Medoc
advanced medical systems

TSA II | NeuroSensory Analyzer

Neurosensory Analyzer Model TSA-II

Optional: Vibratory Sensory Analyzer – VSA- 3000

Operating Manual

DC 00066 TSA-II Operating Manual 11th Edition, January 2019

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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 patient 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 instruction manual/ booklet

Instruction: Indicates an instruction where it is important to follow the user manual literally as described.

1.2 Intended Use

The use of the TSA-II system should be as intended by Medoc Ltd. and as specified in the user manual. The TSA-II is a pain management and pain research system intended to be used for the quantitative assessment of small nerve fiber dysfunctions. It measures sensory thresholds such as cold and warm sensation and heat-induced pain.

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 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-II Technical Reference Manual
- The computer that is used to operate the TSA-II system must be powered through a Medical Grade Isolation Transformer only.

- 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.
- fMRI Thermodes should be used ONLY in fMRI scanners. Outside the fMRI scanner use only the Standard Thermodes. Using fMRI Thermodes outside of the scanner may result in damage to the fMRI Thermode or TSA-II system.
- 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-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 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

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 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.

- Use of a stimulator, which was based on similar technology as the TSA-II device, in evaluating the functionality of human pain reception and transmission of sensory pathways at 6°C, has been reported to have comparable outcomes in assessment of pain reception and sensory pathways to 0°C.

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

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 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 57°C an analog circuit overrides the system and lowers the temperature gradually.

1.5.3 *Thermode Detection*

The system automatically detects that a Thermode is missing, and disables it in order to protect both system and user.

1.6 Equipment Labels, Symbols, Warning Statements and Abbreviations

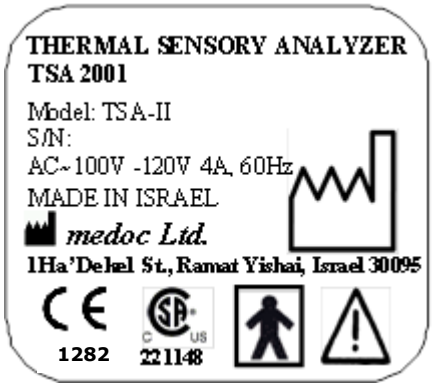

Figure 1: TSA-II Label 110V

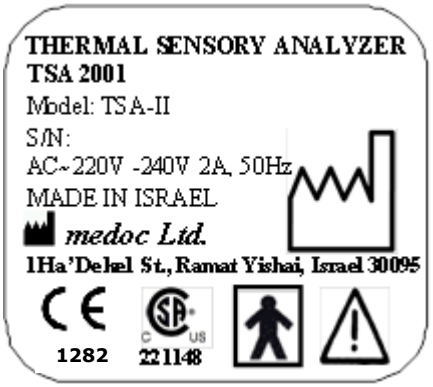

Figure 2: TSA-II Label 230V

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.
	Warning - Connect the power cord to the power outlet, according to the local electrical standards.
	Refer to Manual
	Disposal according to electronic scrap ordinance

Manual edition refers to current version of manufactured system

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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 Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group1 Class A	The [ME EQUIPMENT or ME SYSTEM] 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 [ME EQUIPMENT or ME SYSTEM] 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 measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] 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**
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	0% UT; 0.5cycle at 0°, 45°, 90°,	0% UT; 0.5cycle at 0°, 45°, 90°,	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME

on power supply input lines IEC 61000-4-11	135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	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** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V/m 3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz 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).

	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	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 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 SW instructions to restore communication and perform the self-test

1.9 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	**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 metres (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.				

1.10 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 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 16 mm × 16 mm
Temperature Range	0 – 50.5 °C (Optional 0°C to 53°C)
Baseline Temperature	10 – 45 °C, programmable
Rate of Temperature Change - Linear Mode	0.1 – 8 °C (Range may be lower depending on protocol used) Note: Rate may vary within ± 10%
Stimuli Protocols	Limits Levels TSL Ramp & Hold Chain
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
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.

Parameter	Description
Stimuli Trigger Options	Automatic Manual using keyboard External, via a TTL input (Optional)
Synchronization Options TTL Input (Optional)	Externally trigger the onset of stimulus Voltage: ±5 V Current: 10 – 15 mA Minimum Duration: 10 msec.
Synchronization Options TTL Output (Optional)	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.
MR Compatibility (Optional)	This option requires the use of MRI-safe Thermode and Filter. fMRI Thermode length: 10m fMRI filter body diameter: 70mm fMRI filter cable length: 2m fMRI safe CoVAS is also available with cable length of 10m.
Temperature Set-Point Resolution	0.1°C
Temperature Display Resolution	0.1°C
Temperature Repeatability	± 0.1°C
Absolute Accuracy	± 0.3°C
Ambient Temperature	18 – 24°C
Communication with Computer	USB (requires adaptor) or Serial RS232
Communication with Printer	Via the computer
Computer Requirements	See separate specifications

Parameter	Description
Software Operation System	Windows 7 or 8, 32/64 bit (Windows XP service pack 3 supported but not recommended)
Database	SQL Server Compact Edition
Software Language	English
Database Capacity	Unrestricted (limited by computer hardware capabilities)
Safety	Complies with UL-2601-1:94 and EN-60601-1-1
Safety Limitations on Temperature & Duration	(1) 56 °C during 0 sec. (2) 55 °C during 0.05 sec. (3) 52 °C during 0.4 sec. (4) 51 °C during 1 sec. (5) 50 °C during 5 sec. (6) 49 °C during 10 sec. (7) 47 °C during 60 sec. (8) 6 °C during 5 min. (9) 0 °C during 5 min.
Dimensions	45 cm × 40 cm × 12 cm
Weight (Not including computer)	20 – 30 Kg (depending on Thermode type)
Operation Voltage	100 – 120 VAC, 60Hz, 4A. or 220 – 240 VAC, 50Hz, 2A.
System Overload Protection	2 × 250 V, 2 A fast fuse (for 230 V system). 2 × 120 V, 4 A fast fuse (for 110 V system).
Product Life Time	10 Years
Thermode Life Time	2 Years

Table 3: VSA Specifications

Parameter	Description
Vibrator Pin Size	0.5 inch
Stimulating Area	1.22 cm2
Vibration Frequency	100 Hz
Vibration Range	0 – 130 microns
Vibration Set Point Resolution	0.1 microns
Product Life Time	10 Years

2. Overview

This Operating Manual for the TSA II Neurosensory Analyzer with the VSA-3000 option provides the information you need to install, setup, operate and maintain your TSA II unit with the VSA option. Medoc recommends that the first-time user read through the entire Manual before operating the unit.

The TSA II NeuroSensory Analyzer is a computerized device designed for both clinical and advanced research applications for the quantitative assessment of small nerve fiber dysfunctions. It measures sensory thresholds such as the sensation of warmth, cold, heat-induced pain and cold-induced pain. Vibratory testing is an optional testing method that allows for quantitative assessment of large nerve fiber dysfunctions. It supplements Thermal testing and provides for a more comprehensive test.

The thermal and vibratory sensory thresholds deviate from the normal range in peripheral nerve disease. Thermal and Vibratory Testing methods permit earlier clinical intervention than would otherwise be possible with existing diagnostic tools and techniques.

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 while the larger fibers on which the principle of Vibratory Testing is based mediate the sensations of touch, mild pressure and position of joints.

Thermal Testing quantitatively measures thresholds for warmth, cold, heat-induced pain and cold-induced pain and then compares them to age-matched normal population values. A deviation from the normal range can indicate the existence of peripheral nerve disease. Vibratory Testing performs the same type of measurements and comparisons of thresholds for vibrations.

2.2 Principle of Operation:

For Thermal Testing, a small probe, called a **Thermode**, is attached to the patient'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 the Patient Response Unit (subject). The temperature at which 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.

The Vibratory option measures thresholds for vibratory stimuli. The system is capable of increasing or decreasing the vibration amplitude as needed.

Stimuli method and program can be selected and customized from a list of available options. For a full overview of stimuli method see section 2.7.

2.3 TSA Thermode

The TSA Thermode is comprised of one stimulator layer, which is constructed of a Peltier element with two thermistors (thermal sensors) and one coolant thermistor. The Surface contacting skin of subjects is aluminum coated, for the purpose of heat dispersion. Thermode can be used for both hot and cold stimuli.

For more detailed specifications of the TSA Thermode please refer to Technical Specifications in section 1.10, page 17.

Thermistors: Components that sense changes in temperature and send feedback to the control unit. In response to the required temperature parameter, the temperature control unit commands the heating or cooling the Thermode.

Peltier Elements: Components that consist of semiconductor junctions, which produce a temperature gradient between the upper and lower surfaces produced by the passage of an electric current.

For a list of available Thermode sizes and types, refer to the Accessory list in the full TSA-II Technical Reference Manual

2.4 Terminology

The following terms are used throughout the user manual:

Table 4: 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	An output or input, short and square 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.

2.5 System Status

- **Online:** This is the TSA-II system full operating mode and indicates full communication between MEDOC Main Station and 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 demo 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 for protocol design without executing actual thermal stimulation. It is recommended to turn off the TSA-II system while working in Simulator 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 continuing work with the system. Thermode temperature is set according to the ambient temperature.
- **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.
- **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.
- **Black Box**: The system has detected an error and is saving the details in the internal black box logger.

2.7 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-II supports the following methods (indicated as program types):

Reaction Time Inclusive Methods

- **Limits**: A set of predetermined stimuli is emitted, and for each stimulus, the tested subject is required to respond (stop the stimulus) when perceiving a predefined sensation. For more details refer to section 2.7.1, page 23.
- **Thermal Sensory Limen (TSL)**: The temperature direction changes according to the subject's response, alternating between increasing temperature and decreasing temperature. For more details, refer to section 2.7.3, Page 23

Constant Stimuli Methods

- **Levels**: A set of stimuli is emitted, and for each stimulus, the subject is required to respond. The following stimulus is calculated according to the subject's response. For more details, refer to section 2.7.2, Page 23

- **Ramp & Hold**: A set of stimuli is emitted, and for each stimulus, the subject is required to respond and estimate the perceived magnitude of sensation. For more details, refer to section 2.7.32.7.4, Page 23
- **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. For more details, refer to section2.7.5, Page 231

Before applying any of these methods, make sure to read section 6, page 49, on Test Procedure and Management

2.7.1 *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.

Limits method is also available for vibratory stimuli.

2.7.2 *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.

Levels method is also available for vibratory stimuli.

2.7.3 *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.

2.7.4 *Ramp & Hold Method*

In Ramp & Hold method, a series of stimuli with predefined intensity and duration is given. The intensity of stimuli may surpass the sensory or pain threshold of the subject. During or immediately after each stimulus is given, the subject is asked to estimate the perceived magnitude of sensation on a scale of 0 to 100. The Ramp & Hold method can be used to establish a relationship between stimuli intensity, rate, and/or duration and the perceived sensation.

2.7.5 *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:

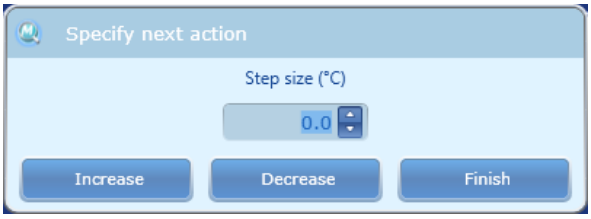


Figure 3: VAS Search – Manual Mode

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.

2.8 Changes from Previous Versions

A few changes have been made to the new version 6.3.6 as following:

- The Suprathreshold method is now called Ramp & Hold method.
- The Staircase method is not available.
- A new optional feature of advanced Pain Rating options.
- Changes have been made in the Pump Control setting in order to shorten time to Baseline Temperature.

For a full description of the Methods described above, please refer to the TSA-II Technical Reference Manual

3. System Components

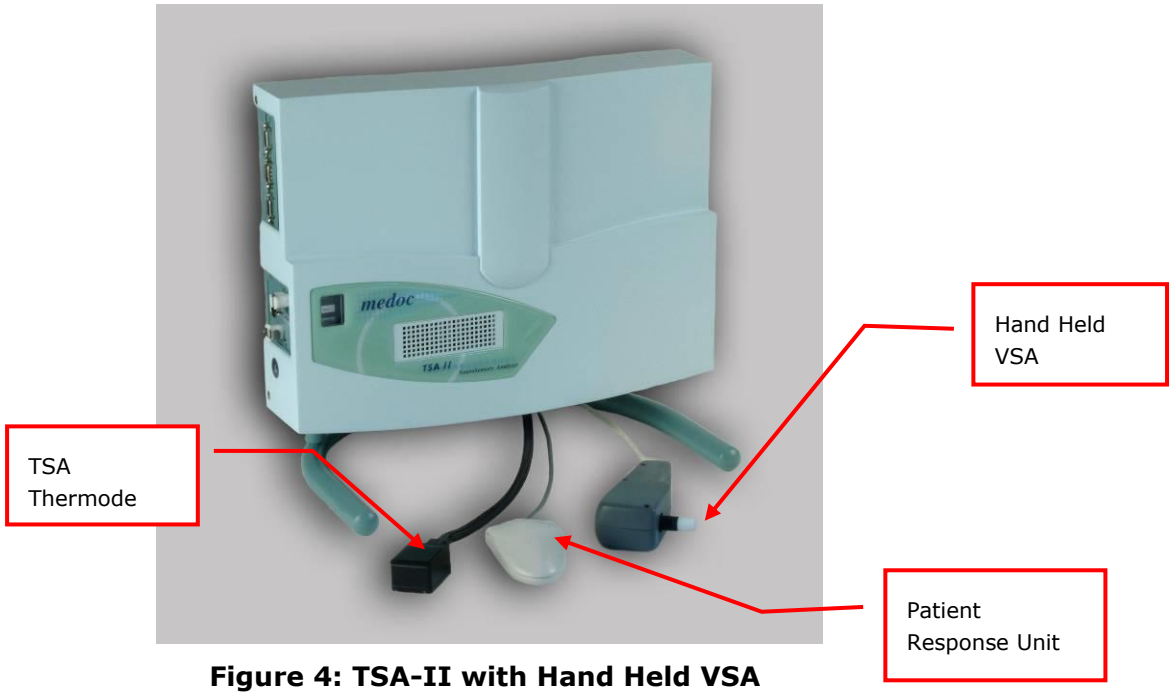


Figure 4: TSA-II with Hand Held VSA

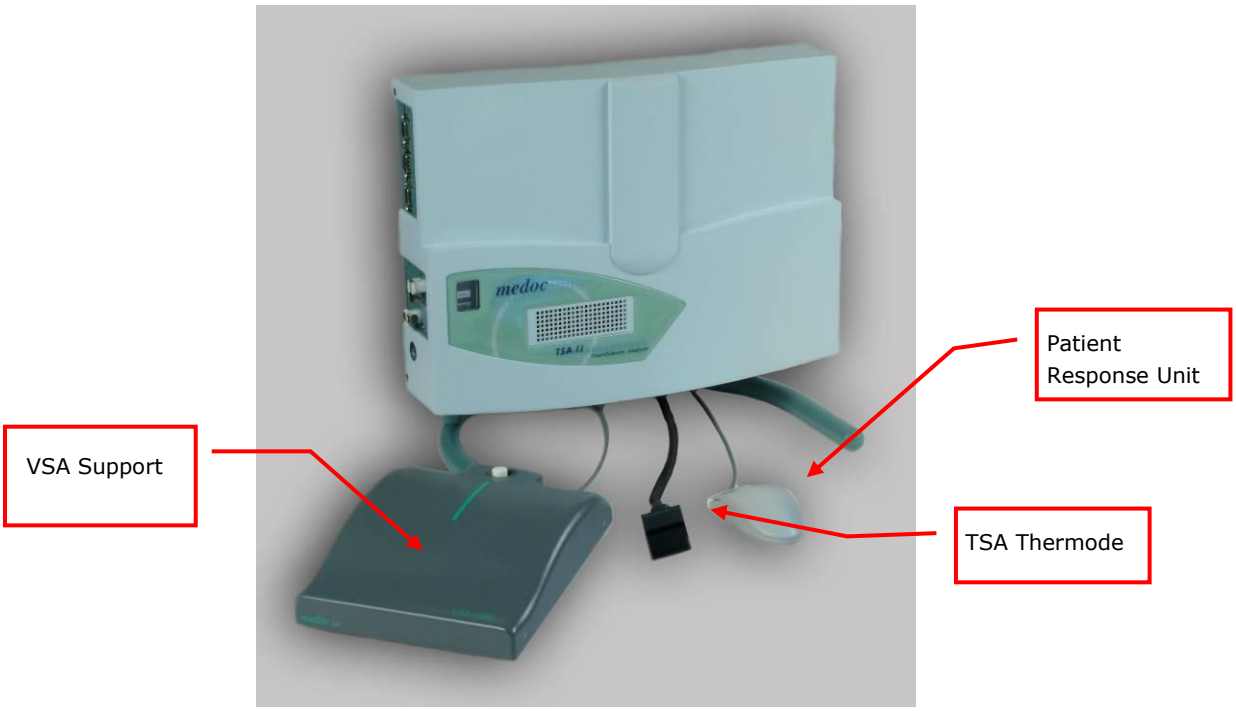


Figure 5: TSA-II with VSA Leg Support

Figure 6: Main Power Switch

3.1 TSA-II Connection Panel

Do not connect any equipment to the service connectors during tested subject examination.

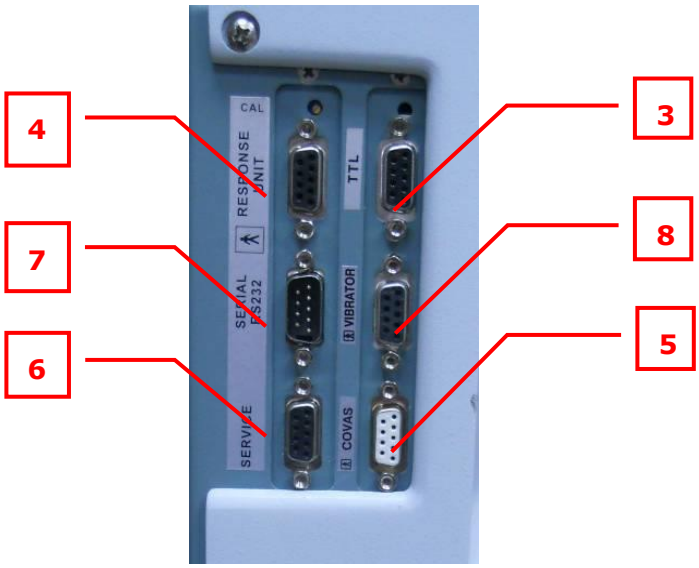


Figure 7: TSA-II Connection Panel 1

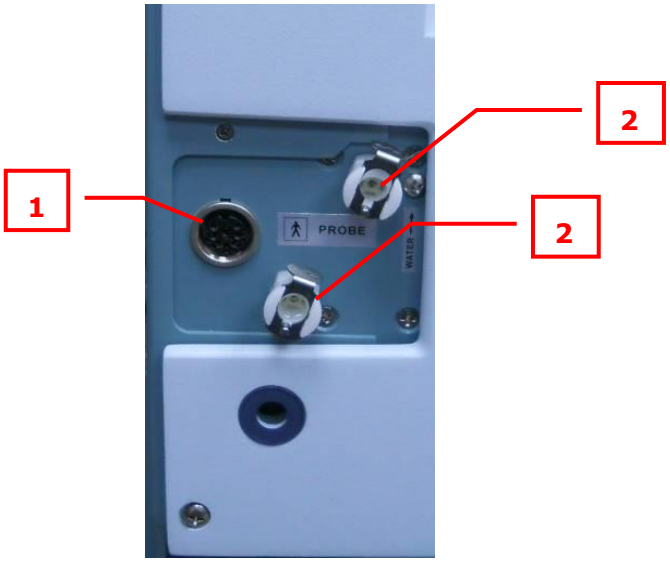
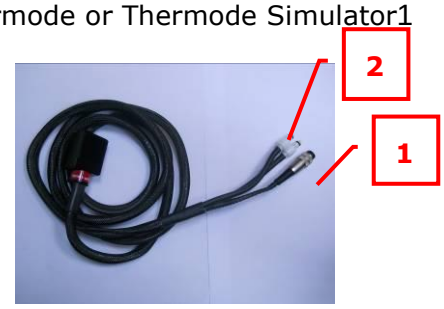


Figure 8: TSA-II Connection Panel

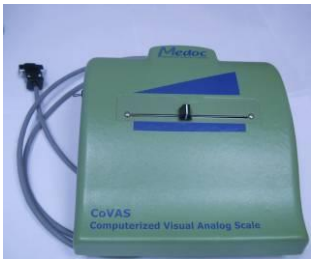
TSA-II panel contains the following receptacles and controls:

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

Table 5: TSA-II Panel receptacles

#	Description	Mate with
1	TSA Thermode Main Receptacle	TSA Thermode or Thermode Simulator1  **Figure 9: TSA Thermode**  **Figure 10: TSA Thermode Simulator**
2	TSA Thermode Coolant Receptacles	

1 TSA Thermode Simulator is used only for Calibration procedure. Please refer to TSA-II Service Manual for details.

#	Description	Mate with
3	TTL Cable Connector (Optional, based on license agreement)	 **Figure 11: TTL In/Out Cable**
4	Response Unit Receptacle a. Use for recording patient response during test	 **Figure 12: Response Unit**
5	CoVAS Receptacle 1. Use for recording patient visual analog scale during test (Optional, based on license agreement)	TSA-II CoVAS or CoVAS key2  **Figure 13: CoVAS**  **Figure 14: CoVAS Key**
6	Service Connector (Optional, based on license agreement)	 **Figure 15: TSA-II Service Cable**

2 TSA-II CoVAS key is used when CoVAS is not connected (CoVAS requires special license and additional hardware)

#	Description	Mate with
7	Serial RS232 Communication Connector	 **Figure 16: RS-232 Cable**
8	VSA Connector (Optional, based on license agreement)	 **Figure 17: Hand Held VSA**

4. Setup and Installation

The TSA-II 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-II system. Proper installation and operation of the equipment is important for ensuring the safety of the tested subjects.

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

For fMRI system, refer to the TSA-II Technical Reference Manual

4.1 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.

Safety	Computer must comply with IEC 950 – EN 60950 – UL 60950
Processor	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 (3 for AlgoMed FPIX and Q-Sense CPM)
Monitor/Display	13" (15" recommended)
Screen Resolution	1366 x 768 pixels, 96 DPI (max. 1920x1080)
Operating System	Windows 7, 8, 10 32/64 bit (Not recommended: Windows XP service pack 3. Please see note below)
Other	Microsoft Office 2007 or above (required for viewing results in excel)

The following Medoc Main Station updates will no longer support Windows XP. Please avoid using Windows XP operating system if possible.

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.

4.2 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.

4.3 Setup and Installation Main Steps

The assembly procedure consists of the following steps:

1. Selecting a location for the system. See section 4.4, page 31.
2. Connecting the Thermodes and any additional accessories to the system. See section 4.5, page 32.
3. Connecting the laptop and and installing Medoc Main Station software. See section 4.6, page 33.
4. Configuring the system.

See TSA-II Technical Reference Service Manual for further details on the system components.

4.4 Selecting a Location

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

1. The room temperature should be kept between 15°C and 25°C (59°F – 77°F).
2. The TSA-II system should not be placed in a location, which is exposed to direct sunlight or constant vibrations, or close to heaters or air conditioners.
3. The space allocated for the system should allow enough room to perform regular system maintenance procedures.
4. The room in which the system will be located should be quiet, allowing the tested subject to concentrate on the examination with minimum distractions.

4.5 Device Connections

1. Ensure that the laptop meets the minimum computer requirements. See section 4.1, page 30
2. Make sure that the Laptop, TSA-II unit and printer (optional) are all **OFF**.
3. Do not connect the Computer to the TSA-II before installing Medoc Main Station software (see section 4.6).
4. Connect the system, Thermodes and accessories according to your application. See Figure 18 and Figure 19.

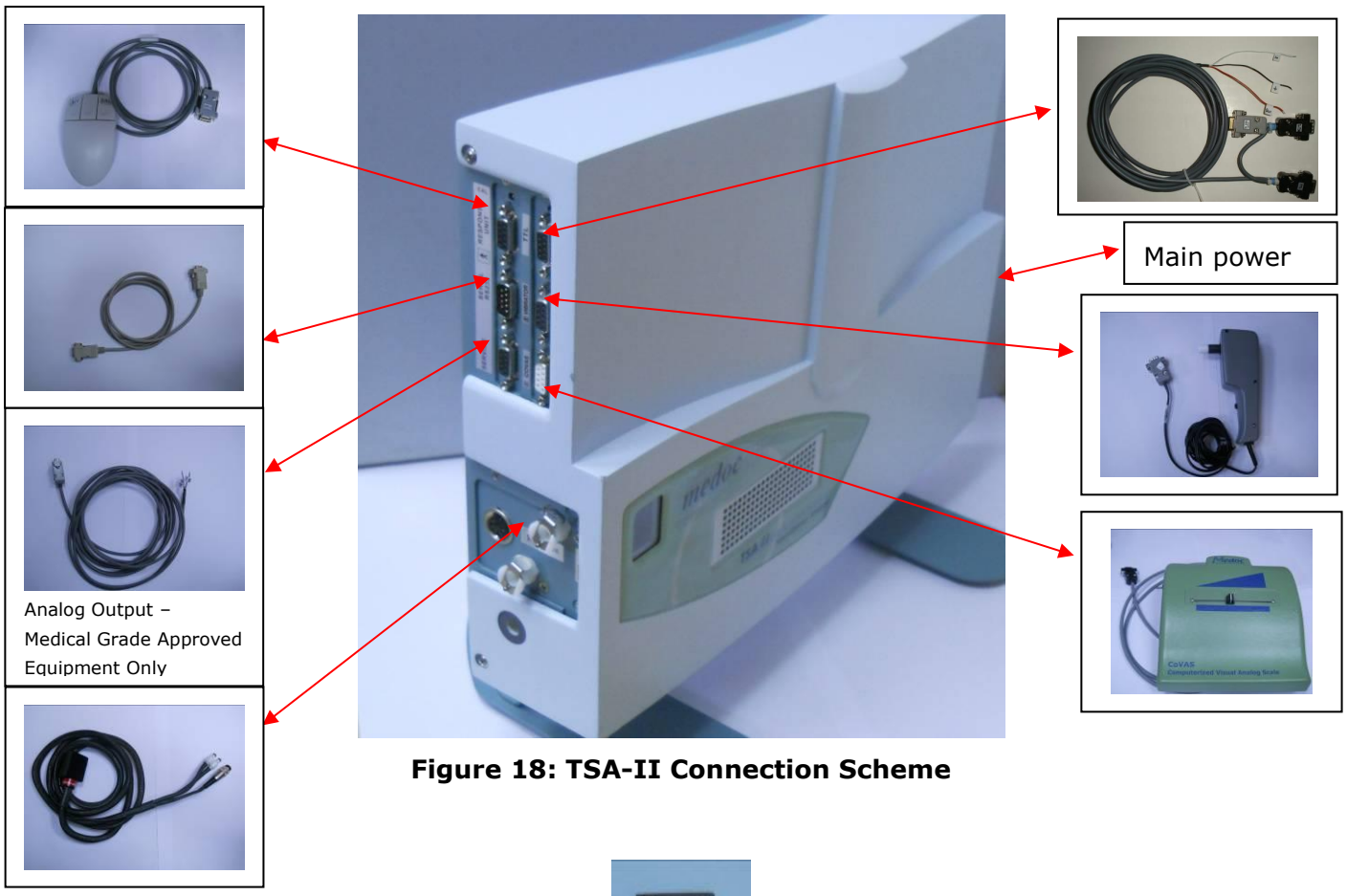


Figure 18: TSA-II Connection Scheme

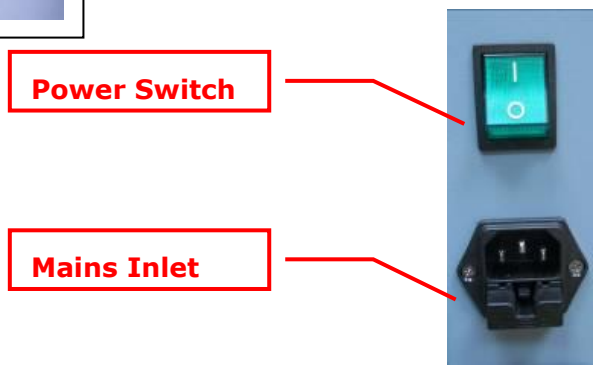


Figure 19: TSA-II Power Inlet

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.

The external laptop and printer must be powered through Medical Grade Isolation Transformer only.

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

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.

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

4.6 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

Users with Administrative privileges may not be enough.

The following instructions will guide you through the installation procedure:

4.6.1 *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:

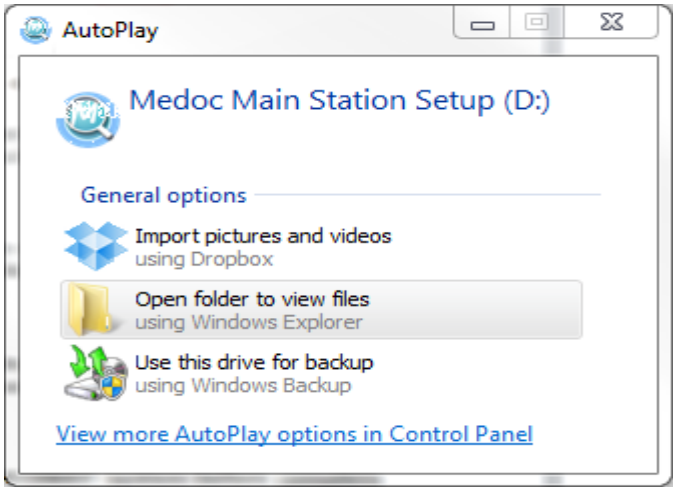


Figure 20: AutoPlay

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

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

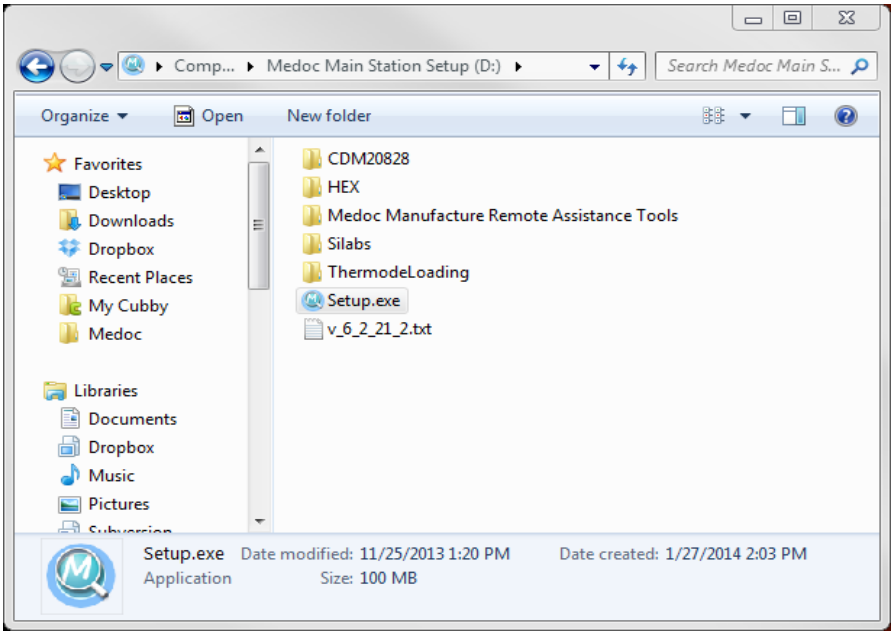


Figure 21: USB Folder Content

4. Double-click **Setup.exe** to start software installation

5. The following screen is displayed:

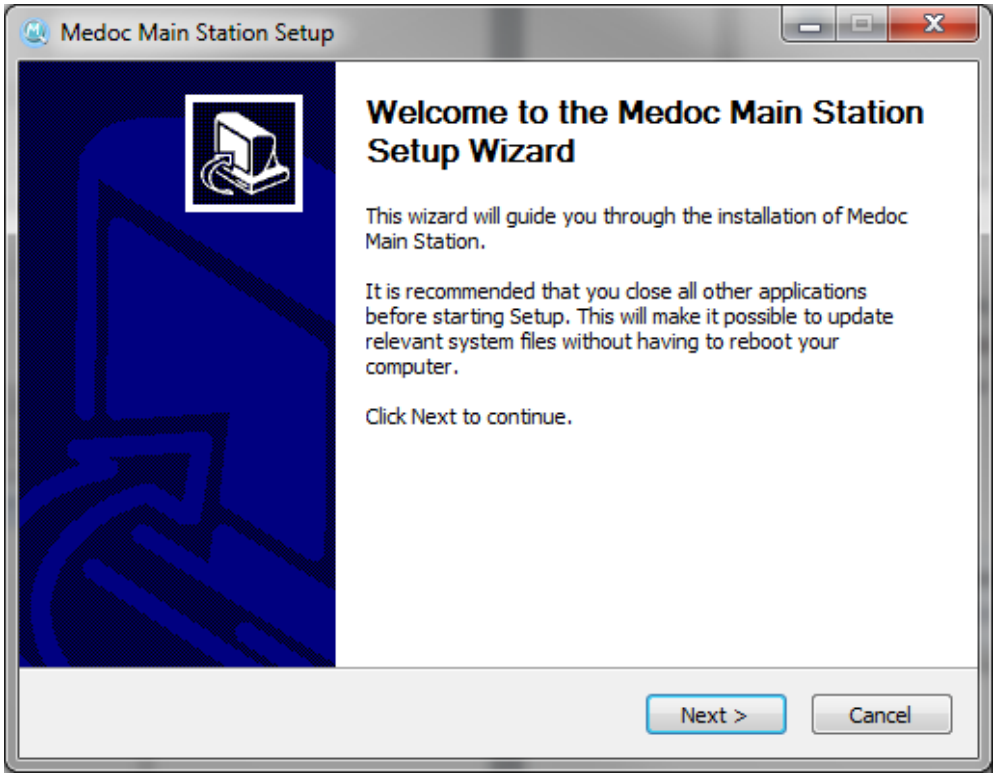


Figure 22: Main Station Installation 1

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

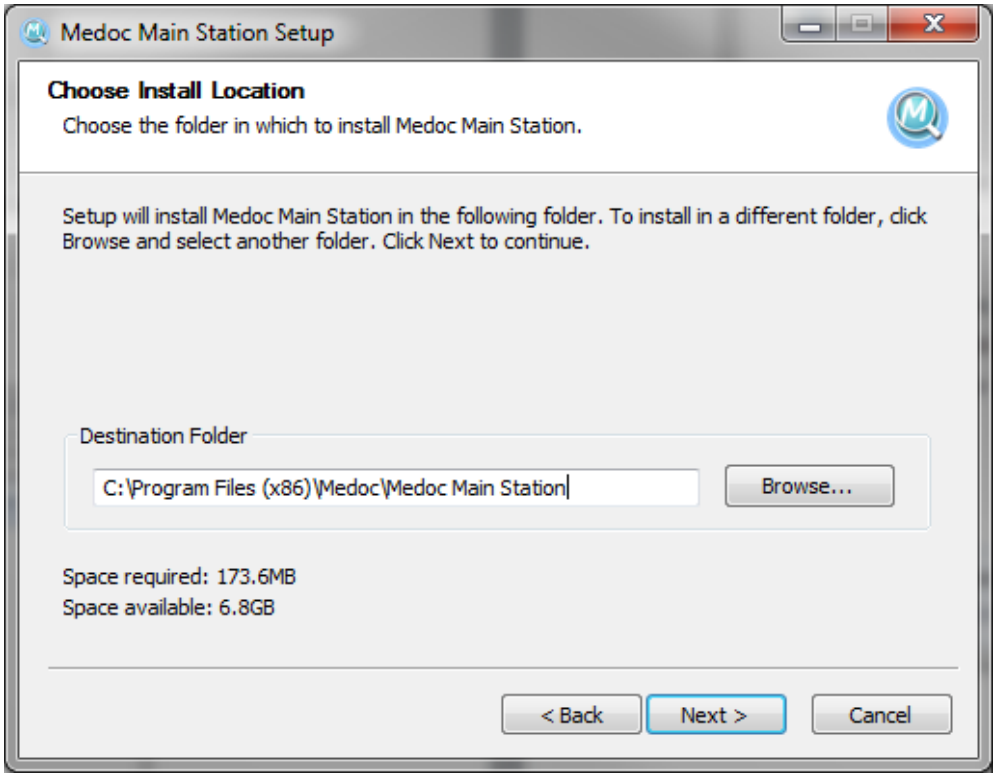


Figure 23: Main Station Installation 2

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:

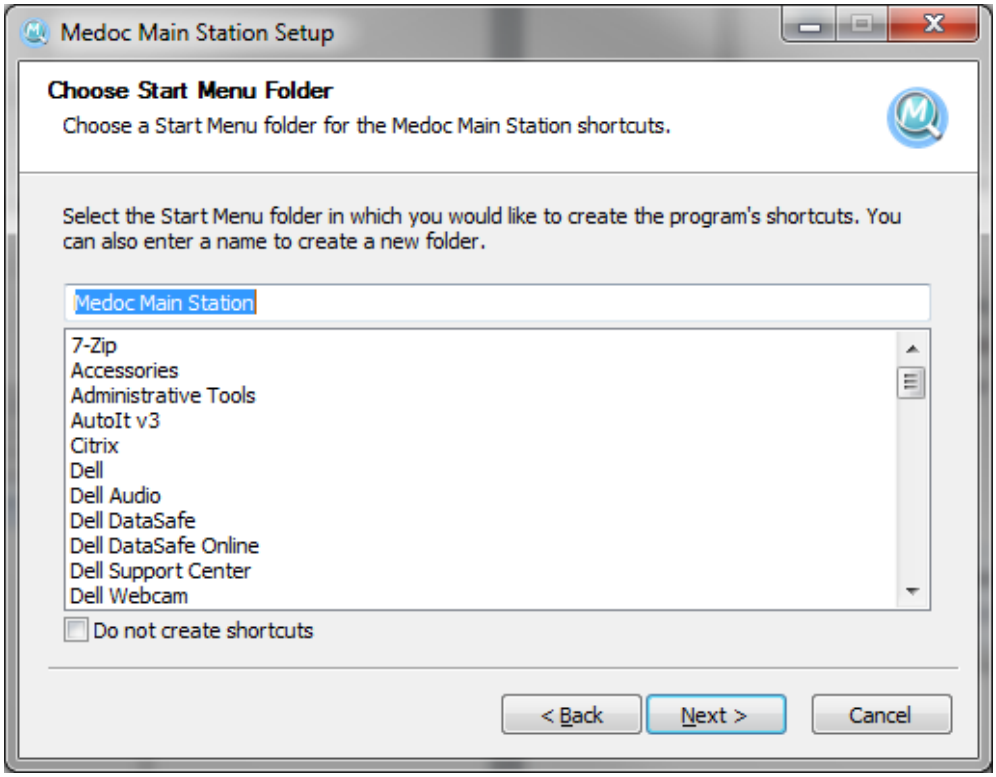


Figure 24: Main Station Installation 3

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

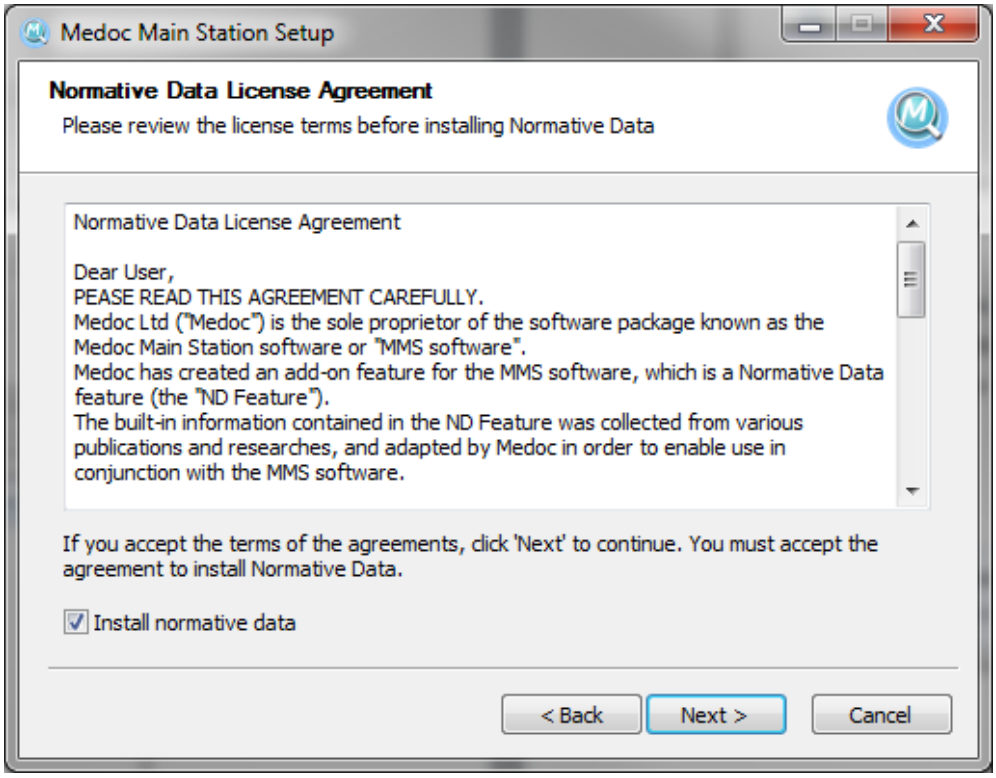


Figure 25: Main Station Installation 4

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

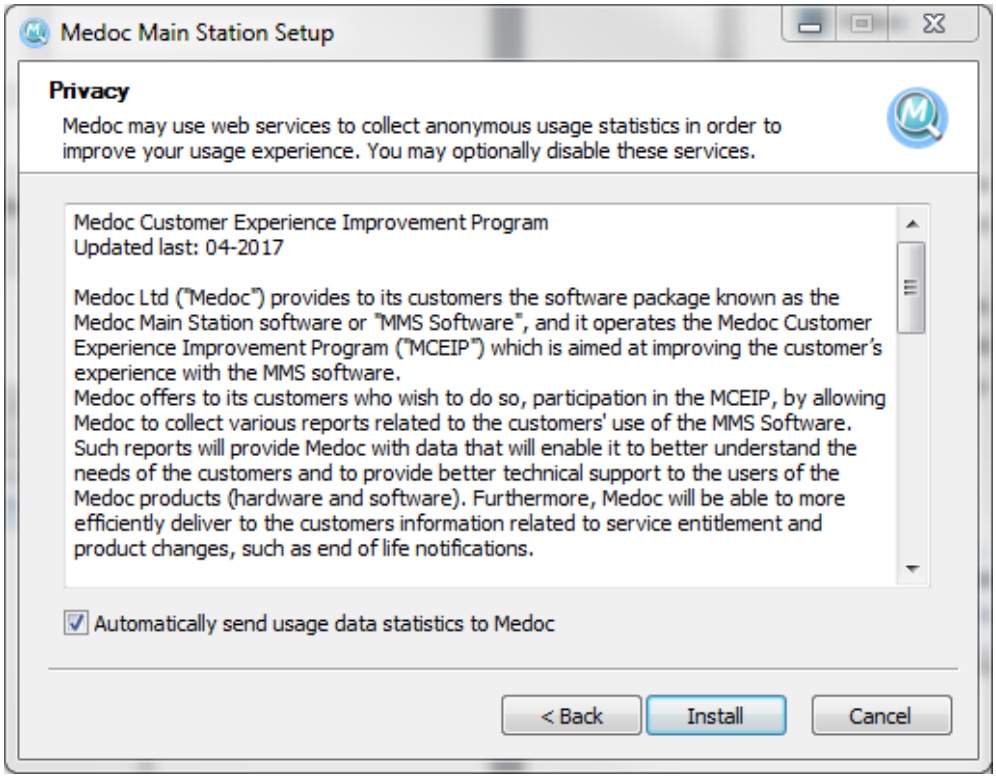


Figure 26: Main Station Installation 5

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:

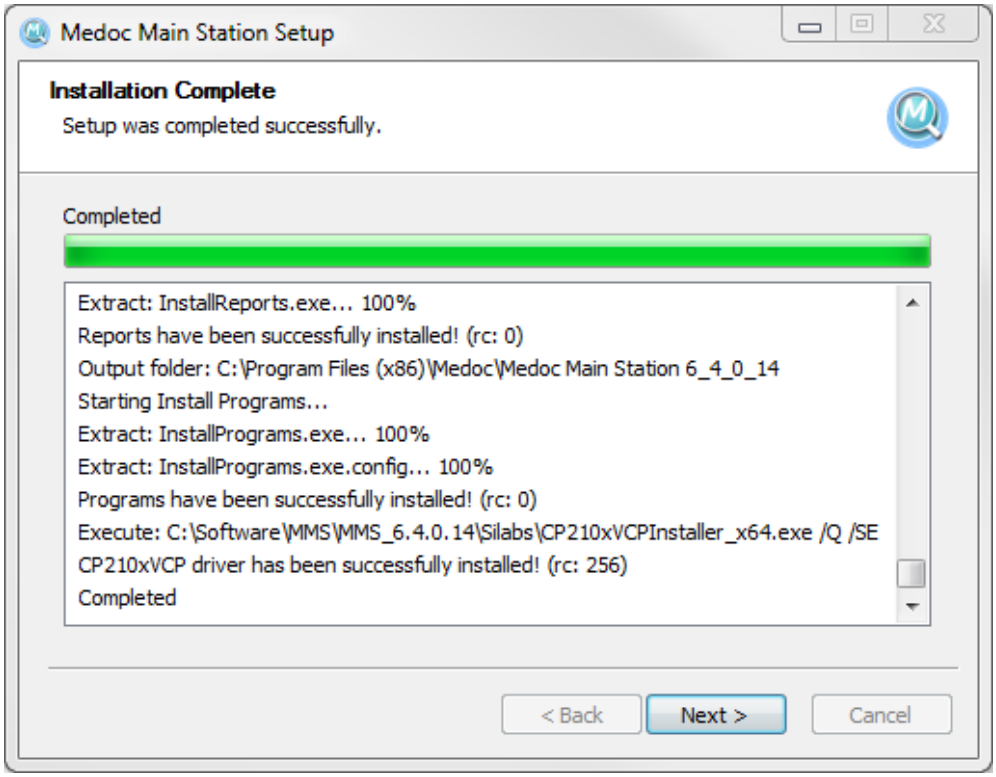


Figure 27: Main Station Installation 6

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

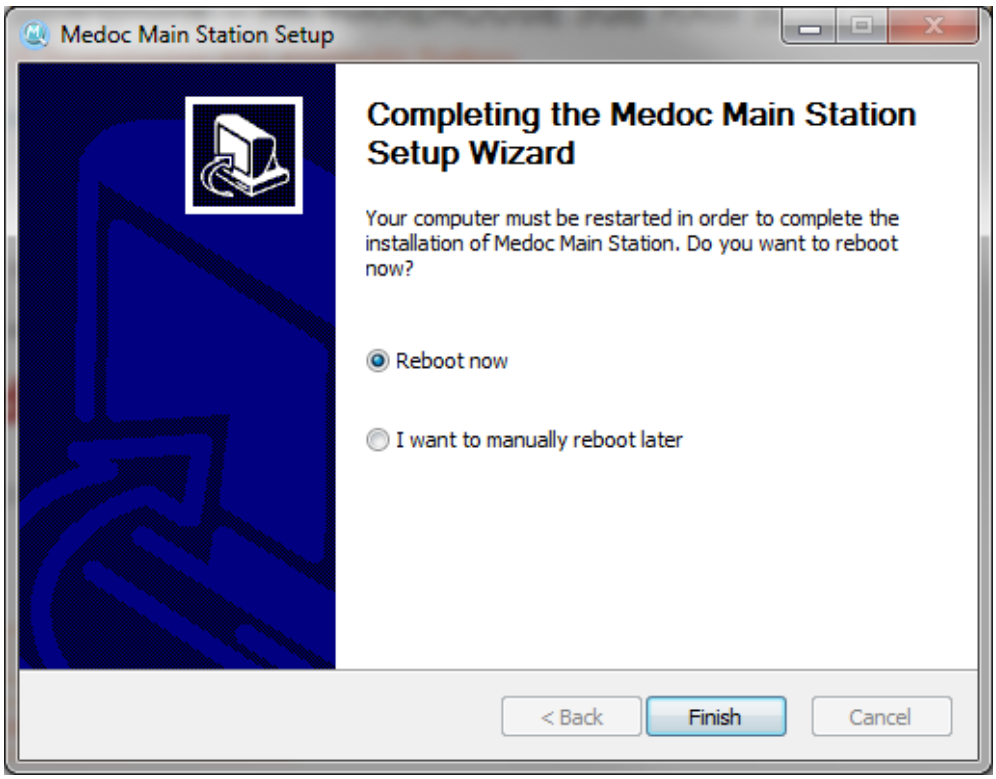


Figure 28: Installation Complete

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

4.7 Unit Protection

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

When all setup and installation procedures have been completed you man start using the system in accordance with the operation instructions in section 5.

4.8 Power up TSA-II 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 computer to the TSA-II system using the supplied serial cable or with USB to Serial adaptor. Connect the serial connector to the side of the TSA-II as shown in Figure 29.

Figure 29: COM Port

2. Power up the TSA-II system by using the main switch on the side of the TSA-II system. See Figure 6, page 26.
3. Start Medoc Main Station software by double-clicking the icon 

Continue to section 4.9, page 41, for detailed instructions on how to activate your product

Continue to section 5, page 42 for detailed operating instructions

4. Make sure the correct Thermode is selected. Refer to the Thermode management section in TSA-II Technical Reference Service Manual.

Select the correct Thermode size according to the Thermode connected to the TSA-II system

5. The system and the software are ready for use.

4.9 Product Activation

When starting Medoc Main Station software for the first time, you will be asked to register your new system and activate the software. Product registration and software activation is simple and fast and it will enable you to maintain full use of Medoc Main Station software as well as:

- ✓ Warranty on your newly purchased Medoc systems
- ✓ Access to Technical Support and Customer Service assistance
- ✓ Software updates and new product notifications
- ✓ Product support alerts

Please note that if you don't activate the software within the designated time, the software will work in demo mode only.

To complete the activation process, simply start Medoc Main Station software and follow the instructions given in the activation wizard. If the activation wizard is not displayed when you start Medoc Main station Software, go to the Home screen, select Options and then select Product Registration. See section 4.9.

If at any point during the product activation process you encounter any difficulties please contact Medoc support at support@medoc-web.com for assistance.

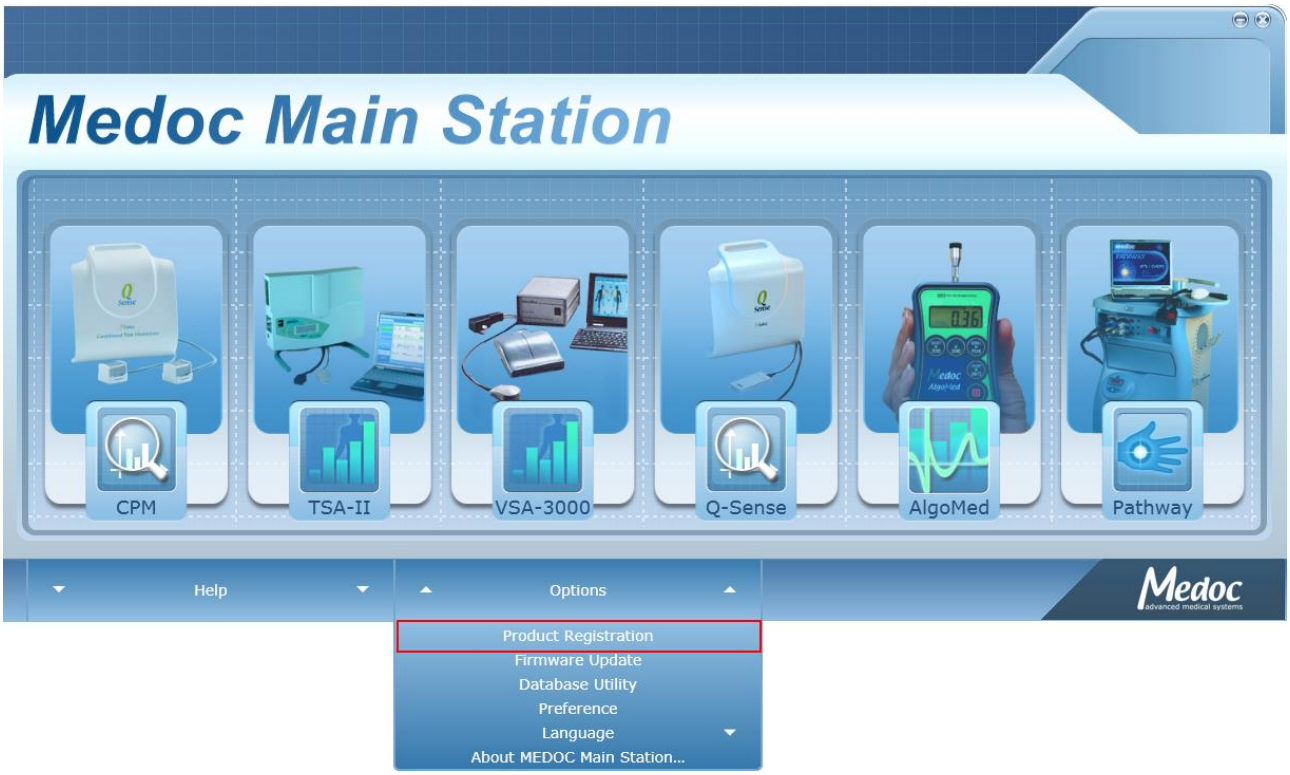


Figure 30: Home screen product registration link

5. Operation

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

This chapter specifies TSA-II behavior at start up and MEDOC Main Station basic components.

5.1 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-II system, make sure that the Thermode main plug and coolant connectors are securely connected to the TSA-II 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.

5.2 Starting TSA-II

1. Turn **ON** the TSA-II unit, by using the main power switch located on the unit side. See Figure 6 page 26.
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 31: Device Selection Screen

5. To select TSA-II, click on the TSA-II image

6. When the login screen is displayed, enter your user name and password and select "**TSA-II**" in the "**connect to**" field.

Initial login Username and Password are both *admin*.

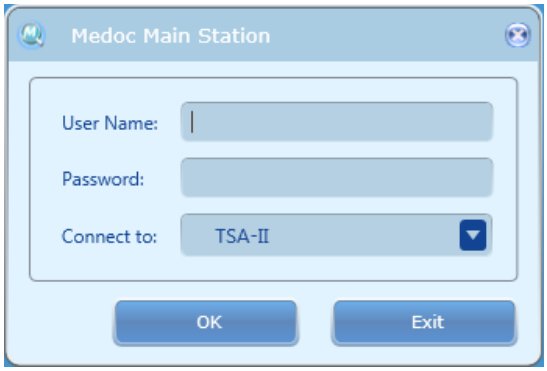


Figure 32: Login Screen

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

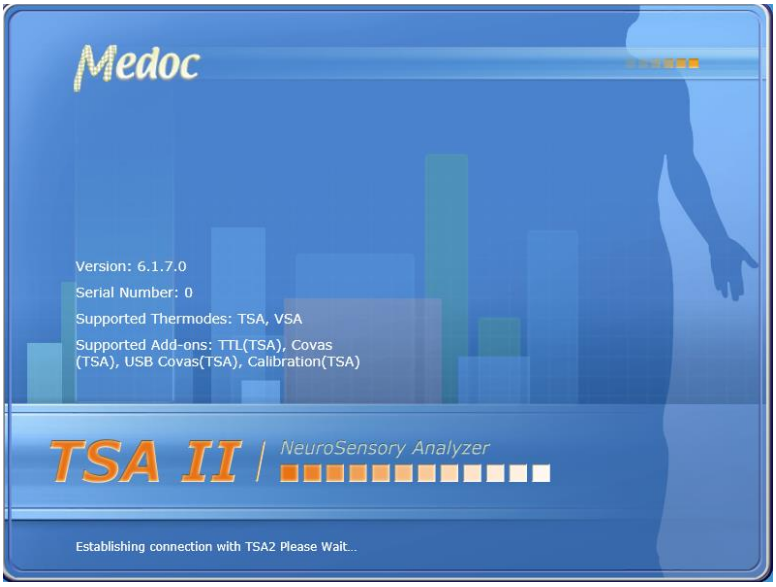


Figure 33: TSA-II Splash Screen

8. When communication is established, the system will enter SAFE MODE and remain in this state until completing the system Self-Test, see section 5.1 מעל. Make sure the Thermode is not attached to the Subject and click on OK on the following message:

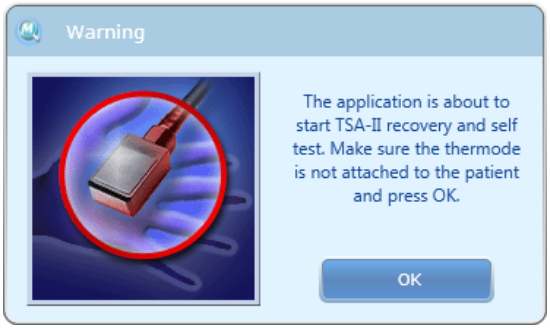


Figure 34: Self-Test Prompt.

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.

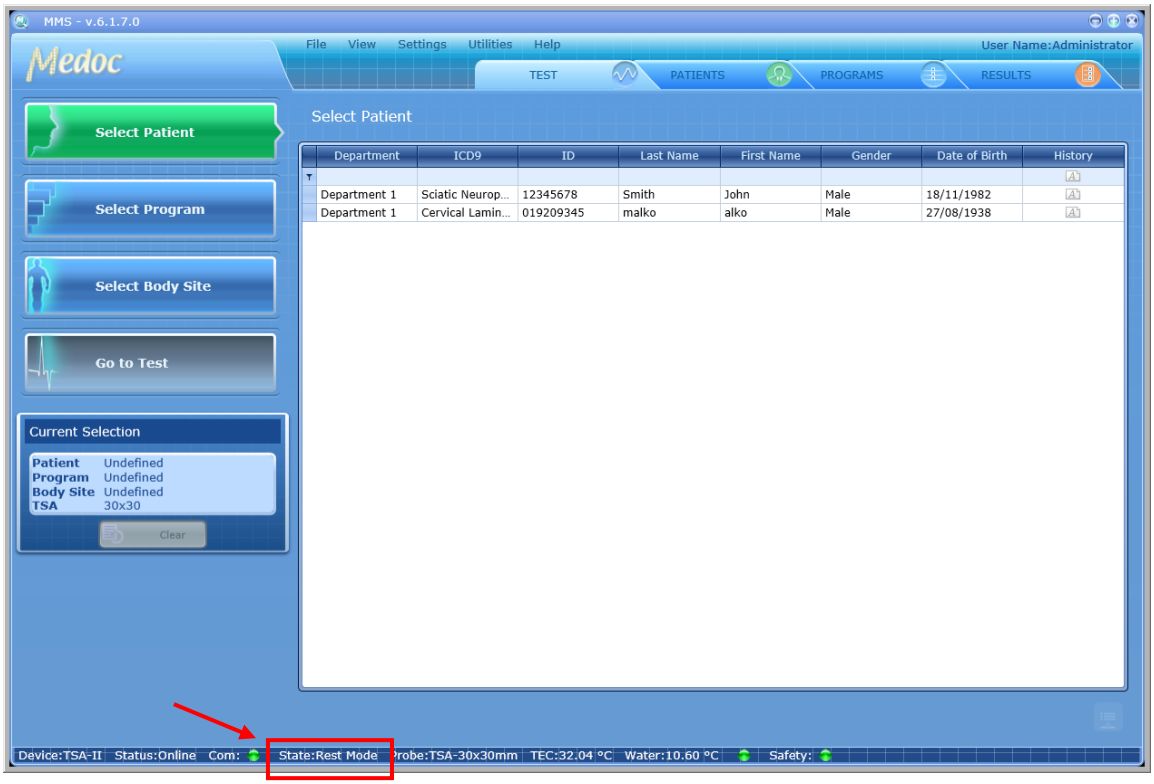


Figure 35: TSA II in Rest Mode

5.3 Basic Operation

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

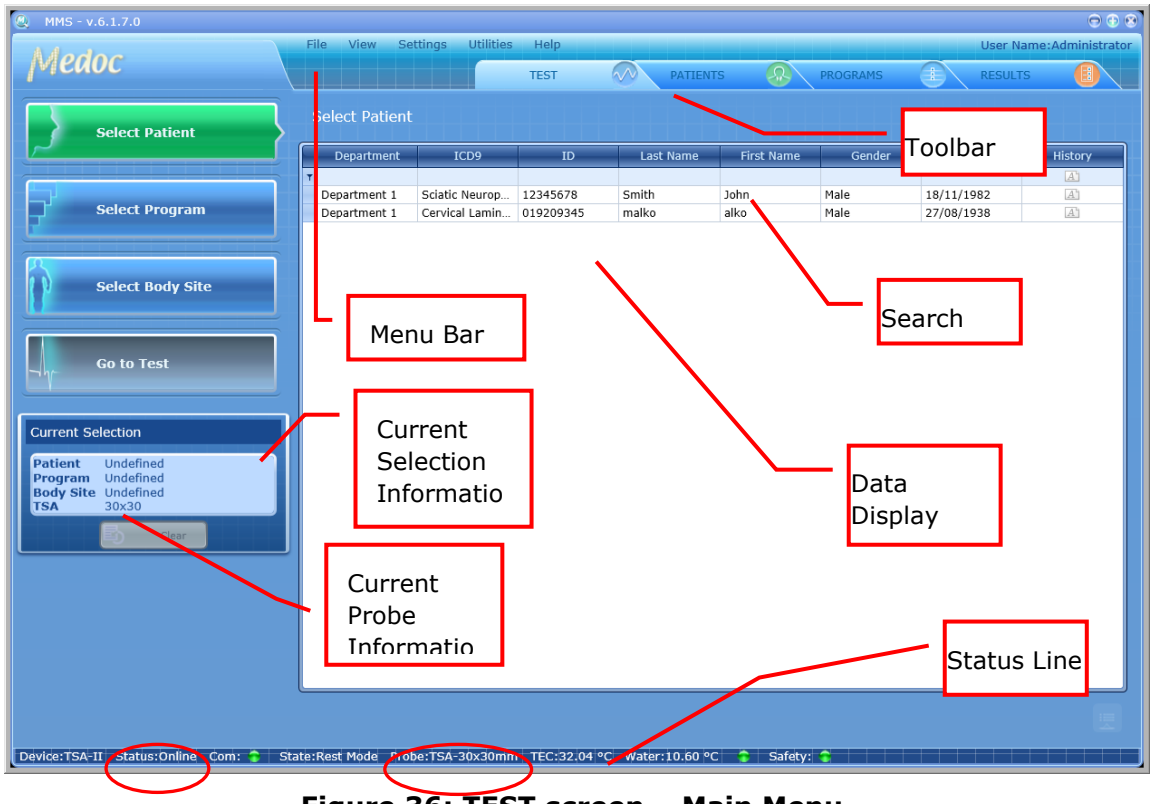


Figure 36: TEST screen – Main Menu

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-II status and Thermode temperature.

The components are detailed in the following sections.

5.3.1 *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-II.
	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.
Settings	Software Settings	Medoc software related configuration and preferences.
	Hardware Settings	TSA-II system and Thermode hardware configuration and management.
	Test Settings	Test configuration and display preferences
	Status	Switch from On-Line to Demo Mode
	Device Mode	Switch between Thermal and Vibratory Mode
Utilities	Department	Manage Department list
	ICD 9	Manage list of ICD 9 codes
	Normative Data	Normative Data database and Editor.
	Black Box	System logs (populated only in case of suspected error)

Menu	Option	Description
	Device Recovery	Manually initiate TSA-II system Self-Test in case safety was triggered.
	Log Files	Software log files.
Help	Operating Manual	Link to the TSA-II Technical Reference Manual
	Service Manual	Link to the TSA-II 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		

5.3.2 *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

5.3.3 *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.

5.3.4 *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.

5.3.5 *Data Display Area*

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

5.3.6 *TSA-II 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-II system, the status line displays the following information as described in Table 7.

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 laptop. 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	Indicates the type and model of the Thermode currently **active**: 30x30mm; 16x16mm; 5x5mm; Intra oral; GSA; **fMRI** or **standard**.
TEC	Temperature of the Thermode.
Water	Temperature of the coolant. When CoVAS is connected and switched on the water 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.

6. Test Procedure and Management

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

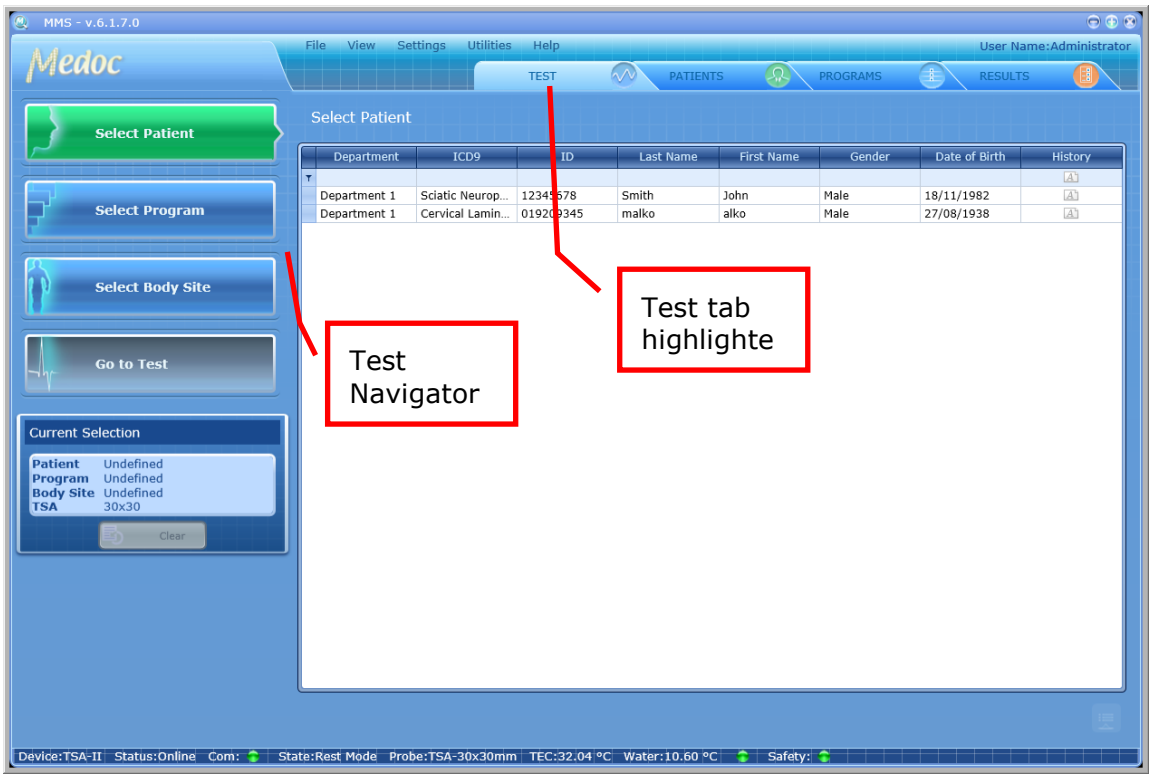


Figure 37: Test Management Main Screen

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.

6.1 Selecting a Patient

1. Click the **Select Patient** button from the Test Navigator
2. Use the Search Row (see section 5.3.3 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.

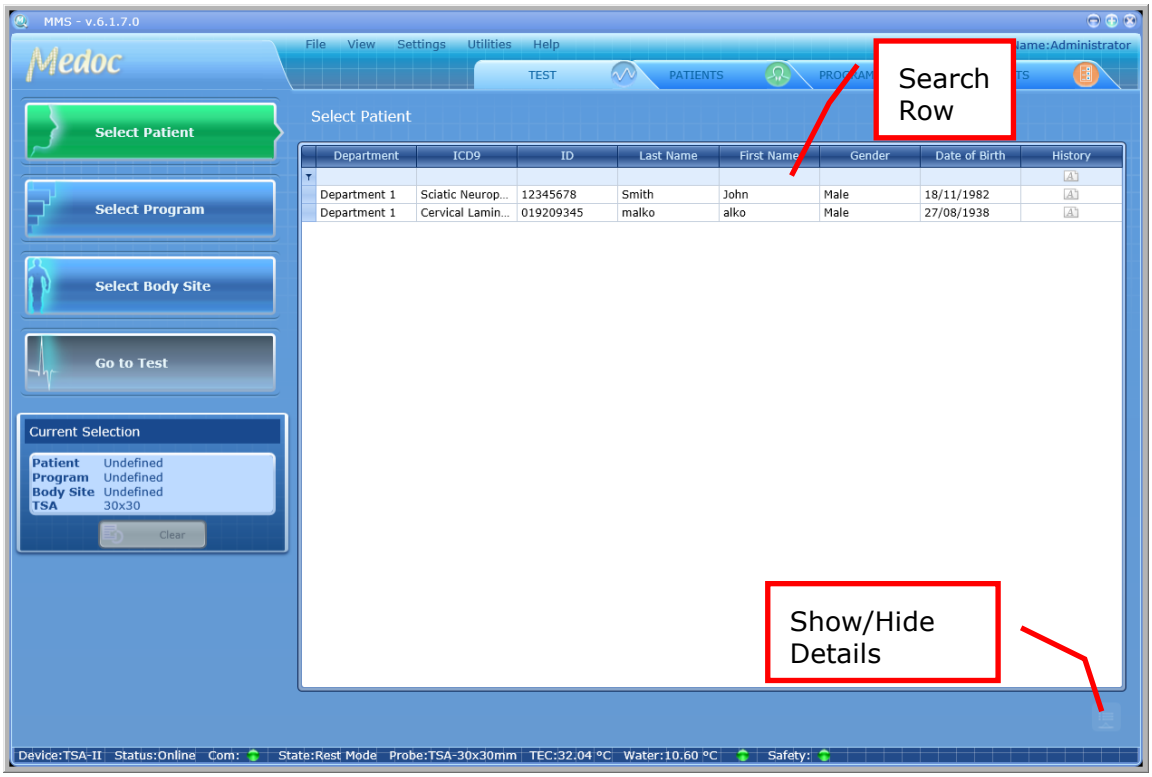


Figure 38: Patient Selection Menu

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-II 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.

6.2 Selecting a Program

1. Click on the **Select Program** button from the Test Navigator
2. Use the Search Row (see section 5.3.3 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.

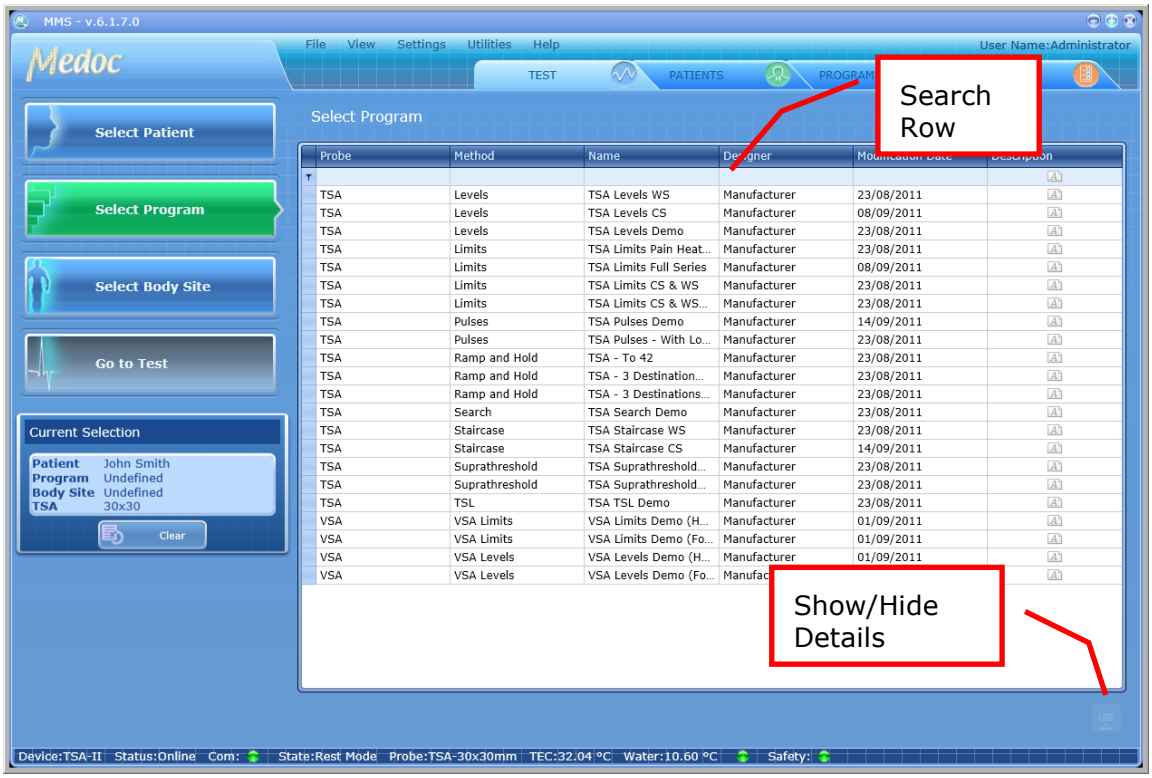


Figure 39: Program Selection Menu

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-II 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.

6.3 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 40: 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 41: 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.

6.4 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 42: 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 **Test Run** button 

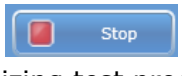
.

At this point attach the Thermode to the tested subject.

Caution! DO NOT use any electrode paste, jelly 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.**

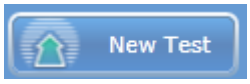
4. Click on the **Start** button 

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.

6.4.1 *Test and Post-Test Options*

Table 8: Test Run Options

A	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.
D	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.
Y	Indicates positive subject response in Limits, Levels, TSL and Search protocols.
N	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. For further details, refer to the TSA-II Technical Reference Manual

Do NOT immerse the Thermode in any kind of liquid.

6.4.2 *Temperature Graph Display*

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

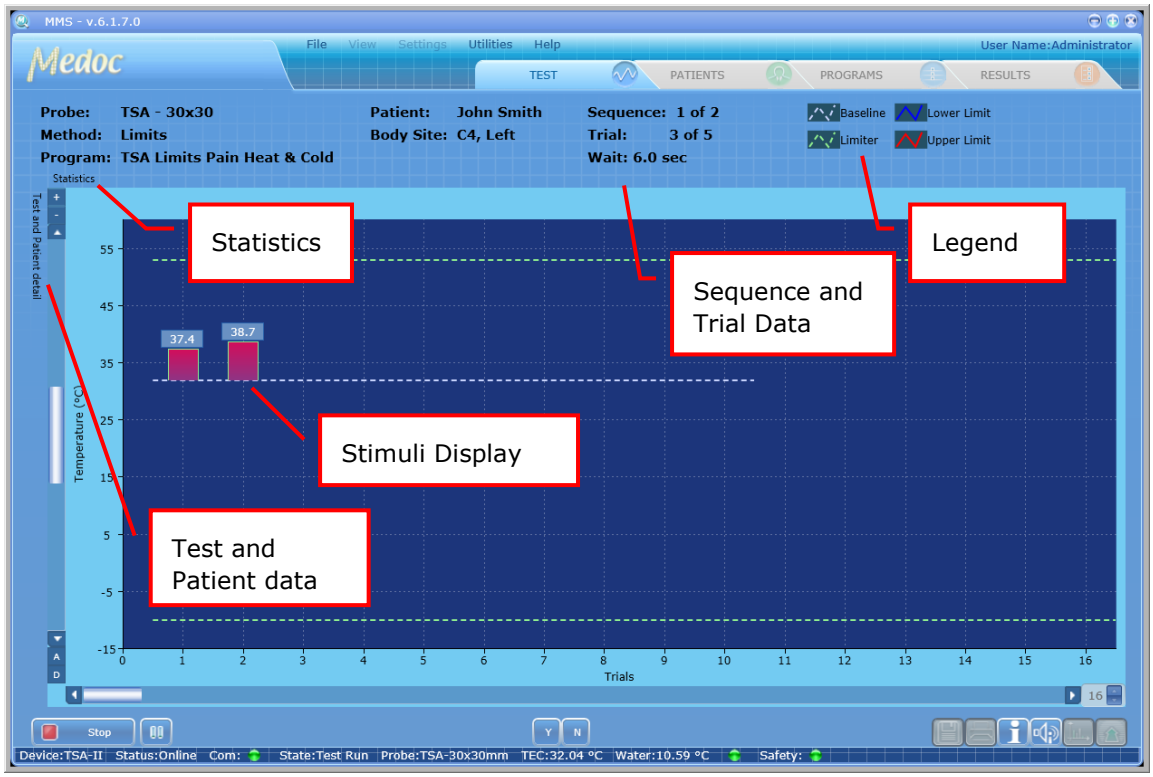


Figure 43: Real-Time Test

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.

6.4.3 *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 below describes the available options.

Table 9: Hot Keys

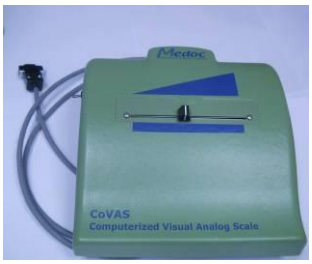
Button	Key	Action
	**S**	Stop (finalize / abort) the test
 /  /  / 	**Spacebar**	Pre-Test / Run Test / Pause / Resume Test.
	**Y**	YES (cannot replace the response unit in the Search method).
	**N**	NO (cannot replace the response unit in the Search method).
	**T**	Manual Trigger
	Tab	Wrong Sensation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

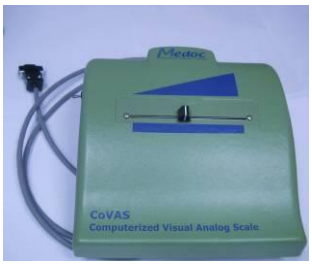
7. Accessories

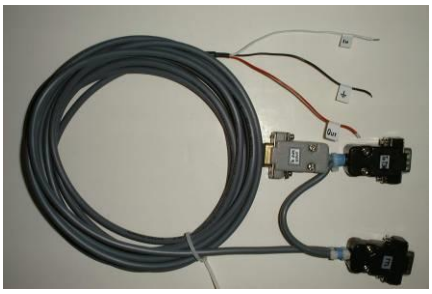
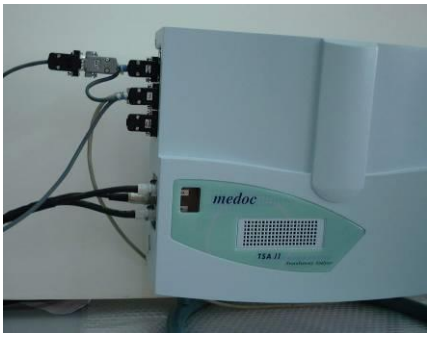
The following list of accessories can be purchased from Medoc, and are listed with their Catalogue numbers, which should be quoted when ordering a specific accessory.

Table 10: Accessories

Description	Cat. No.	
Standard TSA 30x30mm Thermode This is the standard thermal probe, which is capable of heating the skin. Used on large body sites.	AS 00024	
Small Thermode - 16x16mm	AS 00023	
Small Thermode - 5x5mm	AS 00048	
Small Thermode - 2x2mm	AS 00049	

Description	Cat. No.	
MRI Conditional TSA Thermode 30x30mm The Thermode is MRI Conditional, made of non-magnetic / low magnetic components. The Thermode has an extended cable length of 10 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 a MRI environment, which may be caused by the Thermode.	AS 00051 / AS 00052	
Standard Strap - 39 cm (15.3") The standard strap is used for securing the Thermode to the hand.	AS 00004	
Face/Leg Strap – 66 cm (25.9") For securing the Thermode to locations on the face and leg.	AS 00044	
Back/Chest Strap – 122 cm (48") For securing the Thermode to larger areas of the body such as the back and chest.	AS 00045	
Temperature 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 00147	
CoVAS – Computerized Visual Analog Scale While the TSA-II delivers a heat stimulus to a tested subject's body site, the subject simultaneously moves the CoVAS slide. The movement of the slide is between a predefined minimum and maximum (0 to 100), which depicts the level of pain he/she feels.		

Description	Cat. No.	
CoVAS – Computerized Visual Analog Scale for MRI A special MRI safe, non-magnetic / low magnetic version of the CoVAS unit. This unit can operate inside an MRI room and comes with an extended cable that is connected to the Output port on the TSA unit, which is placed outside the MRI room. **Note:** Ensure that the MRI filter has been modified to accommodate the CoVAS connection.		
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.		
MRI Safe **Response Unit** A special MRI safe version of the Response Unit. This unit can operate inside an MRI room and connected through the EMI filter to the Response Unit port on the TSA unit, which is placed outside the MRI room.		
EMI Filter for MRI TSA Thermode This electronic filter is used for preventing magnetic noises in an MRI environment, which may be caused by the Thermode.	AS 00062	

Description	Cat. No.	
Analog Output This is an optional Service port on the *TSA II* unit, which when connected to a recording device, records analog voltage relative to the Thermode's temperature. This option can be used by researchers for analog registration of the temperature and can be added at a later stage of the purchase. A cable with a dual-connector is attached to the TSA port and Patient Response Unit The end of the cable is then connected to a recording device such as a voltmeter. A Voltage/Temperature table is supplied by Medoc, to check voltage outputs at temperatures between 0-50°C	**UP 00007**	
TTL (Transistor Transistor Logic) **Output** A TTL signal can be sent out of the *TSA II* at certain stages of the thermal stimulus. For example, at the beginning of the stimulus or when the temperature reaches its target. This option is mainly used for synchronization of the *TSA II* to MRI devices and used in TPS (Thermal Pain Stimulator). This option can be added at a later stage of the purchase.	UP 00008	
TTL (Transistor Transistor Logic) **Input/Output** In addition to TTL Output, the Input option used for triggering the *TSA II* stimulus by TTL pulse from another device such as MRI scanner. The request for such an option must be stated in the original order for the *TSA II* unit. To add this option at a later stage, the *TSA II* unit must be returned to Medoc.	UP 00009	

"MR safe" means that an object or device, when used in the MR environment, will present no additional risk to the patient but may affect the quality of the diagnostic information.