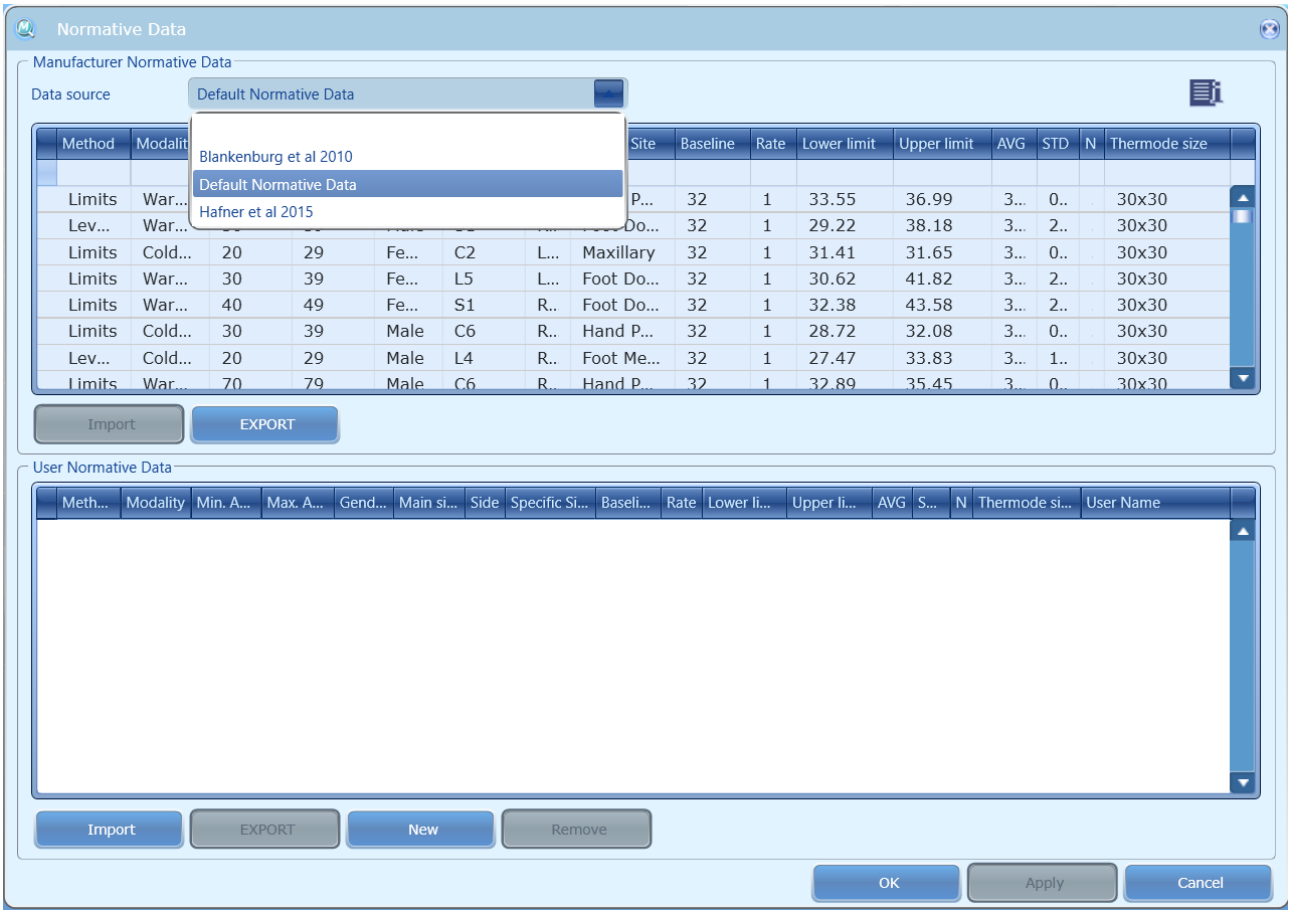


Figure 138 – Selecting Normative Data source

15.4 Normative Data Display

The Normative Data can be displayed on the test screen during the test, and it can also be included with the results and displayed on the report.

The Data will be displayed only if the following test parameters match Normative Data parameters: Method, Modality, Baseline Temperature, Rate, Main Site, Side, Specific Site, Patient Age and Gender

When running a test that matches all Normative Data parameters, the Lower and Upper Limits will be displayed on the screen during the test, as shown in the following screen:

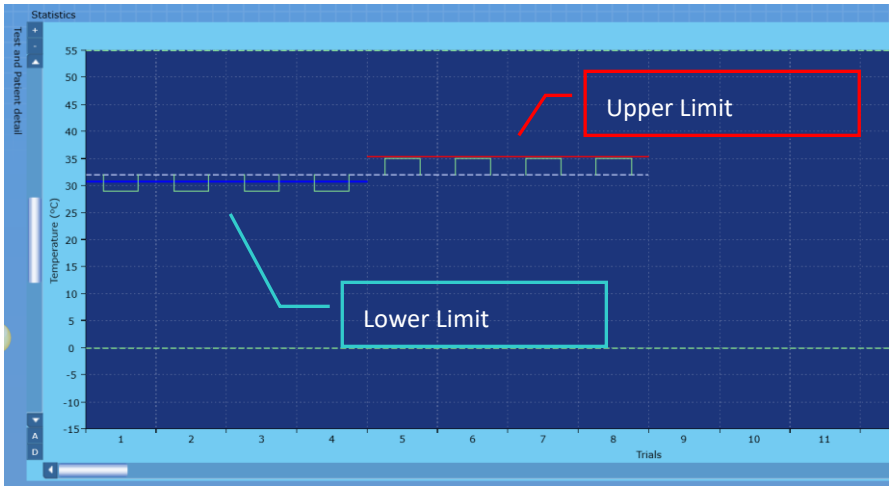


Figure 139: Normative Data display in Test Screen

To control the general display of normative data during the test and in the report change the normative data display setting in Test Settings (see section 11.3.1).

To toggle the display of normative in the current test and relevant report use the 'Normative Data' check box in the test screen

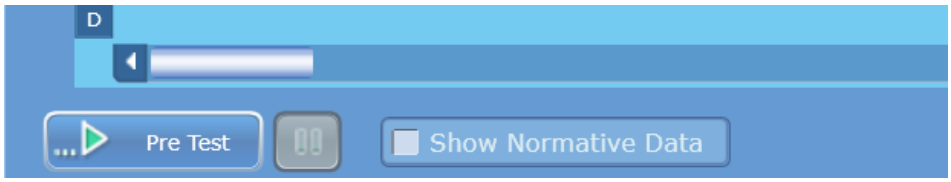


Figure 140: Normative Data Checkbox

16. Appendix B – FTP Support

Enables to upload test results to FTP (file transfer protocol) location for collaboration, multi-center studies or backup. There is an option to automatically save and upload test results immediately after test completion (requires internet connection).

16.1 Export Configuration

Configure the FTP server which will be used when FTP Server is selected during manual export, or when automatic export option is enabled.

When exporting results to an FTP server the results will be automatically named according to the following rule: <Site Name>_<Patient Name>_<Test Date & Time>

To access the Export Configuration panel: from the top menu bar, select **Settings** and then **Software Settings**.

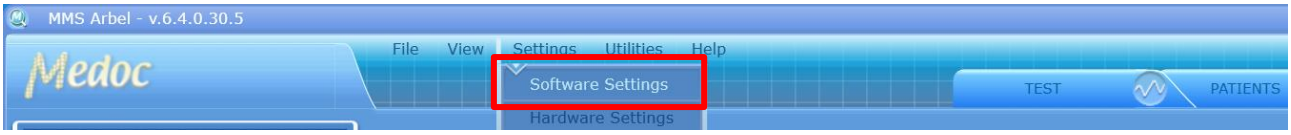


Figure 141: Open Software Settings

In the Software Settings window that opens, select the **Export** tab.

Figure 142: Software settings export tab selection

The following window will be displayed:

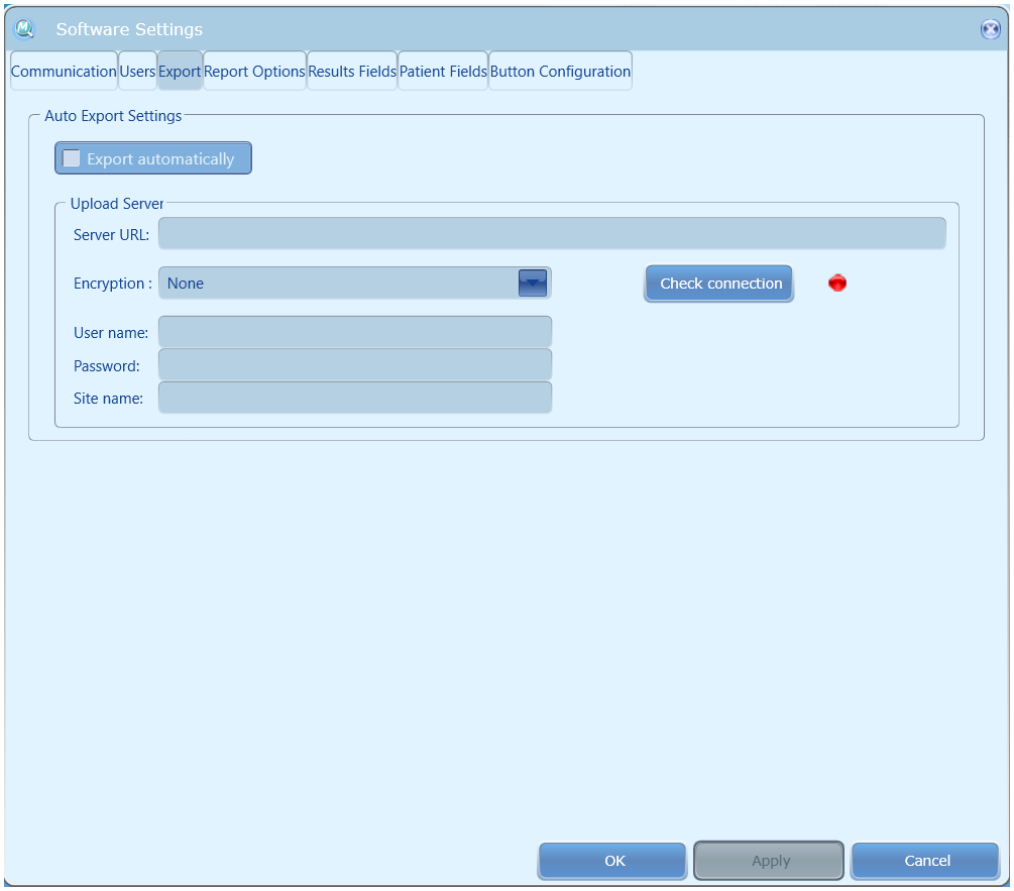


Figure 143: Software Settings Export Tab

16.1.1 **Configure the FTP Upload Server**

To configure the server, enter the following details:

1. Server URL – the FTP address. Use a specific address including the folder to which you want the results to be uploaded to. For example: ftp://ftp.my-ftp-server.com/FolderName
2. User name and password required to access the FTP server
3. Site name – an identifier which will be used in the name of the uploaded result file to distinguish the uploaded file from other files uploaded from different locations.
4. Click Apply to confirm
5. Check the Connection by clicking the “check connection” button

the red indicator to the right will change to green if the connection is successful.

16.1.2 Automatic Export

If automatic export is enabled test results will be automatically uploaded to the FTP server at the end of a test. A message will be displayed at the end of the test, indicating whether or not the upload attempt was successful or not. The computer must be connected to a network in order for the results to be successfully uploaded at the end a test.

To enable automatic export:

1. Make sure the FTP server details are entered correctly and check the connection.
2. Mark the "Export automatically" checkbox.
3. Make sure the automatic save option is enabled (see section 10.3).

17. Appendix C – Pain Rating

Enables advanced options for monitoring Patient Response: customized range for numerical pain rating scale, multiple ratings per trial.

17.52 Pain Rating Parameters Configuration

Pain rating is available only for Ramp & Hold program.

The following options can be configured:

Enable Pain Rating	☑
First pain rating (sec)	0
Pain rating interval (sec)	0
Waiting time for response (sec)	10

Figure 144: Pain Rating Parameters

Enable Pain Rating Checkbox – When checked enables pain rating patient response

First Pain Rating –determines the time of the first pain rating.

Default value is "0", meaning that the first pain rating will occur at the end of the trial.

Pain Rating Interval – determines the interval between pain ratings.

Default value is "0", meaning there will be only one pain rating in trial, at time determined by first pain rating parameter value.

Note: The amount of paint ratings in trial is determined by combination of first pain rating, pain rating interval and duration time parameters value. For example, if the duration time of the trial is 20 sec, first pain rating value is 5 sec and pain rating interval value is 5 sec, there will be 4 pain ratings in the trial 5, 10, 15 and 20 sec after reaching the destination temperature.

Waiting Time for Response – determines the time for which the pain rating dialog will remain on the screen waiting for user to respond.

In addition, **Pain Rating Limits** can be configured from Test Configuration tab in Test Settings window:

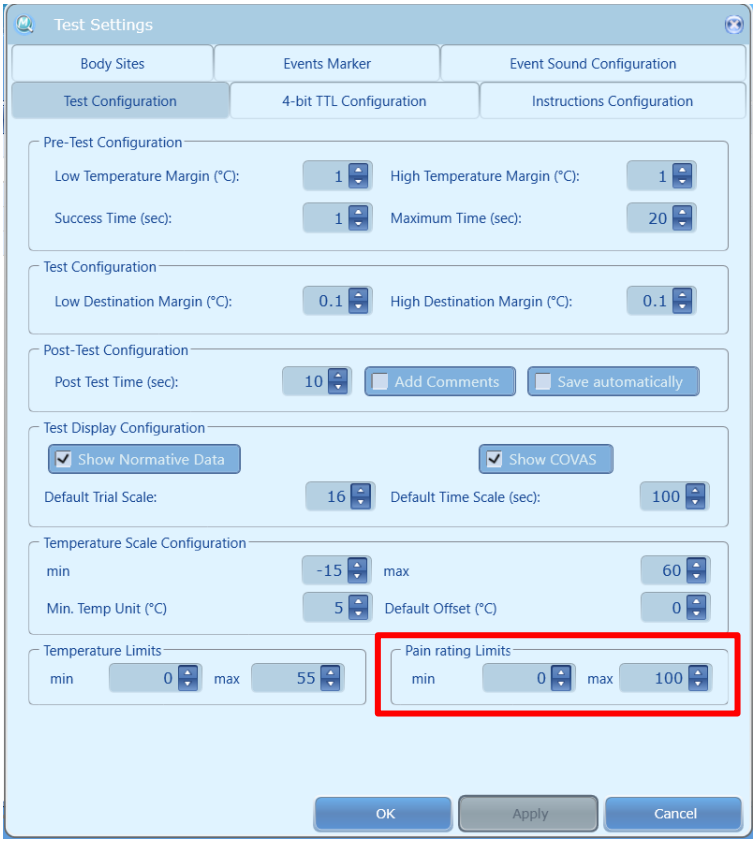


Figure 145: Pain Rating Limits

18. Appendix D - Patient Record Control

Allows full customization of patient fields including the options to add, remove, rename and control input.

18.1 Control Patient Field Entry Format with Input Masks

When you have several users entering patient data, you can control how the data must be entered in specific fields in order to maintain consistency. For example, you can set an input mask for the ID field so the ID numbers will have a very specific format.

Input Masks

An input mask consists of a string of characters which represent the format in which the data should be entered. The input mask strings consist of **Regular Characters**, **Special Characters**, and **Literal Characters**.

The **Regular Characters** represent the alphabetic or numeric characters that must or may be used to enter data in the field. Refer to

Table 36 for a list of Regular Characters and their definitions.

The **Special Characters** represent the case and various delimiters and symbols. Refer to Table 37 for a list of Special Characters and their definitions.

The **Literal Characters** are characters that are not Regular Characters or Special Characters. They are inserted as is into the edit box of the field and the curser will skip over them during editing. The use a Regular Character or a Special Character as a Literal Character, add a backslash (/) before.

Table 36: Regular Characters

Character	Definition
L	User must enter a letter (A-Z, a-z)
l	User can only enter a letter (A-Z, a-z) but it is not required
A	User must enter a letter (A-Z, a-z) or a number (0-9)
a	User can only enter a letter (A-Z, a-z) or a number (0-9) but it is not required
C	User must enter any character
c	User can enter any character but it is not required
0	User must enter a number (0-9)
9	User can enter only a number (0-9) but it is not required
#	User can enter only a number (0-9) and a plus (+) or minus (-) but it is not required

Table 37: Special Characters

Character	Definition
>	All the characters that follow are converted to upper case
<	All the characters that follow are converted to lower case
<>	No case checking is performed
/	Used to separate months, days and years in dates. The character used depends on the regional settings of the computer
:	Used to separate hours, minutes and seconds in time values. The character used depends on the regional settings of the computer
$	Currency symbol. The symbol used depends on the regional settings of the computer

Examples

1. A mask for entering a telephone number: (999)000-00-00. Each ‘0’ Regular Character requires a number in the corresponding position. No number in these positions can be omitted. The Regular Character ‘9’ represents an optional area code. Only a number can be entered in these positions but it is not required. The ‘- ‘and ‘(‘and ‘)’ characters in the mask are literal. A telephone number entered could be: (555)222-33-22 or 222-33-22.
2. A mask for entering a sequence with numbers and letters: \A>LL-00. The ‘\A’ represents a Literal Character which will be entered as ‘A’. The ‘>’ specifies that following characters will be converted to upper case. The ‘LL’ indicates that two letters must be entered in this position. The ‘- ‘is a Literal Character. The ‘00’ is a placeholder for 2 numbers. An entry to this field can be: ASD-88.

18.1.1 Add/Remove Patient Fields

To define and add Patient Card Fields to the Patient Details dialog:

1. From the **Settings>Software Settings>Patient Card Fields** list, select the required fields from the Mandatory or Optional fields, or add a new field from the user-defined list. Add an input mask if needed.
2. To remove a Patient Field, remove the selection mark from the field
3. Click the **Apply** button to confirm changes.

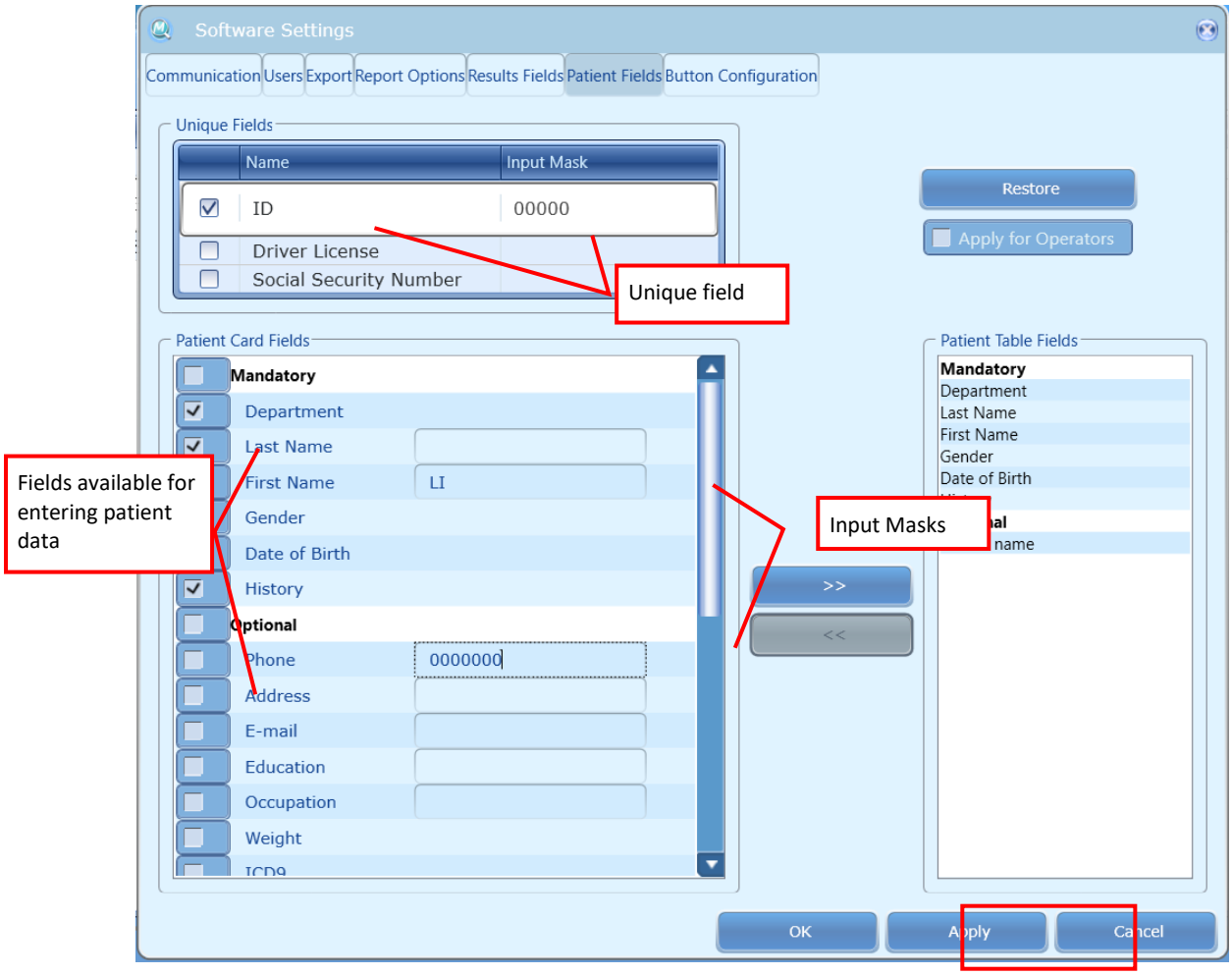


Figure 146: Patient Fields with Input Masks

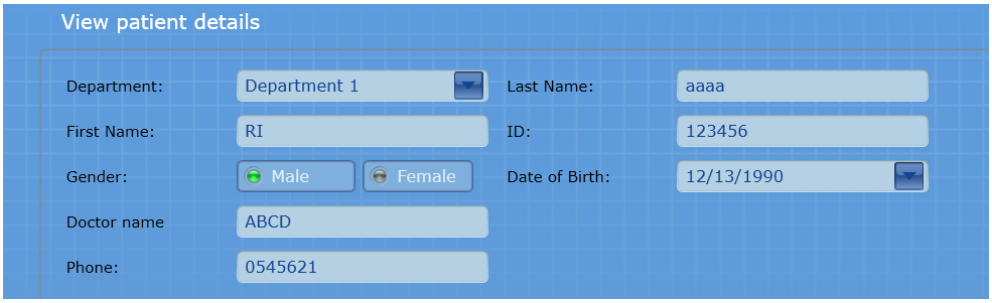


Figure 147: Patient Card with Selected Patient Fields

To add Patient Fields to the Patient Table:

1. Select fields to add from the Patient Card Fields list and click the **Move Right** button >>
2. Click the **Apply** button to confirm changes

To remove Patient Fields from Patient Table:

1. Select fields to remove from the Patient Table Fields and click the **Move Left** button <<
2. Click the **Apply** button to confirm changes

To restore the default Patient Fields:

1. Click the **Restore** button to restore default Patient Fields.
2. Click the **Apply** button to confirm changes

19. Appendix E – Preventive and Periodical Maintenance

- It is recommended to calibrate the Thermodes every 12 months.
- It is recommended to run the system every two months for about 30 minutes (run a test).
- In case the system is not in use for a long period of time, it is recommended to clean dust that has accumulated inside the system using a compressed air can.

20. Appendix F – Cleaning and Disinfecting

Medoc has performed a Cleaning and Disinfection Validation using Mikrozid® sensitive wipes (Schulke & Mayr GmbH).

Composition of the wipes used for the validation test:

100 g solution contains the following active substances: 0.26 g Alkyl(C12-C16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-C16)); 0.26 g Didecyldimethylammonium chloride (DDAC), 0.26 g Alkyl(C12-C14) ethylbenzylammonium chloride (ADEBAC (C12-C14))

The following procedure confirmed a 6.13 average log reduction in vegetative gram-negative bacterial load (Escherichia coli) and a 6.71 average log reduction in gram-positive mycobacteria (Mycobacterium smegmatis), per AAMI TIR 12:2020, as well as reducing organic soil load, per AAMI TIR 30:2011 (R) 2016, to:

- Proteins: <6.4µg/cm^2
- Hemoglobin: <2.2µg/cm^2.

Perform this procedure before initially using the Thermode and after each use, to minimize the spread of pathogens between test subjects.

1. Wrap the thermode with Mikrozid® sensitive wipes for 15 minutes.
2. Wipe the thermode with fresh Mikrozid® sensitive wipes for 20 seconds.
3. Allow to air-dry.
4. Store the thermode in a clean, dry area.

21. Appendix G – List of Accompanying Documents

- Hard Copy
    - Quick Set Up and Installation Guide.
    - Acceptance Test Results
    - Packing List
- Soft Copy
    - Release Notes
    - Operation manual

22. Appendix H – Transportation and Storage

The environment conditions for TSA 2 system transportation and storage are as follows:

- An ambient temperature range of 0 °C to +70 °C.
- A relative humidity range of 10% to 95%, including condensation.
- An atmospheric pressure range of 500 hPa to 1060 hPa.

23. Appendix I – Environmental Conditions

The environment conditions for TSA 2 system during standard use are as follows:

- An ambient temperature range of+18°C to+24 °C
- A relative humidity range of 30% to 75%, including condensation
- An atmospheric pressure range of 700 hPa to 1060 hPa

24. Appendix J – Troubleshooting

This chapter describes some of the TSA 2 system most common error messages and warnings and includes a few possible solutions or troubleshooting steps. If the error persists or is not described in this section, contact Medoc Service for further support.

24.1 Error and Warning Messages

Error messages and warning messages typically look like the message sample below:

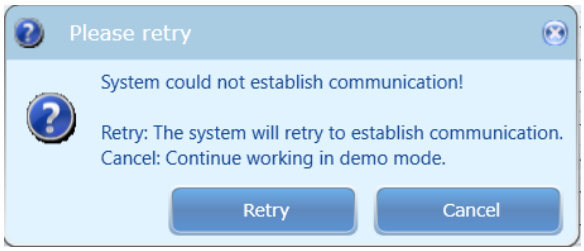


Figure 148: Error and Warning Messages Sample

In most cases, if a message like the one above pops up it will not be possible to continue working with Medoc Main Station until the message is acknowledged by clicking the **OK**, **YES** or **NO** buttons as indicated by the message.

24.1.1 Frequent Warning Messages

The table below listed some of the common warning messages alongside some additional information to assist troubleshooting.

Table 38: Frequent Warning Messages

№	Message Text	Details
1.	The application is about to start TSA 2 recovery and Self-Test. Make sure the Thermode is not attached to the patient and press OK.	System self-test is required after viewing or editing any of the Hardware Settings and if system is in Safe Mode for any reason. Before allowing the system to start the Self-Test, make sure to remove the Thermode from the subject.
2.	TSA 2 is in Safe Mode, and must perform Self-Test before resuming operation. Click YES to perform Self-Test, and resume work. Click NO to continue in Safe Mode.	When system is in Safe Mode, a Self-Test is required before the system can be restored for normal operation. Select **YES** proceed with the Self-Test or **NO** if you want the system to remain in Safe Mode.
3.	Do you want to retry TSA 2 recovery?	The Self-Test may have failed. Select **YES** to rerun the Self-Test or **NO** to continue working in Safe Mode.
4.	The offset has been set to a value lower than default. This may cause the actual pulse temperature to exceed the nominal destination temperature. Click OK to continue	This message indicates that the offset specified in the program is lower than default. Refer to section 7.6.6 further information.
5.	Sensor Heater/TEC missing calibration table entries in range 10 - 48.	The sensor calibration cannot be completed because there are missing points in the required range Complete the missing entries and continue.
6.	Sensor Heater/TEC: The number of defined calibration table entries is less than the required 15.	The calibration cannot be completed because there are not enough calibrated points. Calibrate at least 15 points in order to complete the manual calibration.
7.	The number of defined calibration table entries is more than the required 15, but less than the recommended 20. 1. Click YES if you want TSA 2 to perform interpolation and fill out the missing values. 2. Click NO to enable return to the Hardware Settings and fill in missing values.	The recommended number of points for calibration is 20. Select **YES** to complete the manual calibration based on the existing points (less than 20) or select **NO** to return and calibrate more points.

№	Message Text	Details
8.	Hardware safety was triggered	The system detected that the hardware safety mechanism has been triggered. The system is now Safe Mode in order to prevent any damage. 1. Run a system Self-Test. 1.1. If the Self-Test completes without any further errors the system can return to normal operation. 1.2. If the Self-Test cannot be complete, restart the system and retry. If the Self-Test continues to fail, contact Medoc Service for assistance.
9.	During Self-Test Medoc Main Station detected that the hardware safety was triggered. 1. Click OK to restart Self-Test.	The system detected that the hardware safety mechanism has been triggered. Restart the Self-Test.
10.	The test cannot be started because Medoc Main Station is not connected to any device or Demo Mode.	Medoc Main Station needs to be connected to the TSA 2 system (or to the simulator in Demo Mode) in order to start the test. Check that there is communication between TSA 2 and Medoc Main Station. Refer to section 11.1.1 for further information.
11.	During automatic calibration software safety protection is lowered; therefore, it is not allowed to place Thermode on human subjects! 1. Check that the Thermode is properly placed in the jig and connected to the TSA 2. 2. Click YES to continue calibrating. 3. Click NO to discontinue calibration	Warning notification before automatic calibration. Follow the displayed instructions, and continue.

24.1.2 Frequent Error Messages

The table below listed some of the common error messages alongside some additional information to assist troubleshooting.

Table 39: Frequent Error Message

№	Message Text	Description
1.	No Thermodes are enabled. Error Code: 800D 1. Enable connected Thermode via Hardware Settings, General tab. 2. Click OK, and resume Self-Test when prompted.	No Thermodes are enabled. This will occur after a firmware update or if a fault in the Thermode caused the system to disable it. To enable the Thermode, make sure it is connected to the system and then enable it from the Hardware Settings. Refer to section 10.2
2.	System could not establish communication! Retry: The system will retry to establish communication. Cancel: Continue working without connecting to device.	Medoc Main Station failed to establish communication with the system. 1. Check the communication USB cable is connected between TSA 2 and the computer 2. Verify that the system is turned on (Main power) 3. Select Retry to for the system to reconnect or Cancel to start Medoc Main Station in Demo Mode. 4. If the problem persists, start Medoc Main Station in Demo Mode and refer to section 11.1.1 for further information or see troubleshooting steps in the message below.
3.	Communication with TSA 2 was lost. 1. Click OK to check if communication can be re-established automatically, run self-test and continue working with the system. 2. In case communication is not re-established automatically: 2.1. Close Medoc Main Station and switch OFF the device 2.2. Verify that the communication cable is connected firmly to device and computer 2.3. Turn ON the device and start Medoc Main Station 3. If steps 1 & 2 fail, contact Medoc support for further assistance.	Communication with the system has been disconnected. Click OK to reconnect. If the problem persists follow the instructions in the message text.

№	Message Text	Description
4.	Communication between TSA 2 and PC lost while in Test Run mode. Error Code: 800C	Communication between the computer and TSA 2 has been disconnected while in Test Mode. 1. Restart the TSA 2 system and Medoc Main Station 2. Run the system Self-Test If the problem persists, contact Medoc service.
5.	Unsupported device firmware version. TCU Firmware version: ### Click OK to return to the home screen.	The system firmware version is not compatible with the software. 1. Check what firmware version is supported by the software (from the main screen, select Options and then select About …) 2. If the current firmware version is lower than the supported version, update the firmware to correct version (Refer to the section 4.10 for further instructions). 3. If the current version is higher than the supported version, contact Medoc support for further assistance.
6.	User Name or Password is incorrect.	Verify that you have typed the correct user name and password and try to log in again. If the problem persists, try the *admin* user name and password.
7.	Command: ### failed ###. No response from TSA 2 / TSA 2 returns Acknowledge Code = ###.	A command sent to the system returned a failure. 1. Write the command name or number and acknowledge code if available. 2. Restart the TSA 2 system and Medoc Main Station. If the problem persists, contact Medoc support and provide the details above.
8.	The Thermode cannot be saved because its verification failed.	Calibration data cannot be saved because the verification process failed. Check that the calibration setup is correct and the thermometer is connected to the computer. Recalibrate the Thermode.

№	Message Text	Description
9.	The following safety limitation has been violated. Temperature: XX °C; Allowed time: X (sec). Error Code: 8002	The temperature duration limit has been exceeded. The TSA 2 system automatically switches to Safe Mode in order to prevent any damage. Before attempting to resume normal operation: 1. Check that the parameters of the program used are valid. 2. Check that the Thermodes are intact and undamaged. 3. Run the system Self-Test If the problem persists, stop using the TSA 2 system and contact Medoc service.
10.	Safety cold duration limit violation. Temperature level: # (°C), Time entry: ## (sec). Error Code: 800E	The temperature duration limit has been exceeded. The TSA 2 system automatically switches to Safe Mode in order to prevent any damage. Before attempting to resume normal operation: 1. Check that the parameters of the program used are valid. 2. Check that the Thermodes are intact and undamaged. 3. Run the system Self-Test If the problem persists, stop using the TSA 2 system and contact Medoc service.
11.	Static sensor mismatch. Error Code: 8003	The system has detected a mismatch between the Thermode sensors. TSA 2 switches to Safe Mode in order to prevent any damage. Before attempting to resume normal operation: 1. Check that the Thermodes are intact and undamaged. 2. Run the system Self-Test 3. Re-calibrate the Thermode. If the problem persists, stop using the system and contact Medoc service.
	Static sensor mismatch. Mismatch temperature # (°C). Error Code: 8003	

№	Message Text	Description
12.	Dynamic sensor temperature mismatch. Mismatch temperature: 10 (°C). Error Code: 8004	The system has detected a mismatch between the Thermode sensors during a dynamic temperature change. TSA 2 automatically switches to Safe Mode in order to prevent any damage. The reported mismatch temperature indicates the difference in temperature between the sensors at the time the error occurred. Before attempting to resume normal operation: 1. Check that the Thermodes are intact and undamaged. 2. Run the system Self-Test 3. Re-calibrate the Thermode. If the problem persists, stop using the system and contact Medoc service.
13.	Emergency disconnect during Self-Test failed. Error Code: 8005	The system Self-Test failed due to a problem in the emergency disconnect mechanism. TSA 2 remains in Safe Mode in order to prevent any damage. 1. Check that the Thermode is intact and undamaged. 2. Make sure that the coolant temperature is at most 24°C in the Thermode (status line) 3. If the temperatures are higher than stated above, wait 5-10 minutes and check again. 4. Run Self-Test to verify that the TSA 2 system is enabled to continue working. If the problem persists, stop using the TSA 2 system and contact Medoc service.
14.	Failed to recovery from Safe Mode, TSA 2 returns Acknowledge Code = ##.	The system Self-Test failed due to an error. TSA 2 remains in Safe Mode in order to prevent any damage. Save the Acknowledge Code number or name and restart the TSA 2 system and software. If the problem persists, contact Medoc Service with the acknowledge code number or name.
15.	Failed to recovery from Safe Mode, no response from TSA 2 during timeout period.	The system Self-Test failed due to a communication error. Try to re-establish communication with the system and run the system Self-Test again. Refer to 10.3 for more information.

№	Message Text	Description
16.	Thermode TEC did not respond to temperature changes. Error Code: 8007	The system Self-Test failed due to a problem in one of the Thermodes. TSA 2 remains in Safe Mode to prevent any damage. 1. Check that the Thermode is intact and undamaged. 2. Check that the Thermode plug and connectors are properly attached to the system. 3. Run the system Self-Test again. If the problem persists stop using the TSA 2 system and contact Medoc service.
17.	Coolant overheats. Coolant temperature: 31 (°C). Error Code: 8008	The temperature of the coolant in the Thermode is too high. TSA 2 automatically switches to Safe Mode in order to prevent any damage. 1. Make sure the room temperature is **24°C** or below 2. Wait 5-10 minutes to allow the coolant temperature to decrease. 3. Run the system Self-Test again. If the problem persists, stop using the TSA 2 system and contact Medoc service.
18.	TEC sensor is shorted or disconnected. Error Code: 800A	The Thermode temperature sensors seem to be either shorted or disconnected. TSA 2 automatically switches to Safe Mode in order to prevent and further damage. Before attempting to resume normal operation: 1. Check that the Thermode is intact and undamaged. 2. Check that the Thermode connectors are properly attached to the system. 3. Run the system Self-Test again. If the problem persists, stop using the TSA 2 system and contact Medoc service.

№	Message Text	Description
19.	Coolant sensor is shorted or disconnected. Error Code: 800B	The Thermode coolant sensor seems to be either shorted or disconnected. TSA 2 automatically switches to Safe Mode in order to prevent and further damage. Before attempting to resume normal operation: 1. Check that the Thermode is intact and undamaged. 2. Check that the Thermode connectors are properly attached to the system. 3. Run the system Self-Test again. If the problem persists, stop using the TSA 2 system and contact Medoc service.
20.	Empty command buffer. Error Code: 400C	An error has occurred in the TSA 2 processor during run time. Click OK and continue working as usual. If the problem persists, send the corresponding error code to the Medoc service team.
21.	Time mark missed. Error Code: 400D	An error has occurred in the TSA 2 processor during run time. 1. Click OK and continue working as usual. 2. If the problem persists, restart the TSA 2 system and software. If the problem persists, contact Medoc service with the error code.
22.	Sample buffer full. Error Code: 2001	An error occurred in the TSA 2 processor during run time. Click OK and continue working as usual. If the problem persists, send the corresponding error code to the Medoc service team.
23.	Finite ramp by temperature timeout. Thermode temperature: ## (°C). Error Code: 2002	The temperature ramp could not be completed in the required time. TSA 2 automatically switches to Safe Mode in order to prevent any damage. 1. Check that the coolant temperature is according to the requirement. 2. Check coolant level is according to the requirement 3. Run the system Self-Test to verify that there is no fault in the TSA 2 system or Thermodes. If the problem persists, stop using the TSA 2 system and contact Medoc service.

№	Message Text	Description
24.	Thermode was not detected by TSA 2. The Thermode has been disabled. 1. Make sure that the Thermode is properly connected to the TSA 2 system. 2. Enable the Thermode through the Hardware Settings, General menu. 3. Click Yes to try again. Or 4. Click No to continue working.	The system could not detect one of the enabled Thermodes, and therefore disabled it in order to prevent any damage. Follow the instructions in the message text.
25.	Some of the safety parameters (Temp Vs. Time) are violating the TSA 2 safety limitations. 1. Click OK to continue working with current non-approved safety parameters. 2. Click Restore to restore safety parameters to the TSA 2 definition.	The TSA 2 system has detected that the modified safety limitations do not comply with safety regulations. Select one of the presented options and continue. According to safety regulations, if the safety parameters have been modified, performing tests on human subjects is not permitted without written approval!
26.	 Error start with: System. Null Reference Exception: Object reference not set to an instance of an object. at Medoc. SysInfo Helper. Get Serial Port Names ()	The computer doesn’t have a physical or virtual serial COM port. Follow the instructions below to add a virtual COM port to the computer: 1. Insert the installation USB. Click ‘Cancel’ if the installation starts automatically. Open the folder: “Medoc Manufacturer Remote Assistance Tools”, and copy the file: “Add SERIAL COM to registry.reg” to your desktop. 2. Double click the file to run the file 3. Restart the computer and connect TSA 2 with the USB 4. Turn ON the system and wait for the driver installation to complete 5. Start Medoc Main Station. If the problem persists, contact Medoc service.

Table 40: Errors during calibration

№	Message Text	Description
12.	The thermometer does not respond. 1. Check that the thermometer is turned on. 2. Check that the thermometer is connected to the correct COM (see setting > software setting > calibration COM port).	These errors indicate a problem with thermometer communication. 1. Check that the thermometer is turned on 2. Check that the thermometer is connected to right COM port (open settings > software settings). Change the COM port until connection with thermometer can be established. 3. Restart the calibration
13.	Cannot open thermometer serial communication port, because it is used by Medoc Main Station	
14.	Access denied to Thermometer serial communication port 3.	
15.	Thermometer serial communication port COM1 was not found	
16.	Have not been able to read temperatures from the Thermometer for 4 seconds. 1. Verify that the thermometer communication cables are connected properly. 2. Verify that the thermometer is turned on. 3. Restart the automatic calibration procedure.	
17.	The measured temperature 54(˚C) is out of permitted range [18…53].	During automatic calibration the measured temperature exceeded the allowed range. 1. Change the calibration range in the Automatic calibration properties. 2. Repeat calibration. If the Thermode temperatures still exceeds the allowed limits, calibrate the Thermode manually using a narrower calibration range and repeat the automatic calibration using the default range. Refer to the service manual for further details.

18.	Automatic calibration is terminated when coolant temperature is above 30˚C. Coolant temperature is 31.	The coolant temperature in the Thermode was too high during calibration. 1. Check that the TSA 2 is turned ON and communication is established (see power failure and communication problems above) 2. Check that the Thermodes are properly connected 3. Make sure the room temperature is 24°C or below 4. Check the coolant level and fill the Cooling Unit reservoir if necessary (refer to section 3.2.2 for further instructions) 5. Make sure the coolant temperature in the is below 24 6. Restart the calibration
19.	Temperatures are not the same as the temperatures displayed on the thermometer	Make sure that the operating system decimal symbol is set to dot. To change decimal symbol go to Control Panel→Regional and Languages Options→Regional Options→Decimal Symbol.

24.2 Faulty System Responses

Table 41: Faulty System Responses

Malfunction	Solution
Thermode does not heat	The Thermode does not heat up, and remains at room temperature or cold. The TSA 2 Temperature status, displayed on status bar, indicates a temperature other than the current Rest Mode temperature. The malfunction may be caused due to loss of communication or due to a fault in the Thermode, System or the main voltage supplied to the System. 1. Check communication between the System and computer. Verify that Medoc Main Station is working in ON-LINE mode. 2. Verify that the Emergency button is not pushed in. 3. Verify that the TSA 2 system is not in Safe Mode (Safety indicator, in status bar, is GREEN) – run the system Self-Test to switch to Rest Mode 4. Power OFF the TSA 2 system, and replace the Thermode if available

Malfunction	Solution
	5. Power ON the TSA 2 system and check if the Thermode heats up.
TSA 2 system will not turn ON (Power failure)	1. Check if the fuses need to be replaced (refer to the Service Manual for further information). 2. Check that the power cable is not damaged. Make sure it is connected properly to the TSA 2 inlet. 3. When turning TSA 2 ON, check if the green light on the main switch is on. 4. Make sure the electronic box power switch is ON (open the top left back door to get access to the electronic box power switch). If the problem persists, contact Medoc service.
Constant Communication Problems	1. Check that the COM port selection is set to 'Auto Detect' (Refer to section 11.1.1 for more information) 2. Check the power cables (see power failure above) 3. Check that the communication USB cable is connected properly to the computer and TSA 2. Switch to another USB port on the computer if available 4. Check that the communication driver installed: 5. Turn ON TSA 2 and connect the USB cable to the computer 6. Open the computer device manager and check the driver is listed under 'Ports (COM & LPT)' as: Silicon Labs CP210x USB to UART Bridge (COM#) 7. If connection using 'Auto Detect' setting can't be established, select the specific COM port from the list. 8. Update TSA 2 firmware (refer to 5.9)
Display Settings	1. Make sure that the custom text size (DPI) on the computer is set to 96dpi. 2. Make sure that your screen resolution is set according to minimum computer requirements (refer to 4.1).
Coolant Leakage	1. Dry up any excess coolant from the system 2. Make sure the Thermode coolant connectors are properly connected to the system. 3. Try to locate leakage origin. If the problem persists, stop using the system and contact Medoc service.

Malfunction	Solution
No TEC Response	1. Check that the TSA 2 is turned ON and communication is established (see power failure and communication problems above) 2. Check that the enabled Thermodes are properly connected 3. Restart TSA 2 and Medoc Main Station 4. Check that the TEC temperature displayed in the status line is fluctuating slightly (± 0.1°C) and not fixed 5. Check that the TEC temperature displayed in the status line changes slightly when carefully touching the Thermode contact area. 6. Try to perform a Manual Calibration (refer to the Service Manual for further information) 7. Replace the Thermode if available If the problem persists, contact Medoc service.
Coolant Temperature Too Hot	1. Check that the TSA 2 is turned ON and communication is established (see power failure and communication problems above) 2. Check that the Thermodes are properly connected 3. Make sure the room temperature is 24°C or below 4. Check the coolant level and fill the Cooling Unit reservoir if necessary (refer to 3.2.2 for further instructions) 5. Wait for a few minutes (5-10) for the coolant temp to decrease. If the problem persists, contact Medoc service.

25. Appendix K – External Control

25.1 Overview

The External Control Interface enables external applications to communication with the Medoc Main Station software. The interface enables the user to automate the process of program selection and test initiation, timing of trial onset, emulate patient response and more. In combination with analog output option, the interface can be used to implement complex decision-making protocols.

Communication between Medoc Main Station and the external application can be established using either parallel communication or TCP socket communication. The interface can be used with any experiment control program or research application that supports any of the above communication protocols.

25.2 Use Examples -Open Control Mode

the external application communicates with the Medoc Main Station computer and sends commands to select and start specific programs, start or stop the test, or emulate the subject's response by sending 'Yes' or 'No' commands.

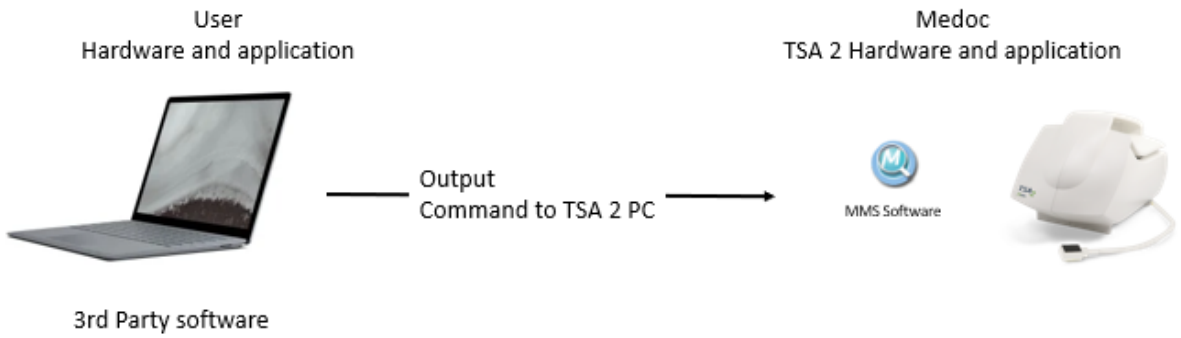


Figure 149: External Control Interface Open Control Loop Example

25.2.1 **Typical Workflow**

The diagram below illustrates a typical workflow, using the Closed Control mode. Medoc Main Station receives commands (TCP socket communication) which determine which test program to use. The external application decides which test program to send based on input it receives from the TSA 2 (analog output) or other sources such as EEG or MRI systems.

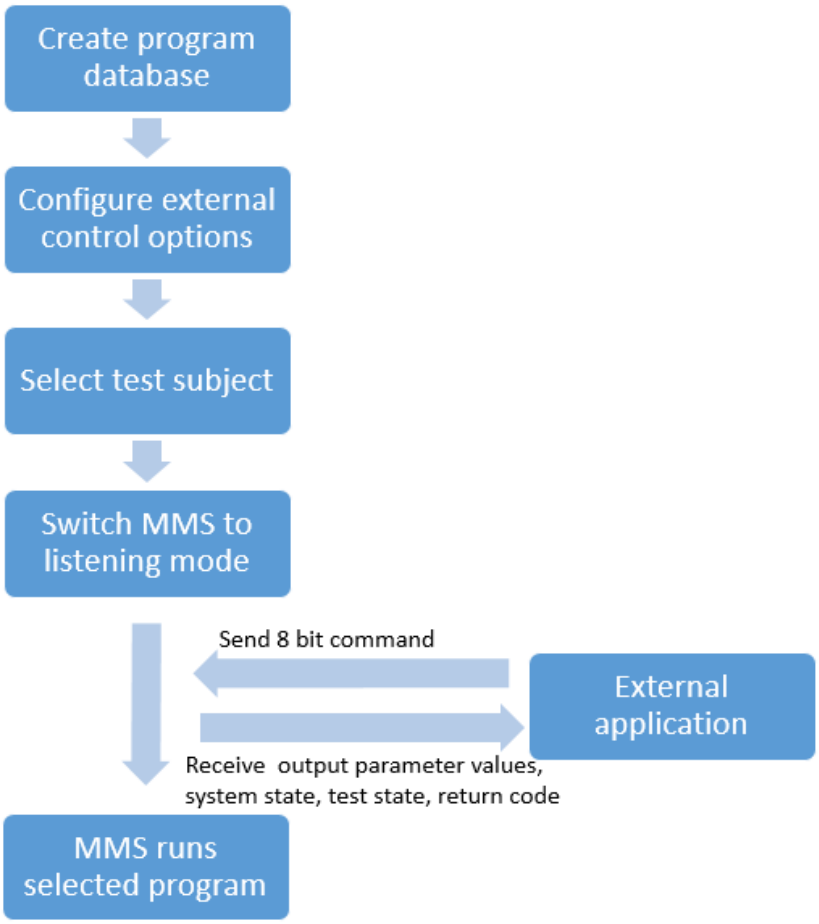


Figure 150: External Control Workflow Example

25.3 Network Communication (TCP Sockets)

Network communication is based on inter-application communication using TCP socket connection. The external application can be running from the same computer as Medoc Main Station or it can be installed on a second computer.

25.3.1 System Requirements

1. Computers must have an IP address (even when using one computer for Medoc Main Station and external controlling application).
2. A local network must exist between both computers.
3. Communication port must be open to data transmitting and receiving on both sides (check firewall settings).
4. Medoc Main Station license must include the External Control Interface. For additional information please contact your local distributor.

25.3.2 TCP Socket Interface Overview

Communication between MMS and the Controlling application is achieved using a TCP Socket. MMS acts as the server-side program and establishes a socket connection on specific port on the computer it is running on (host). The

controlling application acts as the client-side program and establishes a connection to the server program (MMS) on the particular host and port number. The host address and port number can be configured in Medoc Main Station.

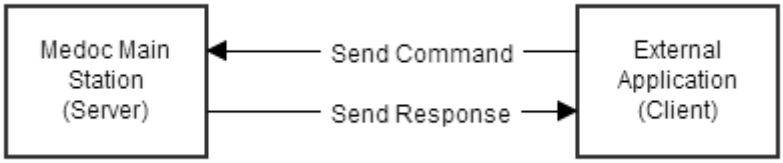


Figure 151: Server Client Relationship

All communications are initiated by client application and consist of two stages:

1. Client application sends command
2. Server application (MMS) sends response after performing the required action

In order to control command order, the commands contain the current time stamp and corresponding response will contain the same time stamp.

For a detailed description of the command and response structure please refer to the documentation provided with the External Control License.

25.4 External Control Configuration

To access the External Control configuration menu: from the top menu bar, select **Settings** and then **External Control**.

25.4.1 Setting Communication Method

The IP address of the Medoc Main Station computer will be displayed as well as the default Port number. The port number can be changed.

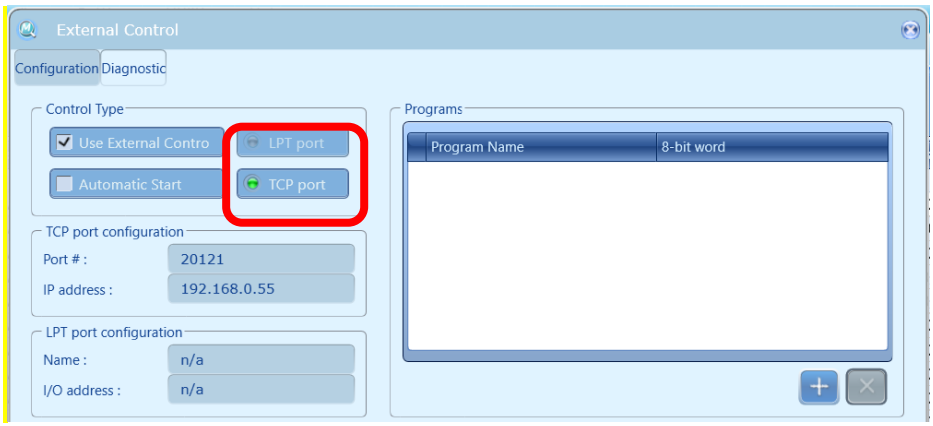


Figure 152: External Control – Select Communication Method

25.4.2 Program Setup

In order to use the external control to select a program, the program must be added to the remote program list and assigned an 8-bit word.

To add programs to the program list:

1. Click on the add program button to add a new row
2. Click the new row on the Program Name column to show the list of available programs and select a program from the list
3. Enter an 8-bit word
4. Click Apply to save and apply the changes

To remove a program, select the row in the table and click the remove button

The program setup can also be exported and saved as backup.

25.4.3 Activating the External Control

To Activate the External Control, enable the '**Use External Control**' option. When External Control is enabled it will be the default operating mode. To return to normal operating mode, disable the '**Use External Control**' option.

Automatic Start

When the '**Automatic Start**' option is enabled, the test will start automatically after the program is selected. When it is disabled, the program will be selected and the test screen will be displayed. In order to start the test, the 'Start' command must be sent.

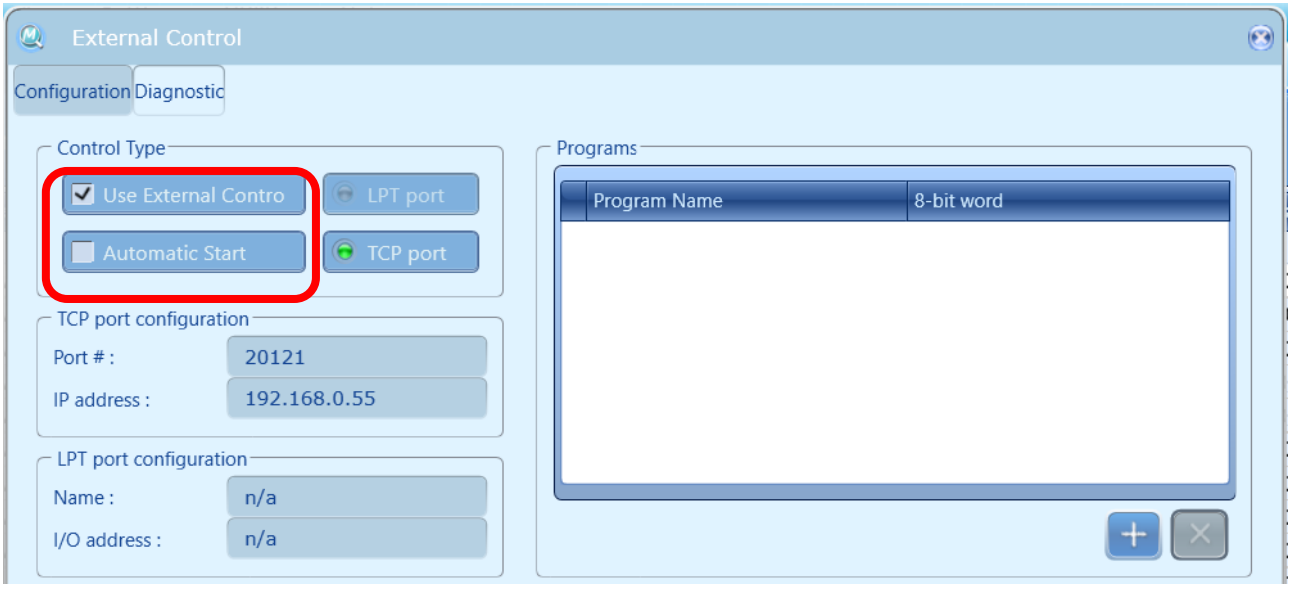


Figure 153: Activating External Control

25.4.4 Common Test Operations

The following common test operations can be performed during a test by sending the equivalent command (ActionCode). Note that the 8-bit words used for these actions are reserved and cannot be assigned to programs.

Table 42: Input - 8bit ActionCodes

Action	Description	8-bit Word	Command Id
Start	Equivalent to the following action button in Test screen: Start Pre-test / Test	00000010	2
Pause	Equivalent to the **Pause** button in **Test** screen	00000011	3
Trigger	Equivalent to the Manual Trigger button.	00000100	4
Stop	Equivalent to the **Stop** button **Test** screen	00000101	5
Abort	The Abort action is used to stop a test without finalizing time, and switch back to Listening Mode.	00000110	6
YES	Equivalent to Response Unit's Yes button.	00000111	7
NO	Equivalent to Response Unit's NO button.	00001000	8
CoVAS	Equivalent to CoVAS (computerized VAS)	00001001	9
VAS	Enter a numerical pain rating	00001010	10
Next Sequence	Specify which sequence to execute next	00001011	11
Increase Temperature	Increase temperature of next trial (works only with VAS Search program)	00001100	12
Decrease Temperature	Decrease temperature of next trial (works only with VAS search program)	00001101	13

Table 43: Output parameter format

Type	Name	Length (bytes)
uint	**Timestamp**	**4**
byte	**Command**	**1**
byte	**SystemState**	**1**
byte	**TestState**	**1**
ushort	**ReturnCode**	**2**
uint	**TestTime**	**4**
short	**Temperature**	**2**
byte	CoVAS	1

byte	Yes	1
byte	No	1
byte	TTL	1
text	Message	ResponseLength - 19

Table 44: Output SystemState code values

SystemState	
0	**IDLE**
1	**READY**
2	**TEST**

Table 45: Output TestState code values

TestState	
0	**IDLE**
1	**RUNNING**
2	**PAUSED**
3	**READY**

Table 46: Output ReturnCode values

ReturnCode	
0x0000	OK
0x0001	ILLEGAL_ARG
0x0002	ILEGAL_STATE
0x0003	ILEGAL_TEST_STATE
0x1000	DEVICE_COMM_ERROR
0x3000	WAITING_MANUAL_OPERATION
0x2000	SAFETY_WARNING
0x4000	SAFETY_ERROR

25.4.5 The External Control Workflow

When the External Control is enabled, the procedure for starting a test will be as following:

1. Select a Patient from the Patient List (required) and a Body site (Optional)
2. Click the Go to Test Button. Medoc Main Station will now be in 'Listening Mode' and wait for the 8-bit word or command to select a program.

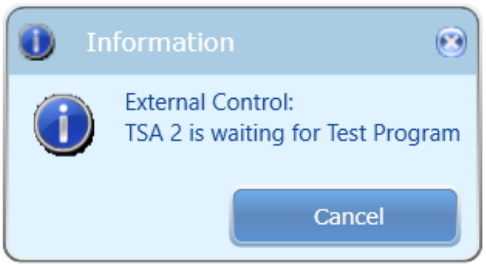


Figure 154 – Listening mode

3. Send the 8-bit word or command from the external application
4. Medoc Main Station will select the program according to the command received and go into Test Mode.
5. If the 'Automatic Start' is enabled, the test will start automatically. Otherwise Medoc Main Station will wait for 'Start' command to be received.
6. During the test Medoc Main Station will remain in 'Listening Mode' and respond to commands such as: 'Yes', 'No' and 'Pause'.
7. At the end of the test, the results will be saved automatically and Medoc Main Station will return to the Program selection screen and wait for the next program command.

25.4.6 Safe Mode

Medoc Main Station will not receive commands from the external application (except for 'Get Status' command in TCP communication) if for any reason TSA system is in Safe Mode. If TSA system is in safe mode, the Operator must use Medoc Main Station software directly to resolve the problem and run a system Self-Test before External Control can be resumed.

25.4.7 Code Example for remote client interface with TSA 2

Syntax for Remote interface

```
using System;
using System.Collections.Generic;
using System.Text;

using Medoc.Remote.Enums;

namespace Medoc.Remote
```

```
{
        /// <summary>
        /// Remote command response
        /// </summary>
        public class RemoteCommandResponse
        {
                private byte m_command;
                private ReturnCode m_result;
                private PathwayTestState m_testState;
                private PathwayState m_systemState;
                private uint m_testTime;
                private uint m_timestamp;
                private string m_message;
    private short m_temperature;
    private byte m_covas;
    private byte m_isYesPressed;
    private byte m_isNoPressed;
    private byte m_ttl;

    private const ushort TIMESTAMP_OFFSET = 0;
    private const ushort COMMAND_OFFSET = 4;
    private const ushort SYSTEM_STATE_OFFSET = 5;
    private const ushort TEST_STATE_OFFSET = 6;
    private const ushort RESULT_OFFSET = 7;
    private const ushort TEST_TIME_OFFSET = 9;
    private const ushort TEMPERATURE_OFFSET = 13;
    private const ushort COVAS_OFFSET = 15;
    private const ushort YES_OFFSET = 16;
    private const ushort NO_OFFSET = 17;
    private const ushort TTL_OFFSET = 18;
    private const ushort ERROR_MESSAGE_OFFSET = 19;

    /// <summary>
    /// Creates RemoteCommand response instance from bytes array
    /// </summary>
    /// <param name="b">Serialized Pathway response</param>
```

```
    public RemoteCommandResponse(byte[] b)
    {
      this.m_timestamp = BitConverter.ToUInt16(b, TIMESTAMP_OFFSET);
      this.m_command = b[COMMAND_OFFSET];
      this.m_systemState = (PathwayState)b[SYSTEM_STATE_OFFSET];
      this.m_testState = (PathwayTestState)b[TEST_STATE_OFFSET];
      this.m_result = (ReturnCode)BitConverter.ToUInt16(b, RESULT_OFFSET);
      this.m_testTime = BitConverter.ToUInt16(b, TEST_TIME_OFFSET);
      this.m_temperature = BitConverter.ToInt16(b, TEMPERATURE_OFFSET);
      this.m_covas = b[COVAS_OFFSET];
      this.m_isYesPressed = b[YES_OFFSET];
      this.m_isNoPressed = b[NO_OFFSET];
      this.m_ttl = b[TTL_OFFSET];
      this.m_message = Encoding.UTF8.GetString(b, ERROR_MESSAGE_OFFSET, b.Length -
ERROR_MESSAGE_OFFSET);
    }

    /// <summary>
    /// Gets the bytes
    /// </summary>
    public byte[] GetBytes()
    {
      List<byte> buffer = new List<byte>();
      buffer.AddRange(BitConverter.GetBytes(m_timestamp));
      buffer.Add(m_command);
      buffer.Add((byte)m_systemState);
      buffer.Add((byte)m_testState);
      buffer.AddRange(BitConverter.GetBytes((ushort)m_result));
      buffer.AddRange(BitConverter.GetBytes(m_testTime));
      buffer.AddRange(BitConverter.GetBytes(m_temperature));
      buffer.Add(m_covas);
      buffer.Add(m_isYesPressed);
      buffer.Add(m_isNoPressed);
      buffer.Add(m_ttl);
      if (m_message != null)
        buffer.AddRange(new System.Text.UTF8Encoding().GetBytes(m_message));
      return buffer.ToArray();
```

```
    }

    /// <summary>
    /// Initializes a new instance of the <see cref="RemoteCommandResponse"/> class.
    /// </summary>
    /// <param name="commandID">Command ID</param>
    /// <param name="timestamp">Cimestamp</param>
    public RemoteCommandResponse(byte commandID, uint timestamp)
        {
            m_command = commandID;
            m_timestamp = timestamp;
        }

        /// <summary>
        /// Sets the result
        /// </summary>
        /// <value>
    public ReturnCode Result
        {
            set
            {
                m_result = value;
            }
        }

        /// <summary>
        /// Sets test time
        /// </summary>
        /// <value>
        public uint TestTime
        {
            set
            {
                m_testTime = value;
            }
        }
```

```
/// <summary>
/// Sets the state of the test
/// </summary>
/// <value>
public PathwayTestState TestState
{
        set
        {
                m_testState = value;
        }
}

/// <summary>
/// Sets the state of the system
/// </summary>
/// <value>
public PathwayState SystemState
{
        set
        {
                m_systemState = value;
        }
}

/// <summary>
/// Sets the message
/// </summary>
/// <value>
public string Message
{
        set
        {
                m_message = value;
        }
}
```

```
/// <summary>
/// Thermode temperature
/// </summary>
public double Temperature
{
  get
  {
    return TempConverter.TCU2PC(this.m_temperature);
  }
  set
  {
    this.m_temperature = TempConverter.PC2TCU(value);
  }
}

/// <summary>
/// COVAS
/// </summary>
public byte Covas
{
  get
  {
    return m_covas;
  }
  set
  {
    m_covas = value;
  }
}

/// <summary>
/// State of response button Yes
/// </summary>
public byte IsYesPressed
{
```

```
        get
        {
            return m_isYesPressed;
        }
        set
        {
            m_isYesPressed = value;
        }
    }

    /// <summary>
    /// State of response button No
    /// </summary>
    public byte IsNoPressed
    {
        get
        {
            return m_isNoPressed;
        }
        set
        {
            m_isNoPressed = value;
        }
    }

    /// <summary>
    /// TTL state
    /// </summary>
    public byte Ttl
    {
        get
        {
            return m_ttl;
        }
        set
        {
```

```
            m_ttl = value;
        }
    }

    public override string ToString()
    {
        StringBuilder sb = new StringBuilder();
        sb.AppendLine(String.Format("Resul: {0}", DecodeError(this.m_result)));
        sb.AppendLine(String.Format("System state: {0}", Enum.GetName(typeof(PathwayState),
this.m_systemState)));
        sb.AppendLine(String.Format("Test state: {0}", Enum.GetName(typeof(PathwayTestState),
this.m_testState)));
        sb.AppendLine(String.Format("Temperature: {0}", this.Temperature));
        sb.AppendLine(String.Format("COVAS: {0}", this.Covas));
        sb.AppendLine(String.Format("YES: {0}", this.IsYesPressed));
        sb.AppendLine(String.Format("NO: {0}", this.IsNoPressed));
        sb.AppendLine(String.Format("TTL: {0}", this.Ttl));
        if (!String.IsNullOrEmpty(this.m_message))
            sb.Append(this.m_message);
        return sb.ToString();
    }

    private string DecodeError(ReturnCode errCode)
    {
        switch (errCode)
        {
            case ReturnCode.DEVICE_COMM_ERROR:
                return "Error: Communication with device has lost";
            case ReturnCode.ILEGAL_STATE:
                return "Error: Illegal system state";
            case ReturnCode.ILEGAL_TEST_STATE:
                return "Error: Illegal test state";
            case ReturnCode.ILLEGAL_ARG:
                return "Error: Illegal command parameter";
            case ReturnCode.OK:
                return "OK";
            case ReturnCode.WAITING_MANUAL_OPERATION:
```

```
            return "Error: Waiting manual operation";
          case ReturnCode.SAFETY_ERROR:
            return "Error: Safety error";
          case ReturnCode.SAFETY_WARNING:
            return "Error: Safety warning";
        }
        return "Unknown error, code =" + errCode;
      }
          }
}
```

Syntax for Temperature short to double format conversion

```
using System.Runtime.InteropServices;

namespace Medoc
{
  /// <summary>
  /// Converts temperatures between TCU and PC
  /// </summary>
          [ComVisible(false)]
          public class TempConverter
  {
                    public const double TCU_TO_PC = 0.01;

                    public static double TCU2PC(short val)
    {
                              return val * TCU_TO_PC;
                    }

    public static double TCU2PC(ushort val) {
      return val * TCU_TO_PC;
    }

    public static double TCU2PC(int val) {
      return val * TCU_TO_PC;
    }
```

```
                public static short PC2TCU(double val)
                {
                        val /= TCU_TO_PC;
                        if(val >= 0)
                                return (short)(val + 0.5);
                        else
                                return (short)(val - 0.5);
                }

    public static ushort PC2TCUUshort(double val)
                {
      val /= TCU_TO_PC;
      if(val > 0)
        return (ushort)(val + 0.5);
      else
        return 0;
    }

    public static int PC2TCUInt(double val) {
      val /= TCU_TO_PC;
      if(val > 0)
        return (int)(val + 0.5);
      else
        return (int)(val - 0.5);
    }
  }

  /// <summary>
  /// Converts rate between TCU and PC
  /// </summary>
        public class RateConverter
        {
                public const double TCU_TO_PC = 0.001;

                public static double TCU2PC(int val)
```

```
                {
                        return val * TCU_TO_PC;
                }

                public static int PC2TCU(double val)
                {
                        val /= TCU_TO_PC;
                        if(val >= 0)
                                return (int)(val + 0.5);
                        else
                                return (int)(val - 0.5);
                }
        }
}
```

25.4.8 Python Code example for external control using VAS Search

```
#!/usr/bin/env python3.6
# -*- coding: utf-8 -*-

from   time                    import   time, sleep
from   datetime                  import   datetime
import socket
import struct
import binascii

##############################################################################

##############################################################################
class FakeEventListener():
   def wait_for_seconds(self, seconds):
      sleep(seconds)

class FakeConfig():
   address = '192.168.1.160'
   port = 20121
   debug = 1
```

```
    timedelayformedoc = 0.1
    vas_search_program = '00011100'

config = FakeConfig()
################################################################################
################################################################################
################################################################################

command_to_id = {
    'GET_STATUS':   0,
    'SELECT_TP':    1,
    'START':        2,
    'PAUSE':        3,
    'TRIGGER':      4,
    'STOP':         5,
    'ABORT':        6,
    'YES':          7,  # used to start increasing the temperature
    'NO':           8,  # used to start decreasing the temperature
    'COVAS':        9,
    'VAS':         10,
    'SPECIFY_NEXT':11,
    'T_UP':        12,
    'T_DOWN':      13,
    'KEYUP':       14,  # used to stop the temperature gradient,
    'UNNAMED':     15
}
# make the same as above but reversed:
id_to_command = {item:key for key, item in command_to_id.items()}

test_states = {
    0   : 'IDLE',
    1   : 'RUNNING',
    2   : 'PAUSED',
    3   : 'READY'
}

states = {
```

```
   0   : "IDLE",
   1   : "READY",
   2   : "TEST IN PROGRESS"
}

response_codes = { 0 :    "OK",
                   1 :    "FAIL: ILLEGAL PARAMETER",
                   2 :    "FAIL: ILLEGAL STATE TO SEND THIS",
                   3 :    "FAIL: NOT THE PROPER TEST STATE",
                   4096:  "DEVICE COMMUNICATION ERROR",
                   8192:  "safety warning, test continues",
                   16384: "Safety error, going to IDLE"
}
##############################################################################
##############################################################################
##############################################################################

#  converter from bytes to int:
def intToBytes(integer, nbytes):
   return integer.to_bytes(nbytes, byteorder='big')
# converter from int to bytes:
def intFromBytes(xbytes):
   return int.from_bytes(xbytes, 'big')


# packs bytes together
def commandBuilder(command, parameter=None):
   if type(command) is str:
      command = command_to_id[command.upper()]

   if type(parameter) is str:
      # then program code, e.g. '00000001'
      parameter = int(parameter, 2)
   elif type(parameter) is float:
      parameter = 100*parameter

   commandbytes = intToBytes(socket.htonl(int(time())), 4)
```

```
    commandbytes += intToBytes(int(command), 1)
    if parameter:
                commandbytes += intToBytes(socket.htonl(int(parameter)), 4)
    return intToBytes(len(commandbytes), 4) + commandbytes # prepending the command data with 4-bytes header
that indicates the command data length



# command sender:
def sendCommand(command, parameter=None, address=config.address, port=config.port,
            el=FakeEventListener()):
    """
        this functions allows sending commands to the MMS


        e.g. :     sendCommand('get_status')
        or         sendCommand('select_tp', '01000000')
    """
    # convert command to bytes:
    commandbytes = commandBuilder(command, parameter=parameter)
    if config.debug:
        print(f'Sending the following bytes: {binascii.hexlify(commandbytes)} -- {len(commandbytes)} bytes')
    # now the connection part:
    for attemps in range(3):
        try:
                s = socket.socket()
                s.connect((address, port))
                s.send(commandbytes)
                data = msg = s.recv(1024)
                while data:
                        data = s.recv(17)
                        msg += data
                resp = medocResponse(msg)
                if config.debug:
                        print("Received: ")
                        print(resp)
                break
        except ConnectionResetError:
            print("==> ConnectionResetError")
```

```
        attemps += 1
        s.close()
        el.wait_for_seconds(config.timedelayformedoc)
        pass

    el.wait_for_seconds(config.timedelayformedoc)
    return resp



# printout:
class medocResponse():
    """
      A container to interpret and store the output response.
    """
    # decoding the bytes we receive:
    def __init__(self, response):
        self.length    = struct.unpack_from('H', response[0:4])[0]
        self.timestamp = intFromBytes(response[4:8])



        self.datetime  = datetime.fromtimestamp(self.timestamp)
        self.strtime   = self.datetime.strftime("%Y-%m-%d %H:%M:%S")

        self.command   = intFromBytes(response[8:9])

        self.state     = intFromBytes(response[9:10])
        # see if we have a documented state for this response:
        if self.state in states:
            self.statestr = states[self.state]
        else:
            self.statestr = 'unknown state code'

        self.teststate = intFromBytes(response[10:11])
        # see if we have a documented test state for this response:
        if self.teststate in test_states:
            self.teststatestr = test_states[self.teststate]
        else:
```

```
        self.teststatestr = 'unknown test state code'


    self.respcode  = struct.unpack_from('H', response[11:13])[0]

    if self.respcode in response_codes:
        self.respstr   = response_codes[self.respcode]
    else:
        self.respstr    = "unknown response code"

    # the test time is in seconds once divided by 1000:
    self.testtime  = struct.unpack_from('I', response[13:17])[0] / 1000.
    # the temperature is in °C once divided by 100:
    self.temp      = struct.unpack_from('h', response[17:19])[0] / 100.
    self.CoVAS     = intFromBytes(response[19:20])
    self.yes       = intFromBytes(response[20:21])
    self.no        = intFromBytes(response[21:22])
    self.message   = response[22:self.length]
    # store the whole response
    self.response  = response


def __repr__(self):
    msg = ""
    msg += f"timestamp     : {self.strtime}\n"
    msg += f"command       : {id_to_command[self.command]}\n"
    msg += f"state         : {self.statestr}\n"
    msg += f"test state    : {self.teststatestr}\n"
    msg += f"response code : {self.respstr}\n"
    msg += f"temperature   : {self.temp}°C\n"
    if   self.statestr == "TEST IN PROGRESS":
        msg += f"test time     : {self.testtime} seconds\n"
    elif self.respstr != "OK":
        msg += f"sup. message  : {self.message}\n"
    if self.yes:
        msg += "~~ also: yes was pressed! ~~\n"
    if self.no:
```

```
        msg += "~~ also: no was pressed! ~~\n"
    return msg
  def __str__(self):
    return self.__repr__()
  def __getitem__(self, s):
    return self.response[s]



if __name__ == "__main__":
  sendCommand('select_tp', config.vas_search_program)
  sleep(15)
  sendCommand('vas', 4) # Set pain rating 4
  sleep(3)
  sendCommand('t_down', 500) # Step 5 degrees down
  sleep(10)
  sendCommand('vas', 7) # Set pain rating 7
  sleep(3)
  sendCommand('t_up', 500) # Step 5 degrees up
  sleep(10)
  sendCommand('vas', 10) # Set pain rating 10
  sleep(3)
  sendCommand('stop')
```

26. Appendix L – fMRI functionality

26.1 fMRI Thermode

TSA 2 fMRI Thermode and accessories are defined and marked as MR Conditional equipment according to the ASTM F2503–08. This does not apply to the main device.

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 2 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 2 system was tested in the following MR Sequences:

1. **Echo Planer Imaging (EPI) bold (fMRI)**
2. **rf_noise and rf_noise spectrum electromagnetic noise interference (Siemens protocol)**

26.1.1 TSA 2 system configuration in fMRI mode:

The fMRI TSA 2 system includes the following components:

- Control room Thermode cable
- TSA 2 fMRI Thermode

The TSA 2 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 2 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.

NOTE: Using the TSA 2 fMRI Thermode at the scanner isocenter during operation, may produce a slight vibration.

26.1.2 Installation –MR Filter

5. A penetration panel in the scanner room is the access point for introduction of various equipment into the scanner room. The waveguide (see Figure 155) 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 155: Typical penetration panel with waveguide tube and 15 pin d-type cutouts (bottom right of the image)

6. Connect the system devices according to the following stages:
   6.1. Place the TSA 2 system in the MRI control room. Leave the TSA 2 OFF.
   6.2. 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.
   6.3. 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.
   6.4. Connect the 15 pin d-type connector to the panel. An adapter is provided to fit most cutouts (see Table 34: Accessories). 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.
   6.5. 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.
   6.6. Connect TSA 2 coolant connectors and electrical connectors to the TSA 2 connector panel as with a regular Thermode. See below figures.

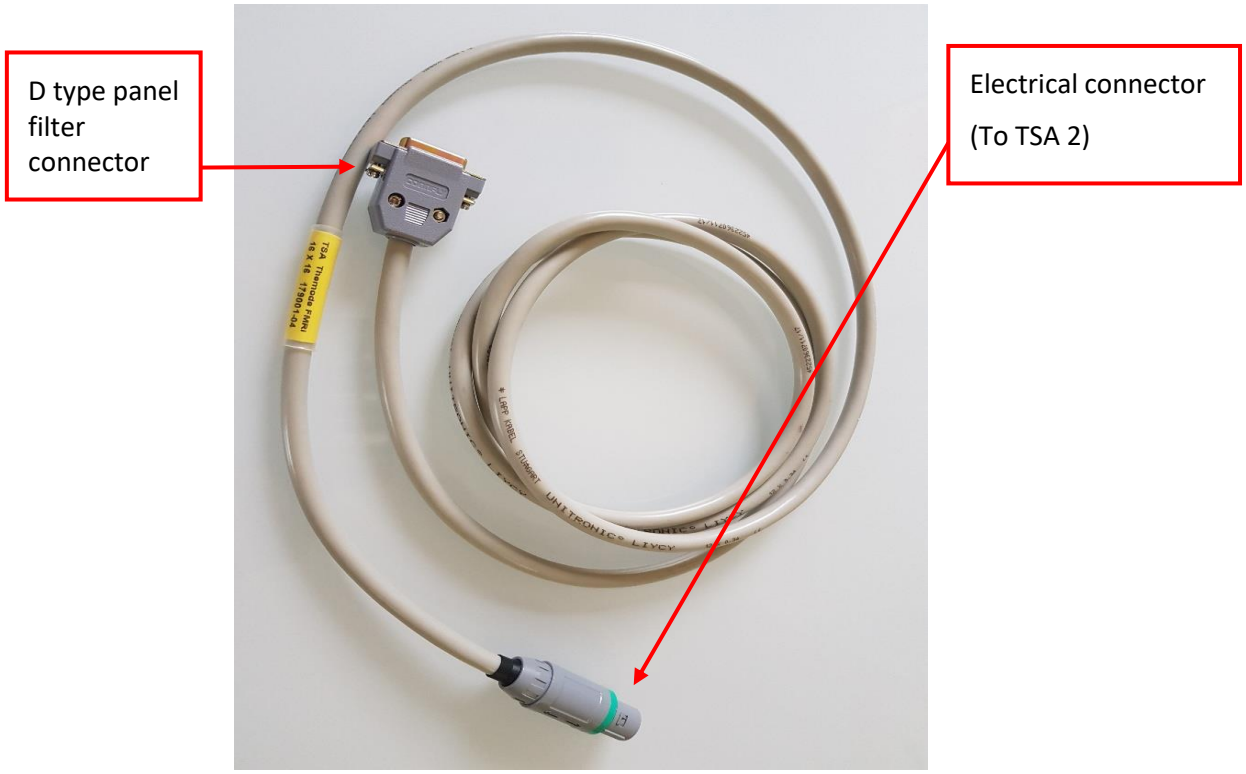


Figure 156: TSA 2 fMRI Thermode Control Room part WA 00077

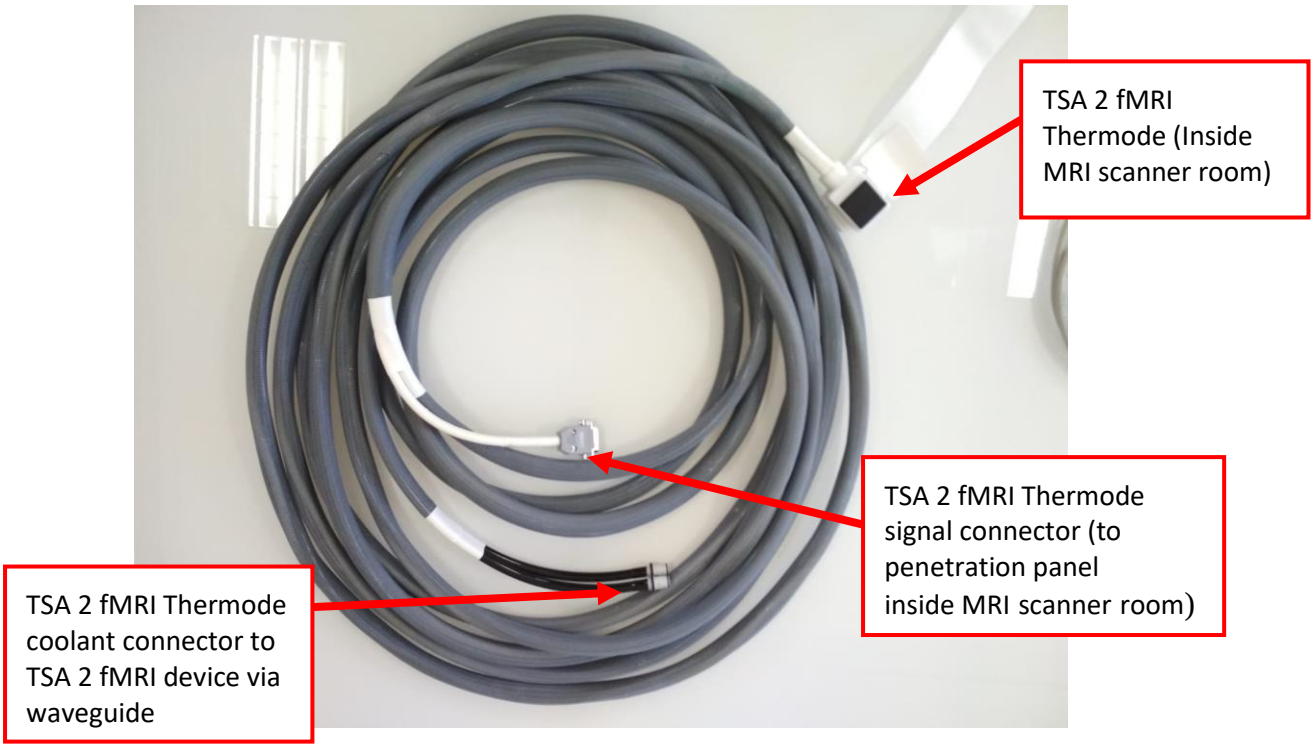


Figure 157: TSA-II fMRI Thermode Shielded room part AS 00178

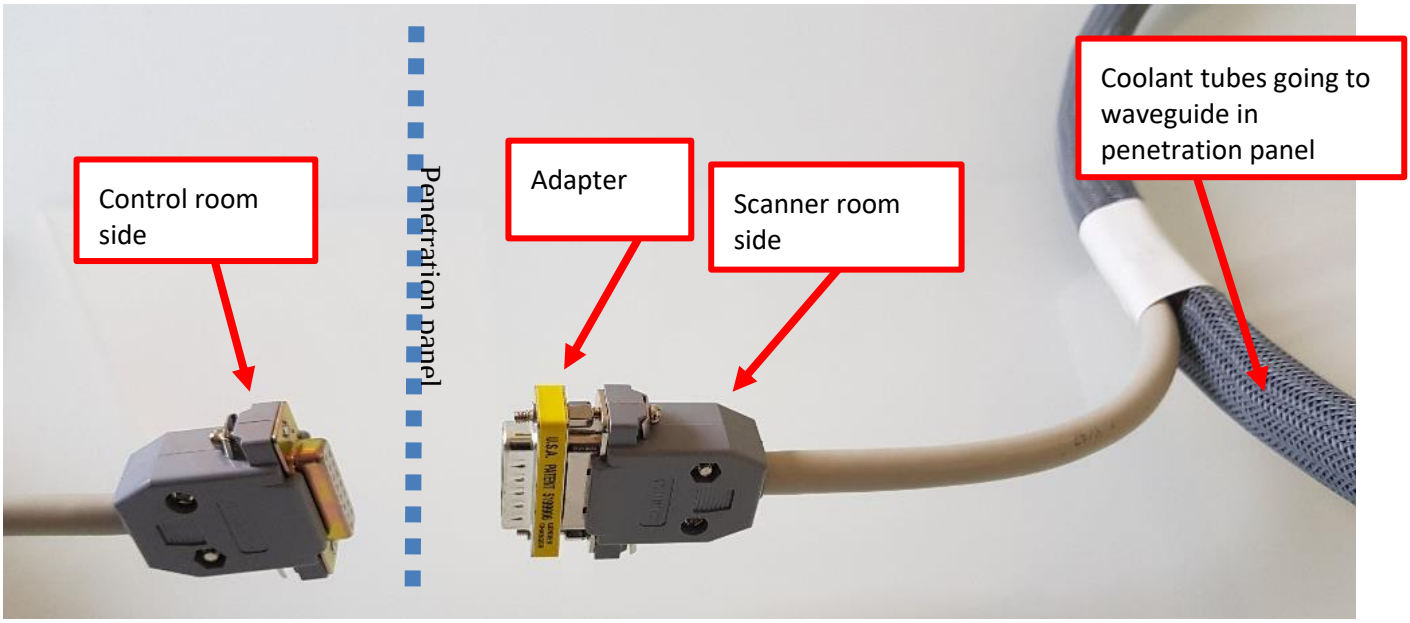


Figure 158: Signal/power cable and adapter connection

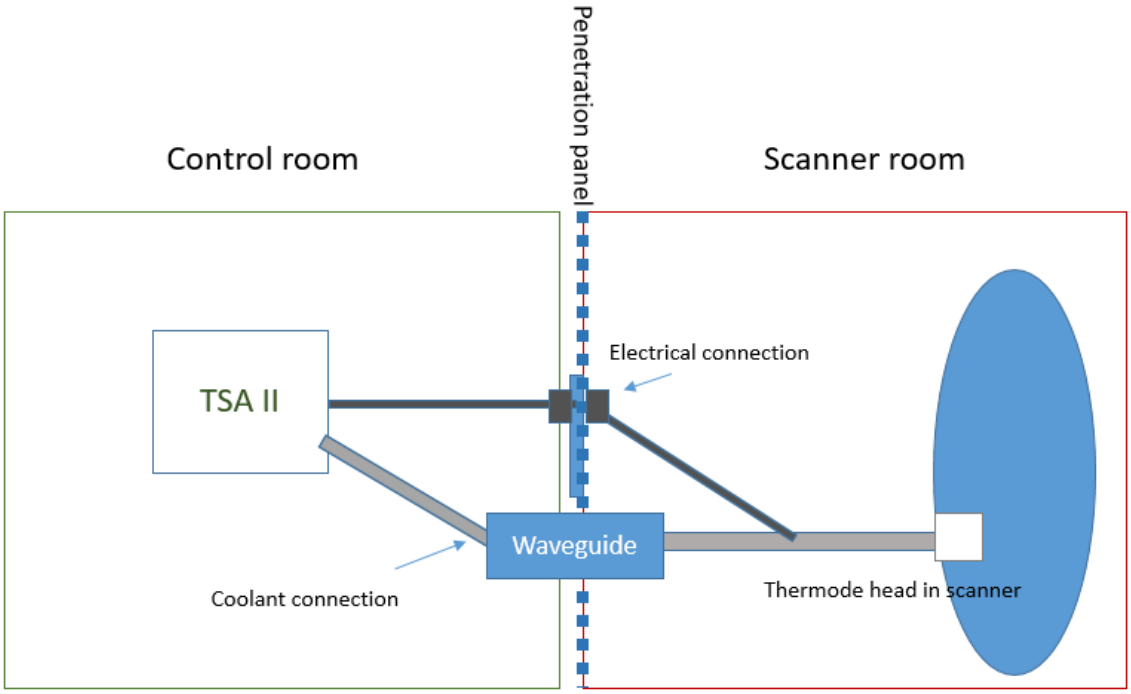


Figure 159 : Schematic diagram of connecting fMRI thermode

7. Conduct three phantom tests:

7.1. Conduct the test, when the TSA 2 is OFF,

7.2. Conduct the test, when the TSA 2 is ON and software is OFF,

7.3. Conduct the test, when the TSA 2 and software are ON and software test is running.

8. 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.

27. Appendix M – Calibration

The Thermode calibration procedure must be performed for each Thermode due to mechanical and electrical differences between the Thermodes.

The calibration procedure requires the Calibration kit supplied by Medoc.

After initial software installation, the Thermode calibration files should be loaded automatically. In case they are not, load Thermode calibration tables from the Installation CD. See Load Thermode file 12.1.4.

Calibration may only be performed by a trained person, and only by using the Thermal Calibration Kit supplied by Medoc.

27.1 Thermode Calibration Overview

- Calibration table consist of 30 temperature points. During calibration each temperature point is assigned two ADC values referring to the calibrated measures according to Thermode type. All values (ADC and temperatures) can be monotonically increasing only.
- The calibrated measures in Thermodes are two thermistors. Their ADC values are referred to as **TEC 1** and **TEC 2**.
- Calibration range is -3˚C - 54˚C for all Thermodes.

- For more information regarding calibration procedure please refer to:
- Automatic calibration (see 27.4)
- Manual calibration (see 27.5)

27.2 Calibration Kit

Thermal Calibration kit (AS 00187) Contents:

- Medoc Calibration Device.
- Thermal grease.
- Thermode adaptor.
- USB Communication cable.
- Calibration Jigs (per Thermode type)

Thermal Grease

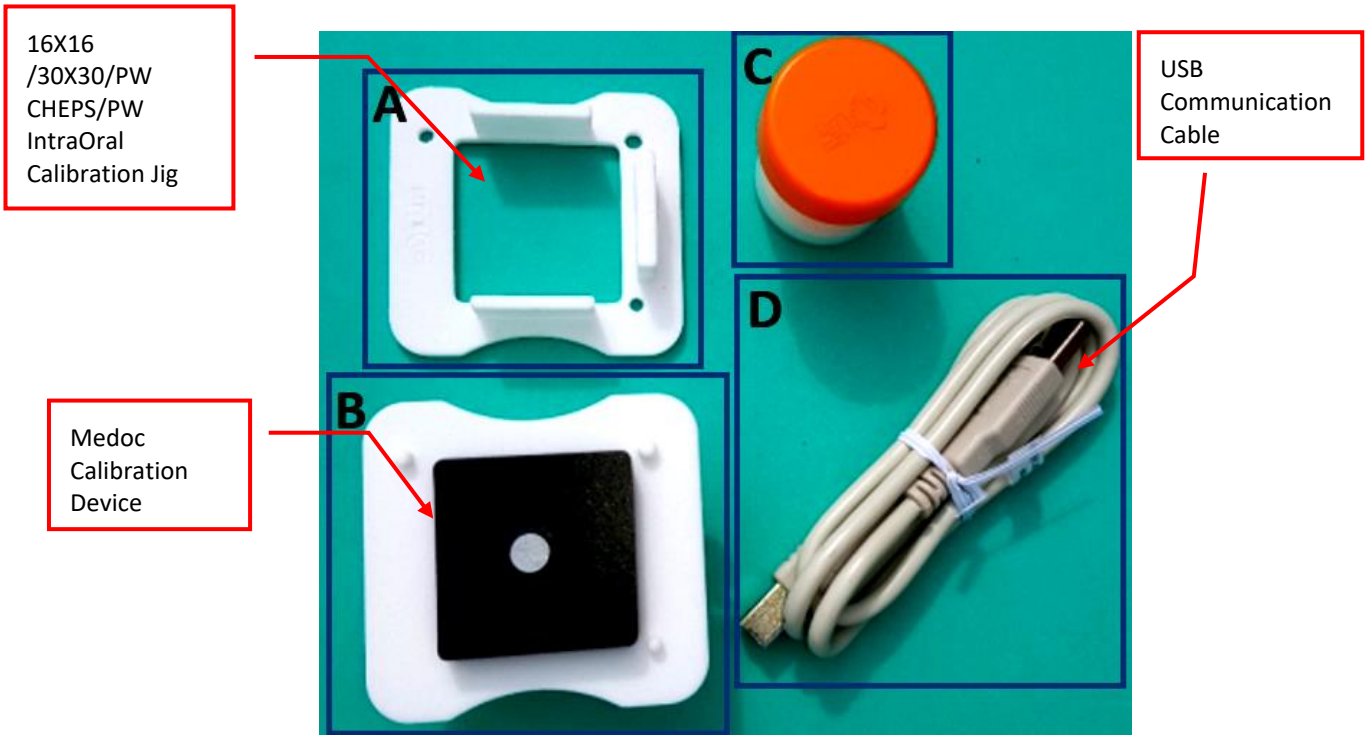


Figure 160. Medoc Calibration Device, Calibration Jig(s), USB Communication Cable, Thermal Grease

27.3 Calibration Device Setup

1. Place the Thermode Calibration Jig over the Calibration Device – using the three alignment pins, as shown in the following figure.

Figure 161 Medoc Calibration Device with Calibration Jig assembled

2. Apply Thermal grease (from the thermal calibration kit) to the center of the foil of the Calibration Device.

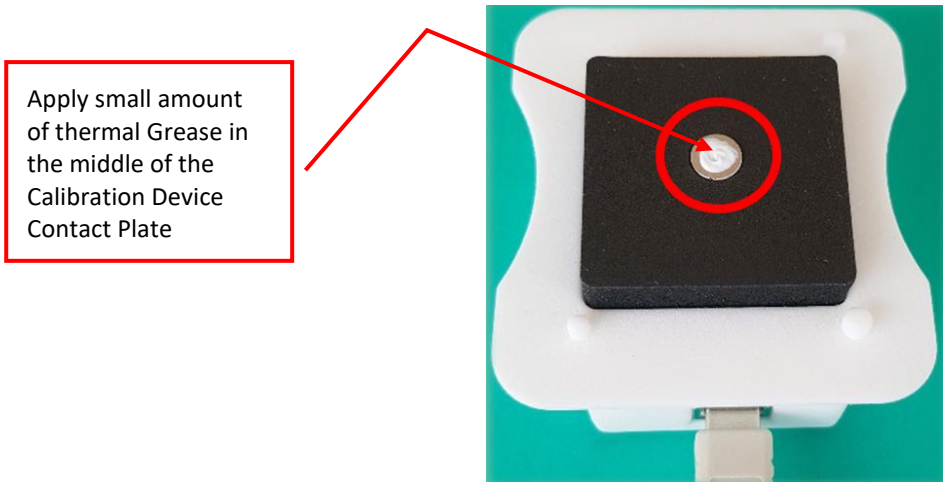


Figure 162 Calibration Device with Thermal Grease applied on it

3. Mount the Thermode in the Calibration Jig and secure with the strap.

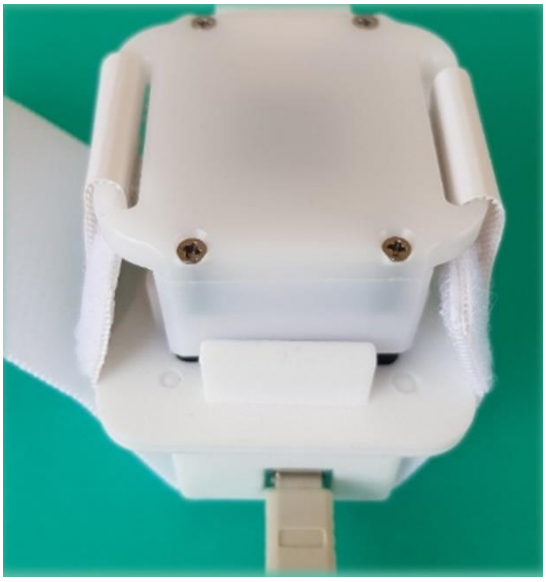


Figure 163 Thermode mounted on the Calibration Device (Top View)

4. Turn ON the TSA 2 system, and continue to preferred calibration procedure.

27.4 Automatic Calibration

Medoc highly recommends carefully reading the entire automatic calibration procedure, prior to the actual Thermode calibration.

Make sure you have completed all instructions mentioned in 27.3 (Calibration Setup).

In order to use the automatic calibration, the decimal symbol on your PC must be set to "." (Decimal point).

27.4.1 Thermometer Communication Setup

Connect one end of the USB Communication cable to the Calibration Device and the other end to the PC/Laptop where MMS is installed.

Check which COM port is used for communication between the Calibration Device and your PC. This can be done by using the device manager on your computer. Should Look similar to the following figure

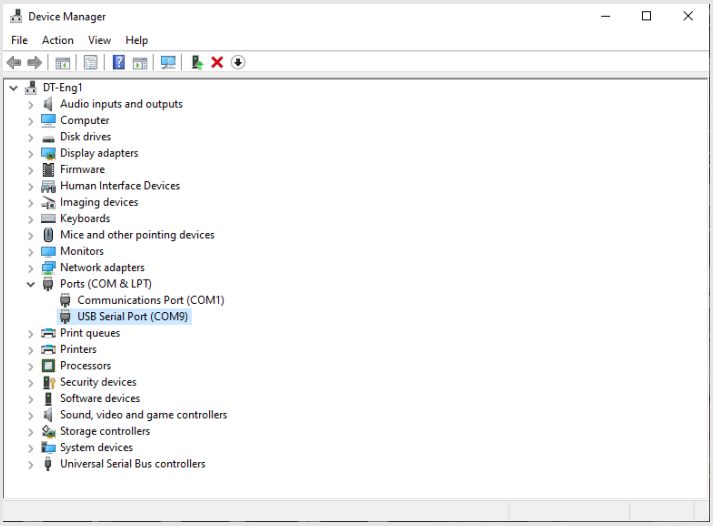


Figure 164 Device Manager showing which COM port used for the Calibration Device

27.4.2 Automatic Calibration Procedure

1. Turn the Thermometer ON.
2. Start Medoc Main Station and make sure that communication is established between the PC and the TSA 2.
3. From the **Settings** menu, select the **Software Settings** option.

The following screen is displayed:

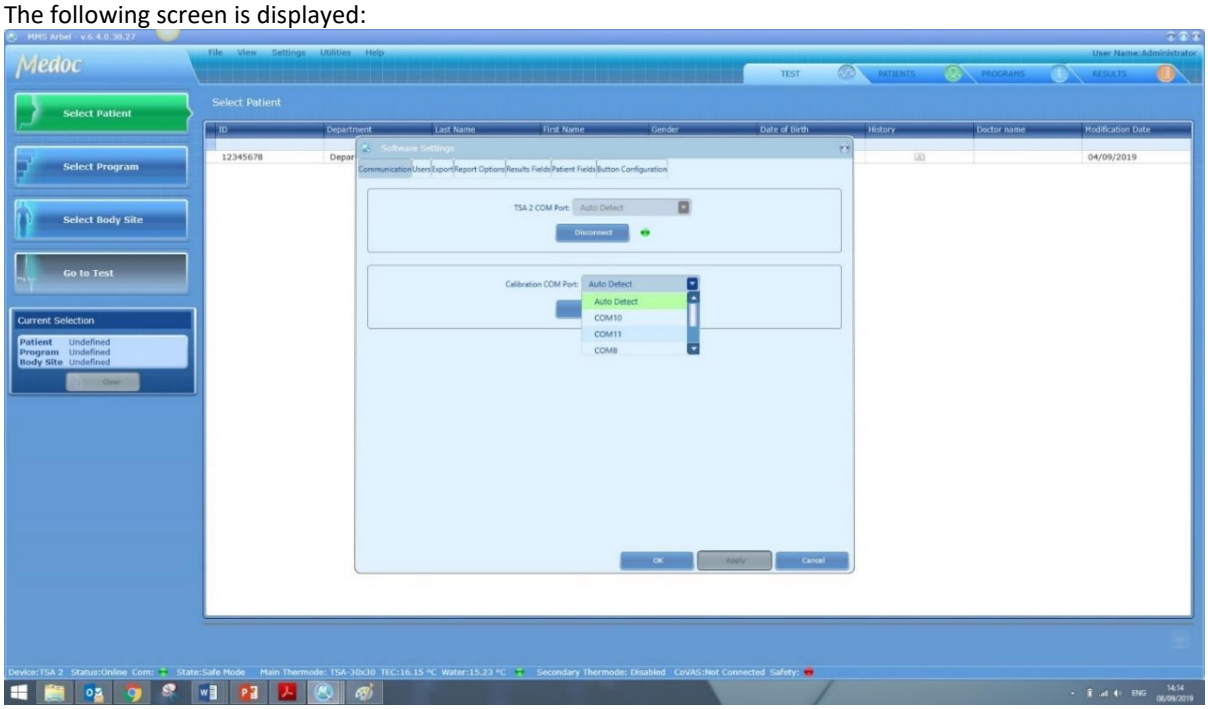


Figure 165: Calibration Port Selection

4. From the **Calibration COM port** drop down list, select the appropriate COM port for the YSI thermometer, according to the COM port to which it is connected.

5. Check whether communication with the YSI thermometer can be established, by pressing the **Check** button.
   Green light indicates “pass”.
   Red light indicates “fail”. In case of a failure, make sure that all communication cables are connected properly and that you have selected the correct COM port.

6. Click the **OK** button.

7. From the **Settings** menu, select the **Hardware Settings** option.
   The following screen is displayed:

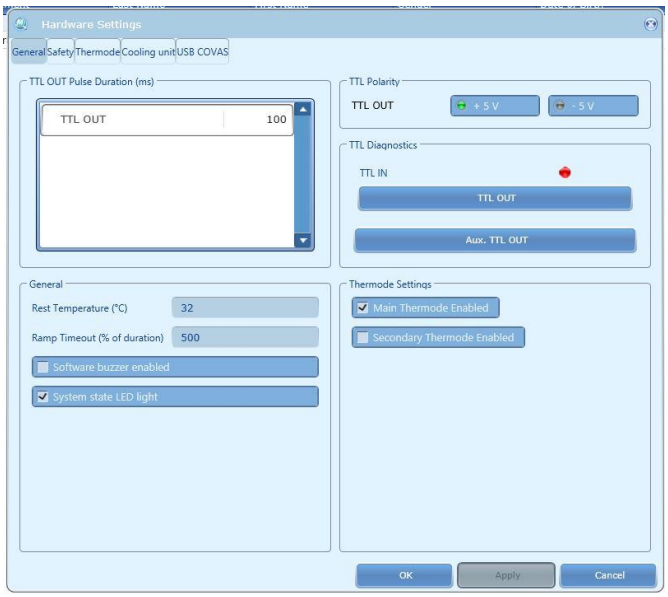


Figure 166: Hardware Settings Menu

Select the **Thermode** tab.
The following screen is displayed:

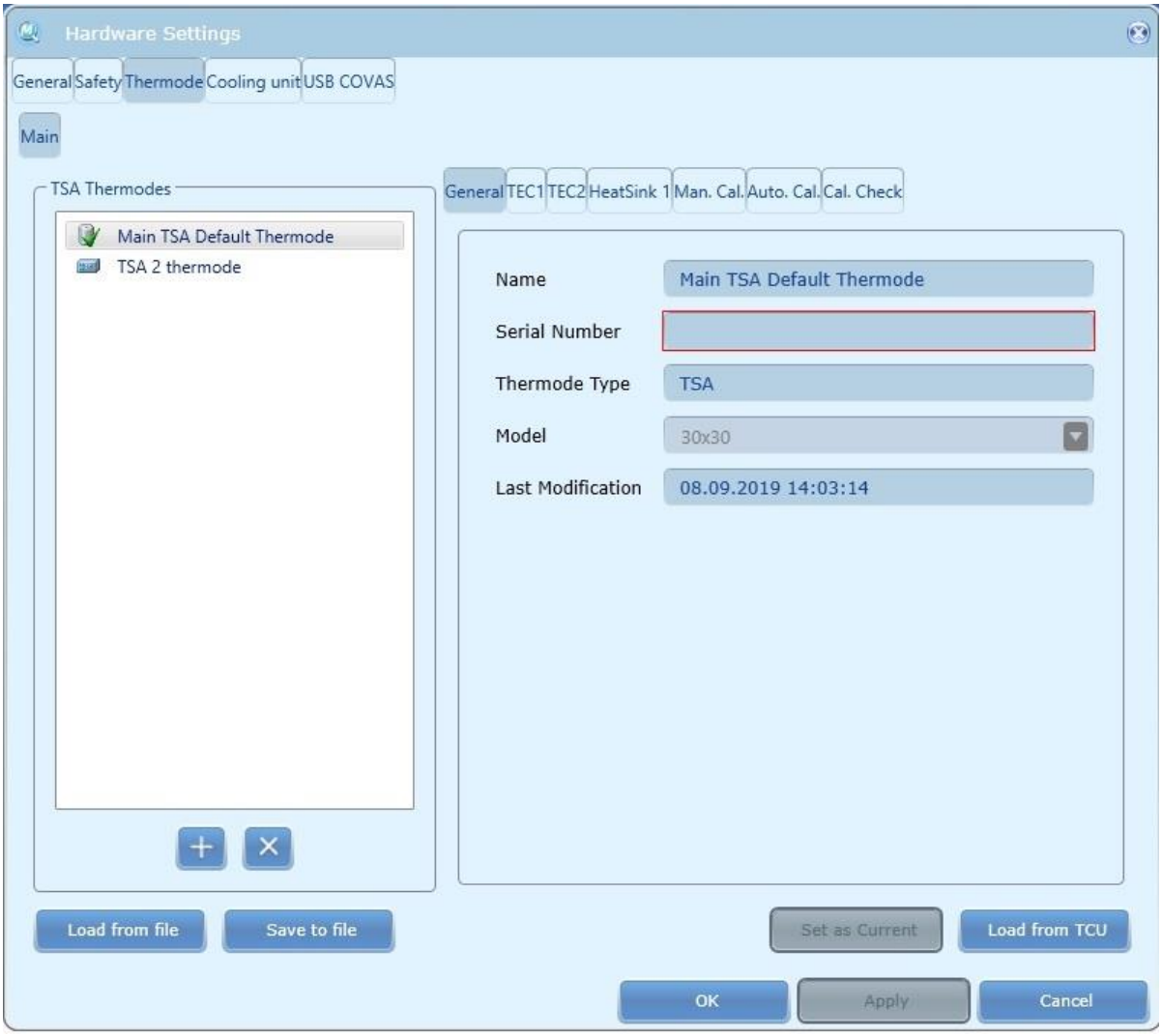


Figure 167: Thermode Calibration – General

The displayed window includes a few additional tabs:

- Thermode type tabs
- Automatic Calibration tab.

8. From the Thermode name list on the left sidebar, select the Thermode you wish to calibrate
9. Click the **Set as current** button. Make sure that the icon of the selected Thermode is marked by a green check-mark.
10. Select the **Automatic Calibrate** tab.

The following screen is displayed:

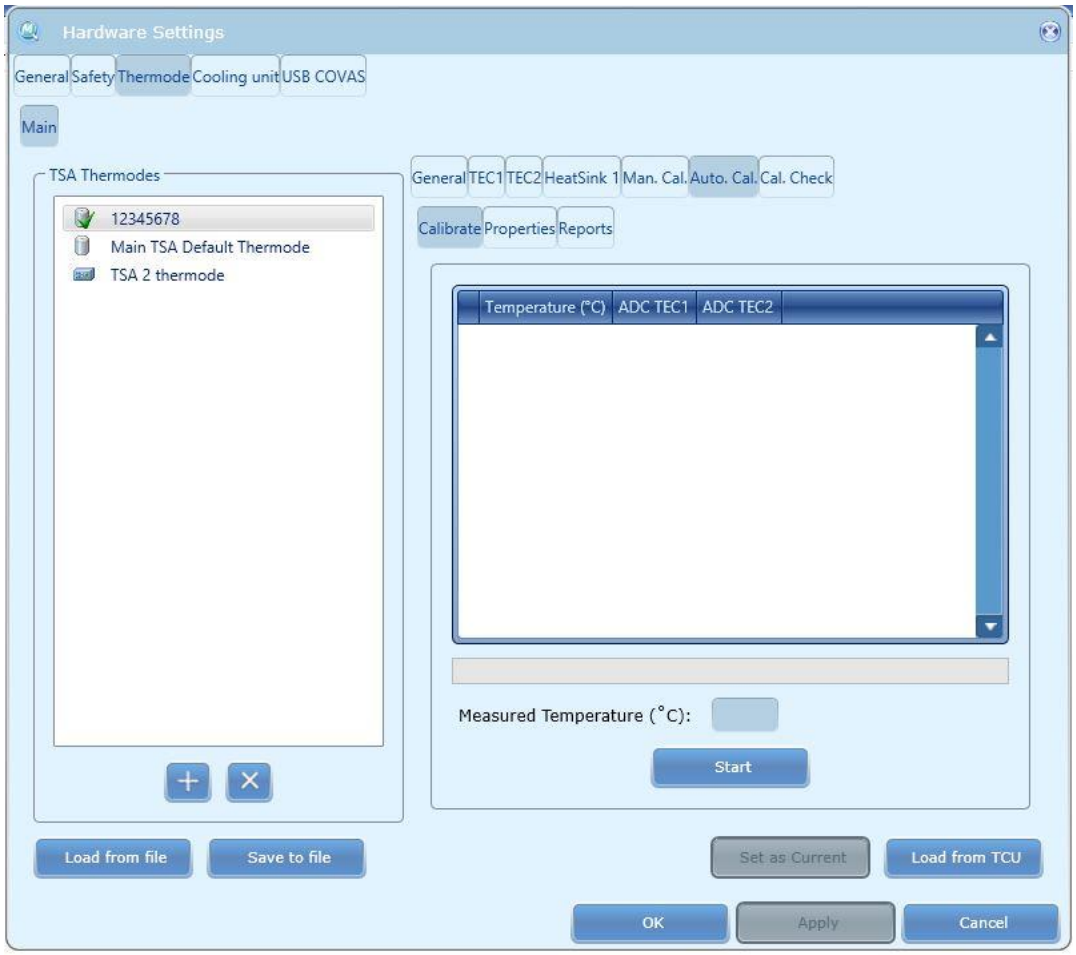


Figure 168: Thermode Automatic Calibration

11. Make sure that the YSI thermometer is turned ON, that it is connected properly to your computer, and that the selected Thermode is placed in the calibration jig.
12. Click the **Start** button.
    A conformation message is displayed, reminding you to check the connection, and pay extra attention to Thermode temperature.
13. Confirm by clicking **YES**. The automatic calibration procedure will start.
14. Wait until the automatic calibration procedure is complete.
    The TSA 2 system sets the new calibration table as current by default.
15. Click the **OK** button.

27.4.3 Concluding Steps

1. Unfasten the strap and remove the Thermode from the jig.
2. Wipe of any excess thermal grease from the Thermode and Thermometer Sensor with a clean cloth **without any detergent**.
3. Disconnect the Thermometer communication cable from the computer.
4. Pack the calibration kit back into its case.

27.4.4 Automatic Calibration Properties

Properties of automatic calibration may be adjusted if needed, however it is recommended to use the default parameters. The properties can only adjusted by software administrator or biomedical engineer.

In order to access and adjust the calibration properties follow these instructions:

1. From the **Settings** menu, select the **Hardware Settings** option Thermode tab.
2. Select the **Auto. Cal.** tab.
   the following screen is displayed:

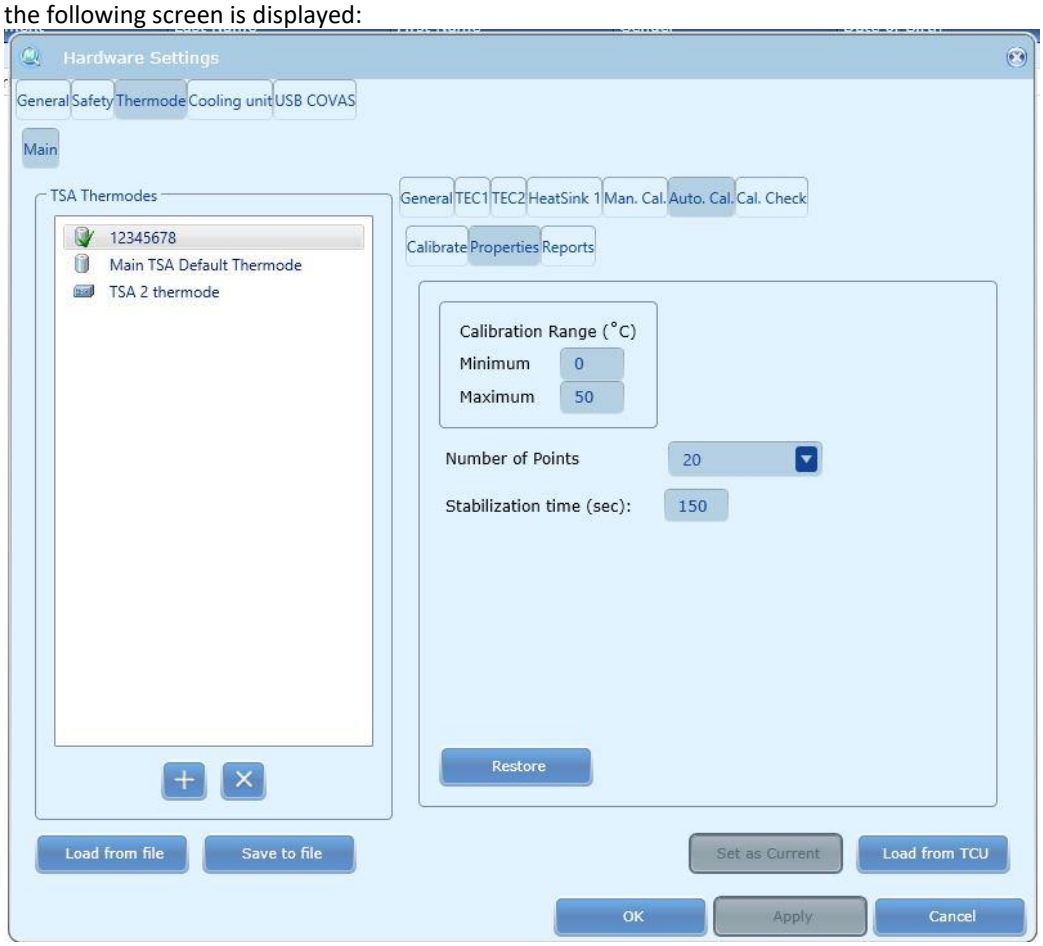


Figure 169: Automatic Calibration Tab

3. Select the **Properties** tab.
   the following screen is displayed:
4. Automatic calibration properties can be adjusted according to the following table:

Table 47: Automatic Calibration Properties

Parameter		Description	Default	Valid Range
Calibration Range	Minimum	The minimum temperature that the automatic calibration will check.	-3 °C	-10°C - 5°C
	Maximum	The maximum temperature that the automatic calibration will check.	54 °C	50°C - 55°C

Parameter		Description	Default	Valid Range
Number of Points		The number of points that the automatic calibration procedure will calibrate.	30	-
Stabilize Time		The stabilization duration that is required before sampling temperature at each temperature point.	150	120 – 1200 sec

27.5 Manual Calibration Procedure

1. Start Medoc Main Station and make sure that communication is established between PC and the TSA 2 system.
2. From the **Settings** menu, select the **Hardware Settings** option.

   The displayed window includes few additional tabs:

   - Thermode type tabs.
   - Manual calibration tab
3. From the Thermode name list on the left sidebar, select the Thermode you wish to calibrate.
4. Click the **Set as current** button. Make sure that the icon of the selected Thermode is marked by a green check-mark.
5. Select the **Man. Cal** tab.
   The following screen is displayed

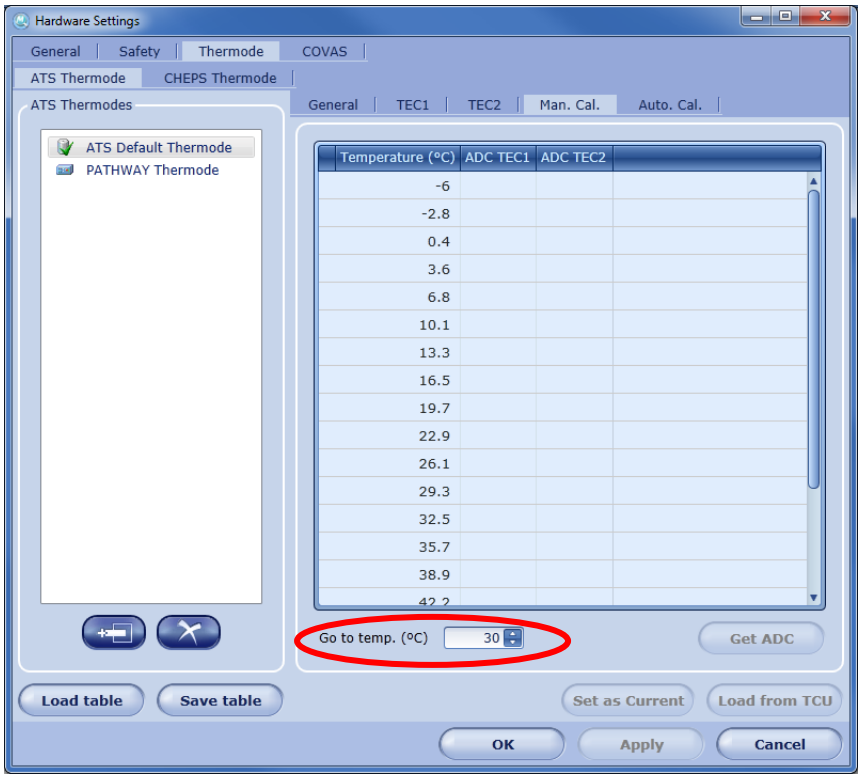


Figure 170: Thermode Calibration – Manual Calibration Tab

The spin box (marked in red) is used to set the required the Thermode temperature.

6. Select the first row in calibration field, corresponding to the first temperature.
7. Increase or decrease the temperature in the spin-box (circled in red, see Figure 170) using the up / down arrows, until the temperature value displayed (in the spin box) is the same as the **Temperature (ºC)** value in the selected row.
8. Wait at least 2 minutes until you see that the temperature on the thermometer screen has stabilized.
9. Replace the temperature value that appears in the selected row of the calibration careen with the temperature value displayed on the thermometer screen.

   For example: if the temperature in the selected row is 26.6, adjust the value in the spin-box to 26.6 by using the arrows. Wait about 2 minutes; then, type the value that appears in the thermometer in the selected row, instead of the initial value of 26.6 in this case.
10. Click the **Get ADC** button, and wait 3 seconds for TSA 2 to calculate the corresponding ADC value. After the calculated value is displayed in the row you can proceed.

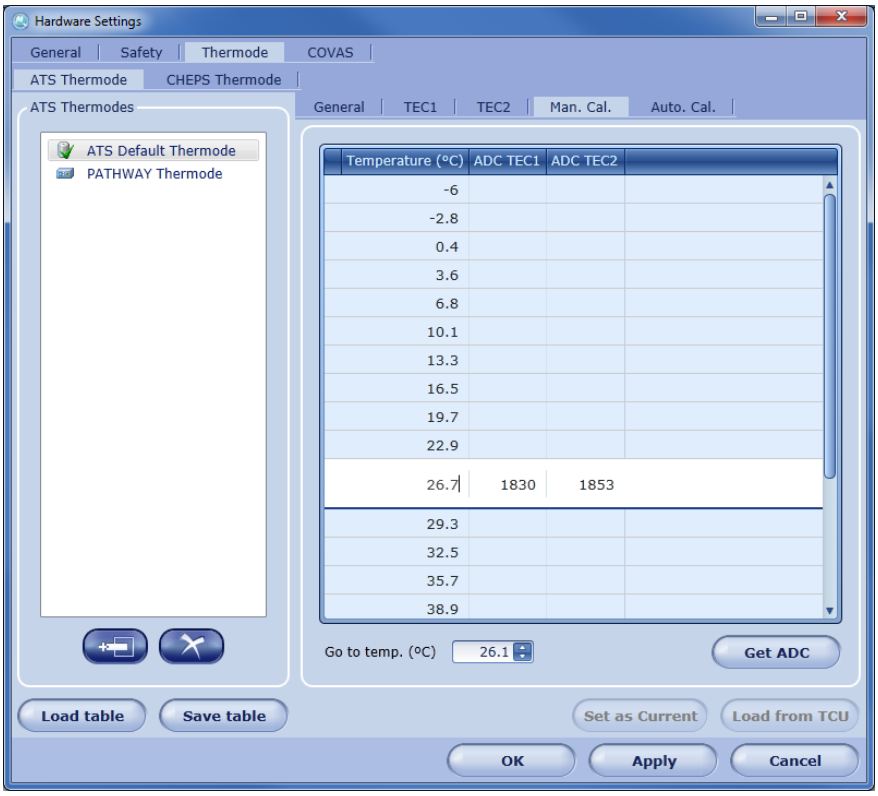


Figure 171: Manual Calibration in Process

11. Continue to the next row – to the next temperature you wish to calibrate.
12. Repeat steps 9 to 14, until the calibration table has been completed for all 20 temperature points.
13. Click the **Apply** button in order to save and complete the calibration calculations.
14. Click the **General** tab and select the recently calibrated Thermode.
15. Click the **Set as Current** button in order to load the new calibration table to the PATHWAY system.

27.5.1 Concluding Steps

1. Unfasten the strap and remove the Thermode from the jig.
2. Wipe of any excess thermal grease from the Thermode and Thermometer Sensor with a clean cloth **without any detergent**.
3. Disconnect the Thermometer communication cable from the computer.
4. Pack the calibration kit back into its case.

27.5.2 Manual Calibration Properties

- Only 20 out of the 30 pairs of values can be calibrated by the user. The remaining values are calculated and filled-in automatically.
- The calibration range for user calibrated pairs are -3˚C - 54˚C

Calibrating temperature points that exceed the required range will cause errors and calibration procedure will not be completed!

- The required range is divided by default into 20 temperature points evenly spaced. These temperatures are displayed in the calibration table and user is recommended to calibrate according to these points.
- The minimum number of pairs required to enable the automatic completion of the calibration table is 15.
- TSA 2 will automatically calculate and fill-in the remaining pairs according to complete calibration range.

27.5.3 Saving calibration tables and back-up:

- Calibration table can be saved at any point during calibration procedure as a ".csv" file. To save table click the Save table button and select location and file name for saving.
- To load a saved table, click the Load table button. The loaded file must be in ".csv" format.

Medoc recommends saving the calibration table during the calibration process in order to prevent any loss of data in case of communication error during the process.

28. Appendix N – List of Indications

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Abraham, A., Barnett, C., Katzberg, H. D., Lovblom, L. E., Perkins, B. A., & Bril, V. (2018). Nerve function varies with hemoglobin A1c in controls and type 2 diabetes. Journal of diabetes and its complications, 32(4), 424-428.	TSA 2	not expressly stated	cold sensation	Levels	endocrinology	Diabetes mellitus type 2	53 healthy controls, 223 patients with DM2

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Abraham, A., Barnett, C., Lovblom, L. E., Perkins, B. A., Bril, V., & Katzberg, H. D. (2018). Cramps frequency and severity are correlated with small and large nerve fiber measures in type 1 diabetes. *Clinical Neurophysiology*, *129*(1), 122-126.	TSA 2	not expressly stated	Cold sensation	Levels	endocrinology	Diabetes Mellitus type 1 and type 2	37 healthy controls, 51 patients with DM1, 69 patients with DM2
Abrams, D. I., Jay, C. A., Shade, S. B., Vizoso, H., Reda, H., Press, S., ... & Petersen, K. L. (2007). Cannabis in painful HIV-associated sensory neuropathy: a randomized placebo-controlled trial. *Neurology*, *68*(7), 515-521.	TSA 2	15.7 cm2 thermode (?)	tonix noxious heat stimulus	ramp-and-hold	virology / neurology / pain medicine	painful HIV-associated sensory neuropathy	50 patients with painful HIV-associated neuropathy
Adams, J. T. (2018). Clinical decision making and application of an active rehabilitation program for a person with the neuromuscular symptoms of Allgrove syndrome: a case report. Physiotherapy theory and practice.	TSA 2	not expressly stated	warm and cold perception thresholds	not expressly stated	genetic disorder	Allgrove syndrome	case report 1 patient
Ahmad, S., De Oliveira Jr, G. S., Bialek, J. M., & McCarthy, R. J. (2014). Thermal quantitative sensory testing to predict postoperative pain outcomes following gynecologic surgery. Pain Medicine, 15(5), 857-864.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold,cold pain threshold, heat pain threshold	limits	surgery / pain medicine / pharmacokinetics	patients undergoing abdominal myomectomy or hysterectomy (gynaecological surgery)	120 patients after abdominal myomectomy or hysterectomy
Ahn, H., Suchting, R., Woods, A. J., Miao, H., Green, C., Cho, R. Y., ... & Fillingim, R. B. (2018). Bayesian analysis of the effect of transcranial direct current stimulation on experimental pain sensitivity in older adults with knee osteoarthritis: randomized sham-controlled pilot clinical study. Journal of pain research, 11, 2071.	TSA 2	not expressly stated	heat pain threshold, heat pain tolerance	limits	orthopaedics / treatment efficacy	osteoarthritis	40 patients with knee osteoarthritis
Alappattu, M. J., George, S. Z., Robinson, M. E., Fillingim, R. B., Moawad, N., LeBrun, E. W., & Bishop, M. D. (2015). Painful intercourse is significantly associated with evoked pain perception and cognitive aspects of pain in women with pelvic pain. Sexual medicine, 3(1), 14-23.	TSA 2	not expressly stated	cold pain threshold, heat pain threshold	limits	gynacology / pain medicine	women with chronic pelvic pain	14 women with chronic pelvic pain, 28 pain-free women

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Albo, C., Kumar, S., Pope, M., Kidwell, K. M., Xu, H., Bowman, L., ... & Kutlar, A. (2020). Characteristics and potential biomarkers of adult sickle cell patients with chronic pain. European Journal of Haematology, 105(4), 419-425.	Q-Sense	not expressly stated	warm detection threshold, cold detection threshold	limits	haematology / neurology / pain medicine	Sickle Cell Disease	72 adolescent and adults patients with Sickle Cell Disease
Andersen, H. H., Arendt-Nielsen, L., Yosipovitch, G., & Elberling, J. (2017). A prospective case of postherpetic itch monitored by quantitative sensory testing for 1 year while undergoing 8% topical capsaicin treatments. Itch, 2(3), e8.	Q-Sense	30*30 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold	limits	virology / neurology / pain medicine	chronic postherpetic itch	1 patient case report
Aniskin, D. B., Fink, E., Prosser, J., Cohen, L. J., Boda, N., Steinfeld, M., & Galynker, I. I. (2011). The effect of pain on stroop performance in patients with opiate dependence in sustained remission. *Journal of addiction medicine*, *5*(1), 50-56.	TSA 2	30*30 mm thermode	heat pain thresholds	limits	addiction	opiate dependence	23 opiate-dependent subjects who maintained protracted abstinence, 24 healthy controls
Assa, T., Geva, N., Zarkh, Y., & Defrin, R. (2019). The type of sport matters: Pain perception of endurance athletes versus strength athletes. European Journal of Pain, 23(4), 686-696.	TSA 2	30*30 mm thermode	heat pain threshold, heat pain tolerance, noxious tonic heat stimulus	limits, ramp-and-hold	sports medicine / pain medicine	endurance athletes, strength athletes	19 endurance athletes, 19 strength athletes
Atherton, D. D., Taherzadeh, O., Elliot, D., & Anand, P. (2008). Age-dependent development of chronic neuropathic pain, allodynia and sensory recovery after upper limb nerve injury in children. *Journal of Hand Surgery (European Volume)*, *33*(2), 186-191.	TSA 2	15 25mm2 thermode (?)	warm detection threshold, cold detection threshold	limits	paediatrics / neurology / pain medicine	children and adolescents with distal upper limb nerve injury	49 children and adolescents after distal upper limb nerve injury
Awai, L., & Curt, A. (2015). Preserved sensory-motor function despite large-scale morphological alterations in a series of patients with holocord syringomyelia. *Journal of neurotrauma*, *32*(6), 403-410.	PATHWAY CHEPS	not expressly stated	pulses for contact heat evoked potentials	pulses	neurology	holocord syringomyelia	7 patients with holocord syringomyelia
Azmi, S., Ferdousi, M., Alam, U., Petropoulos, I. N., Ponirakis, G., Marshall, A., ... & Malik, R. A. (2017). Small-fibre neuropathy in men with type 1 diabetes and erectile dysfunction: a cross-sectional study. Diabetologia, 60(6), 1094.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	not expressly stated	endocrinology/urology	type 1 diabetes and erectile dysfunction	29 patients with type 1 diabetes without erectile disorder, 41 patients with type 1 diabetes with erectile disorder, 34 healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Azmi, S., Ferdousi, M., Liu, Y., Adam, S., Siahmansur, T., Ponirakis, G., ... & Soran, H. (2021). The role of abnormalities of lipoproteins and HDL functionality in small fibre dysfunction in people with severe obesity. Scientific Reports, 11(1), 1-9.	TSA 2	not expressly stated	cold detection threshold, warm detection threshold	not expressly stated	endocrinology / neurology	severe obesity	47 patients with severe obesity, 30 healthy controls
Baad-Hansen, L., Pigg, M., Ivanovic, S. E., Faris, H., List, T., Drangsholt, M., & Svensson, P. (2013). Intraoral somatosensory abnormalities in patients with atypical odontalgia—a controlled multicenter quantitative sensory testing study. PAIN®, 154(8), 1287-1294.	PATHWAY, TSA 2	30*30 mm thermode, Intraoral thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold,	limits, thermal sensory limen	neurology / pain medicine	atypical odontalgia	47 patients with atypical odontalgia, 69 healty controls
Baier, B., Zu Eulenburg, P., Geber, C., Rohde, F., Rolke, R., Maihöfner, C., ... & Dieterich, M. (2014). Insula and sensory insular cortex and somatosensory control in patients with insular stroke. European journal of pain, 18(10), 1385-1393.	TSA 2	2.8*2.8 cm thermode (?)	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold,	limits	neurology	acute unilateral ischaemic stroke	24 patients with acute unilateral ischaemic stroke affecting primarily the Insular Cortex
Bakshi, N., Lukombo, I., Shnol, H., Belfer, I., & Krishnamurti, L. (2017). Psychological characteristics and pain frequency are associated with experimental pain sensitivity in pediatric patients with sickle cell disease. *The Journal of Pain*, *18*(10), 1216-1228.	TSA 2	30*30 mm thermode	warm perception, cold perception, cold pain threshold, heat pain threshold, heat pain tolerance, heat temporal summation	limits+ramp-and-hold(?)	neurology/pediatrics	pediatric Sickle Cell Disease	29 children with Sickle Cell Disease, 26 healthy children controls
Bär, K. J., de la Cruz, F., Berger, S., Schultz, C. C., & Wagner, G. (2015). Structural and functional differences in the cingulate cortex relate to disease severity in anorexia nervosa. Journal of psychiatry & neuroscience: JPN, 40(4), 269.	TSA 2	30*30 mm thermode	tonic noxious heat stimulation	ramp-and-hold	psychiatry / neuroimaging / pain medicine	anorexia nervosa	26 patients with anorexia nevosa
Bar-Shalita, T., Vatine, J. J., Yarnitsky, D., Parush, S., & Weissman-Fogel, I. (2014). Atypical central pain processing in sensory modulation disorder: absence of temporal summation and higher after-sensation. Experimental brain	Pathway CHEPS	CHEPS thermode	phasic temporal summation	ramp-and-hold	psychology / neuroimaging	sensory modulation disorder	12 patients with sensory over-responsivity (sub-type of sensory modulation disorder) and 12 healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
research, 232(2), 587-595.							
Benjaboonyanupap, D., Paungmali, A., & Pirunsan, U. (2015). Effect of therapeutic sequence of hot pack and ultrasound on physiological response over trigger point of upper trapezius. Asian journal of sports medicine, 6(3).	TSA 2	5 cm2 (?)	tonix noxious heat stimulus	ramp-and-hold	orthopaedics / pain medicine / treatment efficacy	myofascial pain syndrome	30 patients with latent myofascial triggerpoints in the upper trapezius muscle bilaterally
Bhatt, R. R., Gupta, A., Labus, J. S., Zeltzer, L. K., Tsao, J. C., Shulman, R. J., & Tillisch, K. (2019). Altered brain structure and functional connectivity and its relation to pain perception in girls with irritable bowel syndrome. Psychosomatic medicine, 81(2), 146.	TSA 2	not expressly stated	heat pain thresholds	limits	paediatrics / endocrinology / pain medicine	paediatric irritable bowel syndrome	32 girls (children and adolescents) with Irritable Bowel Syndrome and 26 matched healthy controls
Bilek, E., Zang, Z., Wolf, I., Henrich, F., Moessnang, C., Braun, U., ... & Tost, H. (2019). Neural network-based alterations during repetitive heat pain stimulation in major depression. European Neuropsychopharmacology, 29(9), 1033-1040.	TSA 2 + Pathway CHEPS	CHEPS thermode + not expressly stated TSA 2 thermode	noxious heat pain stimulation	ramp-and-hold	psychiatry / neuroimaging	major depressive disorder	37 patients with major depressive disorder and 33 healthy control without a history of mental illness
Bisset, L., Carty, M., & Smith, A. (2018). Unilateral Lateral Epicondylalgia Shows a Pro-nociceptive Pain Profile. The Clinical journal of pain, 34(10), 954-959.	TSA 2	30*30 mm thermode	cold pain threshold	limits	orthopaedics	lateral epicondylitis	25 patients with lateral epicondylitis and 15 healthy controls
Bjurström, M. F., Nicol, A. L., Amid, P. K., Lee, C. H., Ferrante, F. M., & Chen, D. C. (2017). Neurophysiological and clinical effects of laparoscopic retroperitoneal triple neurectomy in patients with refractory postherniorrhaphy neuropathic inguinodynia. Pain Practice, 17(4), 447-459.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	not expressly stated	surgery / pain medicine	Chronic postherniorrhaphy inguinal pain patients referred for evaluation of surgical treatment	10 patients undergoing laparoscopic retroperitoneal triple neurectomy, and 3 patients undergoing open triple neurectomies with meshectomy
Blankenburg, M., Boekens, H., Hechler, T., Maier, C., Krumova, E., Scherens, A., ... & Zernikow, B. (2010). Reference values for quantitative sensory testing in children and adolescents: developmental and	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal	limits, thermal sensory limen	neurology / normative data	paediatrics / healthy	176 healthy children and adolescents

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
gender differences of somatosensory perception. PAIN®, 149(1), 76-88.			sensory limen, cold pain threshold, heat pain threshold				
Blankenburg, M., Junker, J., Hirschfeld, G., Michel, E., Aksu, F., Wager, J., & Zernikow, B. (2018). Quantitative sensory testing profiles in children, adolescents and young adults (6–20 years) with cerebral palsy: Hints for a neuropathic genesis of pain syndromes. European Journal of Paediatric Neurology, 22(3), 470-481.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	neurology / paediatircs / pain medicine	cerebral palsy	100 children/adolescents/young adults with cerebral palsy
Blume, K. R., Racz, J., Franz, M., Dietrich, C., Puta, C., Friedel, R., ... & Weiss, T. (2018). Quantitative sensory testing after macroreplantation: evidence for a specific somatosensory profile. Pain, 159(7), 1289-1296.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	orthopaedics	amputees, patients after upper limb macro re-plantation	19 patients after macro-replantation at the wrist
Bordeleau, M., Carrondo Cottin, S., Cantin, L., Gaudin, D., Alnemari, A., Canuel, J. F., ... & Prud'Homme, M. (2020). Effects of tonic spinal cord stimulation on external mechanical and thermal stimuli perception using quantitative sensory testing: a multicenter stimulation ON-OFF study on chronic pain patients. The Clinical journal of pain, 36(3), 189-196.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	not expressly stated	neurology / pain medicine / treatment efficacy	spinal cord stimulator (SCS)	48 patients with chronic leg pain due to failed back surgery syndrome or complex regional pain syndrome treated with SCS
Bossio, J. A., Pukall, C. F., & Steele, S. S. (2016). Examining penile sensitivity in neonatally circumcised and intact men using quantitative sensory testing. *The Journal of Urology*, *195*(6), 1848-1853.	TSA 2	5*5 mm thermode	warm detection threshold, heat pain threshold	limits	urology/neurology	circumcised men	30 circumcised men and 31 uncircumcised men

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Brill, S., Sprecher, E., Smith, F. J. D., Geva, N., Gruener, H., Nahman-Averbuch, H., & Defrin, R. (2018). Chronic pain in pachyonychia congenita: evidence for neuropathic origin. British Journal of Dermatology, 179(1), 154-162.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold	limits	dermatology / genetic disorder	Pachyonychia congenita	62 Pachyonychia congenita patients and 45 helathy controls
Briso, A. L. F., Rahal, V., Azevedo, F. A. D., Gallinari, M. D. O., Gonçalves, R. S., Frascino, S. M. B., ... & Cintra, L. T. A. (2018). Neurosensory analysis of tooth sensitivity during at-home dental bleaching: a randomized clinical trial. Journal of Applied Oral Science, 26.	TSA 2	Intraoral thermode	cold sensation threshold	limits	dental / pharmacokinetic s	tooth sensitivity	25 healthy volunteers undergoing dental bleaching procedure
Calero-Romero, I., Suter, M. R., Waeber, B., Feihl, F., & Kuntzer, T. (2018). Axon reflex–mediated vasodilation is reduced in proportion to disease severity in TTR-FAP. *Neurology Genetics*, *4*(4).	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	neurology / genetic disorder	familial amyloid polyneuropathy	7 patients with familial amyloid polyneuropathy and 10 healthy controls
Campero, M., Hughes, R., Orellana, P., Bevilacqua, J. A., & Guiloff, R. J. (2018). Spinal cord infarction with ipsilateral segmental neuropathic pain and flaccid paralysis. A functional role for human afferent ventral root small sensory fibres. Journal of the neurological sciences, 395, 84-87.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold	limits	neurology	spinal cord infraction	case report 1 patient
Carlstedt, T., Misra, V. P., Papadaki, A., McRobbie, D., & Anand, P. (2012). Return of spinal reflex after spinal cord surgery for brachial plexus avulsion injury: Case report. Journal of neurosurgery, 116(2), 414-417.	Pathway CHEPS	CHEPS thermode	pulses for contact heat evoked potentials	pulses	neurosurgery / neurology	total leftsided (nondominant) brachial plexus injury with Horner syndrome	1 patient case report of a brachial plexus avulsion injury and subsequent surgical nerve graft
Carmona, S., Weinschelbaum, R., Pardal, A., Marchesoni, C., Zuberbuhler, P., Acosta, P., ... & Reisin, R. (2017). Neuro-otological and peripheral nerve involvement in Fabry disease. Audiology research, 7(2), 42-46.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / genetic disorder	Fabry disease	46 patients with Fabry disease
Carvalho, B., Angst, M. S., Fuller, A. J., Lin, E., Mathusamy, A. D., & Riley, E. T. (2006). Experimental heat pain for detecting pregnancy-induced analgesia in humans. Anesthesia &	TSA 2	16*16 mm thermode	heat pain tolerance	limits	obstetrics / pain medicine / neurology	pregnancy	20 healthy, term parturients and 19 healthy female volunteers

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Analgesia, 103(5), 1283-1287.							
Carvalho, B., Zheng, M., & Aiono-Le Tagaloa, L. (2014). Evaluation of Experimental Pain Tests to Predict Labour Pain and Epidural Analgesic Consumption. Survey of Anesthesiology, 58(2), 75-76.	TSA 2	16*16 mm thermode	heat pain threshold, heat pain tolerance and notious heat stimulus rating	limits, ramp-and-hold	obstetrics / pain medicine / neurology	women during labour	50 healthy nulliparous and multiparous women with a singleton full term pregnancy undergoing induction of labour and desiring a labour epidural
Casey, K. L., Geisser, M., Lorenz, J., Morrow, T. J., Paulson, P., & Minoshima, S. (2012). Psychophysical and cerebral responses to heat stimulation in patients with central pain, painless central sensory loss, and in healthy persons. Pain, 153(2), 331-341.	TSA 2	16*16 mm thermode	warm detection threshold, heat pain threshold, heat pain tolerance	limits	neurology / neurosurgery	central pain, central nervous system lesions without pain	10 patients with central pain (CP), 10 patients with central nervous system (CNS) lesions but no pain, 15 healthy controls
Chalaye, P., Lafrenaye, S., Goffaux, P., & Marchand, S. (2014). The role of cardiovascular activity in fibromyalgia and conditioned pain modulation. *PAIN®*, *155* (6), 1064-1069.	TSA 2	30*30 mm thermode	heat pain thresholds, heat pain tolerance, tonic noxious heat pain	limits, ramp-and-hold	neurology/pain medicine	fibromyalgia	23 patients with fibromyalgia, 25 healthy controls
Chen, L. H., Yeh, Y. M., Chen, Y. F., Hsu, Y. H., Wang, H. H., Lin, P. C., ... & Shen, M. R. (2020). Targeting interleukin-20 alleviates paclitaxel-induced peripheral neuropathy. Pain, 161(6), 1237-1254.	PATHWAY	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	not expressly stated	oncology / gynacology / pain medicine	gynacological cancer treated with paclitaxel	15 gynecological cancer patients, 12 healthy controls
Chiappelli, J., Shi, Q., Wijtenburg, S. A., Quiton, R., Wisner, K., Gaston, F., ... & Hong, L. E. (2018). Glutamatergic response to heat pain stress in schizophrenia. *Schizophrenia bulletin*, *44*(4), 886-895.	PATHWAY	30*30 mm thermode	heat pain threshold, heat pain tolerance	limits, ramp-and-hold	Psychiatry / neurology / pain medicine	schizophrenia	22 healthy controls and 23 patients with schizophrenia
Cornelissen, L., Donado, C., Kim, J., Chiel, L., Zurakowski, D., Logan, D. E., ... & Berde, C. B. (2014). Pain hypersensitivity in juvenile idiopathic arthritis: a quantitative sensory testing study. Pediatric Rheumatology, 12(1), 1-12.	TSA 2	16*16 mm thermode, 30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	paediatrics / neurology / pain medicine	juvenile idiopathic arthritis	60 children and adolescents with juvenile rheumatoid arthritis, 151 healthy children and adolescents

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Cowan, R. L., Beach, P. A., Atalla, S. W., Dietrich, M. S., Bruehl, S. P., Deng, J., ... & Monroe, T. B. (2017). Sex differences in the psychophysical response to contact heat in moderate cognitive impairment Alzheimer's disease: A cross-sectional brief report. Journal of Alzheimer's Disease, 60(4), 1633-1640.	PATHWAY CHEPS	not expressly stated	thresholds for various heat perception levels (warmth; mild pain; moderate pain)	limits	geriatrics / psychiatry / pain medicine	Alzheimer's disease	28 patients with mild to moderate Alzheimer's disease
Dapunt, U., Gantz, S., Zhuk, A., Gather, K., Wang, H., & Schiltenwolf, M. (2018). Quantitative sensory testing in physically active individuals and patients who underwent multidisciplinary pain therapy in the longitudinal course. *Journal of pain research*, *11*, 2323.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	orthopaedics / pain medicine/ treatment efficacy	chronic musculoskeletal pain	20 healthy controls, 30 athletes, 30 chronic musculoskeletal pain patients
de Graaf, J., Valkenburg, A. J., Tibboel, D., & van Dijk, M. (2012). Thermal detection thresholds in 5-year-old preterm born children;: IQ does matter. *Early human development*, *88*(7), 487-491.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits, levels	paediatrics / neurology	prematurely born 5-year olds	21 children (5 years old) born prematurely
de Hoogd, S., Valkenburg, A. J., van Dongen, E. P., Daeter, E. J., van Rosmalen, J., Dahan, A., ... & Knibbe, C. A. (2019). Short-and long-term impact of remifentanil on thermal detection and pain thresholds after cardiac surgery: A randomised controlled trial. European journal of anaesthesiology, 36(1), 32.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold	limits	surgery / pharmacokinetics	elective cardiac surgery via sternotomy (coronary artery bypass grafting and/or valve replacement)	126 patients undergoing cardiothoracic surgery via sternotomy
de Kruijf, M., Bos, D., Huygen, F. J., Niessen, W. J., Tiemeier, H., Hofman, A., ... & van Meurs, J. B. (2016). Structural brain alterations in community dwelling individuals with chronic joint pain. American Journal of Neuroradiology, 37(3), 430-438. with Chronic Joint Pain	TSA 2	2*2 cm thermode (?)	warm detection threshold, cold detection threshold, heat pain threshold	limits	gerontology / neurology / pain medicine	older adults	3892 elder general population cohort above the age of 45
de Kruijf, M., Peters, M. J., C. Jacobs, L., Tiemeier, H., Nijsten, T., Hofman, A., ... & van Meurs, J. B. (2016). Determinants for quantitative sensory testing and the association with chronic musculoskeletal pain in the general elderly population. Pain Practice, 16(7), 831-841.	TSA 2	2*2 cm thermode (?)	warm detection threshold, cold detection threshold, heat pain threshold	limits	Gerontology / neurology / pain medicine	older adults	4053 elder general population cohort above the age of 45 of which 1779 with chronic pain

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
de la Coba, P., Bruehl, S., Garber, J., Smith, C. A., & Walker, L. S. (2018). Is resolution of chronic pain associated with changes in blood pressure-related hypoalgesia?. Annals of Behavioral Medicine, 52(7), 552-559.	TSA 2	30*30 mm thermode	heat pain threshold, heat pain tolerance, temporal summation	limits, pulses	pain medicine / treatment efficacy / neurology	childhood functional abdominal pain	adolescents and young adults: 99 functional abdominal pain patients whose pain was resolved, 51 functional abdominal pain patients with unresolved pain
Defrin, R., Gruener, H., Schreiber, S., & Pick, C. G. (2010). Quantitative somatosensory testing of subjects with chronic post-traumatic headache: implications on its mechanisms. European Journal of Pain, 14(9), 924-931.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold	limits	neurology / pain medicine	traumatic head injury, chronic post-traumatic headache	17 patients with Traumatic head injury and Chronic post-traumatic headache, 11 patients with traumatic head injury without headache of any kind, 17 pain-free healthy men
Defrin, R., Pick, C. G., Peretz, C., & Carmeli, E. (2004). A quantitative somatosensory testing of pain threshold in individuals with mental retardation. Pain, 108(1-2), 58-66.	TSA 2	30*30 mm thermode	heat pain thresholds	levels+limits	congenital	mental retardation	25 individuals with mild mental retardation and 14 normal controls
Devigili, G., Rinaldo, S., Lombardi, R., Cazzato, D., Marchi, M., Salvi, E., ... & Lauria, G. (2019). Diagnostic criteria for small fibre neuropathy in clinical practice and research. Brain, 142(12), 3728-3736.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits and levels	neurology	small fiber neuropathy	342 patients with suspected sensory neuropathy
Dezawa, K., Noma, N., Watanabe, K., Sato, Y., Kohashi, R., Tonogi, M., ... & Imamura, Y. (2016). Short-term effects of orthognathic surgery on somatosensory function and recovery pattern in the early postoperative period. *Journal of oral science*, *58*(2), 177-184.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold,	limits, thermal sensory limen	dental / surgery / neurology	patients after orthognathic surgery	14 patients undergoing orthognatic surgery as follows: 1 underwent bilateral sagittal split osteotomy (BSSO) to the mandibular rami with no other surgery, and 13 underwent BSSO in combination with a Le Fort I osteotomy, and 32 healthy controls
Di Stefano, G., Celletti, C., Baron, R., Castori, M., Di Franco, M., La Cesa, S., ... & Camerota, F. (2016). Central sensitization as the mechanism underlying pain in joint hypermobility syndrome/Ehlers–Danlos syndrome, hypermobility type. European Journal of Pain, 20(8), 1319-1325.	PATHWAY ATS	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / pain medicine / genetic disorders	joint hypermobility syndrome/Ehlers–Danlos syndrome, hypermobility type (JHS/EDS-HT)	27 patients with JHS/EDS-HT
Dougherty, P. M., Cata, J. P., Burton, A. W., Vu, K., & Weng, H. R. (2007). Dysfunction in multiple primary afferent fiber subtypes revealed by quantitative sensory testing in patients with chronic vincristine-	not expressly stated	36*36 mm thermode (?)	warm detection threshold, cold detection threshold, cold pain threshold,	limits	toxicology / oncology / neurology	oncology patients treated with Vincristine	15 hematologic cancer, specifically lymphoma, leukemia, or multiple myeloma, and the other patients had Ewing's sarcoma (n = 2) or breast cancer (n = 1)

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
induced pain. Journal of pain and symptom management, 33(2), 166-179.			heat pain threshold,				
Drummond, P. D., Finch, P. M., Birklein, F., Stanton-Hicks, M., & Knudsen, L. F. (2018). Hemisensory disturbances in patients with complex regional pain syndrome. Pain, 159(9), 1824-1832.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold, tonix noxious heat stimulus	limits + ramp-and-hold	neurology	complex regional pain syndrome (CRPS)	104 patients with CRPS; of which n=71 CRPS-type 1, n=33 CRPS-type 2
Edwards, R. R., Mensing, G., Cahalan, C., Greenbaum, S., Narang, S., Belfer, I., ... & Jamison, R. N. (2013). Alteration in pain modulation in women with persistent pain after lumpectomy: influence of catastrophizing. Journal of pain and symptom management, 46(1), 30-42.	not expressly stated	30*30 mmm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold,	limits	surgery / neurology / pain medicine	women after lumpectomy	71 patients who had been diagnosed with early-stage breast cancer and had undergone unilateral breast cancer surgery and radiation therapy at least one year before participation
Edwards, R. R., Wasan, A. D., Bingham, C. O., Bathon, J., Haythornthwaite, J. A., Smith, M. T., & Page, G. G. (2009). Enhanced reactivity to pain in patients with rheumatoid arthritis. Arthritis research & therapy, 11(3), 1-9.	TSA 2	not expressly stated	heat pain thresholds, noxious heat pulses (supra-threshold)	limits, pulses	Neurology / rheumatology / pain medicine	rheumatoid arthritis	19 patients with rheumatoid arthritis and 21 healthy controls
Eijkenboom, I., Sopacua, M., Hoeijmakers, J. G., De Greef, B. T., Lindsey, P., Almomani, R., ... & Gerrits, M. M. (2019). Yield of peripheral sodium channels gene screening in pure small fibre neuropathy. *Journal of Neurology, Neurosurgery & Psychiatry*, *90*(3), 342-352.	not expressly stated	not expressly stated	not expressly stated	not expressly stated	neurology	small fiber neuropathy	1502 patients with suspected small fiber neuropathy
Eldeghaidy, S., Yang, Q., Abualait, T., Williamson, A. M., Hort, J., & Francis, S. T. (2021). Thermal taster status: Temperature modulation of cortical response to sweetness perception. Physiology & Behavior, 230, 113266.	Pathway	Intraoral thermode	alternating warm and cold stimuli	ramp-and-hold	thermal taster status	thermal taster status	24 participants balanced between thermal tasters and thermal non-tasters

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Eliav, E., Teich, S., Nitzan, D., El Raziq, D. A., Nahlieli, O., Tal, M., ... & Benoliel, R. (2003). Facial arthralgia and myalgia: can they be differentiated by trigeminal sensory assessment?. Pain, 104(3), 481-490.	TSA 2	5*5 mm thermode	warm detection threshold	levels	neurology / pain medicine	painful temporomandibular disorder	72 patients with painful temporormandibular disorder; (28 myalgia, 44 artalgia, 14disc displacement without reduction, 16 disc displacement with reduction, 14 secondary osteoarthritis associated with disc derangement), 22 healthy volunteers
Ellrich, J., Ristic, D., & Yekta, S. S. (2006). Impaired thermal perception in cluster headache. Journal of neurology, 253(10), 1292-1299.	TSA 2	256 mm2 thermode?	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen	limits, thermal sensory limen	neurology / pain medicine	cluster headache	25 patients sufferiung from unilateral cluster headache and 60 healthy volunteers
Elman, I., Upadhyay, J., Langleben, D. D., Albanese, M., Becerra, L., & Borsook, D. (2018). Reward and aversion processing in patients with post-traumatic stress disorder: functional neuroimaging with visual and thermal stimuli. Translational psychiatry, 8(1), 1-15.	TSA 2	30*30 mm thermode	cold pain threshold, heat pain threshold, noxious heat stimulation	limits, ramp-and-hold	psychology / psychiatry / neuroimaging	post traumatic stress disorder (PTSD)	12 patients with PTSD, 12 healthy controls
Failla, M. D., Moana-Filho, E. J., Essick, G. K., Baranek, G. T., Rogers, B. P., & Cascio, C. J. (2018). Initially intact neural responses to pain in autism are diminished during sustained pain. *Autism*, *22*(6), 669-683.	TSA 2	30*30 mm thermode	heat pain threshold, tonic heat pain	limits+ramp-and-hold(fMRI)	psychiatry	autism spectrum disorder	16 adults with autism spectrum disorder and 16 typical controls
Fang, W. C., Chou, K. M., Sun, C. Y., Lee, C. C., Wu, I. W., Chen, Y. C., & Pan, H. C. (2020). Thermal Perception Abnormalities Can Predict Diabetic Kidney Disease in Type 2 Diabetes Mellitus Patients. *Kidney and Blood Pressure Research*, *45*(6), 926-938.	TSA 2	30 × 46 mm thermode(?)	warm detection threshold, cold detection threshold	limits	endocrinology	type 2 diabetes / diabetic kidney disease	432 patients with type 2 diabetes
Fillingim, R. B., & Edwards, R. R. (2005). Is self-reported childhood abuse history associated with pain perception among healthy young women and men?. The Clinical journal of pain, 21(5), 387-397.	TSA 2	30*30 mm thermode	warm detection threshold, heat pain threshold, heat pain tolerance	limits	psychology / pain medicine	self-reported childhood abuse	110 participants with self-reported childhood abuse
Fuchs, X., Diers, M., Trojan, J., Kirsch, P., Milde, C., Bekrater-Bodmann, R., ... & Flor, H. (2021). Phantom limb pain after unilateral arm amputation is associated with decreased heat pain	PATHWAY ATS	30*30 mm thermode	warm detection threshold, heat pain threshold	limits	neurology / orthopaedics	unilateral upper-limb amputees	37 unilateral upper-limb amputees, 19 healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
thresholds in the face. European Journal of Pain.							
Gagné, M., Côté, I., Boulet, M., Jutzeler, C. R., Kramer, J. L., & Mercier, C. (2020). Conditioned pain modulation decreases over time in patients with neuropathic pain following a spinal cord injury. Neurorehabilitation and Neural Repair, 34(11), 997-1008.	TSA 2	30*30 mm thermode	heat pain threshold, supra-threshold noxious heat stimulus	limits, ramp-and-hold	neurology/pain medicine	spinal cord injury (SCI)	35 patients with spinal cord injury
Galor, A., Levitt, R. C., McManus, K. T., Kalangara, J. P., Seiden, B. E., Park, J. J., ... & Felix, E. R. (2016). Assessment of somatosensory function in patients with idiopathic dry eye symptoms. *JAMA ophthalmology*, *134*(11), 1290-1298.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold, tonic noxious heat and cold stimulation, heat and cold temporal summation	limits, ramp-and-hold, pulses	ophtalmology	idiopathic dry eye	118 patients with dry eye symptoms
Gandhi, W., Pomares, F. B., Naso, L., Asenjo, J. F., & Schweinhardt, P. (2020). Neuropathic pain after thoracotomy: tracking signs and symptoms before and at monthly intervals following surgery. European Journal of Pain, 24(7), 1269-1289.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold, tonic noxious heat stimulation	limits, ramp-and-hold	surgery / neurology / pain medicine	posterolateral thoracotomy	37 patients with lung cancer undergoing full or partical resection of one lung through a posterolateral thoracotomy
Goffaux, P., Lafrenaye, S., Morin, M., Patural, H., Demers, G., & Marchand, S. (2008). Preterm births: can neonatal pain alter the development of endogenous gating systems?. European Journal of Pain, 12(7), 945-951.	TSA 2	30*30 mm thermode	heat pain threshold, tonic heat pain	limits, ramp-and-hold	paediatrics / pain medicine	preterm born children	26 children between the ages of 7 and 11; of which; 13 were born prematurely (632 weeks gestational age) and 13 were born full-term.
Gombert, S., Rhein, M., Winterpacht, A., Münster, T., Hillemacher, T., Leffler, A., & Frieling, H. (2020). Transient receptor potential ankyrin 1 promoter methylation and peripheral pain sensitivity in Crohn's	TSA 2	not expressly stated	warm and cold perception thresholds, heat and cold pain thresholds	limits	endocrinology	Crohn's disease	55 patients with Crohn's disease, 75 healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
disease. *Clinical epigenetics*, *12*(1), 1-11.							
González-Duarte, A., Lem-Carrillo, M., & Guerrero-Torres, L. (2016). Normative values of quantitative sensory testing in Hispanic Latino population. Brain and Behavior, 6(7), e00466.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / normative data	healthy	50 healthy Hispanic/Latino population
Granot, M., & Nagler, R. M. (2005). Association between regional idiopathic neuropathy and salivary involvement as the possible mechanism for oral sensory complaints. The Journal of Pain, 6(9), 581-587.	TSA 2	15*15 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold, tonic noxious heat stimulus	limits, ramp-and-hold	neruology / ear-nose-throat	oral sensorial complaints (OSC): idiopathic sensorial disturbances of burning mouth syndrome (BMS), taste disturbances (dysgeusia), and dry mouth (xerostomia)	35 patients with OSC and 19 healthy cotnrols
Granot, M., Dagul, P., Darawsha, W., & Aronson, D. (2015). Pain modulation efficiency delays seeking medical help in patients with acute myocardial infarction. Pain, 156(1), 192-198.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, tonic noxious heat pain	limits, ramp-and-hold	cardiology / pain medicine	acute ST elevation myocardial infarction (STEMI)	69 patients with acute STEMI
Granot, M., Friedman, M., Yarnitsky, D., & Zimmer, E. Z. (2002). Enhancement of the perception of systemic pain in women with vulvar vestibulitis. BJOG: an international journal of obstetrics and gynaecology, 109(8), 863-866.	TSA 2	30*30 mm thermode	heat pain threshold, phasic noxious heat stimuli	limits, ramp-and-hold	gynaecology / pain medicine	vulvar vestibulitis syndrome	44 women with the vulvar vestibulitis syndrome and 41 controls
Granot, M., Khoury, R., Berger, G., Krivoy, N., Braun, E., Aronson, D., & Azzam, Z. S. (2007). Clinical and experimental pain perception is attenuated in patients with painless myocardial infarction. PAIN®, 133(1-3), 120-127.	TSA 2	30*30 mm thermode	heat pain threshold, phasic noxious heat stimuli, tonic noxious heat stimulus	limits, ramp-and-hold	cardiology / pain medicine	myocardial infarction (MI)	92 patient with acute MI
Granot, M., Lowenstein, L., Yarnitsky, D., Tamir, A., & Zimmer, E. Z. (2003). Postcesarean section pain prediction by preoperative experimental pain assessment. The Journal of the American Society of Anesthesiologists, 98(6), 1422-1426.	TSA 2	30*30 mm thermode	heat pain threshold, phasic noxious heat stimuli	limits, ramp-and-hold	obstetrics / surgery / pain medicine	post caesarian section pain	58 women scheduled for elective caesarian section

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Grinberg, K., Granot, M., Lowenstein, L., Abramov, L., & Weissman-Fogel, I. (2018). Negative illness perceptions are associated with a pronociceptive modulation profile and augmented pelvic pain. The Clinical journal of pain, 34(12), 1141-1148.	TSA 2	30*30 mm thermode	heat pain threshold	limits	gynacology / pain medicine	chronic pelvic pain syndrome (CPPS)	39 patients with chronic pelvic pain syndrome; of which n=21 Painful Bladder Syndrome, and n=18 provoked vestibulodynia
Gröne, E., Üçeyler, N., Abahji, T., Fleckenstein, J., Irnich, D., Mussack, T., ... & Lang, P. M. (2014). Reduced intraepidermal nerve fiber density in patients with chronic ischemic pain in peripheral arterial disease. PAIN®, 155(9), 1784-1792.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold,	limits, thermal sensory limen	Vascular surgery / pain medicine / neurology	peripheral arterial disease (PAD), intermittend claudication, critical limb ischemia	40 patients with symptomatic PAD (Fontaine stages II-IV), 20 with intermittent claudication (CI), and 20 with critical limb ischemia (CLI) were enrolled; 12 volunteers served as healthy controls.
Gustorff, B., Sycha, T., Lieba-Samal, D., Rolke, R., Treede, R. D., & Magerl, W. (2013). The pattern and time course of somatosensory changes in the human UVB sunburn model reveal the presence of peripheral and central sensitization. Pain, 154(4), 586-597.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	dermatology / pain medicine	healthy adults with UVB sunburn	22 healthy right-handed volunteers 24 h after UVB irradiation
Guzman-Sanchez, D. A., Ishiuji, Y., Patel, T., Fountain, J., Chan, Y. H., & Yosipovitch, G. (2007). Enhanced skin blood flow and sensitivity to noxious heat stimuli in papulopustular rosacea. Journal of the American Academy of Dermatology, 57(5), 800-805.	TSA 2	16*16 mm thermode	heat pain threshold	limits	dermatology / neurology	papulopustular rosacea (PPR), erythematotelangiectatic rosacea (ETR)	8 subjects with papulopustular rosacea (PPR), 8 subjects with erythematotelangiectatic rosacea (ETR) and 8 control subjects
Haack, M., Scott-Sutherland, J., Santangelo, G., Simpson, N. S., Sethna, N., & Mullington, J. M. (2012). Pain sensitivity and modulation in primary insomnia. European journal of pain, 16(4), 522-533.	TSA 2	30*30 mm thermode	warm detection threshold, heat pain thresholds, phasic noxious heat pulses, tonic noxious heat stimulus	limits, pulses, ramp-and-hold	neurology / sleep medicine / pain medicine	primary insomnia	17 patients with primary insomnia, 17 healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Habib, A. S., Kertai, M. D., Cooter, M., Greenup, R. A., & Hwang, S. (2019). Risk factors for severe acute pain and persistent pain after surgery for breast cancer: a prospective observational study. *Regional Anesthesia & Pain Medicine*, *44*(2), 192-199.	TSA 2	not expressly stated	not expressly stated	not expressly stated	surgery / oncology / pain medicine	elective breast cancer surgery	124 women presenting for elective breast cancer surgery; Axillary dissection was performed in 19 patients and sentinel node biopsy in 73 patients.
Hafner, J., Lee, G., Joester, J., Lynch, M., Barnes, E. H., Wrigley, P. J., & Ng, K. (2015). Thermal quantitative sensory testing: a study of 101 control subjects. Journal of Clinical Neuroscience, 22(3), 588-591.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	neurology / normative data	healthy	101 healthy participants
Hagander, L., Harlid, R., & Svanborg, E. (2009). Quantitative sensory testing in the oropharynx: a means of showing nervous lesions in patients with obstructive sleep apnea and snoring. Chest, 136(2), 481-489.	Pathway	Intraoral thermode	cold detection thresholds	levels	neurology / sleep medicine	habitual snoring / obstructive sleep apnea syndrome (OSAS)	31 patients with obstructive sleep apnea, 13 habitual snorers, and 23 nonsnoring control subjects
Haroutounian, S., Ford, A. L., Frey, K., Nikolajsen, L., Finnerup, N. B., Neiner, A., ... & Bottros, M. M. (2018). How central is central poststroke pain? The role of afferent input in poststroke neuropathic pain: a prospective, open-label pilot study. *Pain*, *159*(7), 1317-1324.	TSA 2	not expressly stated	warm and cold perception thresholds, heat and cold pain thresholds	limits	neurology	central post-stroke pain	8 patients with central post stroke pain in at least one limb
Heide, R., Bostock, H., Ventzel, L., Grafe, P., Bergmans, J., Fuglsang-Frederiksen, A., ... & Tankisi, H. (2018). Axonal excitability changes and acute symptoms of oxaliplatin treatment: In vivo evidence for slowed sodium channel inactivation. *Clinical Neurophysiology*, *129*(3), 694-706.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	oncology / neurology	ocncology patients treated with oxaliplatin	12 patients treated with standard adjuvant oxaliplatin (XELOX) after high-risk colorectal cancer (stage II or stage III) (DCCG, 2015) or enrolled in a protocol receiving two cycles of XELOX as neoadjuvant treatment and 16 healthy controls
Hermann, C., Hohmeister, J., Demirakça, S., Zohsel, K., & Flor, H. (2006). Long-term alteration of pain sensitivity in school-aged children with early pain experiences. Pain, 125(3), 278-285.	TSA 2	16*16 mm thermode	heat pain threshold, tonic heat pain	limits, ramp-and-hold, search	pain medicine / neurology	school-aged children with neonatal intensive care history (NICU)	19 school-aged children born pre-term with NICU history, 20 school-aged children born full-term with NICU history, 20 school-aged children born fullterm
Hoitsma, E., De Vries, J., & Drent, M. (2011). The small fiber neuropathy screening list: construction and cross-validation in sarcoidosis. Respiratory medicine, 105(1), 95-100.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	limits and levels	neurology	sarcoidosis	139 patients with sarcoidosis

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Holley, A. L., Wilson, A. C., Cho, E., & Palermo, T. (2017). Clinical phenotyping of youth with new-onset musculoskeletal pain: a controlled cohort study. The Clinical journal of pain, 33(1), 28.	TSA 2	30*30 mm thermode	heat pain threshold	limits, ramp-and-hold	Paediatrics / pain medicine	youth with acute and chronic musculoskeletal pain	191 youth (ages 10-17); 69 new onset musculoskeletal pain, 62 chronic pain, and 60 without chronic pain
Huang, J. S., Terrones, L., Simmons, A. N., Kaye, W., & Strigo, I. (2016). A pilot study of fMRI responses to somatic pain stimuli in youth with functional and inflammatory gastrointestinal disease. Journal of pediatric gastroenterology and nutrition, 63(5), 500.	TSA 2	30*30 mm thermode	tonic noxious heat stimuli	ramp-and-hold	gastroentorology / neuroimaging / pain medicine	adolescents and young adults with irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD)	Twenty 16–20 years old with IBS (n=10) and IBD (n=10) and abdominal pain during disease exacerbations, and 10 healthy adult controls
Indelicato, E., Nachbauer, W., Eigentler, A., Rudzki, D., Wanschitz, J., & Boesch, S. (2018). Intraepidermal Nerve Fiber Density in Friedreich's Ataxia. *Journal of Neuropathology & Experimental Neurology*, *77*(12), 1137-1143.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	Genetic disorder / Neurology	Friedreich's Ataxia	17 patients with Friedreich's Ataxia
Isak, B., Pugdahl, K., Karlsson, P., Tankisi, H., Finnerup, N. B., Furtula, J., ... & Fuglsang-Frederiksen, A. (2017). Quantitative sensory testing and structural assessment of sensory nerve fibres in amyotrophic lateral sclerosis. Journal of the neurological sciences, 373, 329-334.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, heat pain threshold	limits	neurology	amyotrophic lateral sclerosis (ALS)	32 ALS patients and 32 healthy controls
Isoardo, G., Ciullo, S., Titolo, P., Fontana, E., Battiston, B., Stella, M., ... & Adenzato, M. (2021). The relationship between alexithymia, sensory phenotype and neurophysiological parameters in patients with chronic upper limb neuropathy. Journal of Neural Transmission, 128(1), 61-71.	TSA 2	not expressly stated	cold pain threshold, heat pain threshold	limits	neurology / pain medicine	chronic upper limp neuropathy	62 patients (34 with carpal tunnel syndrome, 7 with brachial plexopathy, 3 with cervical painful radiculopathy, 5 with ulnar entrapment neuropathy at elbow and 13 with post-burn hypertrophic scars), and 48 healthy controls
Isoardo, G., Stella, M., Cocito, D., Risso, D., Migliaretti, G., Cauda, F., ... & Ciaramitaro, P. (2012). Neuropathic pain in post-burn hypertrophic scars: A psychophysical and neurophysiological study. Muscle & nerve, 45(6), 883-890.	TSA 2	not expressly stated	heat pain thresholds, cold sensation threshold	limits, levels	neurology / dermatology / pain medicine	post-burn pathologic scars (PPS)	13 patients with post-burn pathologic scars (PPS)

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Jeziorska, M., Atkinson, A., Kass-Iliyya, L., Javed, S., Kobylecki, C., Gosal, D., ... & Malik, R. A. (2019). Increased Intraepidermal nerve Fiber degeneration and impaired regeneration relate to symptoms and deficits in Parkinson's disease. Frontiers in neurology, 10, 111.	TSA 2	not expressly stated	warm and cold perception thresholds, heat and cold pain thresholds	not expressly stated	neurology	Parkinson's disease	23 patients with Parkinson's disease, 10 healthy controls
Kalladka, M., Proter, N., Benoliel, R., Czerninski, R., & Eliav, E. (2008). Mental nerve neuropathy: patient characteristics and neurosensory changes. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology, 106(3), 364-370.	TSA 2	5*5 mm thermode	warm detection threshold	levels	Dental / Neurology	mental nerve neuropathy	28 patients with mental nerve neuropathy , 8 healthy controls
Kallio-Laine, K., Seppänen, M., Lokki, M. L., Lappalainen, M., Notkola, I. L., Seppälä, I., ... & Kalso, E. (2008). Widespread unilateral pain associated with herpes simplex virus infections. The Journal of Pain, 9(7), 658-665.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	not expressly stated	virology / neurology/ pain medicine	herpes simplex infection	17 patients with serologically confirmed latent HSV infection, 51 healthy controls
Kashi, Y., Ratmansky, M., & Defrin, R. (2018). Deficient pain modulation in patients with chronic hemiplegic shoulder pain. Pain Practice, 18(6), 716-728.	TSA 2	30*30 mm thermode	phasic and tonic noxious heat stimuli	ramp-and-hold	Neurology / orthopaedics / pain medicine	Chronic hemiplegic shoulder pain (HSP)	16 post-stroke with hemiplegic shoulder pain, 14 post-stroke patients without hemiplegic shoulder pain
Kim, H. K., Kim, K. S., & Kim, M. E. (2017). Thermal perception as a key factor for assessing effects of trigeminal nerve injury. J Oral Facial Pain Headache, 31(2), 129-138.	TSA 2	5*5 mm thermode	warm detection threshold, cold detection threshold, heat pain threshold	limits	neurology	trigeminal nerve injury	85 patients with peripheral nerve neuropathy resulting from trigeminal nerve injury
Kindler, L. L., Valencia, C., Fillingim, R. B., & George, S. Z. (2011). Sex differences in experimental and clinical pain sensitivity for patients with shoulder pain. European Journal of Pain, 15(2), 118-123.	TSA 2	not expressly stated	Heat pain threshold, heat pain tolerance, phasic noxious heat pulses	limits, pulses	orthopaedics / pain medicine	rotator cuff pathology	59 patients with rotator cuff pathology presenting for surgical intervention
Kinfe, T., von Willebrand, N., Stadlbauer, A., Buchfelder, M., Yearwood, T. L., Muhammad, S., ... & Magerl, W. (2020). Quantitative sensory phenotyping in chronic neuropathic pain patients treated with unilateral L4-dorsal root ganglion stimulation. Journal of Translational Medicine, 18(1), 1-14.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold,	limits, thermal sensory limen	neurology / treatment efficacy / pain medicine	complex regional pain syndrome (CRPS)	12 patients with CRPS resistant to conservative therapies, eligible for L4-Dorsal Root Ganglion stimulation

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
			heat pain threshold				
Klyne, D. M., Moseley, G. L., Sterling, M., Barbe, M. F., & Hodges, P. W. (2019). Are signs of central sensitization in acute low back pain a precursor to poor outcome?. The Journal of Pain, 20(8), 994-1009.	TSA 2	30*30 mm thermode	cold pain threshold, heat pain threshold, tonic noxious heat stimulus	limits, ramp-and-hold	neurology / pain medicine / orthopaedics	acute low back pain	129 patients with acute low back pain
Kober, H., Buhle, J., Weber, J., Ochsner, K. N., & Wager, T. D. (2019). Let it be: mindful acceptance down-regulates pain and negative emotion. Social cognitive and affective neuroscience, 14(11), 1147-1158.	TSA 2	not expressly stated	noxious and non-noxious heat stimulation	ramp-and-hold	psychology / neuroimaging / treatment efficacy	healthy adults	17 healthy participants
Koszewicz, M., Markowska, K., Waliszewska-Prosol, M., Poreba, R., Gac, P., Szymanska-Chabowska, A., ... & Budrewicz, S. (2021). The impact of chronic co-exposure to different heavy metals on small fibers of peripheral nerves. A study of metal industry workers. Journal of Occupational Medicine and Toxicology, 16(1), 1-8.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / toxicology / occupational health	heavy metal exposure	41 employees of a Copper mine exposed to heavy metals for at least 5 years, 36 healthy controls
Kramer, S., Baeumler, P., Geber, C., Fleckenstein, J., Simang, M., Haas, L., ... & Irnich, D. (2019). Somatosensory profiles in acute herpes zoster and predictors of postherpetic neuralgia. Pain, 160(4), 882-894.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	virology / neurology/ pain medicine	acute herpes zoster	74 patients with acute herpes zoster infection, 20 healthy controls
Kramer, S., Zims, R., Simang, M., Rüger, L., & Irnich, D. (2014). Hypnotic relaxation results in elevated thresholds of sensory detection but not of pain detection. BMC complementary and alternative medicine, 14(1), 1-8.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold,	limits, thermal sensory limen	complementary medicine (hypnosis) / treatment efficacy	healthy	22 healthy participants undergoing hypnosis

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
			heat pain threshold				
Krauss, J. K. (2016). Subtle sensory abnormalities detected by quantitative sensory testing in patients with trigeminal neuralgia. Pain Physician, 19, 507-517.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold, thermal sensory limen	limits, thermal sensory limen	neurology	classic idiopathic trigeminal neuralgia	48 patients with classic idiopathic trigeminal neuralgia, 27 healthy young adults
Krüger, S., Boettger, M. K., & Hilberg, T. (2018). Somatosensory profile of patients with haemophilia. *Haemophilia*, *24*(1), 97-103.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	haematology	Haemophilia	30 patients with moderate to severe hhaemophilia A or B, 30 healthy controls
Kumar, K. R., Liang, C., Needham, M., Burke, D., Sue, C. M., & Ng, K. (2011). Axonal hyperpolarization in inclusion-body myopathy, paget disease of the bone, and frontotemporal dementia (IBMPFD). Muscle & nerve, 44(2), 191-196.	TSA 2	not expressly stated	not expressly stated	not expressly stated	neurology / genetic disorder	Inclusion-body myopathy, Paget disease of the bone, and frontotemporal dementia (IBMPFD)	3 patients with Inclusion-body myopathy, Paget disease of the bone, and frontotemporal dementia (IBMPFD)
Kumru, H., Portell, E., Marti, M., Albu, S., Tormos, J. M., Vidal, J., & Valls-Sole, J. (2013). Mechanical and thermal hyperalgesia in patients with poliomyelitis. *Clinical Neurophysiology*, *124*(7), 1431-1438.	TSA 2/Pathway(?)	5.7 cm2 thermode (?)	warm detection threshold, heat pain threshold	limits	virology / neurology / pain medicine	Paralytic poliomyelitis (pPM)	15 patients with : Paralytic poliomyelitis and 15 controls
Kuo, M. C., Huang, J. C., Wu, P. Y., Mai, H. C., Chen, S. C., Chiu, Y. W., ... & Chen, H. C. (2020). Associations of Small Fiber Neuropathy with Geriatric Nutritional Risk Index and Arterial Stiffness in Hemodialysis. Disease Markers, 2020.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	not expressly stated	Nephrology / neurology / pain medicine	hemodialysis	170 patient undergoing 3-times a week hemodialysis treatment

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Kuperman, P., Granovsky, Y., Granot, M., Bahouth, H., Fadel, S., Hyams, G., ... & Yarnitsky, D. (2018). Psychophysic-psychological dichotomy in very early acute mTBI pain: a prospective study. *Neurology*, *91*(10), e931-e938.	TSA 2	30*30 mm thermode	tonic noxious heat stimulation	ramp-and-hold	neurology	mild traumatic brain injury	100 patients with acute mild brain injury and 80 healthy controls
Kuppens, K., Hans, G., Roussel, N., Struyf, F., Fransen, E., Cras, P., ... & Nijs, J. (2018). Sensory processing and central pain modulation in patients with chronic shoulder pain: a case-control study. Scandinavian journal of medicine & science in sports, 28(3), 1183-1192.	TSA 2	not expressly stated	tonic noxious cold stimulation	ramp-and-hold	orthopaedics	chronic shoulder pain	25 patients with chronic shoulder pain and 25 healthy controls
Lahav, Y., Solomon, Z., Siegel, A., Tsur, N., & Defrin, R. (2020). Punishing the Self: Post-Traumatic Guilt Mediates the Link Between Trauma and Deficient Pain Modulation. The Journal of Pain, 21(3-4), 364-374.	TSA 2	30*30 mm thermode	heat pain threshold, heat pain tolenrance threshold, tonic noxious heat stimulus	limits, ramp-and-hold	psychology / pain medicine	torture survivors	59 torture survivors and 44 controls
Lai, H. H., Gardner, V., Ness, T. J., & Gereau IV, R. W. (2014). Segmental hyperalgesia to mechanical stimulus in interstitial cystitis/bladder pain syndrome: evidence of central sensitization. The Journal of urology, 191(5), 1294-1299.	PATHWAY ATS	30*30 mm thermode	heat pain threshold	limits	urology / neurology / pain medicine	interstitial cystitis/bladder pain syndrome	10 patients with interstitial cystitis/bladder pain syndrome, 10 healthy controls
Lamhoot, T., Adelson, M., Sason, A., Schreiber, S., & Peles, E. (2021). Post-traumatic stress disorder due to sexual abuse and its relation to pain sensitivity among patients in methadone maintenance treatment. Psychiatry Research, 298, 113828.	PATHWAY CHEPS	CHEPS thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold, pulses for contact heat evoked potentials	limits, thermal sensory limen, pulses	neurology / pain medicine	spinal cord injury with and without neuropathic pain	12 patients with spinal cord injury with neuropathic pain, 12 patients with spinal cord injury without neruopathic pain, 12 able-bodied healthy controls
Landmann, G., Dumat, W., Egloff, N., Gantenbein, A. R., Matter, S., Pirotta, R., ... & Riederer, F. (2017). Bilateral sensory changes and high burden of disease in patients with chronic pain and unilateral nondermatomal	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology/ pain medicine	nondermatomal sensory deficits (NDSD)	25 chronic pain patients with NDSD, and 23 patients with chronic pain without NDSD

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
somatosensory deficits: A quantitative sensory testing and clinical study. The Clinical journal of pain, 33(8), 746.							
Lankes, F., Schiekofer, S., Eichhammer, P., & Busch, V. (2020). The effect of alexithymia and depressive feelings on pain perception in somatoform pain disorder. Journal of psychosomatic research, 133, 110101.	TSA 2	7.84 cm2 thermode (?)	cold pain threshold, heat pain threshold	limits	psychology / pain medicine	somatoform pain disorder / depressive disorder	40 subjects with persistent somatoform pain disorder, 40 patients with a diagnosis of depressive disorder without any clinical pain, and 40 healthy subjects
Lee, C. Y., Narm, K. S., Lee, J. G., Paik, H. C., Chung, K. Y., Shin, H. Y., ... & Kim, D. J. (2018). A prospective randomized trial of continuous paravertebral infusion versus intravenous patient-controlled analgesia after thoracoscopic lobectomy for lung cancer. Journal of thoracic disease, 10(6), 3814.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold, tonic noxious cold stimulus	limits, ramp-and-hold	surgery / oncology / anesthesiology / pain medicine	thoracoscopic lobectomy for lung cancer	78 patients who were either diagnosed or suspected with early lung cancer (clinical stage T1–2aN0M0); divided into group (n= 38) intravenous patient controlled analgesia (iv-PCA), and a group (n= 41) continuous paravertebral infusion (c-PVI) of local anesthetics.
Lee, J. H., Boland-Freitas, R., Liang, C., Howells, J., & Ng, K. (2020). Neuropathy in sporadic inclusion body myositis: A multi-modality neurophysiological study. Clinical Neurophysiology, 131(11), 2766-2776.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	neurology	sporadic inclusion body myositis	20 patients with sporadic inclusion body myositis
Lee, Y. S., Lee, D. J., Han, S. W., & Kim, K. T. (2014). Effect of Neuro-Feedback Training and Transcutaneous Electrical Nerve Stimulation (TENS) in Stress, Quantitative Sensory Threshold, Pain on Tension Type Headache. The Journal of Korean Physical Therapy, 26(6), 442-448.	TSA 2	not expressly stated	cold pain threshold, heat pain threshold	limits	neurology / pain medicine	tension-type headache	22 patients with tension-type headache
Lefaucheur, J. P. (2017). Measurement of electrochemical conductance of penile skin using Sudoscan®: A new tool to assess neurogenic impotence. *Neurophysiologie Clinique/Clinical Neurophysiology*, *47*(3), 253-260.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold	limits	endocrinology/urology	type 2 diabetes and impotence	25 patients with type 2 diabetes with impotence and 25 age matched healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
LEFAUCHEUR, J. P., YIOU, R., SALOMON, L., CHOPIN, D. K., & ABBOU, C. C. (2000). Assessment of penile small nerve fiber damage after transurethral resection of the prostate by measurement of penile thermal sensation. The Journal of urology, 164(4), 1416-1419.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold	limits	Urology / Andrology / neurology	penile small nerve fiber damage following transurethral resection of the prostate (TURP) for benign prostatic hypertrophy (BPH).	18 consecutive male patients prior to and one month after a transurethral resection of the prostate (TURP) for benign prostatic hypertrophy (BPH)
Leone, C., Galosi, S., Mollica, C., Fortunato, M., Possidente, C., Milone, V., ... & Terrinoni, A. (2021). Dissecting pain processing in adolescents with Non-Suicidal Self Injury: could suicide risk lurk among the electrodes?. European journal of pain.	PATHWAY ATS / Q-Sense CPM	30*30 mm thermode, dual thermode Q-Sense 30*30mm	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold, tonic noxious heat stimulation	limits, ramp-and-hold	psychiatry / pain medicine	non-suicidal self-injury (NSSI) disorder	30 adolescents suffering from non-suicidal self-injury (NSSI) disorder, and 20 controls
Lev, R., Granovsky, Y., & Yarnitsky, D. (2010). Orbitofrontal disinhibition of pain in migraine with aura: an interictal EEG-mapping study. Cephalalgia, 30(8), 910-918.	PATHWAY CHEPS	CHEPS thermode	pulses for contact heat evoked potentials	pulses	Pain medicine / nuerology	migraine with aura	21 migraine patients with aura
Lev, R., Granovsky, Y., & Yarnitsky, D. (2013). Enhanced pain expectation in migraine: EEG-based evidence for impaired prefrontal function. Headache: The Journal of Head and Face Pain, 53(7), 1054-1070.	Pathway CHEPS	CHEPS thermode	pulses for contact heat evoked potentials	pulses	neurology	migraine	19 patients with migraine without aura, 20 patients with migraine with aura, 22 age and sex matched healthy controls
Levy, D., Abdian, L., Dekel-Steinkeller, M., & Defrin, R. (2018). Experimental evidence for weaker endogenous inhibition of trigeminal pain than extra-trigeminal pain in healthy individuals. Cephalalgia, 38(7), 1307-1315.	TSA 2	30*30 mm thermode (*2) - dual thermode use	noxious heat pain stimulation	ramp-and-hold	neurology / pain medicine	healthy	17 healthy participants
Li, X., Cao, Y., Wong, R. M., Ho, K. Y., & Wilder-Smith, C. H. (2013). Visceral and somatic sensory function in functional dyspepsia. Neurogastroenterology & Motility, 25(3), 246-e165.	PATHWAY ATS/CHEPS	30*30 mm thermode	tonic noxious heat stimulation	ramp-and-hold	endocrinology / neurology / pain medicine	functional dyspepsia (FD)	34 functional dyspepsia (FD) patients, 42 healthy controls
Lieber, S., Blankenburg, M., Apel, K., Hirschfeld, G., Driever, P. H., & Reindl, T. (2018). Small-fiber neuropathy and pain sensitization in survivors of pediatric acute lymphoblastic leukemia. European Journal of Paediatric Neurology, 22(3), 457-469.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold	limits, thermal sensory limen	oncology / paediatrics	pediatric acute lymphoblastic leukemia after stem cell transplantation	25 relapse-free long-term survivors of pediatric acute lymphoblastic leukemia after stem cell transplantation

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
			pain threshold, heat pain threshold				
Liem, E. B., Joiner, T. V., Tsueda, K., & Sessler, D. I. (2005). Increased sensitivity to thermal pain and reduced subcutaneous lidocaine efficacy in redheads. The Journal of the American Society of Anesthesiologists, 102(3), 509-514.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold, cold pain tolerance, heat pain tolerance	limits	neurology / genetics	Redheads	30 healthy redheads, 30 healthy dark haired people
Maclachlan, L. R., Collins, N. J., Hodges, P. W., & Vicenzino, B. (2020). Psychological and pain profiles in persons with patellofemoral pain as the primary symptom. European Journal of Pain, 24(6), 1182-1196.	PATHWAY ATS	30*30 mm thermode	warm detection threshold, cold detection threshold,cold pain threshold, heat pain threshold	limits	orthopaedics / pain medicine	Patellofemoral pain (PFP)	150 patients with patellofemoral pain, and 61 healthy controls
Marchi, M., Provitera, V., Nolano, M., Romano, M., Maccora, S., D'Amato, I., ... & Lauria, G. (2018). A novel SCN9A splicing mutation in a compound heterozygous girl with congenital insensitivity to pain, hyposmia and hypogeusia. Journal of the Peripheral Nervous System, 23(3), 202-206.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	genetic / neurology	congenital insensitivity to pain, hyposmia and hypogeusia	case report 1 patient
McKnight, J., Nicholls, P. G., Loretta, D., Desikan, K. V., Lockwood, D. N. J., Wilder-Smith, E. P., & van Brakel, W. H. (2010). Reference values for nerve function assessments among a study population in northern India-ii: Thermal sensation thresholds. Neurology Asia, 15(1), 27-38.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	levels	neurology / normative data	healthy	326 healthy Northern-Indian volunteers
Mehrabyan, A., Guest, S., Essick, G., & McGlone, F. (2011). Tactile and thermal detection thresholds of the scalp skin. Somatosensory & motor research, 28(3-4), 31-47.	TSA 2	intraoral thermode, 16*16 mm thermode	warm detection threshold, cold detection threshold	limits	neurology / genetic disorder	androgen-related alopecia (ARA)	10 men with normal hair growth pattern, 12 men with normal hair growth pattern and shaved scalp, 10 men with bold sites
Meier, P. M., Zurakowski, D., Berde, C. B., & Sethna, N. F. (2009). Lumbar sympathetic blockade in children with complex regional pain syndromes: a double blind placebo-controlled crossover trial.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold,	limits	paediatrics / pain medicine / pharmacokinetics / treatment efficacy	adolescents with complex regional pain syndrome (CRPS) type 1 and 2	23 adolescent CRPS patients treated with Intravenous lidocaine or Lumbar Sympathetic Blockage

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
The Journal of the American Society of Anesthesiologists, 111(2), 372-380.			heat pain threshold				
Mellick, G. A., & Mellick, L. B. (2006). Clinical presentation, quantitative sensory testing, and therapy of 2 patients with fourth thoracic syndrome. Journal of manipulative and physiological therapeutics, 29(5), 403-408.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology /osteopathy / treatment efficacy	Fourth thoracic (4T) syndrome	2 case reports of patients with 4T syndrome
Mo, X., Zhang, J., Fan, Y., Svensson, P., & Wang, K. (2015). Thermal and mechanical quantitative sensory testing in chinese patients with burning mouth syndrome–a probable neuropathic pain condition?. The journal of headache and pain, 16(1), 1-7.	TSA 2	Intraoral thermode, 30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / pain medicine	burning mouth syndrome	25 patients with burning mouth syndrome, 19 healthy controls
Moloney, N., Hall, T., & Doody, C. (2013). Sensory hyperalgesia is characteristic of nonspecific arm pain: a comparison with cervical radiculopathy and pain-free controls. *The Clinical journal of pain*, *29*(11), 948-956.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / pain medicine	non-specific arm pain / cervical radiculopathy	40 office workers with non-specific arm pain, 17 patients with cervical radiculopathy, 40 healthy controls
Moshourab, R., Bégay, V., Wetzel, C., Walcher, J., Middleton, S., Gross, M., & Lewin, G. R. (2017). Congenital deafness is associated with specific somatosensory deficits in adolescents. Scientific reports, 7(1), 1-9.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	genetic / neurology	Congenital deafness	One hundred and twenty-five healthy (125) and 39 hearing impaired participants adolescents and young adults
Moskal, D., Maisto, S. A., De Vita, M., & Ditre, J. W. (2018). Effects of experimental pain induction on alcohol urge, intention to consume alcohol, and alcohol demand. Experimental and clinical psychopharmacology, 26(1), 65.	Q-Sense CPM	30*30 mm thermode (*2) - dual thermode use	heat pain threshold, heat pain tolerance, pain80	limits, ramp-and-hold	addiction / psychology	alcohol use disorder	66 young adults with hazardous drinking habits
Münster, T., Tiebel, N., Seyer, H., & Maihöfner, C. (2012). Modulation of somatosensory profiles by spinal cord stimulation in primary Raynaud' s syndrome. Pain Practice, 12(6), 469-475.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold,	limits	neurology / vascular	primary Raynaud's syndrome	1 patient case study

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Nedelec, B., Hou, Q., Sohbi, I., Choinière, M., Beauregard, G., & Dykes, R. W. (2005). Sensory perception and neuroanatomical structures in normal and grafted skin of burn survivors. Burns, 31(7), 817-830.	TSA 2	32*32 mm thermode (?)	warm detection threshold, cold detection threshold, heat pain threshold,	levels	plastoc surgery / dermatology / neurology	skin-grafted burn survivors	15 skin-grafted burn survivors with deep partial- or full-thickness thermal burn injuries
Ness, T. J., Fillingim, R. B., Randich, A., Backensto, E. M., & Faught, E. (2000). Low intensity vagal nerve stimulation lowers human thermal pain thresholds. *Pain*, *86*(1-2), 81-85.	TSA 2	30*30 mm thermode	heat pain threshold	limits	neurology/treatment efficacy	epilepsy	8 epilepsy patients with left cervical vagal nerve stimulators
Ness, T. J., Lloyd, L. K., & Fillingim, R. B. (2014). An endogenous pain control system is altered in subjects with interstitial cystitis. The Journal of urology, 191(2), 364-370.	TSA 2	30*30 mm thermode	heat pain thresholds, heat pain tolerance, noxious heat pulses	limits, ramp-and-hold	urology / neurology / pain medicine	interstitial cystitis/bladder pain syndrome	29 patients with Interstitial Cystitis/Bladder Pain Syndrome and 14 matched controls
Olesen, S. S., Hansen, T. M., Graversen, C., Valeriani, M., & Drewes, A. M. (2013). Cerebral excitability is abnormal in patients with painful chronic pancreatitis. European Journal of Pain, 17(1), 46-54.	PATHWAY CHEPS	CHEPS thermode	pulses for contact heat evoked potentials	pulses	neurology / endocrinology / pain medicine	chronic pancreatitis (CP)	15 patients with chronic pancreatitis and 15 healthy controls
Ophir, A., Karakis, I., Richter, E. D., Abarbanel, J. M., Wormser, U., Aschner, M., & Finkelstein, Y. (2014). An uncommon pattern of polyneuropathy induced by lifetime exposures to drift containing organophosphate pesticides. Neurotoxicology, 45, 338-346.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	limits	toxicology / neurology / occupational health	low-level exposure to organophosphates (OP)	60 individuals living in agricultura; communities who had been exposed to organophosphates (OP) pesticides
Ozasa, K., Nishihara, C., Watanabe, K., Young, A., Khan, J., Sim, C., ... & Noma, N. (2020). Somatosensory profile of a patient with mixed connective tissue disease and Sjögren syndrome. The Journal of the American Dental Association, 151(2), 145-151.	TSA 2	10*10 mm thermode (?)	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold,	limits, thermal sensory limen	neurology / pain medicine	mixed connective tissue disease (MCTD) and Sjögren syndrome	1 case study of mixed connective tissue disease (MCTD) and Sjögren syndrome and 5 healthy controls
Pan, C. L., Tseng, T. J., Lin, Y. H., Chiang, M. C., Lin, W. M., & Hsieh, S. T. (2003). Cutaneous innervation in Guillain–Barré syndrome: pathology and clinical correlations. Brain, 126(2), 386-397.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	limits+levels	neurology	demyelinating Guillan Barre Syndrome (GBS)	20 patients with demyelinating GBS

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Paterakis, K., Schmitter, M., & Said Yekta-Michael, S. (2018). Efficacy of epinephrine-free articaine compared to articaine with epinephrine (1: 100 000) for maxillary infiltration, a randomised clinical trial. Journal of oral rehabilitation, 45(6), 467-475.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	dental / pharmacokinetics	dental patients	30 patients who needed an occlusal filling (occlusal caries ICDAS-II code 4-5, with caries excavation feasible within 5 minutes) in the premolar region and had healthy, restoration-free, vital canines on both sides of the maxilla
Payne, L. A., Seidman, L. C., Sim, M. S., Rapkin, A. J., Naliboff, B. D., & Zeltzer, L. K. (2019). Experimental evaluation of central pain processes in young women with primary dysmenorrhea. Pain, 160(6), 1421.	TSA 2	30*30 mm thermode	heat pain threshold, heat pain tolerance	limits	gynaecology / pain medicine	Primary Dysmenorrhea	32 adolesncents and young women with Primary Dysmenorrhea, 34 controls
Pfau, D. B., Krumova, E. K., Treede, R. D., Baron, R., Toelle, T., Birklein, F., ... & Maier, C. (2014). Quantitative sensory testing in the German Research Network on Neuropathic Pain (DFNS): reference data for the trunk and application in patients with chronic postherpetic neuralgia. PAIN®, 155(5), 1002-1015.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	virology / neurology / pain medicine	chronic postherpetic neuralgia	72 patients with chronic postherpetic neuralgia, 162 healthy controls
Phillips, C., Essick, G. K., Chung, Y., & Blakey, G. (2012). Non-invasive therapy for altered facial sensation following orthognathic surgery: an exploratory randomized clinical trial of intranasal vitamin B12 spray. Journal of maxillofacial trauma, 1(1), 20.	TSA 2	2.6 cm2 thermode(?)	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / surgery / treatment efficacy	bilateral sagittal split osteotomy / maxillary procedure for treatment of a developmental dentofacial disharmony	35 patients undergoing bilateral sagittal split osteotomy either alone or combined with a maxillary procedure for treatment of a developmental dentofacial disharmony treated with B12 intranasal spray or no spray
Pogatzki-Zahn, E. M., Drescher, C., Englbrecht, J. S., Klein, T., Magerl, W., & Zahn, P. K. (2019). Progesterone relates to enhanced incisional acute pain and pinprick hyperalgesia in the luteal phase of female volunteers. Pain, 160(8), 1781-1793.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	surgery / pain medicine / women's healthy	acute incisional pain	15 healthy female volunteers with a regular menstrual cycle
Pogatzki-Zahn, E. M., Pereira, M. P., Cremer, A., Zeidler, C., Dreyer, T., Riepe, C., ... & Ständer, S. (2020). Peripheral sensitization and loss of descending inhibition is a hallmark of chronic pruritus. Journal of	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations,	limits, thermal sensory limen	neurology	chronic pruritus	120 patients with Chronic Pruritus of inflammatory origin (atopic dermatitis), neuropathic origin (brachioradial pruritus), and chronic prurigo of nodular type and 40 matched healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Investigative Dermatology, 140(1), 203-211.			thermal sensory limen, cold pain threshold, heat pain threshold				
Potvin, S., & Marchand, S. (2016). Pain facilitation and pain inhibition during conditioned pain modulation in fibromyalgia and in healthy controls. Pain, 157(8), 1704-1710.	TSA 2	not expressly stated	heat pain threshold, pain 50, tonix noxious heat stimulus	limits, ramp-and-hold	neurology / pain medicine	fibromyalgia	96 fibromyalgia patients and 71 healthy controls
Potvin, S., Stip, E., & Marchand, S. (2016). Markedly reduced thermal pain perception in a schizoaffective patient with tardive dyskinesia. Case reports in psychiatry, 2016.	TSA 2	30*30 mm thermode	heat pain threshold, heat pain tolerance, noxious heat stimuli	limits	Psychiatry / neurology / pain medicine	schizoaffective disorder	1 case study in a Schizoaffective Patient with Tardive Dyskinesia
Priano, L., Miscio, G., Grugni, G., Milano, E., Baudo, S., Sellitti, L., ... & Mauro, A. (2009). On the origin of sensory impairment and altered pain perception in Prader–Willi syndrome: A neurophysiological study. European Journal of Pain, 13(8), 829-835.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / genetic disorder	Prader–Willi syndrome	14 patients with Prader–Willi syndrome, 10 obese non-diabetic patients, 10 normal-weight controls
Prosser, J. M., Steinfeld, M., Cohen, L. J., Derbyshire, S., Eisenberg, D. P., Cruciani, R. A., & Galynker, I. I. (2008). Abnormal heat and pain perception in remitted heroin dependence months after detoxification from methadone-maintenance. Drug and alcohol dependence, 95(3), 237-244.	TSA 2	30*30 mm thermode	warm detection threshold, heat pain threshold	limits	addiction / pain medicine	opiate dependence	23 opioid users after methadone treatment in protracted abstinence, and 28 healthy controls
Prottengeier, J., Elsner, S., Wehrfritz, A., Moritz, A., Schmidt, J., & Meyer, M. (2020). Nociception testing during fixed-wing ambulance flights. An interventional pilot study on the effects of flight-related environmental changes on the nociception of healthy volunteers. PloS one, 15(2), e0217530.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	pain medicine / neurology	fixed-wingambulance flights	25 healthy volunteers undergoing during fixed-wing ambulance flights
Rakel, B. A., Blodgett, N. P., Zimmerman, M. B., Logsden-Sackett, N., Clark, C., Noiseux, N., ... & Sluka, K. A. (2012). Predictors of postoperative movement and resting pain following total knee replacement. PAIN®, 153(11), 2192-2203.	TSA 2	16*16 mm thermode	heat pain threshold	limits	surgery / orthopaedics / pain medicine	total knee replacement	215 patients undergoing total knee replacement

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Ramaswamy, S., Wodehouse, T., Langford, R., Thomson, S., Taylor, R., & Mehta, V. (2019). Characterizing the somatosensory profile of patients with failed back surgery syndrome with unilateral lumbar radiculopathy undergoing spinal cord stimulation: a single center prospective pilot study. Neuromodulation: Technology at the Neural Interface, 22(3), 333-340.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / surgery / treatment efficacy / pain medicine	failed back surgery / radicular pain / spinal cord stimulation	23 patients with Failed Back Surgery Syndrome and unilateral radicular pain, due to undergo percutaneous Spinal Cord Stimulation
Reddy, S. M., Vergo, M. T., Paice, J. A., Kwon, N., Helenowski, I. B., Benson, A. B., ... & Harden, R. N. (2016). Quantitative sensory testing at baseline and during cycle 1 oxaliplatin infusion detects subclinical peripheral neuropathy and predicts clinically overt chronic neuropathy in gastrointestinal malignancies. Clinical colorectal cancer, 15(1), 37-46.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	oncology / neurology / toxicology / pain medicine	gastrointestinal malignancy, and scheduled to start an oxaliplatin-based chemotherapy regimen	30 patients with gastrointestinal malignancy, and scheduled to start an oxaliplatin-based chemotherapy regimen
Reed, B. D., Sen, A., Harlow, S. D., Haefner, H. K., & Gracely, R. H. (2017). Multimodal vulvar and peripheral sensitivity among women with vulvodynia: a case-control study. *Journal of lower genital tract disease*, *21*(1), 78.	TSA 2	5*5 mm thermode	warm detection threshold, cold detection threshold, supra-threshold heat pain, supra-threshold cold pain	limits	gynacology / pain medicine	vulvodynia	43 patients with vulvodynia and 41 healthy controls
Reynolds, W. S., Brown, E. T., Danford, J., Kaufman, M., Wein, A., Dmochowski, R., & Bruehl, S. (2017). Temporal summation to thermal stimuli is elevated in women with overactive bladder syndrome. Neurourology and urodynamics, 36(4), 1108-1112.	TSA 2	30*30 mm thermode	pulses	pulses	urology / neurology / pain medicine	overactive bladder syndrome	20 adult women with overactive bladder syndrome and 23 healthy controls
Rodrigues Júnior, I. A., Silva, I. C. C., Gresta, L. T., Lyon, S., Villarroel, M. D. F., & Arantes, R. M. E. (2012). Degree of skin denervation and its correlation to objective thermal sensory test in leprosy patients. *PLoS neglected tropical diseases*, *6*(12), e1975.	TSA 2	30*30 mm thermode	warm and cold perception thresholds, heat and cold pain thresholds	limits	neurology	leprosy	22 leprocy patients

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Rolke, R., Baron, R., Maier, C. A., Tölle, T. R., Treede, R. D., Beyer, A., ... & Wasserka, B. (2006). Quantitative sensory testing in the German Research Network on Neuropathic Pain (DFNS): standardized protocol and reference values. Pain, 123(3), 231-243.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	neurology	healthy	180 subjects for normative data
Rolke, R., Rolke, S., Vogt, T., Birklein, F., Geber, C., Treede, R. D., ... & Voelter-Mahlknecht, S. (2013). Hand-arm vibration syndrome: clinical characteristics, conventional electrophysiology and quantitative sensory testing. Clinical Neurophysiology, 124(8), 1680-1688.	not expressly stated	not expressly stated	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	occupational health / neurology	hand-arm vibration syndrome	Thirty-two patients were examined (54 ± 11 years, 91% men) at the more affected hand compared to 16 matched controls
Romano, R. R., Carter, M. A., Dietrich, M. S., Cowan, R. L., Bruehl, S. P., & Monroe, T. B. (2021). Could Altered Evoked Pain Responsiveness Be a Phenotypic Biomarker for Alzheimer's Disease Risk? A Cross-Sectional Analysis of Cognitively Healthy Individuals. Journal of Alzheimer's Disease, (Preprint), 1-7.	Q-Sense	30*30 mm thermode	thresholds for various heat perception levels (just noticeable pain; weak pain; moderate pain)	limits	genetics / geriatrics / pain medicine	apolipoprotein 4 (APOE4) allele, a genetic marker associated with increased risk of developing late-onset Alzheimer's disease (AD)	12 APOE4 positive subjects, 37 APOE4 negative subjects
Rudge, P., Jaunmuktane, Z., Hyare, H., Ellis, M., Koltzenburg, M., Collinge, J., ... & Mead, S. (2019). Early neurophysiological biomarkers and spinal cord pathology in inherited prion disease. Brain, 142(3), 760-770.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	neurology / genetic disorder	patients with, or at risk of developing, Prion disease	31 patients with or at risk of inheriting the P102L mutation were recruited
Ryu, J., Bar-Shalita, T., Granovsky, Y., Weissman-Fogel, I., & Torres, E. B. (2020). Personalized Biometrics of Physical Pain Agree with Its Psychological Perception by Participants with Sensory Over Responsivity.	Pathway CHEPS	CHEPS	pulses for contact heat evoked potentials	pulses	psychology / pain medicine	sensory over-responsiveness	9 persons with sensory over-responsiveness, 11 controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Sampaio, F. A., Sampaio, C. R., Cunha, C. O., Costa, Y. M., Alencar, P. N., Bonjardim, L. R., ... & Conti, P. C. (2019). The effect of orthodontic separator and short-term fixed orthodontic appliance on inflammatory mediators and somatosensory function. Journal of oral rehabilitation, 46(3), 257-267.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold	limits	dental / treatment efficacy	patients with orthodontic separator and short-term fixed orthodontic appliance	22 patients with orthodontic separator and short-term fixed orthodontic appliance
Samuelsson, K., Radovic, A., Press, R., Auranen, M., Ylikallio, E., Tyynismaa, H., ... & Hietaharju, A. (2019). Screening for Fabry disease and Hereditary ATTR amyloidosis in idiopathic small-fiber and mixed neuropathy. Muscle & nerve, 59(3), 354-357.	TSA 2	not expressly stated	warm and cold perception thresholds	not expressly stated	neurology	small fiber neuropathy and polyneuropathy	155 patients with idiopathic small fiber neuropathy and polyneuropathy
Santiago, B. V. M., Bersot, C. D. A., de Lemos Souza, F. C., Gonçalves, O. R., & Villela, N. R. (2019). Role of the Qst-Testing for the Determination of the Nervus Intermedius Neuralgia Phenotype–Case Report. International Journal of Anesthesia and Clinical Medicine, 7(1), 7.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold,	limits	neurology / pain medicine	Nervus Intermedius Neuralgia	1 patient case study
Sapio, M. R., Iadarola, M. J., LaPaglia, D. M., Lehky, T., Thurm, A. E., Danley, K. M., ... & Han, J. C. (2019). Haploinsufficiency of the brain-derived neurotrophic factor (BDNF) gene is associated with reduced pain sensitivity. Pain, 160(5), 1070.	TSA 2	16*16 mm thermode	noxious and non-noxious heat and cold stimulation	ramp-and-hold	genetics	WAGR (Wilms tumor, aniridia, genitourinary anomaly, range of intellectual disabilities) syndrome	12 children / adolescents / adults with WAGR syndrome
Savic, G., Bergström, E. M., Davey, N. J., Ellaway, P. H., Frankel, H. L., Jamous, A., & Nicotra, A. (2007). Quantitative sensory tests (perceptual thresholds) in patients with spinal cord injury. Journal of Rehabilitation Research & Development, 44(1).	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	not expressly stated	neurology	spinal cord injury	28 patients with spinal cord injury, 10 healthy controls
Schestatsky, P., Lladó-Carbó, E., Casanova-Molla, J., Álvarez-Blanco, S., & Valls-Solé, J. (2008). Small fibre function in patients with meralgia paresthetica. Pain, 139(2), 342-348.	Pathway CHEPS	CHEPS thermode	pulses for contact heat evoked potentials	pulses	neurology / pain medicine	meralgia paresthetica (MP)	14 patients with idiopathic MP, and 14 healthy subjects

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Schiff, E., & Eisenberg, E. (2003). Can quantitative sensory testing predict the outcome of epidural steroid injections in sciatica? A preliminary study. Anesthesia & Analgesia, 97(3), 828-832.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	neurology / treatment efficacy / pain medicine	sciatica	20 patients with unilateral painful sciatica caused by disc herniation, undergoing epidural steroid injections
Schliessbach, J., Siegenthaler, A., Bütikofer, L., Vuilleumier, P., Jüni, P., Stamer, U., ... & Curatolo, M. (2018). Predicting drug efficacy in chronic low back pain by quantitative sensory tests. European journal of pain, 22(5), 973-988.	TSA 2	30*30 mm thermode	heat pain threshold, heat pain tolerance, cold pain threshold	limits	pain medicine / treatment efficacy / pharmacokinetics	chronic low back pain	98 chronic low back pain patients
Schmahl, C., Meinzer, M., Zeuch, A., Fichter, M., Cebulla, M., Kleindienst, N., ... & Bohus, M. (2010). Pain sensitivity is reduced in borderline personality disorder, but not in posttraumatic stress disorder and bulimia nervosa. *The World Journal of Biological Psychiatry*, *11*(2-2), 364-371.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	psychiatry / pain medicine	borderline personality disorder, post traumatic stress disorder, Bulimia Nervosa	16 patients with borderline personality disorder, 16 patieents with post traumatic stress disorder, 20 patients with Bulimia Nervosa, 24 healthy controls
Schwartzman, R. J., & Grothusen, J. R. (2008). Brachial plexus traction injury: quantification of sensory abnormalities. Pain Medicine, 9(7), 950-957.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	limits	neurology / pain medicine	Brachial Plexus Traction Injury	38 patients who were suffering neck and upper extremity pain, and paraesthesias of the shoulder, arm, and hand that had resulted from a motor vehicle rear end collision, fall on the outstretched arm or direct injury to the plexus, and 20 healthy controls
Sermeus, L. A., Schepens, T., Hans, G. H., Morrison, S. G., Wouters, K., Breebaart, M. B., ... & Vercauteren, M. P. (2019). A low dose of three local anesthetic solutions for interscalene blockade tested by thermal quantitative sensory testing: a randomized controlled trial. Journal of clinical monitoring and computing, 33(2), 307-316.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	pharmacokinetics / oncology / treatment efficacy	surgical patients	30 patients undergoing arthroscopic shoulder surgery; patients were randomly assigned to receive an ultrasound-guided interscalene brachial plexus block (US-ISB) with one of three Local anestetics: 0.5% LBup (0.5% levobupivacaine), 0.5% LBupEpi (0.5% levobupivacaine with 1/200,000 epinephrine), or 0.75% Rop (0.75% ropivacaine)
Sharma, M. L., Marley, K., McGlone, F. P., Gupta, M., & Marshall, A. G. (2018). Dissociation of Spinothalamic Modalities Following Anterolateral Cordotomy. Canadian Journal of Neurological Sciences, 45(3), 354-356.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	surgery / neurology	anterolateral cordotomy	case report 1 patient

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Sheen, Y. J., Li, T. C., Lin, J. L., Tsai, W. C., Kao, C. D., Bau, C. T., & Sheu, W. H. H. (2018). Association between thermal threshold abnormalities and peripheral artery disease in patients with type 2 diabetes. Medicine, 97(51).	Q-Sense	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	endocrinology	type 2 diabetes	725 patients with type 2 diabetes
Shillo, P., Selvarajah, D., Greig, M., Gandhi, R., Rao, G., Wilkinson, I. D., ... & Tesfaye, S. (2019). Reduced vitamin D levels in painful diabetic peripheral neuropathy. Diabetic Medicine, 36(1), 44-51.	TSA 2	not expressly stated	not expressly stated	not expressly stated	endocrinology	type 2 diabetes / painful diabetic neuropathy	45 patients with type 2 diabetes
Shukla, G., Goyal, V., Srivastava, A., & Behari, M. (2012). Quantitative thermal sensory testing and sympathetic skin response in primary Restless legs syndrome–A prospective study on 57 Indian patients. Annals of Indian Academy of Neurology, 15(4), 260.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold	limits	neurology / sleep medicine	Primary Restless Legs syndrome	57 patients with primary restless legs syndrome
Silva, K. E., Rosner, J., Ullrich, N. J., Chordas, C., Manley, P. E., & Moulton, E. A. (2019). Pain affect disrupted in children with posterior cerebellar tumor resection. Annals of clinical and translational neurology, 6(2), 344-354.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	surgery / paediatrics / neurology / oncology	cerebellar low-grade glioma and posterior cerebellar tumor resection	12 pediatric patients with cerebellar low-grade glioma after posterior cerebellar tumor resection and 12 healthy matched controls
Simpson, N. S., Scott-Sutherland, J., Gautam, S., Sethna, N., & Haack, M. (2018). Chronic exposure to insufficient sleep alters processes of pain habituation and sensitization. Pain, 159(1), 33.	TSA 2	30*30 mm thermode	warm detection threshold, heat pain threshold	limits	sleep medicine / pain medicine	restricted sleep with limited recovery	17 healthy participants undergoing sleep restriction with limited recovery
Slawek, D. E., Merlin, J. S., Owens, M. A., Long, D. M., Gonzalez, C. E., White, D. M., ... & Goodin, B. R. (2020). Increasing age is associated with elevated circulating interleukin-6 and enhanced temporal summation of mechanical pain in people living with HIV and chronic pain. *PAIN Reports*, *5*(6), e859.	TSA 2	30*30 mm thermode	phasic heat temporal summation	ramp-and-hold	haematology	HIV	80 HIV positive patients
Smith, A. D., Jull, G., Schneider, G., Frizzell, B., Hooper, R. A., & Sterling, M. (2014). Cervical radiofrequency neurotomy reduces central hyperexcitability and improves neck movement in individuals with chronic whiplash.	TSA 2	not expressly stated	cold pain threshold, heat pain threshold	limits	orthopaedics / pain medicine / treatment efficacy	chronic whiplash associated disorder	54 chronic whiplash associated disorder patients after cervical facet joint blockade

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Pain medicine, 15(1), 128-141.							
Staud, R., Mokthech, M., Price, D. D., & Robinson, M. E. (2015). Evidence for sensitized fatigue pathways in patients with chronic fatigue syndrome. Pain, 156(4), 750.	PATHWAY ATS	30*30 mm thermode	noxious tonic heat stimulus	ramp-and-hold	Neurology / pain medicine	chronic fatigue syndrome	39 patients with chronic fatigue syndrome, 21 healthy controls
Stevanato, G., Devigili, G., Eleopra, R., Fontana, P., Lettieri, C., Baracco, C., ... & Bevilacqua, M. (2014). Chronic post-traumatic neuropathic pain of brachial plexus and upper limb: a new technique of peripheral nerve stimulation. Neurosurgical review, 37(3), 473-480.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / surgery / pain medicine	post-traumatic brachial plexus lesions or distal peripheral nerve complaining of severe intractable chronic pain	7 patiets with Seven patients with post-traumatic brachial plexus lesions or distal peripheral nerve complaining of severe intractable chronic pain
Street, L. M., Harris, L., Curry, R. S., & Eisenach, J. C. (2019). Capsaicin-induced pain and sensitisation in the postpartum period. British journal of anaesthesia, 122(1), 103-110.	TSA 2	16*16 mm thermode	tonic noxious heat stimulation	ramp-and-hold	obstetrics / pain medicine / neurology	post partum women	46 postpartum women and 40 matched controls
Strigo, I. A., Matthews, S. C., Simmons, A. N., Oberndorfer, T., Klabunde, M., Reinhardt, L. E., & Kaye, W. H. (2013). Altered insula activation during pain anticipation in individuals recovered from anorexia nervosa: evidence of interoceptive dysregulation. International Journal of Eating Disorders, 46(1), 23-33.	TSA 2	30*30 mm thermode	tonic noxious heat stimulation	ramp-and-hold	psychiatry / neuroimaging / pain medicine	anorexia nervosa	12 women recovered from anorexia nervosa
Strobel, A. V., Tankisi, H., Finnerup, N. B., Fuglsang-Frederiksen, A., Jennum, P., Svendsen, K. B., ... & Otto, M. (2018). Somatosensory function is impaired in patients with idiopathic REM sleep behaviour disorder. *Sleep medicine*, *42*, 83-89.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	sleep medicine	Idiopathic REM sleep behaviour disorder	13 patients with idiopathic REM sleep behaviour disorder, 15 healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Suttrup, I., Oberdiek, D., Suttrup, J., Osada, N., Evers, S., & Marziniak, M. (2011). Loss of sensory function in patients with idiopathic hand dystonia. Movement Disorders, 26(1), 107-113.	Pathway CHEPS	CHEPS thermode	pulses for contact heat evoked potentials	pulses	neurology	Idiopathic hand dystonia	10 patients with idiopathic hand dystonia, 10 healthy matched controls
Tavakoli, M., Marshall, A., Banka, S., Petropoulos, I. N., Fadavi, H., Kingston, H., & Malik, R. A. (2012). Corneal confocal microscopy detects small-fiber neuropathy in Charcot–Marie–Tooth disease type 1A patients. Muscle & nerve, 46(5), 698-704.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	not expressly stated	neurology / genetic disorders	Charcot-Marie-Tooth disease type 1A (CMT1A) / hereditary motor and sensory neuropathy (HMSN)	12 patients with CMT1A and 12 healthy controls
Tavakoli, M., Mitu-Pretorian, M., Petropoulos, I. N., Fadavi, H., Asghar, O., Alam, U., ... & Malik, R. A. (2013). Corneal confocal microscopy detects early nerve regeneration in diabetic neuropathy after simultaneous pancreas and kidney transplantation. Diabetes, 62(1), 254-260.	TSA 2	not expressly stated	cold detection threshold, warm detection threshold	limits	neurology / endocrinology	simultaneous pancreas–kidney transplantation (SPK)	15 patients with type 1 Diabetes undergoing (SPK) surgery, 10 healthy volunteers
Teles, A. R., Ocay, D. D., Shebreen, A. B., Tice, A., Saran, N., Ouellet, J. A., & Ferland, C. E. (2019). Evidence of impaired pain modulation in adolescents with idiopathic scoliosis and chronic back pain. The Spine Journal, 19(4), 677-686.	Q-Sense	30*30 mm thermode	heat pain thresholds, heat pain tolerance	limits	orthopaedics / paediatrics / pain medicine	adolescent odiopathic scoliosis/chronic back pain	94 adolescent idiopathic scoliosis with chronic back pain
Thimineur, M., Kitaj, M., Kravitz, E., Kalizewski, T., & Sood, P. (2002). Functional abnormalities of the cervical cord and lower medulla and their effect on pain: observations in chronic pain patients with incidental mild Chiari I malformation and moderate to severe cervical cord compression. The Clinical journal of pain, 18(3), 171-179.	TSA 2	not expressly stated	warm detection threshold, heat pain threshold	limits	neurology / pain medicine	mild Chiari I malformations, cervical compressions	32 patients with mild Chiari I malformations, 53 patients with cervical compressions, 52 patients accepted into the pain program without history of head injury or central nervous system deficiency, 25 controls
Tin, S. N. W., Zouari, H. G., Ayache, S. S., Tropeano, A. I., Ajzenberg, C., Xhaxho, J., ... & Créange, A. (2019). Coaching of lifestyle recommendations improves sensory neurophysiological parameters in neuropathies related to glycemic disorder or metabolic syndrome. A pilot study.	TSA 2	not expressly stated	not expressly stated	not expressly stated	Neurology / endocrinology	glycemic disorders or metabolic syndrome	11 patients with glycemic disorders or metabolic syndrome

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Neurophysiologie Clinique, 49(1), 59-67.							
Tschugg, A., Löscher, W. N., Lener, S., Wildauer, M., Hartmann, S., Neururer, S., & Thomé, C. (2017). Gender differences after lumbar sequestrectomy: a prospective clinical trial using quantitative sensory testing. European Spine Journal, 26(3), 857-864.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	not expressly stated	neurology / treatment efficacy / pain medicine	lumbar disc herniation confirmed on MRI treated by a lumbar sequestrectomy	53 patients with a single lumbar disc herniation confirmed on MRI treated by a lumbar sequestrectomy
Tseng, M. T., Hsieh, S. C., Shun, C. T., Lee, K. L., Pan, C. L., Lin, W. M., ... & Hsieh, S. T. (2006). Skin denervation and cutaneous vasculitis in systemic lupus erythematosus. Brain, 129(4), 977-985.	TSA 2	not expressly stated	cold detection threshold, warm detection threshold	levels	neurology / rheumatology / pain medicine	systemic lupus erythematosus (SLE)	45 patients with SLE, and an unknown # of healthy controls
Turri, M., Teatini, F., Donato, F., Zanette, G., Tugnoli, V., Deotto, L., ... & Squintani, G. (2018). Pain modulation after oromucosal cannabinoid spray (SATIVEX®) in patients with Multiple Sclerosis: A study with quantitative sensory testing and laser-evoked potentials. Medicines, 5(3), 59.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / pain medicine / pharmacokinetics	multiple sclerosis	28 patients with multiple sclerosis
Ulrich, A., Min, K., & Curt, A. (2015). High sensitivity of contact-heat evoked potentials in “snake-eye” appearance myelopathy. Clinical Neurophysiology, 126(10), 1994-2003.	PATHWAY	CHEPS thermode	pulses for contact heat evoked potentials	pulses	neurology	focal central cord lesions referred to as “snake-eye” appearance myelopathy (SEAM)	33 patients with “snake-eye” appearance myelopathy (SEAM)
Valkenburg, A. J., Tibboel, D., & van Dijk, M. (2015). Pain sensitivity of children with Down syndrome and their siblings: quantitative sensory testing versus parental reports. Developmental Medicine & Child Neurology, 57(11), 1049-1055.	TSA 2	30*30 mm thermode	warm and cold perception thresholds, heat and cold pain thresholds	levels+limits	congenital/pediatrics	Down syndrome	42 children with Down syndrome and 24 siblings
van de Donk, T., van Cosburgh, J., van Dasselaar, T., van Velzen, M., Drewes, A. M., Dahan, A., & Niesters, M. (2020). Tapentadol treatment results in long-term pain relief in patients with chronic low back pain and associates with reduced segmental	PATHWAY ATS	30*30 mm thermode	tonic noxious heat stimulus	ramp-and-hold	neurology / pain medicine / treatment efficacy / pharmacokinetics	chronic low back pain	53 chronic low back patients treated with tapentadol (N=23) or placebo (n=23)

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
sensitization. Pain Reports, 5(6).							
Van den Bergh, P. Y., Thonnard, J. L., Duprez, T., & Laterre, E. C. (2000). Chronic demyelinating hypertrophic brachial plexus neuropathy. Muscle & Nerve: Official Journal of the American Association of Electrodiagnostic Medicine, 23(2), 283-288.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	limits	neurology	Chronic demyelinating hypertrophic brachial plexus neuropathy	case report 1 patient with Chronic demyelinating hypertrophic brachial plexus neuropathy
Van Wilgen, C. P., Konopka, K. H., Keizer, D., Zwerver, J., & Dekker, R. (2013). Do patients with chronic patellar tendinopathy have an altered somatosensory profile?–AQ uantitative S ensory T esting (QST) study. *Scandinavian journal of medicine & science in sports*, *23*(2), 149-155.	PATHWAY	not expressly stated	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold	limits, thermal sensory limen	Sports medicine / orthopaedics / pain medicine	chronic patellar tendinopathy	12 athletes with clinically diagnosed chronic patellar tendinopathy (PT) and 20 control athletes
von Leupoldt, A., Sommer, T., Kegat, S., Eippert, F., Baumann, H. J., Klose, H., ... & Büchel, C. (2009). Down-regulation of insular cortex responses to dyspnea and pain in asthma. American journal of respiratory and critical care medicine, 180(3), 232-238.	TSA 2	30*30 mm thermode	noxious and non-noxious heat stimulation	ramp-and-hold	pneumology / neurology / pain medicine	asthma	14 patients with mild-to-moderate asthma, 14 healthy controls
Wang, F., Ding, X., Zhang, J., Song, X., Wu, Y., Svensson, P., & Wang, K. (2018). Somatosensory changes at forearm donor sites following three different surgical flap techniques. International Journal of Surgery, 53, 326-332.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	plastic surgery / neurology / treatment efficacy	oral and maxillofacial reconstructive surgery patients	31 patients undergoing oral and maxillofacial reconstructive surgery involving the use of a traditional radial forearm flap (TRFF) or two modified radial forearm flap techniques (MRFF-I; MRFF-II) participated in the study.
Wilcox, C. E., Adinoff, B., Clifford, J., Ling, J., Witkiewitz, K., Mayer, A. R., ... & Bogenschutz, M. (2020). Brain activation and subjective anxiety during an anticipatory anxiety task is related to clinical outcome during prazosin treatment for alcohol use disorder. NeuroImage: Clinical, 26, 102162.	Pathway	30*30 thermode	"pain threshold for high heat temperature", tonic noxious heat stimulus	limits, ramp-and-hold	addiction / psychology / neuroimaging	alcohol use disorder	34 patients with alcohol use disorder

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Wu, Q., Inman, R. D., & Davis, K. D. (2013). Neuropathic pain in ankylosing spondylitis: a psychophysics and brain imaging study. Arthritis & Rheumatism, 65(6), 1494-1503.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	orthopaedics / neurology / neuroimaging	ankylosing spondylitis (AS)	17 patients with ankylosing spondylitis, 17 healthy controls
Yarnitsky, D., & Sprecher, E. (1994). Thermal testing: normative data and repeatability for various test algorithms. Journal of the neurological sciences, 125(1), 39-45.	TSA 2	25*50 thermode	warm detection threshold, cold detection threshold	limits + levels	neurology / normative data	healthy	106 healthy participants
Yekta, S. S., Lückhoff, A., Ristić, D., Lampert, F., & Ellrich, J. (2012). Impaired somatosensation in tongue mucosa of smokers. Clinical oral investigations, 16(1), 39-44.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, paradoxical heat sensations, thermal sensory limen, cold pain threshold, heat pain threshold,	limits, thermal sensory limen	toxicology / neurology	smokers	40 smokers and 40 non-smokers
Yekta-Michael, S. S., Stein, J. M., & Marioth-Wirtz, E. (2015). Evaluation of the anesthetic effect of epinephrine-free articaine and mepivacaine through quantitative sensory testing. Head & face medicine, 11(1), 1-13.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	dental / pharmacokinetics	need of small nonsurgical dental treatment in region of maxillary premolares	21 need of small nonsurgical dental treatment in region of maxillary premolares
Yiou, R., De Laet, K., Hisano, M., Salomon, L., Abbou, C. C., & Lefaucheur, J. P. (2012). Neurophysiological testing to assess penile sensory nerve damage after radical prostatectomy. *The journal of sexual medicine*, *9*(9), 2457-2466.	TSA 2	16*16 mm thermode	warm detection threshold, cold detection threshold	limits	urology/neurology	patients after Radical Prostatectomy	12 patients undergoing laparoscopic nerve-sparing radial prostatectomy, 13 patients undergoing laparoscopic non-nerve-sparing radial prostatectomy, 11 patients undergoing retropubic non-nerve-sparing radial prostatectomy, and 6 patients undergoing transperineal non-nerve-sparing radial prostatectomy
Yosipovitch, G., Chan, Y. H., Tay, Y. K., & Goh, C. L. (2003). Thermosensory abnormalities and blood flow dysfunction in psoriatic skin. British Journal of Dermatology, 149(3), 492-497.	TSA 2	12-cm2 thermode?	cold detection threshold, warm detection threshold, heat pain threshold	limits	Dermatology / neurology	chronic plaque type psoriasis	41 patients with chronic plaque type psoriasis and 39 healthy controls
Zanette, G., Cacciatori, C., & Tamburin, S. (2010). Central sensitization in carpal tunnel syndrome with extraterritorial spread of sensory symptoms. Pain, 148(2), 227-236.	TSA 2	30*30 mm thermode	cold pain threshold, heat pain threshold	limits	neurology / pain medicine	carpal tunnel syndrome	48 patients with carpal tunnel syndrome, 24 healthy controls

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Zhang, C., Xie, B., Li, X., & Yao, Y. (2014). Contact heat-evoked potentials as a useful means in patients with Guillain–Barré syndrome. Neurological Sciences, 35(8), 1209-1214.	Pathway CHEPS	CHEPS thermode	pulses for contact heat evoked potentials	pulses	neurology	Guillan Barre Syndrome (GBS)	60 patients with confirmed diagnosis of Guillan Barre Syndrome (GBS)
Zhang, G., Sun, Y., Wang, L., Tian, H., & Liang, L. (2017). Association of serum Ninjurin2 levels with neurologic damage and postherpetic neuralgia occurrence: an observational cohort study in chinese herpeszoster patients. Oncotarget, 8(42), 71520.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	neurology / virology / pain medicine	Acute herpetic neuralgia (AHN)	74 patients with Acute herpetic neuralgia (AHN), 60 healthy volunteers
Zhao, Y., Hemmer, S., Pepke, W., Akbar, M., Schiltenwolf, M., & Dapunt, U. (2020). Investigation of Risk Factors for Pain Chronification in Patients Suffering from Infections of the Spine. *Journal of Clinical Medicine*, *9*(12), 4056.	TSA 2	30*30 mm thermode	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	infection / neurology / pain medicine	infections of the spine	14 patients diagnosed with spondylodiscitis or spinal implant-associated infections of the thoracic or lumbar spine
Zhi, W. I., Baser, R. E., Kwon, A., Chen, C., Li, S. Q., Piulson, L., ... & Bao, T. (2021). Characterization of chemotherapy-induced peripheral neuropathy using patient-reported outcomes and quantitative sensory testing. Breast Cancer Research and Treatment, 186(3), 761-768.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold, cold pain threshold, heat pain threshold	limits	oncology / neurology	chemotherapy-induced peripheral neuropathy (CIPN)	116 patients with moderate-to-severe CIPN, 10 patients without CIPN
Zhong, W., Zhang, W., Yang, M., Li, G., Ma, Q., & Yang, X. (2014). Impact of diabetes mellitus duration on effect of lower extremity nerve decompression in 1,526 diabetic peripheral neuropathy patients. Acta neurochirurgica, 156(7), 1329-1333.	TSA 2	not expressly stated	warm detection threshold, cold detection threshold	limits	endocrinology / surgery / neurology	diabetic peripheral neuropathy patients treated with DELLON surgical nerve decompression	1,526 diabetic peripheral neuropathy patients treated with DELLON surgical nerve decompression

Citation	Device used	Thermode used	Modality: type of test (sensation/ pain, etc.)	Modality : type of program	General	Patient indication	Groups (#)
Zhou, Q., Fillingim, R. B., Riley III, J. L., & Verne, G. N. (2009). Thermal hypersensitivity in a subset of irritable bowel syndrome patients. World journal of gastroenterology: WJG, 15(26), 3254.	TSA 2	30*30 mm thermode	heat pain thresholds, heat pain tolerance	limits	endocrinology / pain medicine	irritable bowel syndrome	42 patients with Diarrhea-predominant irritable bowel syndrome, 24 patients with constipation-predominant irritable bowel syndrome, 52 healthy controls
Zhou, Q., Verne, M. L., Zhang, B., & Verne, G. N. (2018). Evidence for somatic hypersensitivity in veterans with Gulf war illness and gastrointestinal symptoms. The Clinical journal of pain, 34(10), 944-949.	TSA 2	30*30 mm thermode	heat pain thresholds	limits	endocrinology	Gulf war illness with and without chronic gastrointestinal symptoms	138 gulf war veterans of whom; 53 veterans with gulfwar illness with gastrointestinal symptoms; 47 veterans with gulf war illness without gastrointestinal symptoms; 38 veterans without gulfwar illness
Zouari, H. G., Wahab, A., Ng Wing Tin, S., Sène, D., & Lefaucheur, J. P. (2019). The clinical features of painful small-fiber neuropathy suggesting an origin linked to primary Sjögren's syndrome. Pain Practice, 19(4), 426-434.	TSA 2	16*16 mm thermode	warm detection threshold	limits	neurology / pain medicine	primary Sjorgen's syndrome small fiber neuropathy, idiopathic small fiber neuroapthy	25 patients with primary Sjorgen's syndrome small fiber neuropathy, 25 patients with idiopathic small fiber neuropathy