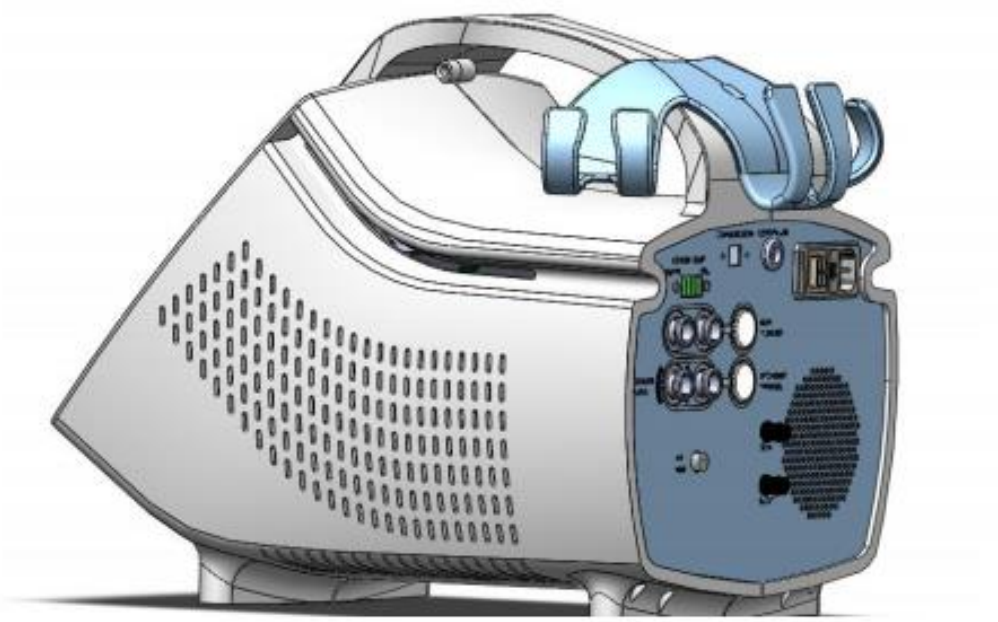
TSA 2



Thermal Sensory Analyzer

Operation Manual

Short Version

Medoc
advanced medical systems

DC 00574 TSA-II Operation Manual Short Version 3rd Edition, May 2020

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CE 1282

C SA US

This device complies with 93/42/EEC MDD

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1. Safety Guidelines and Regulations

Disclaimer

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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

1.1 User Manual Icons

The following icons are used throughout the user manual:

	**Warning: A condition that could cause serious injury or death to a subject and/or operator if instructions are not followed.**
	**Caution: A condition that could cause possible damage to equipment, or cause the system to function inaccurately.**
	**Note: Indicates important user information regarding the use of the system.**
	**Advice: Refer to Operation Manual/booklet.**
	**Instruction: Indicates an instruction where it is important to follow the user manual literally as described.**

1.2 Intended Use

The TSA-II 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.

1.3 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-II system complies with safety requirements for medical electrical systems (based on the IEC 60601-1 standard).
- The TSA-II system complies with electromagnetic emission levels (based on table 201 in the IEC 60601-1-2 standard).
- The TSA-II 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.
- It is recommend keeping a distance of 3 meters between portable and mobile RF communications equipment and the TSA-II (based on table 206 in the IEC 60601-1-2 standard).

1.4 Safety Requirements

The TSA-II 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-II system.

Connecting or replacing external TSA-II accessories is allowed.

Keep all liquids away from the TSA-II system.

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

Do not block airflow anywhere around the TSA-II system.

1.4.1 Warnings

- Only personnel properly trained to operate the TSA-II system should use this system.
- 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 subject'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 DC 00082 TSA-II Operation Manual (Can be found in the MMS software under “Help”).
- The use of accessories or cables other than those specified, with the exception of accessories or cables sold by the manufacturer as replacement parts, may result in increased emissions, or decreased electrical immunity of the device.
- Connecting any device or accessory that has no medical grade certificate to the TSA-II system is not allowed.
- Using a Thermode without the appropriate calibration table may result in potential harm or injury.
- Using the TSA-II 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 to the TSA-II 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 its 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 TSA-II, 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.

1.4.2 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 its 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-II system must never be connected to a network while it is used for running tests.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use caution when using the TSA-II 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.

1.4.3 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.

1.5 System Protection and Safety

1.5.1 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.

1.5.2 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 than 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's hardware settings, the 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 the Thermode voltage and the Thermode is cooled by the coolant flowing through it.

1.6 Equipment Labels, Symbols, and Warning Statements.

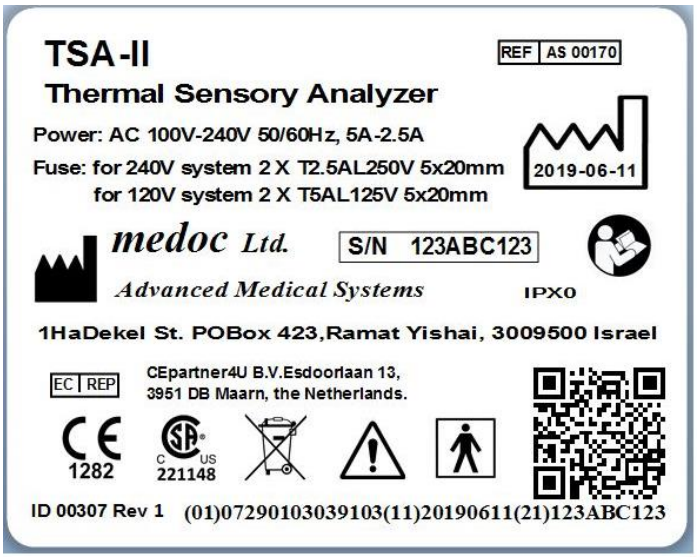


Figure 1 : TSA-II Label

Table 1: Equipment Labels (see also figure 1)

Equipment Label	Description
I / O	Power switch ON/OFF
COM	Communications connector.
	Date of Manufacture (YYYY-MM-DD)
	Manufacturer
	Degree of protection against electric shock – Applied Part Type BF.
	Warning - Connect the power cord to the power outlet, according to the local electrical standards.
	Refer to Manual
	Disposal according to electronic scrap ordinance

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

1.7 Electromagnetic Immunity

The TSA-II is intended for use in the electromagnetic environment specified below. The customer or the user of the TSA-II 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-II requires continued operation during power mains interruptions, it is recommended that the TSA-II 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-II 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-II is suitable for use in all establishments other than domestic. It 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 measures, such as re-orienting, or relocating the TSA-II or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

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 TSA-II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	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 meters (m). 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: 

1.8 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's microcontroller, safety mechanisms are activated automatically, and the Thermode will be disconnected. An error message will pop up, indicating that system communication has been lost (see the Troubleshooting Appendix in the Operation Manual) and a buzzer will sound. Remove the Thermode from the subject, and follow the on-screen instructions to restore communication, and perform the self-test.

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and TSA-II

The TSA-II is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TSA-II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TSA-II 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{12}{E_1}\right]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = \left[\frac{23}{E_1}\right]\sqrt{P}$
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.				

1.9 Technical Data

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

Some of the specifications require specific license/hardware, and are not available in the standard configuration.

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

Table 2: TSA-II Specifications

Parameter	Description
TSA Thermode (probe) active area	30 mm × 30 mm (standard) 16 mm × 16 mm 30 mm × 30 mm fMRI 16 mm × 16 mm fMRI Intra vaginal Intra oral / clitoral
Temperature range	0 – 53 °C
Baseline temperature	10 – 45 °C, programmable
Ascent/descent rate- Linear mode	0.1 – 13 °C (Range may be lower depending on protocol used)
Stimuli protocols	Limits Levels Ramp & Hold Pulses TSL (Thermal Sensory Limen) Search VAS Search Chain CPM (for dual Thermode configuration)
Stimulus duration at destination temperature	0 – 600 sec. (limited by protocol and safety cut-off. See below)

Parameter	Description
Inter-sequence time interval (Time interval between sequences)	0 – 600 sec., in 0.1 sec. resolution
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)	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

Parameter	Description
Temperature display resolution	0.1°C
Temperature repeatability	± 0.15°C
Absolute accuracy	± 0.3°C
Ambient temperature	18 – 24°C
Communication with computer	USB
Computer Requirements	See separate specifications.
Software Operation System	Windows 8 or 10, 32/64 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	(1) 52 °C up to 0.4 sec. (2) 51 °C up to 1 sec. (3) 50 °C up to 5 sec. (4) 49 °C up to 10 sec. (5) 47 °C up to 60 sec. (6) 6 °C up to 80 sec. (7) 0 °C up to 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	3000 usage hours

2. Overview

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

The TSA-II is a computerized device designed for both clinical, and advanced research applications for the quantitative assessment of peripheral small nerve fiber function, and central sensory modulation. 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.

2.1 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.

2.2 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, nor 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. For other techniques of threshold determination, please refer to the complete Operating Manual.

2.3 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 anodized aluminium. Thermode can be used for both hot and cold stimuli.

Thermode cable 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 1.9, page 15.

For a list of available Thermode sizes and types, refer to the Accessory list in the full TSA-II Operation Manual (DC 00082).

2.4 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	Thermode Electric Cooler (TEC), a Peltier element used as the active heat generator in the Thermode.
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, 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.

2.5 System Status

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

2.6 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-II active states are as follows:

- **Rest Mode**: The TSA-II 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-II 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 a test can be run. 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 Mode**: 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.

2.7 Application Methods

TSA-II 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) upon the test subject's response, and stops according to predefined trials.
- **Chain:** This method can chain any of the predefined methods, any number of times, in any order.
- **Conditioned Pain Modulation (CPM):** Deliver thermal stimuli using two Thermodes, by integrating two separate protocols, one for each Thermode.

2.7.1 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”.

2.7.1.1 “Return to Baseline” Option

The diagram (see figure 2) shows a general view of the sequence and predefined parameters. For the definition of each parameter, see DC 00082 TSA-II Operation Manual (can be found in the Software under “Help”).

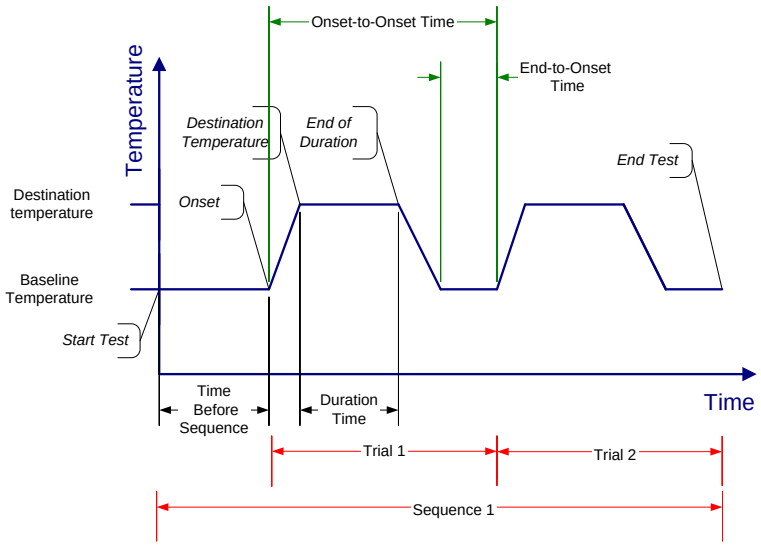


Figure 2: Ramp & Hold Sequence – Return to Baseline

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 the 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*.

2.7.1.2 "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. (see figure 3)

This is available only for sequences consisting of one trial.

See definition of each parameter in DC 00082 TSA-II Operation Manual (can be found in the software under "help").

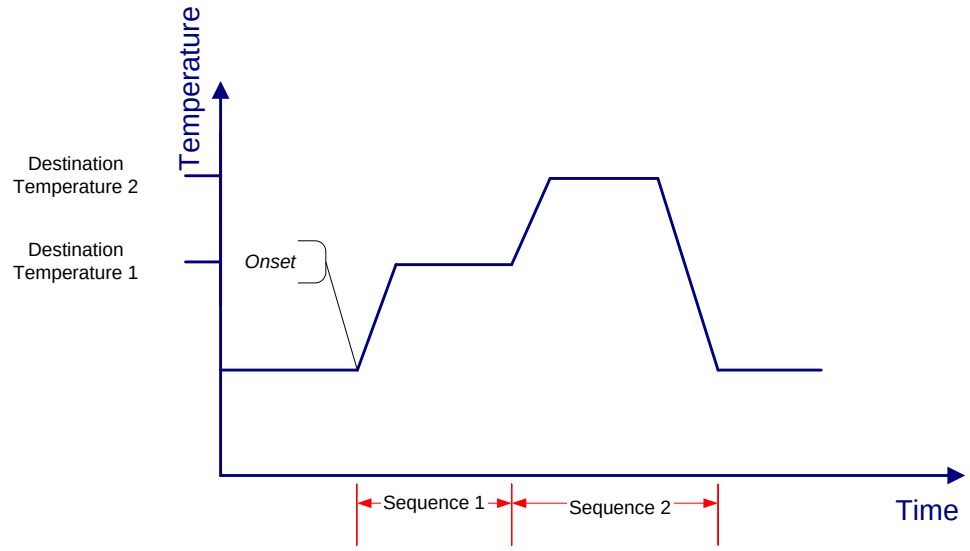


Figure 3: Ramp & Hold Sequence – Return to Next Destination

2.7.2 VAS Search Method

In VAS Search method, the 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 subject's pain rating.

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

In "Manual mode", only the first stimulus is predefined, the change in temperature of the next stimulus set by the operator during the program run using the following window that pops up after each trial: (see figure 4)

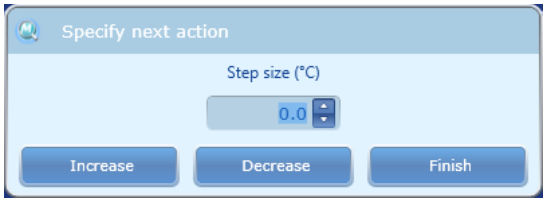


Figure 4: VAS Search – Manual Mode

In this window the user selects whether 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 has been reached.

In "Automatic mode" the target pain rating and the step size are predetermined during program creation. The temperature intensity of each trial is defined according to these parameters and the subject's 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.

2.7.3 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".

2.7.3.1 Pulses Without a Low Destination

The schema below (see figure 5) shows a pulses sequence without a low destination.

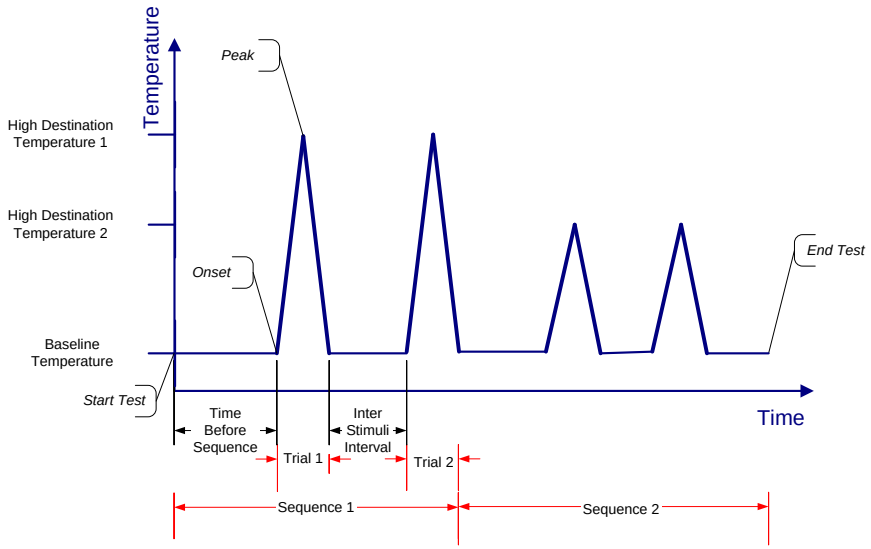


Figure 5: Pulses Sequence – Without Low Destination

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 will remain at the Baseline Temperature for the time given by the parameter *Time Before Sequence*.

See DC 00082 TSA-II Operation Manual (can be found in the software under “help”), for a full description of program details and parameters.

2.7.3.2 Pulses 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.

(see figure 6)

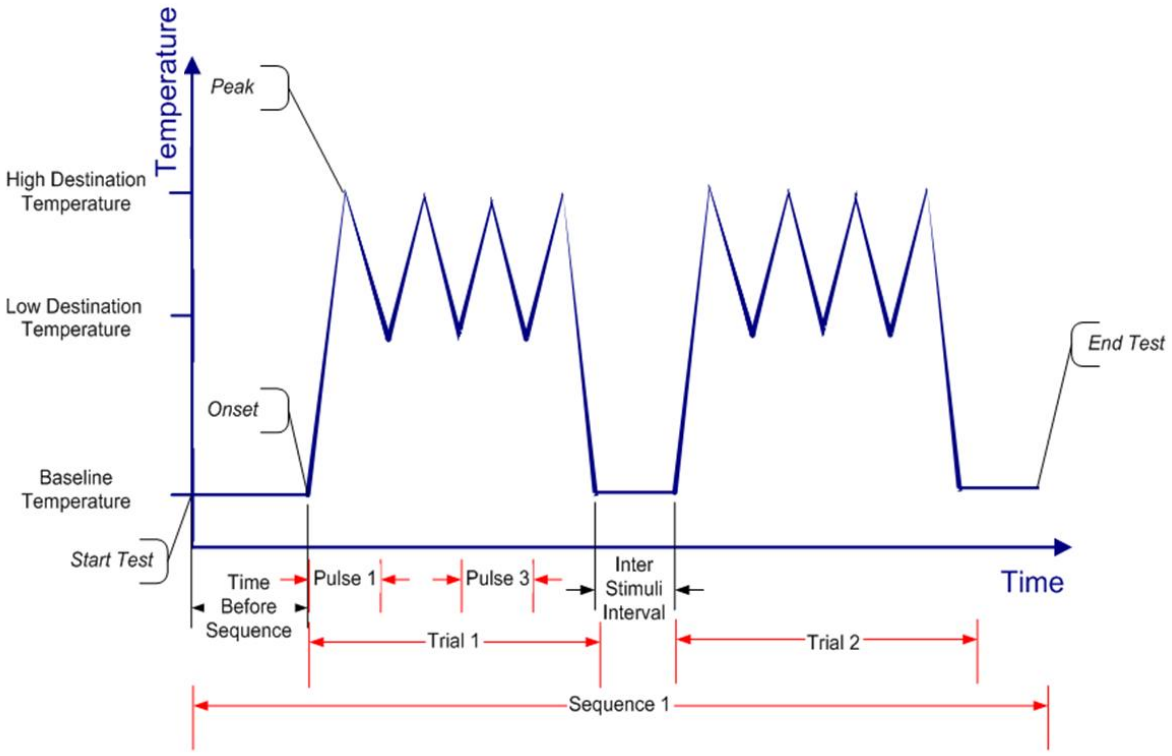


Figure 6: Pulses Sequence – With Low Destination

2.7.4 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 latter 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 (in case the modality is heat, for cold the mode of action is vice versa). The temperature increase and decrease rates are parameters of the sequence. Temperature safety limits are controlled during the test by standard TSA-II safety mechanisms.
- CoVAS – The user controls the direction and rate of the temperature change. The CoVAS responder should be in the middle position "CoVAS 50" at the beginning of the test. When the CoVAS responder is moved to the right of the middle position, it will cause the temperature to rise. When the CoVAS responder is moved to the left of the middle position, the temperature will drop. The rate of temperature change is dependent on the distance of the responder from the "CoVAS middle position". If the CoVAS responder is not in the middle position at the beginning of the test, a message appears, and the test cannot be started.

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

See DC 00082 TSA-II Operation Manual (can be found in the software under "help"), for a full description of program details and parameters.

2.7.5 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.

2.7.6 Levels Method

In the Levels method, stimuli are increased by a predetermined initial step until the first YES response. Stimuli are then decreased by one half of 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.

2.7.7 Thermal Sensory Limen (TSL) Method

The TSL method is a reaction time inclusive method in which the stimuli temperature direction changes with every response from the subject. The stimuli continuously alternate between warm and cold sensation for a pre-determined number of trials.

2.7.8 Chain Method

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

See DC 00082 TSA-II Operation Manual (can be found in the software under “help”), for a full description of program details and parameters.

2.7.9 CPM Method

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

See DC 00082 TSA-II Operation Manual (can be found in the software under “help”), for a full description of program details and parameters.

2.8 System Components

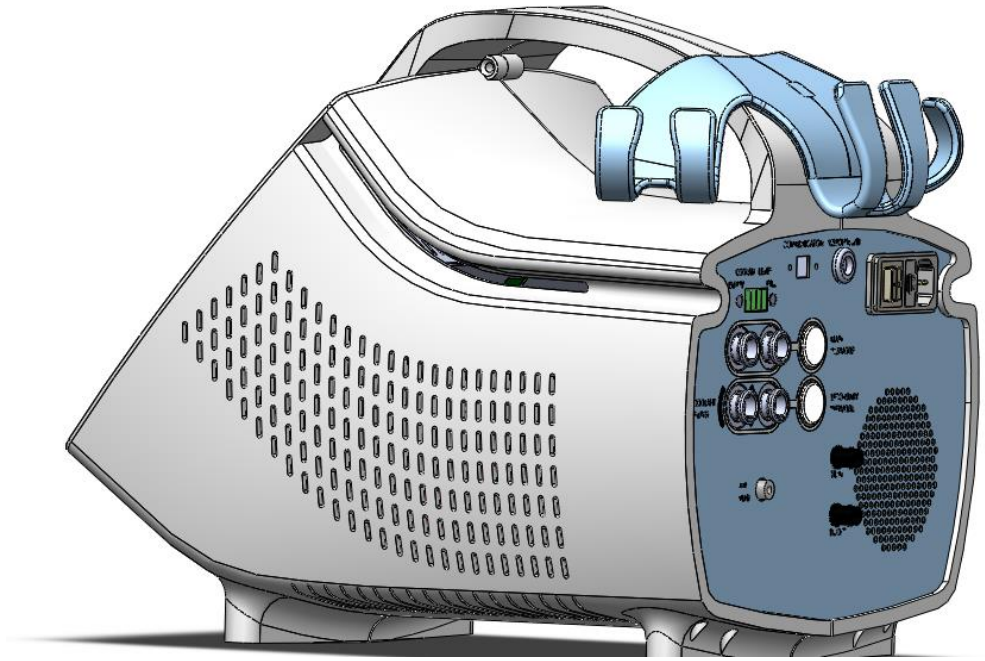


Figure 7: TSA-II Side view

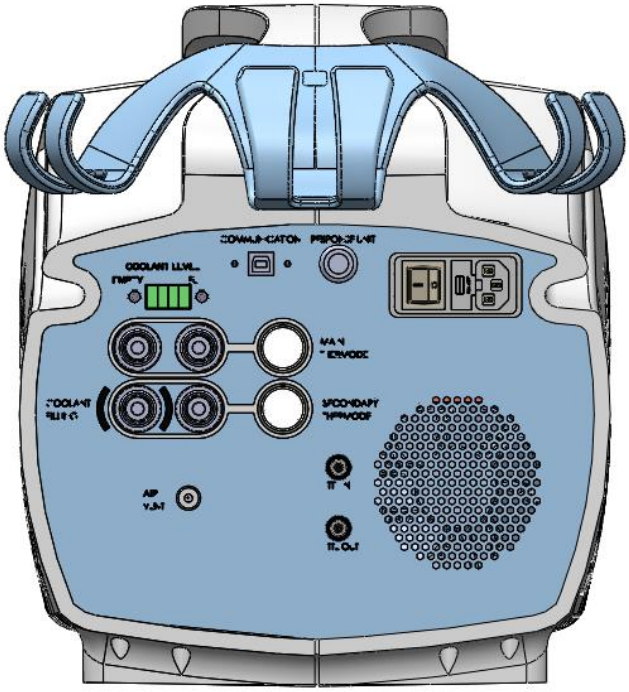


Figure 8: TSA-II Back view

2.9 TSA-II Connector Panel

Do not connect any equipment when the Thermode is attached to a subject.

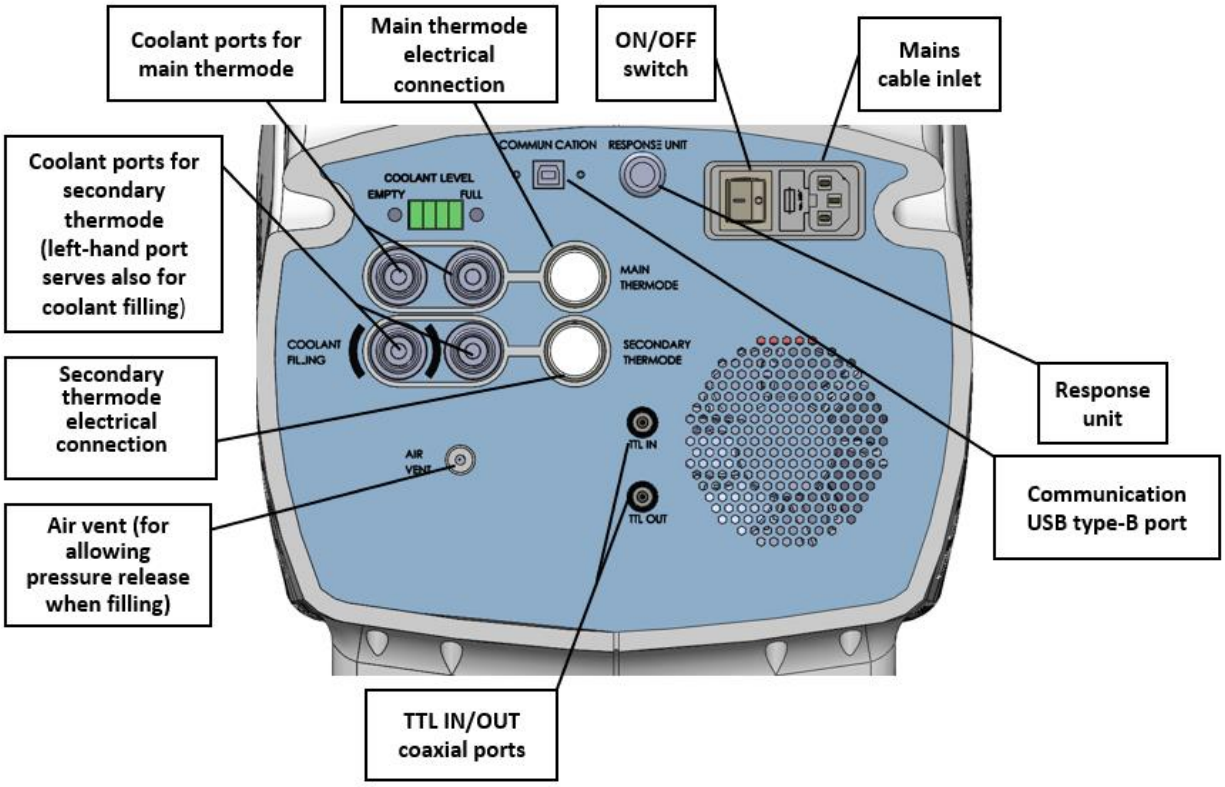
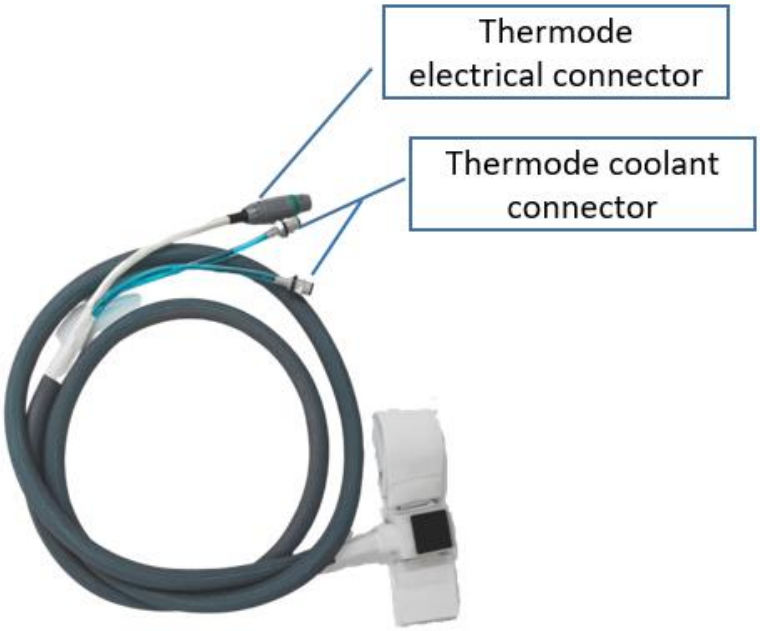


Figure 9: TSA-II Connector Panel

TSA-II connector panel contains the following receptacles and controls: (see table 4)

Accessories and configuration are defined based on your license agreement. Not all accessories are supplied in the standard configuration.

Table 4: TSA-II Panel Receptacles

Receptacle	Mate with
Mains cable inlet	 **Figure 10: Power cable**
Main TSA Thermode electrical connection Main TSA Thermode coolant ports	 **Figure 11: TSA Thermode**

Receptacle	Mate with
Patient Response Unit receptacle	 **Figure 12: Patient Response Unit**
USB Communication cable connector	 **Figure 13: USB Communication cable**
TTL Cable connector	 **Figure 14: TTL In or Out Cable (not supplied)**

2.10 Coolant Level Management

2.10.1 Coolant Level Indication

The coolant level indication can be found in the upper left quadrant of the connector panel. (see figure 15)

Figure 15: Coolant Level Indication

2.10.2 Coolant Filling

1. Use the “coolant filling kit AS 00171” 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 16) and the second one with a connector at its end (see figure 17).

2. Connect the syringe to the tube without the connector, fill the syringe with the coolant liquid. (see figure 16 below)

3. Disconnect the tube (without the connector) and switch to the transparent tube with the connector at the end (see figure 17 below)

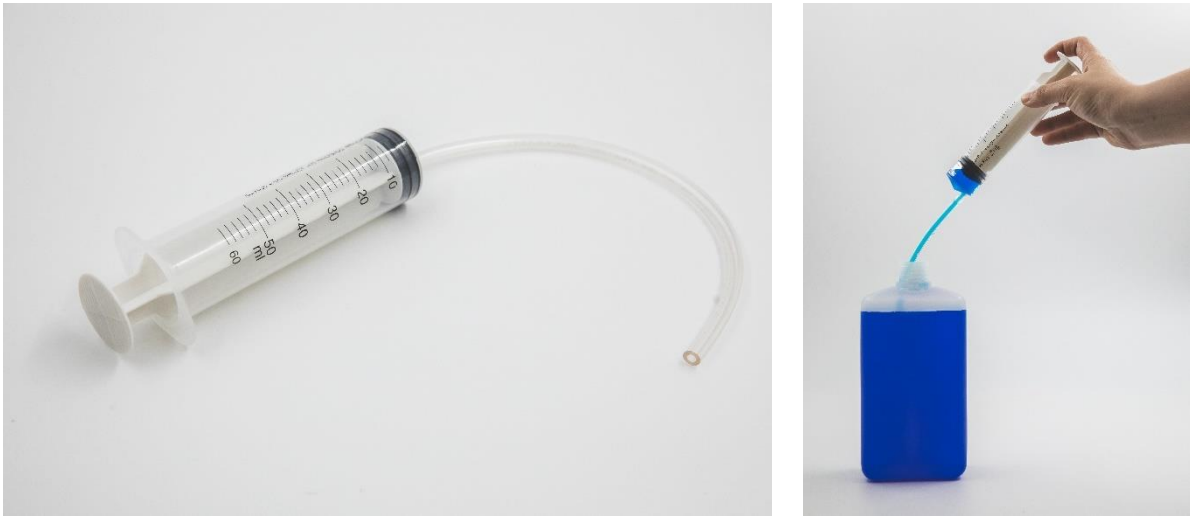


Figure 16: Filling the syringe with coolant liquid

Figure 17: Syringe and tube with connector

4. Connect the connector to the lower left coolant port on the connector panel. (see figure 18) **The Main Thermode should be connected and the system should be turned ON.**

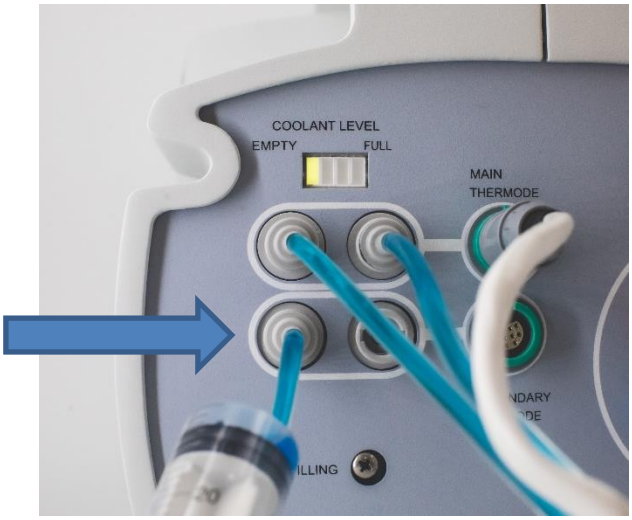


Figure 18: Connecting the syringe to the system

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.
6. Using a Philips head screw driver, open the vent screw, located below the water ports. Unscrew 3 turns counter-clockwise. (see figure 19)

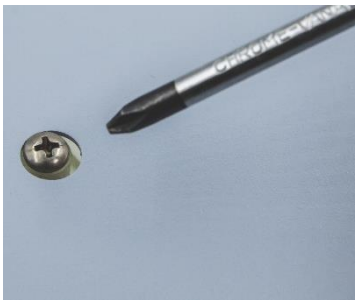


Figure 19: Air vent screw

7. Fill the system **slowly** with cooling liquid (ONLY) and check the Coolant Level LED lights indicator (located above of the Thermode ports, see figure 15).
8. As soon as the fourth LED (full) lights up, stop filling the system.
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. <u>Important notes:</u>
    - It is recommended to fill the system before it reaches the lower indicator (most left of the four LED lights).
    - 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.

2.11 Status LED Indication

The LED lights on the side of the system provide the user information regarding the system state. (see figures 20-22)

2.11.1 Green

Rest mode and test mode. (see figure 20)

Figure 20: Green Light LED

2.11.2 White

Safe mode/during self-test/when the system is not connected to software. (see figure 21)

Figure 21: White Light LED

2.11.3 Red

Error was triggered - refer to software error messages for further instructions. (see figure 22)

Figure 22: Red Light LED

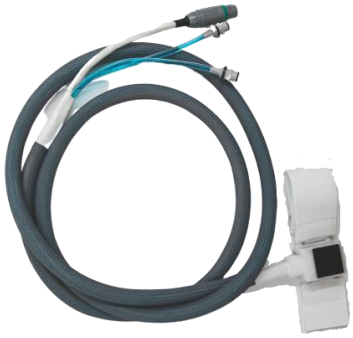
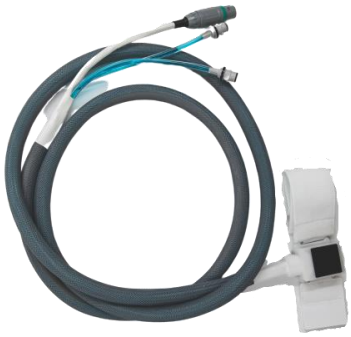
2.11.4 Turning OFF LED Lights

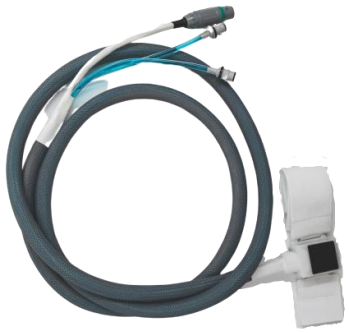
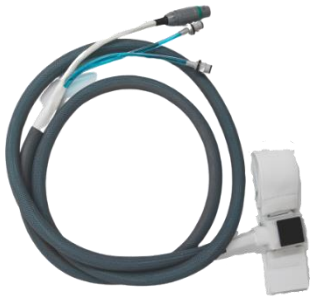
It is possible to turn off the LED light indications. Refer to DC 00082 Operation Manual for further instructions (can be found in the Software under “Help”).

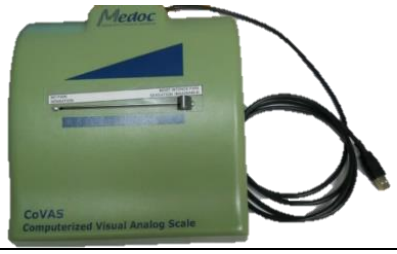
3. Accessories

The following list of accessories (table 5) can be purchased from Medoc, and are listed with their Catalogue numbers, which should be quoted when ordering a specific accessory.

Table 5: Accessories

Description	Cat. No.	
TSA-II Thermode Standard 30mm x 30mm (Main/ Secondary) This is the standard thermal probe, which is capable of heating or cooling the skin.	AS 00176	
TSA-II Thermode 16mm x 16mm (Main/ Secondary) This is a smaller than standard thermal probe, which is capable of heating or cooling the skin.	AS 00177	

Description	Cat. No.	
TSA -II Thermode 30mm × 30mm fMRI (Main/ Secondary) 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 the MRI environment, which may be caused by the Thermode.	AS 00178	
TSA -II Thermode 16mm ×16 mm fMRI (Main/ Secondary) 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 the MRI environment, which may be caused by the Thermode.	AS 00179	
TSA -II Thermode Intra Vaginal	AS 00183	
TSA -II Thermode Intra Oral / Clitoral	AS 00182	

Description	Cat. No.	
Standard Strap - 39 cm (15.3") The standard strap is used for securing the Thermode to the body site.	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's 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 00247	
Thermode Calibration Kit This kit is used for checking and calibrating the temperature calibration of the TSA II unit, which can be a requirement of certain grant-funded research/study protocols. See the service manual for operation details.	AS 00184	
Coolant filling kit Includes syringe, tube without connector for filling syringe, tube with connector for filling coolant into TSA-II system, and Dowtherm SR1 coolant bottle 1L.	AS 00171	

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

Please see fMRI information appendix (Appendix L - DC 00082 TSA-II Operation Manual) for more details.

4. Appendix A – List of Accompanying Documents

- Hard Copy:
    - Quick Set Up and Installation Guide.
    - Acceptance Test Results.
    - Packing List.
- Soft Copy:
    - User guide
    - Release Notes

5. Appendix B – Transportation and Storage Conditions

The environmental conditions for TSA-II 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.

6. Appendix C – Environmental Conditions

The environmental conditions for TSA-II 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

7. Appendix D – Abbreviations

- TTL - Transistor to Transistor Logic
- CPM - Conditioned Pain Modulation
- TSL - Thermal Sensory Limen
- EMI - Electromagnetic Interference
- ESD - Electro-Static Discharge