

TSA-200I

NEUROSENSORY ANALYZER MODEL TSA-II

OPTIONAL: Vibratory Sensory Analyzer – VSA- 3000



Technical Reference Manual

This User Manual contains proprietary information of Medoc Ltd. and may not be reproduced in any form without prior written consent from Medoc Ltd.

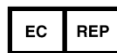
DC 00072 TSA-II Technical Reference Manual 2nd Edition, December 2012



1 Ha-Dekel St., PO Box 423 Ramat Yishai 30095, ISRAEL
Tel.: +972-4-9038800 / Fax: +972-4-9038808
E-Mail medoc@medoc-web.com

Medoc U.S.A

Compass Medical Technologies, Inc.
1502 West Highway 54 - Suite 404
Durham, North Carolina, 27707, U.S.A
Tel.: +1-(919) 402-9600 / Fax: +1-(919) 402-9607
E-Mail: medoc@mindspring.com



European Authorized Representative

CEpartner4U BV
Esdoornlaan 13 3951 DB Maarn, The Netherlands
Phone: +31 343 442.524 / Fax: +31 343 442 162
Mobile: +31 6 516 536.26
E-Mail: office@CEpartner4U.nl



This device complies with 93/42/EEC MDD



Table of Contents

1.	<i>Safety Guidelines and Regulations</i>	11
1.1	User Manual Icons	11
1.2	Intended Use	12
1.3	Safety and Regulatory Summary	12
1.4	Safety Requirements	12
1.4.1	Warnings	12
1.4.2	Cautions	13
1.4.3	Equipment Classification	13
1.5	System Protection	14
1.5.1	System Self-Test	14
1.5.2	Temperature Safety Mechanisms	14
1.5.3	Thermode Detection	14
1.6	Equipment Labels, Symbols, Warning Statements and Abbreviations	15
1.7	Electromagnetic Immunity	16
1.8	Recommended Separation Distance between Portable and Mobile RF Communications Equipment and TSA-II	18
1.9	Technical Data	19
2.	<i>Overview</i>	22
2.1	Medical background:	22
2.2	Principle of operation:	22
2.3	TSA Thermode	22
2.4	Terminology	23
2.5	System Status	24
2.6	System States	24
2.7	Application Methods	24
2.7.1	Limits Method	25
2.7.2	Levels Method	25
2.7.3	Thermal Sensory Limen (TSL)	25
2.7.4	Suprathreshold Method	25
2.7.5	Staircase Method	26
3.	<i>System Components</i>	27
3.1	TSA-II Connection Panel	28
4.	<i>Setup and Installation</i>	31
4.1	Computer Requirements	31
4.1.1	Hardware	31
4.1.2	Software	31
4.2	Installation CD Content	32
4.3	Setup and Installation Main Steps	32
4.4	Selecting a Location	32
4.5	Device Connections	33
4.6	Software Installation	34
4.7	Unit Protection	38

4.8	Power up TSA-II System.....	38
5.	Operation.....	40
5.1	Safety Procedures and System Self-Test.....	40
5.2	Starting TSA-II.....	40
5.3	Basic Operation	42
5.3.1	Menu Bar	43
5.3.2	Toolbar.....	44
5.3.3	Search Row	44
5.3.4	Current Selection Information.....	44
5.3.5	Data Display Area.....	45
5.3.6	TSA-II Status Line.....	45
6.	Test Procedure and Management.....	46
6.1	Selecting a Patient.....	46
6.2	Selecting a Program	48
6.3	Selecting a Body Site	49
6.4	Running the Test	50
6.4.1	Test and Post-Test Options	52
6.4.2	Temperature Graph Display	53
6.4.3	Test Run Keyboard Shortcuts (Hot Keys)	54
7.	Program Management	55
7.1	Program List	55
7.2	Creating a New Program	56
7.3	Program Editor.....	57
7.4	Program Details	59
7.4.1	Limits.....	59
7.4.2	Levels.....	60
7.4.3	Thermal Sensory Limen (TSL)	62
7.4.4	Suprathreshold	64
7.4.5	Staircase	65
7.4.6	Chain Program Option	66
7.5	Marking Events	68
7.5.1	Temperature Events	68
7.5.2	Standard Events	69
7.6	Unique Test Instructions.....	72
7.7	Removing A Program	73
7.8	Duplicate A Program	73
7.9	Edit A Program.....	73
7.10	Import / Export Program.....	74
8.	Patient Management.....	75
8.1	Patients List	75
8.2	Add New Patient	77
8.3	Remove Patient.....	77
8.4	Edit Patient Details	78
8.5	Department Management	78
8.6	Import / Export Patient Lists	78

9.	Results Management	80
9.1	Results List	80
9.2	Import / Export Results	82
9.3	Print Results and Reports	85
9.3.1	Analysis Report Dialog	86
10.	System Configuration	91
10.1	Software Settings	91
10.1.1	TSA-II	91
10.1.2	Patient Fields	92
10.1.3	Results Fields	94
10.1.4	Report Options	95
10.1.5	Button Configuration	100
10.1.6	Authorization	100
10.2	Hardware Settings	105
10.2.1	General	106
10.2.2	Safety	106
10.2.3	Thermode	107
10.2.4	CoVAS	108
10.3	Test Settings	108
10.3.1	Test Configuration	109
10.3.2	Instructions Configuration	111
10.3.3	Event Sound Configuration	113
10.3.4	Event Marker	115
10.3.5	Body Site Editor	116
11.	System Information	118
12.	The Black Box	120
12.1	Exporting the Black Box File	120
12.2	Creating a Black Box Entry on Demand	120
12.3	The Contents of the Black Box File	121
13.	Appendix A – Normative Data	122
13.1	Normative Data Editor	122
13.1.1	Manufacturer Normative Data	123
13.1.2	User Normative Data	123
13.2	Normative Data Display	125
14.	Appendix D – fMRI Conditional TSA-II	126
14.1	TSA-II system configuration in fMRI mode:	126
14.2	Installation – TSA-II MR Filter	127
15.	Appendix F – Data Base Back Up and Restore	130
15.1	Backing Up and Restoring the Database	130
16.	Appendix G – Accessories	131
17.	Appendix H – System and Module Description	135
17.1	System Description	135
18.	Appendix I – Preventive and Periodical Maintenance	136
18.1	Periodical System Run and Visual Check	136
18.2	Periodical Thermode Calibration	137

18.3	Ground Conductivity Test (for fMRI system only)	137
18.4	Periodical Thermode Maintenance	137
19.	<i>Appendix J – Cleaning and Disinfecting</i>	138
20.	<i>Appendix K – List of Accompanying Documents</i>	139
21.	<i>Appendix L – Transportation and Storage conditions</i>	140
22.	<i>Appendix M – Environmental Conditions</i>	141
	<i>Appendix N – Troubleshooting – Operator Level</i>	142
22.1	Numbered Software Error and Warning Messages	142
22.1.1	Frequent Warning Messages	142
22.1.2	Frequent Error Messages	146
22.2	Faulty System Responses	149

List of Figures

Figure 1: TSA-II Label 110V.....	15
Figure 2: TSA-II Label 230V.....	15
Figure 2: Methods of Threshold Determination	Error! Bookmark not defined.
Figure 3: TSA-II with Hand Held VSA	27
Figure 4: TSA-II with VSA Leg Support.....	27
Figure 5: Main Power Switch	28
Figure 6: TSA-II Connection Panel.....	28
Figure 7: TSA Thermode	29
Figure 8: TSA Thermode Simulator.....	29
Figure 9: TTL In/Out Cable	29
Figure 10: Response Unit	29
Figure 11: CoVAS.....	30
Figure 12: CoVAS Key.....	30
Figure 13: TSA-II Service Cable.....	30
Figure 14: RS-232 Cable	30
Figure 15: Hand Held VSA.....	30
Figure 16: TSA-II Wiring Scheme.....	33
Figure 17: TSA-II Electrical Connectors	Error! Bookmark not defined.
Figure 11: Main Station Installation 1	35
Figure 12: Main Station Installation 2	35
Figure 13: Main Station Installation 3	36
Figure 14: Main Station Installation 3	36
Figure 15: Normative Data license agreement	37
Figure 17: Main Station Installation 4	Error! Bookmark not defined.
Figure 18: Main Station Installation 5	37
Figure 19: Installation Complete.....	38
Figure 38: TSA-II USB License Key	Error! Bookmark not defined.
Figure 42: TSA-II USB License Key	Error! Bookmark not defined.
Figure 21: Device selection Screen.....	40
Figure 22: Login Screen.....	41
Figure 43: Welcome Screen.....	41
Figure 45: Communication Established System Self-Test.....	Error! Bookmark not defined.
Figure 46: Self-Test Prompt.....	Error! Bookmark not defined.
Figure 47: TSA II in Rest Mode	42
Figure 48: TEST screen – Main Menu	42
Figure 49: Test Management Main	46
Figure 50: Patient Selection Menu	47
Figure 51: Patient Details Screen.....	Error! Bookmark not defined.
Figure 52: Programs List.....	48
Figure 53: Program Details screen.....	Error! Bookmark not defined.
Figure 54: Select Body Site screen	49
Figure 55: Select Body Site – Specific site selection	50
Figure 56: Pre-Test Screen.....	51
Figure 57: Real-Time Test	53
Figure 58: Real-Time Test with Details	Error! Bookmark not defined.
Figure 59: Program Management screen.....	55
Figure 60: Program Management – Program Preview	Error! Bookmark not defined.
Figure 61: Program graph preview.....	Error! Bookmark not defined.
Figure 62: New Program Screen.....	56
Figure 63: Program Menu – Limits	59
Figure 64: A Limits Method Test	Error! Bookmark not defined.
Figure 65: Statistical analysis of results	Error! Bookmark not defined.
Figure 66: Program Menu – Levels	60
Figure 67: A Levels Method Test	Error! Bookmark not defined.
Figure 68: Statistical Analysis of the Results.....	Error! Bookmark not defined.

Figure 69: Program Menu – TSL.....	63
Figure 70: A TSL Method Test.....	Error! Bookmark not defined.
Figure 71: Statistical Analysis of the Results.....	Error! Bookmark not defined.
Figure 72: Program Menu – Suprathreshold	64
Figure 73: A Suprathreshold Method Test.....	Error! Bookmark not defined.
Figure 74: Statistical Analysis of the Results.....	Error! Bookmark not defined.
Figure 75: Program Menu – Staircase	65
Figure 76: A Staircase Method Test.....	Error! Bookmark not defined.
Figure 77: Statistical Analysis of the Results.....	Error! Bookmark not defined.
Figure 78: Program Chain.....	67
Figure 79: Temperature Points Dialog.....	68
Figure 80: Limits – Standard Events Dialog	69
Figure 81: Levels – Standard Events Dialog	70
Figure 82: TSL – Standard Events Dialog.....	70
Figure 83: Suprathreshold – Standard Events Dialog.....	71
Figure 84: Staircase – Standard Events Dialog.....	72
Figure 85: Test Instructions Editor	73
Figure 86: Patients List	75
Figure 87: Patient Management – Patient details preview.....	76
Figure 88: Patients Editor Screen	77
Figure 89: Edit Department Menu	78
Figure 90: Results List	80
Figure 91: Result preview display	81
Figure 92: Export Result File Opened In Excel – Description Tab Sample.....	83
Figure 93: Export Result File Opened In Excel – Data Tab Sample	83
Figure 94: Analysis Reports Dialog	85
Figure 95: Analysis Report.....	86
Figure 96: Single Results Report	88
Figure 97: Multiple Results Report	88
Figure 98: Site to Site Results Report	89
Figure 99: Pre / Post Results Report.....	89
Figure 100: Trend Results Report.....	89
Figure 101: Custom Report Results	89
Figure 102: Bilateral Results Report	90
Figure 103: Software Settings Dialogue.....	91
Figure 104: Patient Fields Configuration Screen	92
Figure 105: Results Fields Configuration Screen	94
Figure 106: Report Options tab.....	95
Figure 107: Detailed Report example.....	96
Figure 108: Detailed Report Options.....	97
Figure 109: Custom made Report Name dialog	98
Figure 110: Report Editor Screen.....	98
Figure 111: TSA-II Simple Print replace.....	99
Figure 112: Buttons configuration Software Settings.....	100
Figure 113: User Authorization Software Settings.....	101
Figure 114: Hardware settings – General tab.....	105
Figure 115: Hardware settings – Safety tab	106
Figure 116: Hardware settings – Thermode tab	107
Figure 117: Hardware settings – COVAS tab	108
Figure 118: Test Configuration Settings.....	109
Figure 119: Instructions Configuration.....	111
Figure 120: Test Instructions Editor	112
Figure 121: Audio save button	113
Figure 122: Instructions Configuration.....	113
Figure 123: Sound Effect Library.....	114
Figure 124: Event Marker	115
Figure 125: Body Sites Editor	116

Figure 126: System Information	118
Figure 127: Sysinfo File Sample	119
Figure 128: Black Box – Software	120
Figure 129: Black Box Excel – Description Tab Sample.....	121
Figure 130: Black Box Excel – Data Tab Sample	121
Figure 131: Normative Data Editor Screen.....	122
Figure 132: Normative Data display in test screen	125
Figure 133: System Block Diagram	127
Figure 134: fMRI TSA filter.....	128
Figure 135: fMRI filter front view	128
Figure 136: Database Utility	130
Figure 137: TSA-II System Diagram	135
Figure 138: Error and Warning Messages Sample.....	142

List of Tables

Table 1: Equipment Labels	15
Table 51: TSA-II Specifications	19
Table 52: VSA Specifications	21
Table 3: Terminology	23
Table 4: TSA-II Panel receptacles.....	29
Table 5: Menu Bar options	43
Table 6: Status line parameters	45
Table 7: Test Run options	52
Table 8: Hot Keys	54
Table 9: Probe Type options	Error! Bookmark not defined.
Table 10: Program Details	Error! Bookmark not defined.
Table 11: Program Parameters	59
Table 12: Program Details	Error! Bookmark not defined.
Table 13: Program Parameters	61
Table 14: Program Details	Error! Bookmark not defined.
Table 15: Program Parameters	63
Table 16: Program Details	64
Table 17: Program Parameters	64
Table 18: Program Details	65
Table 19: Program Parameters	65
Table 20: Program Details	67
Table 21: Program Table	67
Table 22: Events - Limits	69
Table 23: Events - Levels	70
Table 24: Events - TSL	71
Table 25: Events - Suprathreshold.....	71
Table 26: Events - Staircase	72
Table 27: Report Analysis Configuration	86
Table 28: Report Analysis Configuration	90
Table 29: Software Settings – TSA-II	91
Table 30: Patient's Field	92
Table 31: Patient's Field	94
Table 32: Report Options	95
Table 33: Report Options	97
Table 34: Authorization parameters	101
Table 35: Authorization Levels	102
Table 36: Hardware Settings Tab Sheets.....	105
Table 37: Hardware Settings – General tab options	106
Table 38: Hardware Settings – CoVAS tab options	108
Table 39: Test Settings Tab Sheets	108
Table 40: Pre-test parameters	109
Table 41: Test configuration parameters.....	110
Table 42: Post test parameters	110
Table 43: Presentation configuration.....	110
Table 44: Additional test parameters.....	110
Table 45: Temperature limiter parameters	110
Table 46: Manufacture Normative Data information	123
Table 47: Manufacture Normative Data options	123
Table 48: User Normative Data information	123
Table 49: User Normative Data options	124
Table 50: Accessories.....	131
Table 53: Warnings.....	142
Table 54: Errors	146
Table 55: Faulty System Responses.....	149

1. Safety Guidelines and Regulations

Disclaimer

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

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

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

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

1. Warnings
2. Cautions
3. Notes
4. Important Notices
5. User Notices

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, section 14, page [126](#).

- 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.

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 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 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

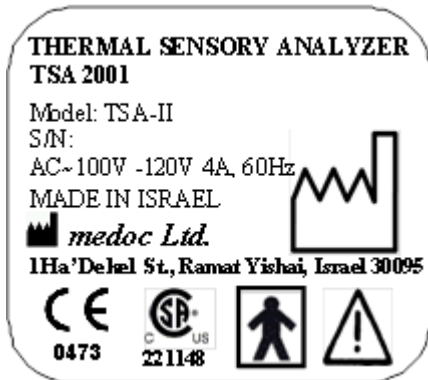


Figure 1: TSA-II Label 110V

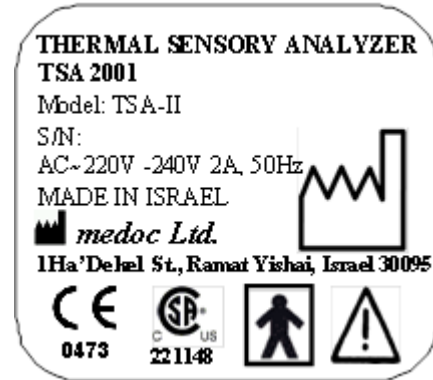


Figure 2: TSA-II Label 230V

Table 1: Equipment Labels

Equipment Label	Description
	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




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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-4	3 A/m 50 & 60 Hz	3 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	±1 kV line(s) and neutral	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	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If a dip or an interruption of mains power occurs, the current of the TSA-II may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
NOTE UT is the a.c. mains voltage prior to application of the test level			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>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.</p> <p>Recommended separation distance $d=1.2 \cdot \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d=2.3 \cdot \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey* should be less than the compliance level in each frequency range**</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1 At 80 MHz and 800 MHz, 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.			
<p>* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TSA-II is used exceeds the applicable RF compliance level above, the TSA-II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TSA-II.</p>			
<p>** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

1.8 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	80 MHz to 800 MHz	80 MHz to 2.5 GHz
	$d = 1.2 * \sqrt{P}$	$d = 1.2 * \sqrt{P}$	$d = 2.3 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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.

1.9 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 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 x 30 mm 16 mm x 16 mm
Temperature range	0 – 50.5 °C (Optional -10°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 Staircase Suprathreshold 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.
Stimuli trigger options	Automatic Manual using keyboard External, via a TTL input (Optional)

Parameter	Description
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
Software Operation System	Microsoft® Windows XP 32-bit SP-3 or Windows 7
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

Parameter	Description
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. (10) -10 °C during 5 min.
Dimensions	45 cm x 40 cm x 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 x 250 V, 2 A fast fuse (for 230 V system). 2 x 120 V, 4 A fast fuse (for 110 V system).
Product life time	10 Years

Table 3: VSA Specifications

Parameter	Description
Vibrator Pin Size	0.5 inch
Stimulating Area	1.22 cm ²
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 water 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 [1.9](#), page [19](#).

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.



Refer to section 16, page 131 to view the full range of Thermode types and sizes.

2.4 Terminology

The following terms are used throughout the user manual:

Table 4: Terminology

Term	Description
Thermode	The probe which is applied on the subject's skin to give actual stimulation in the TSA-II system.
TEC	Thermo Electric Cooler (TEC), a Peltier element used as the active heat generator in the Thermode.
Cooling Unit	An internal system which is used to refrigerate and circulated the coolant through the system and Thermode.
Rest (Adaptation) Temperature	The initial/rest temperature of the Thermode, after system initialization and in between tests.
Baseline Temperature	The initial temperature the stimulus starts from
Destination Temperature	The final temperature the stimulus ends with.
Onset	The time which marks the start of a stimulus
Destination	The time which marks the stimulus has reached the destination temperature
End of Duration	The time which marks the stimulus has completed the specified duration at the destination temperature.
Pulse	A short and fast stimulus specified by the baseline and destination temperatures only. The rate is automatically set to the maximum capability.
Trial	Represents one stimulus
Sequence	A set of trials with the same specifications
Test	A set of sequences.
TTL	Transistor-Transistor Logic (TTL). An output or input signal which enables synchronization between the TSA-II system and other devices.
Event	A test incident (such as Onset or Destination) which can be indicated by TTL or sound.
LUT	Look Up Table (LUT), is the calibration table which determines the absolute temperature in the TSA-II system.

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 [25](#).
- **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 [25](#)

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 [2.7.3](#), Page [25](#)
- **Staircase:** 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 [2.7.3](#), Page [26](#)
- **Suprathreshold:** 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 [2.7.3](#), Page [25](#)



Before applying any of these methods, make sure to read section 6, page 46, on Test Procedure and Management which addresses the following topics: Test subject selection, program selection, and stimuli administration.

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.

For a full description of program details and parameters see section [7.4.1](#), page [58](#).

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.

A modified Levels method allows you to hold Temperature for predefined Time at destination. See section [7.4.2](#), page [60](#) for full description of program details and parameters.

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.

See section [7.4.3](#), page [62](#) for full description of program details and parameters.

2.7.4 Suprathreshold Method

In Suprathreshold 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 Suprathreshold method can be used to establish a relationship between stimuli intensity, rate, and/or duration and the perceived sensation

See section [7.4.3](#), page [64](#) for full description of program details and parameters.

2.7.5 Staircase Method

In the Staircase method, three step sizes are predetermined. A **coarse** step is used initially until the first **YES** response is achieved. Subsequently, stimuli are decreased by **intermediate** steps, until a **NO** response is given. The subsequent stimuli are increased or decreased by the **fine** search step. The direction changes according to the response; increasing for NO, decreasing for YES. Four negative (**NO**) responses are required, after a fine search has begun, to terminate the test. Threshold is determined by taking the mean of all results during the fine step search stage.

See section [7.4.5](#), page [65](#) for full description of program details and parameters.

3. System Components

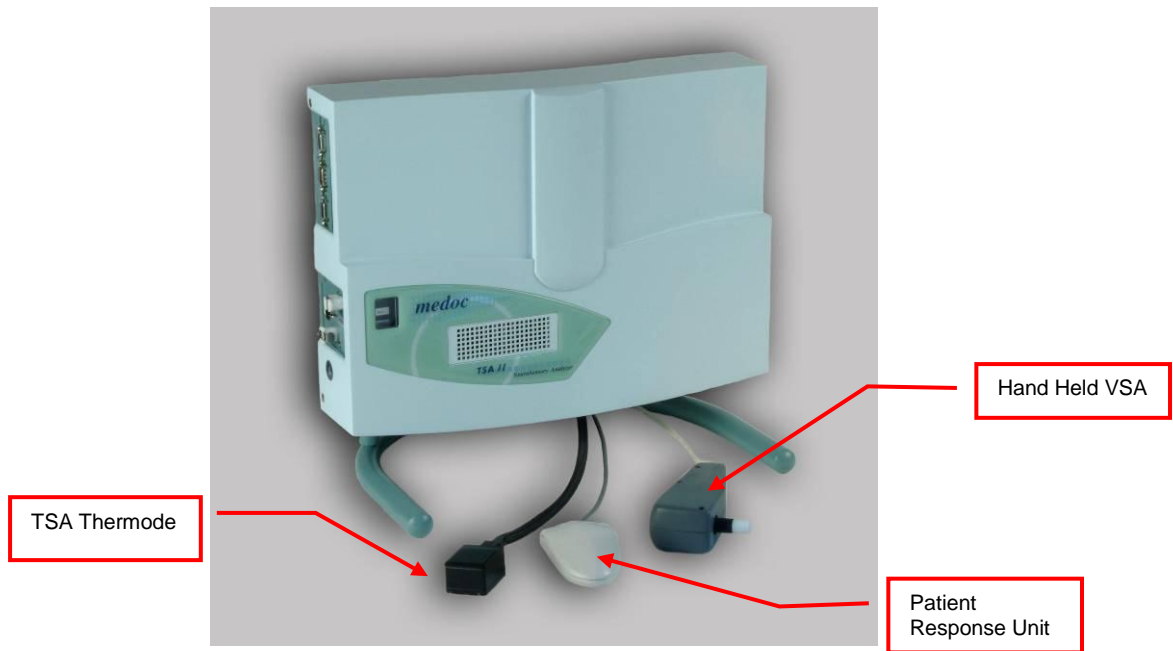


Figure 3: TSA-II with Hand Held VSA

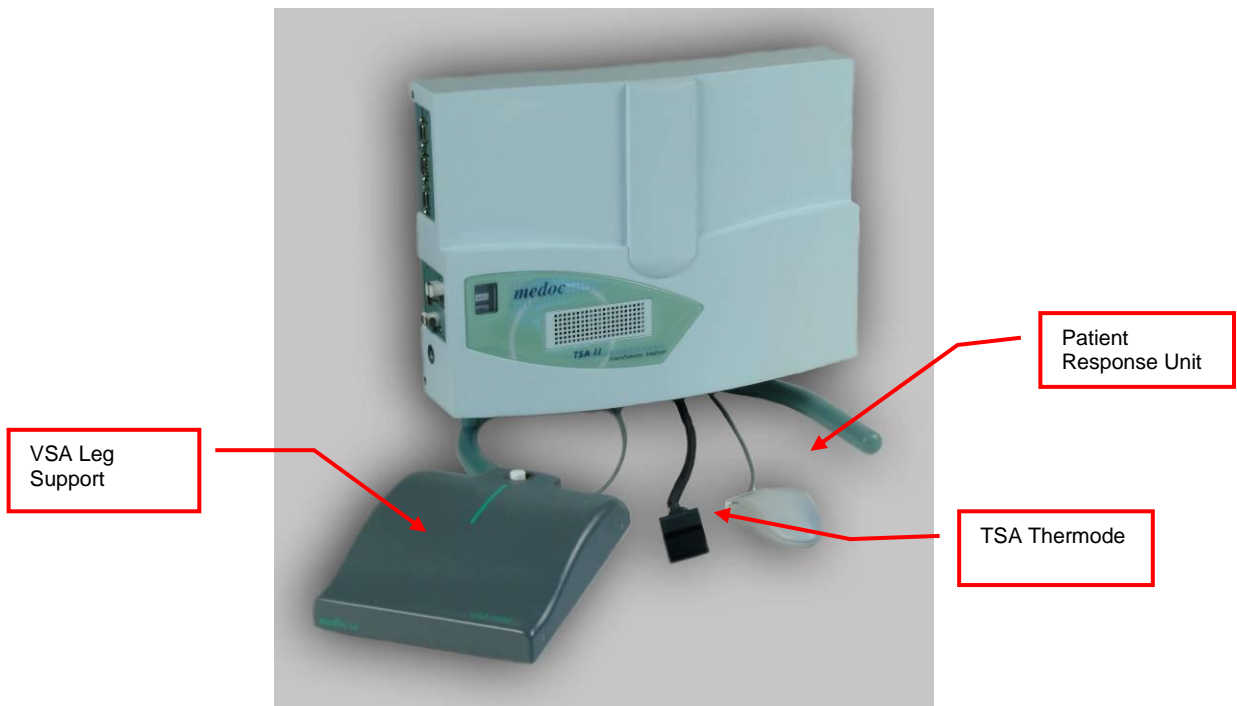


Figure 4: TSA-II with VSA Leg Support



Figure 5: Main Power Switch

3.1 TSA-II Connection Panel



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

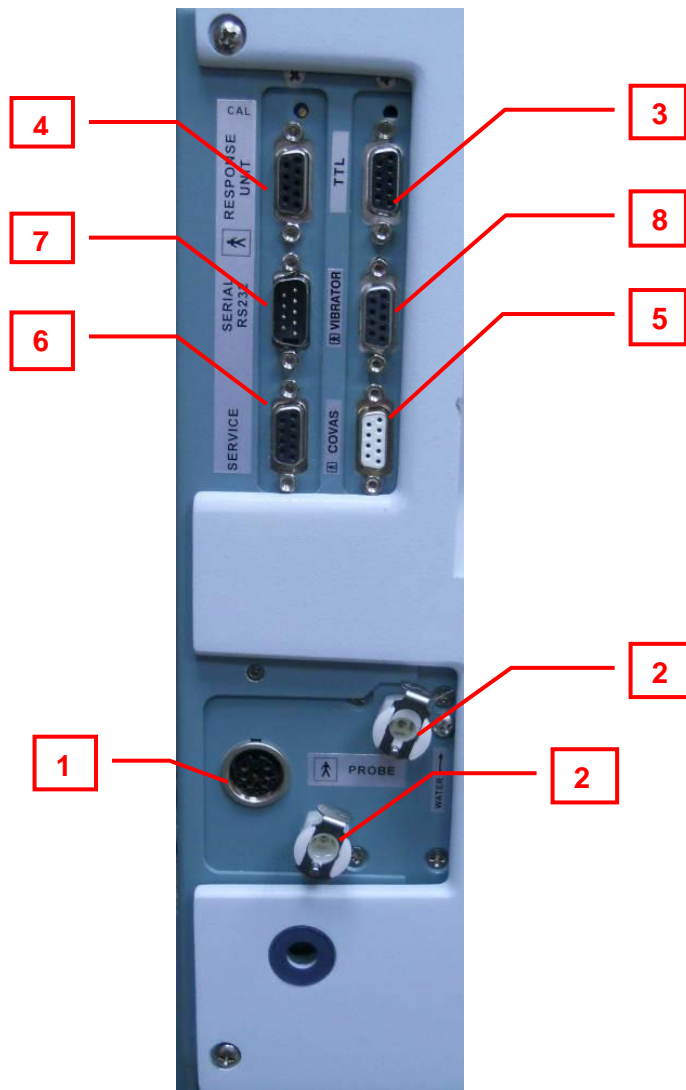


Figure 6: TSA-II Connection Panel

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 Simulator ¹
2	TSA Thermode coolant receptacles	
3	TTL Cable connector (Optional, based on license agreement)	
4	Response Unit receptacle a. Use for recording patient response during test	



Figure 7: TSA Thermode



Figure 8: TSA Thermode Simulator

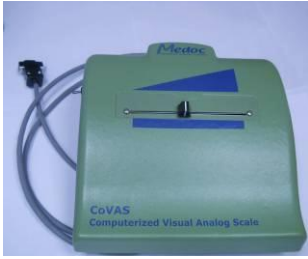






Figure 9: TTL In/Out Cable



Figure 10: Response Unit

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

#	Description	Mate with
5	CoVAS receptacle 1. Use for recording patient visual analog scale during test (Optional, based on license agreement)	TSA-II CoVAS or CoVAS key2  <p>Figure 11: CoVAS</p>  <p>Figure 12: CoVAS Key</p>
6	Service Connector (Optional, based on license agreement)	 <p>Figure 13: TSA-II Service Cable</p>
7	Serial RS232 communication connector	 <p>Figure 14: RS-232 Cable</p>
8	VSA Connector (Optional, based on license agreement)	 <p>Figure 15: Hand Held VSA</p>

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

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 preliminary setting-up of the unit. Proper installation and operation of the equipment is important for ensuring the safety of the tested subjects.

The TSA-II system is license protected. The licensed software can be operated with any laptop on which the system software has been installed. Refer to section 4.1 below for minimum computer hardware requirements.



For fMRI mode system installation see section 14, page 126.



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

4.1 Computer Requirements

4.1.1 Hardware

- CPU – Pentium 4 and up (Intel® Atom and similar are not supported)
- 2 GB extended memory (RAM) and up
- Minimum 6 GB of free hard-disk space
- CD drive
- Serial or USB port for communication
- At least one additional USB physical port
- Minimum screen resolution of 1366 × 768 is recommended
- SAFETY: Complies with IEC 950 - EN 60950 - UL 60950
- Medoc Main Station Software is not supported on netbook computers



Laptop and printer are not supplied by Medoc.

Medoc requires that the computer used should be dedicated only to TSA-II system and takes no responsibility for any conflicts which may occur with other programs installed on the same computer.

4.1.2 Software

- Supported Operating Systems: Microsoft® Windows XP Service Pack 3 and up, Windows 7 Professional Edition or higher (32bit and 64bit systems).
- Microsoft® Office (XP or higher) is required for reading exported results in Excel format
- For optimal system performance it is required to disable the following programs on the dedicated computer while in use: Anti-virus, screen saver, hibernate mode, network connections, modem programs, or any other application that consumes PC resources



For best display results ensure that Screen resolution is at least 1366 x 768 pixels, and DPI setting is Normal size or 96 DPI

4.2 Installation CD Content

The installation CD 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 CD contains all of the unique system files. Keep the CD 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 32.
2. Connecting the various components and devices to the system.
3. Connecting the laptop and printer.
4. Installing the MEDOC Main Station software. See section 4.6, page 34.
5. 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 requirements set by Medoc (See section 0, page 31).
2. Make sure that the Laptop, TSA-II unit and printer (optional) are all **OFF**.



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

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 16 and Figure 17.

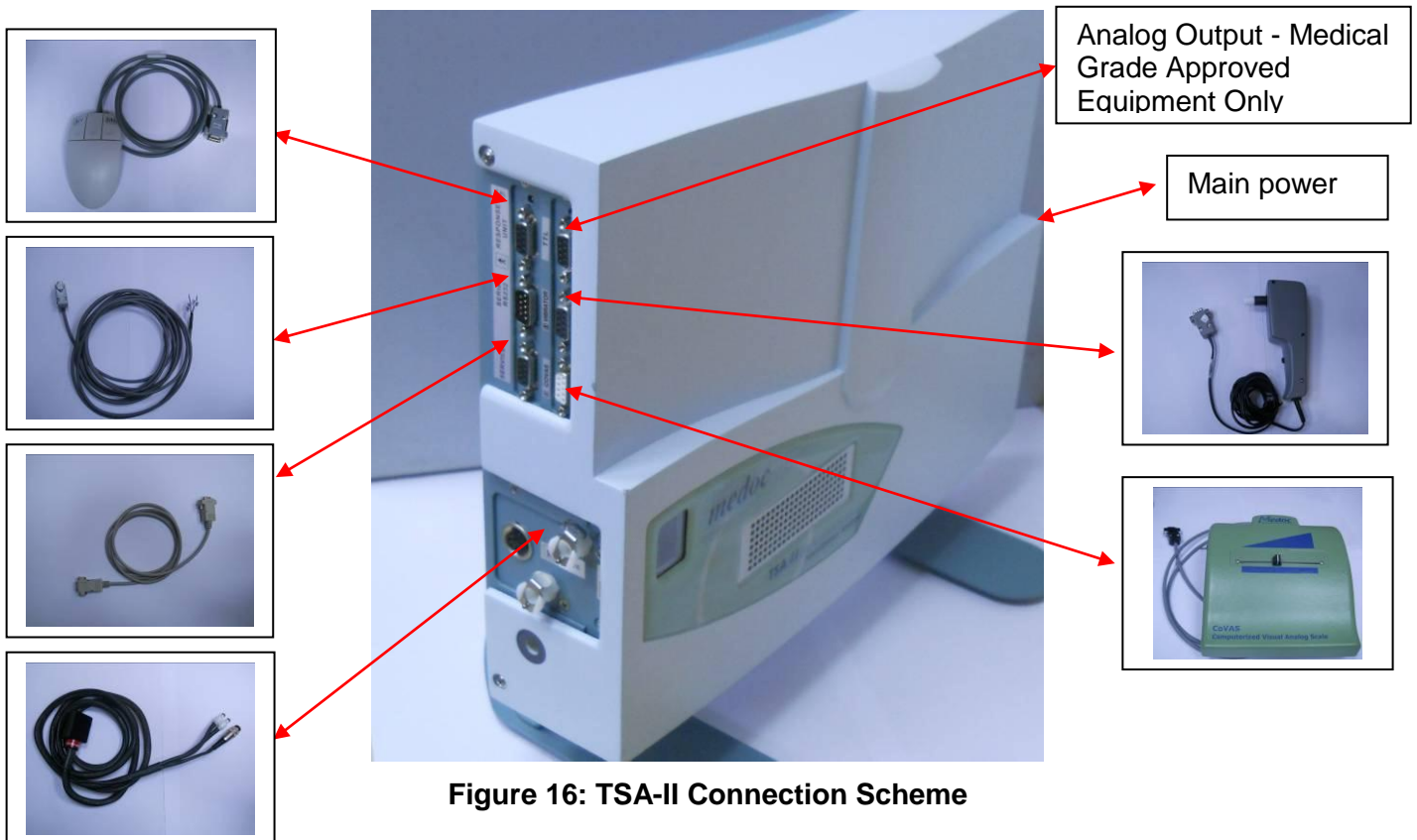


Figure 16: TSA-II Connection Scheme

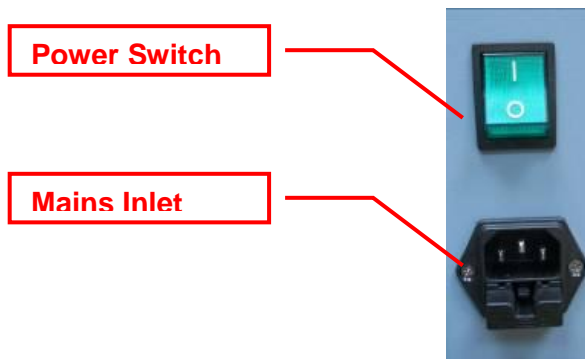


Figure 17: TSA-II Power Inlet



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.

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.



It is not allowed to connect the TSA-II computer to a network while running tests with the system!

The following instructions will guide you through the installation procedure:

1. Power **ON** the laptop and wait until the operating system is fully loaded.
2. **Insert** the MEDOC Main Station installation CD into the CD drive.
The install wizard is displayed preparing for the MEDOC Main Station installation.



If the installation does not start automatically, go to My Computer, open the MEDOC Main Station Installation CD and double-click the Setup.exe

3. The following screen is displayed:

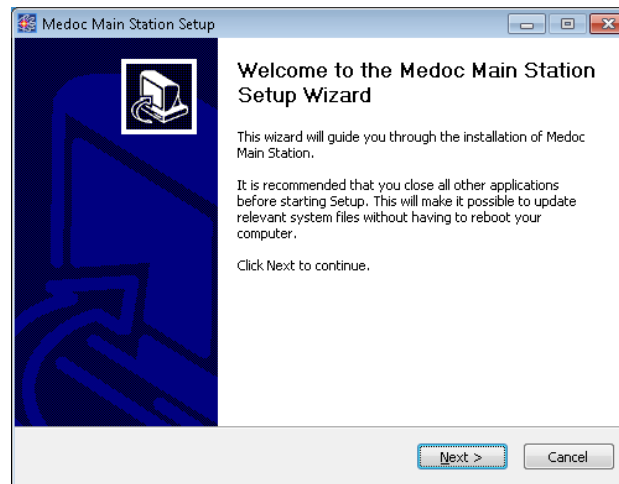


Figure 18: Main Station Installation 1

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

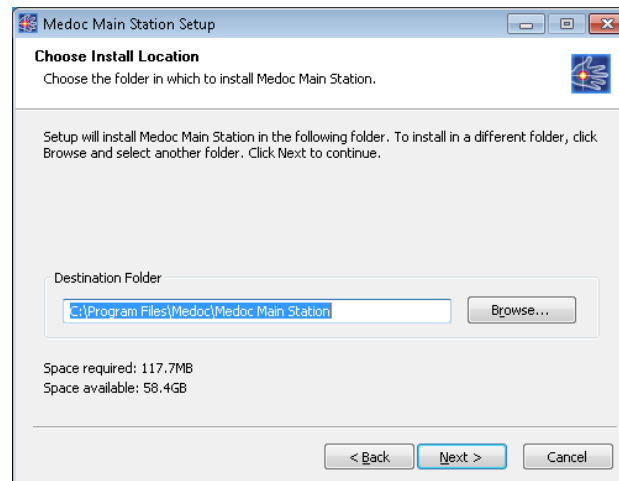


Figure 19: Main Station Installation 2



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

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

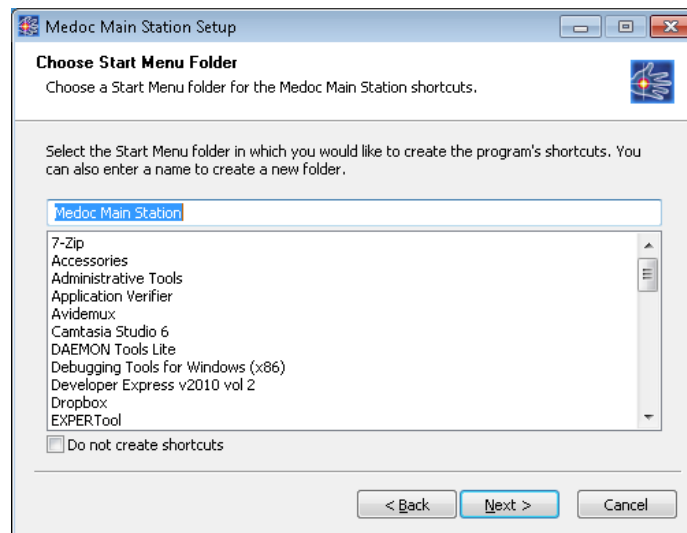


Figure 20: Main Station Installation 3

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

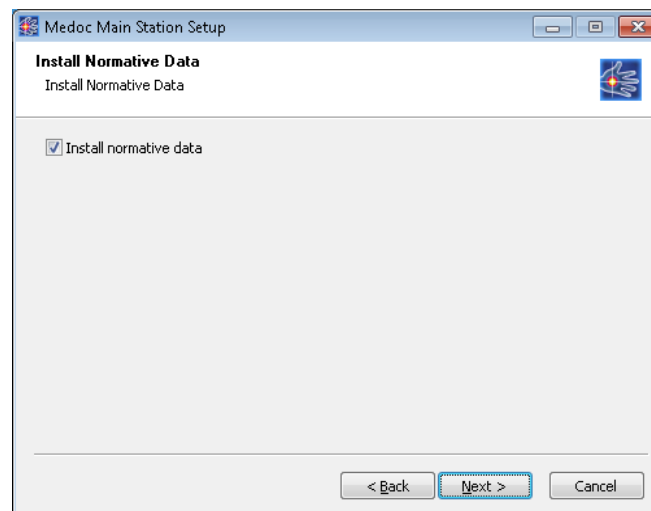


Figure 21: Main Station Installation 4

7. Select whether you wish to install the Normative Data or not, using the check box.
Click **Next** to continue the installation.
In case you select to install Normative Data, the following screen is displayed:

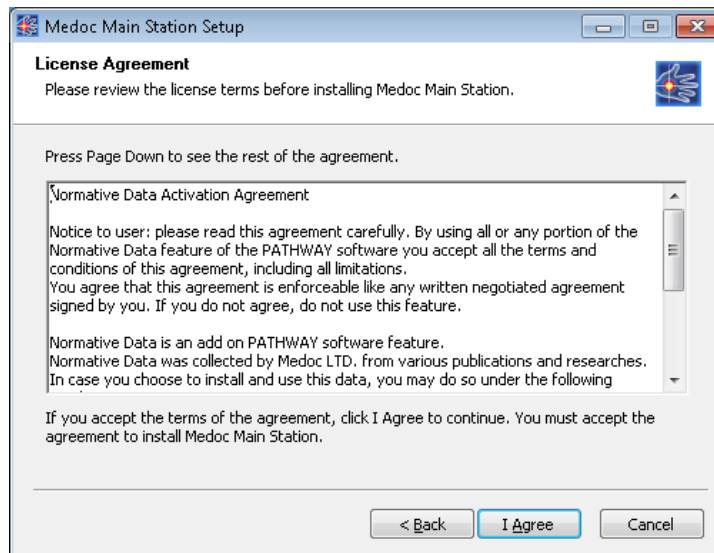


Figure 22: Normative Data license agreement

- If you accept the Normative Data license agreement, click **Next** to continue the installation.
 - If you do not accept the Normative Data license agreement, return to the previous screen by clicking **Back**. Uncheck the “Install Normative Data” Checkbox and click **Next** to continue.
8. Installation is now in progress.
 9. When the installation is complete the following screen is displayed:

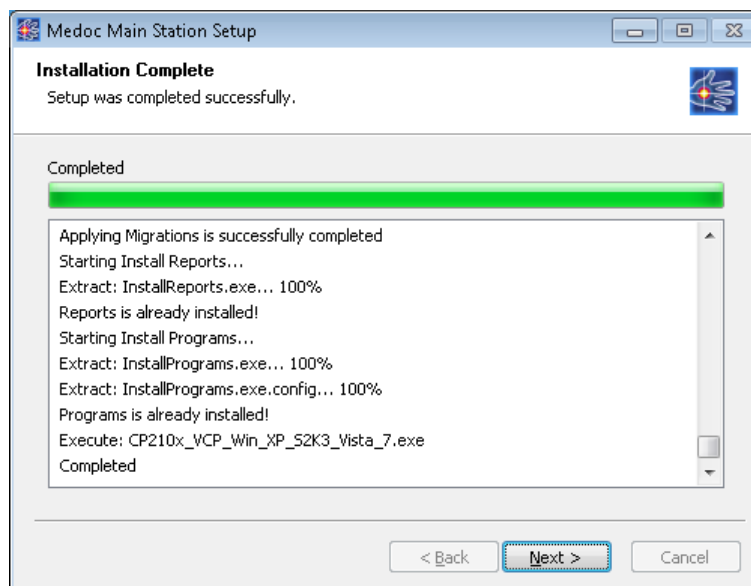


Figure 23: Main Station Installation 5

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

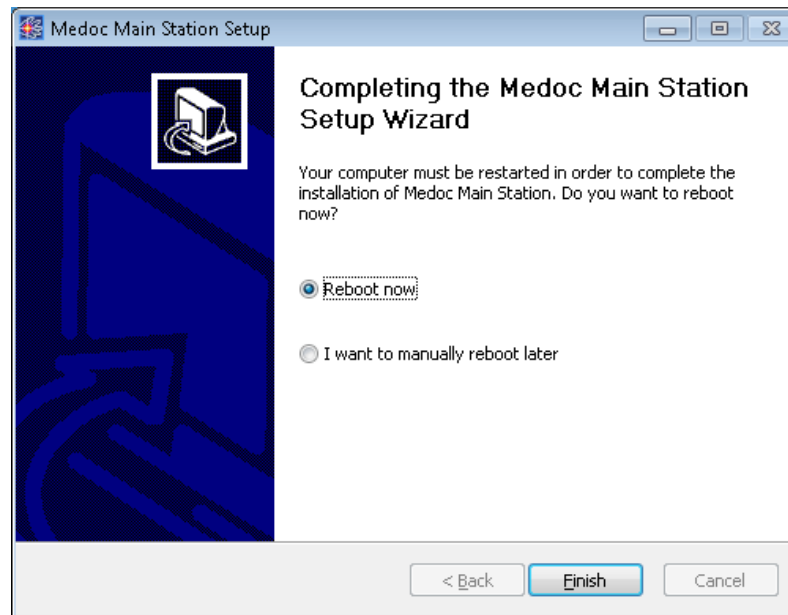


Figure 24: Installation Complete

11. Click **Finish** to close the wizard.
12. **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 can 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 25](#).



Figure 25: COM Port

2. Power up the TSA-II system by using the main switch on the side of the TSA-II system. See [Figure 5](#), page 28.

3. Start Medoc Main Station software by double-clicking the icon 



Continue to section 5, page 40 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.

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 water 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 5](#) page 28.
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 26: 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*.
For more information on user management please refer to section 10.1.6

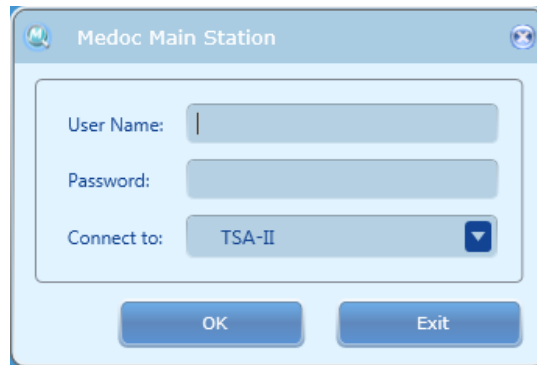


Figure 27: Login Screen

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

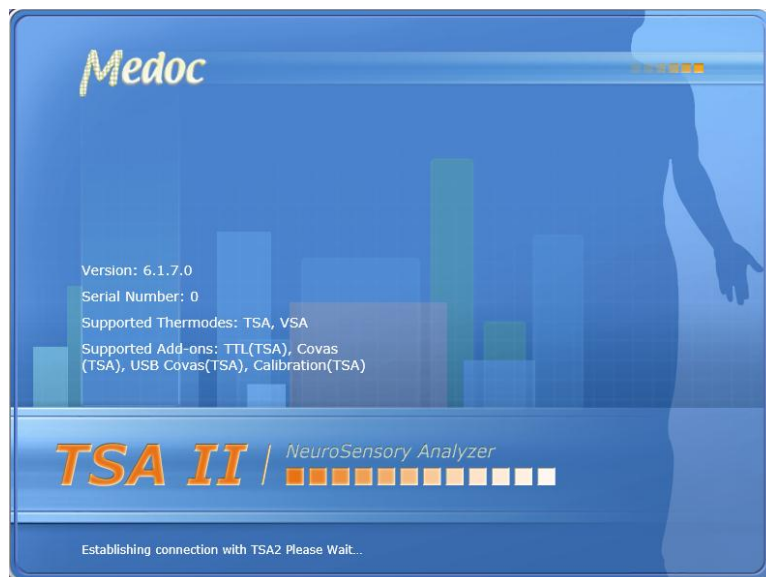


Figure 28: TSA-II Splash Screen

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 above. Make sure the Thermode is not attached to the Subject and click on OK on the following message:

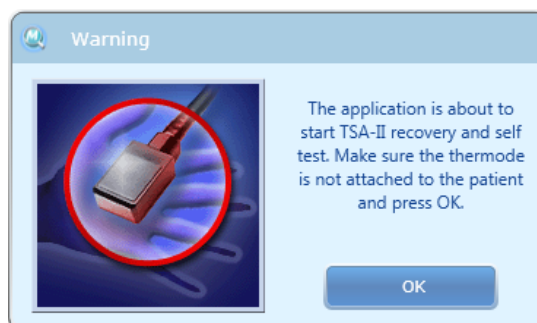


Figure 29: Self-Test Prompt.

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.

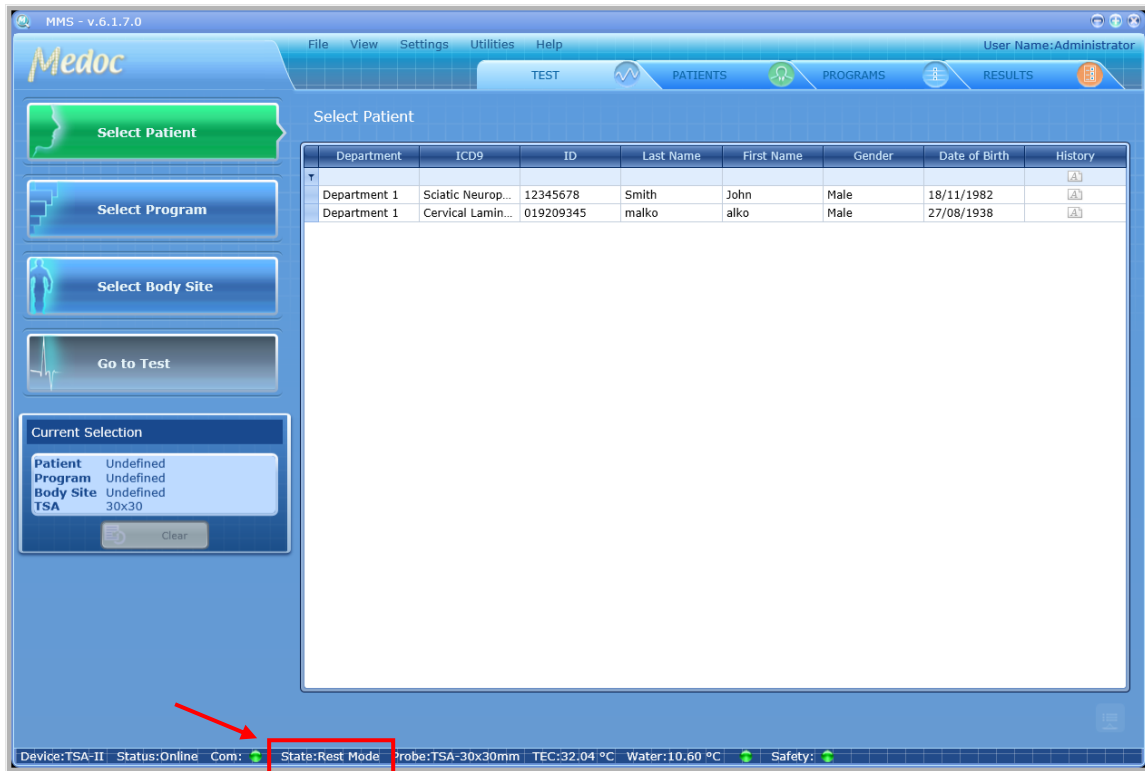


Figure 30: TSA II in Rest Mode

5.3 Basic Operation

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

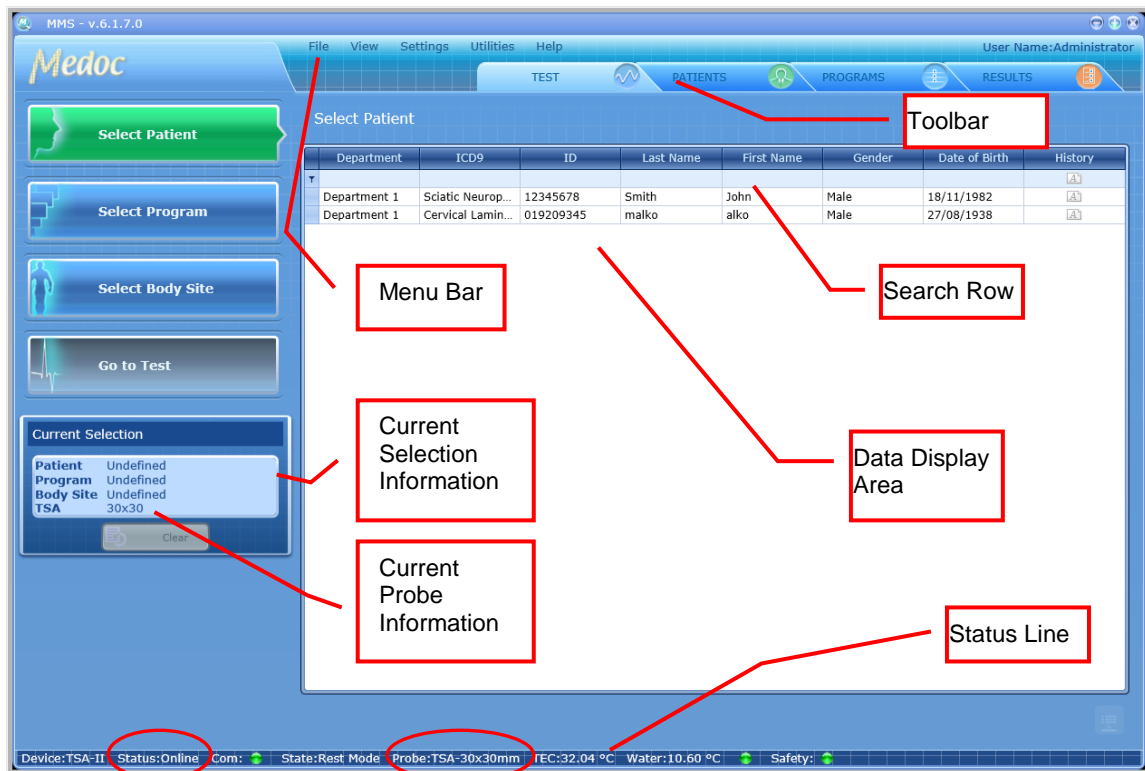


Figure 31: TEST screen – Main Menu



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). Refer to section 9.3 for further information.
	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.

Menu	Option	Description
	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)
	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

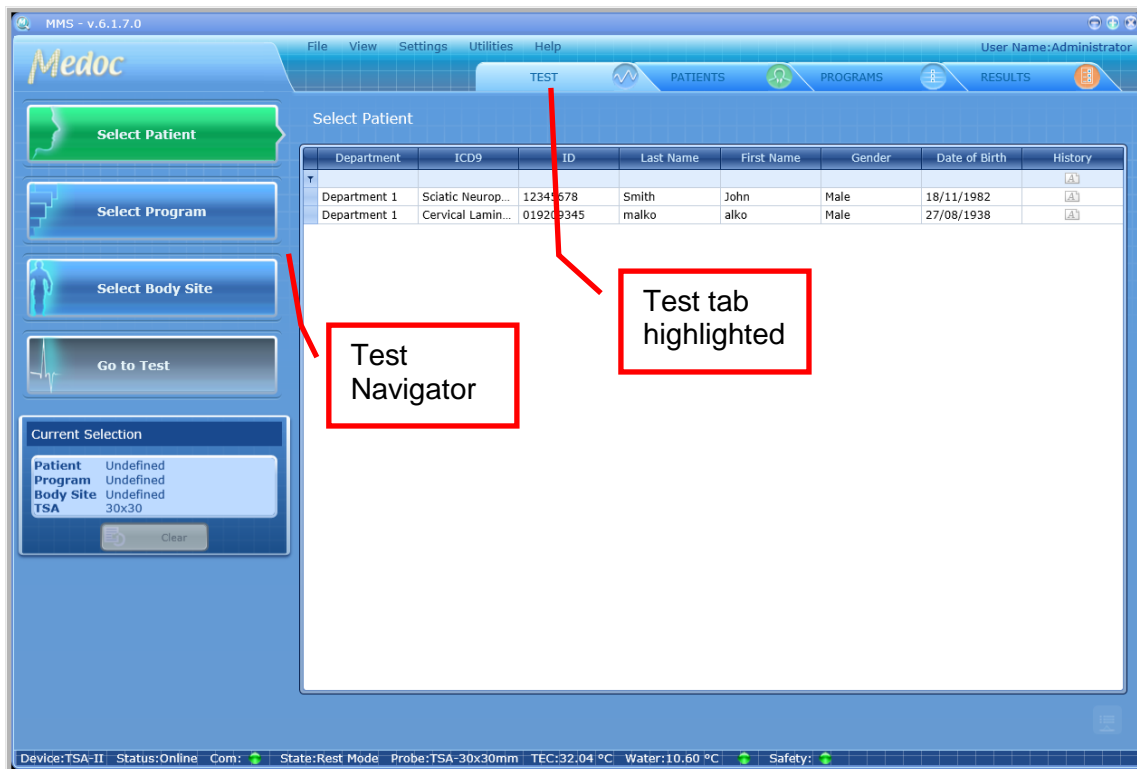


Figure 32: Test Management Main Screen

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.

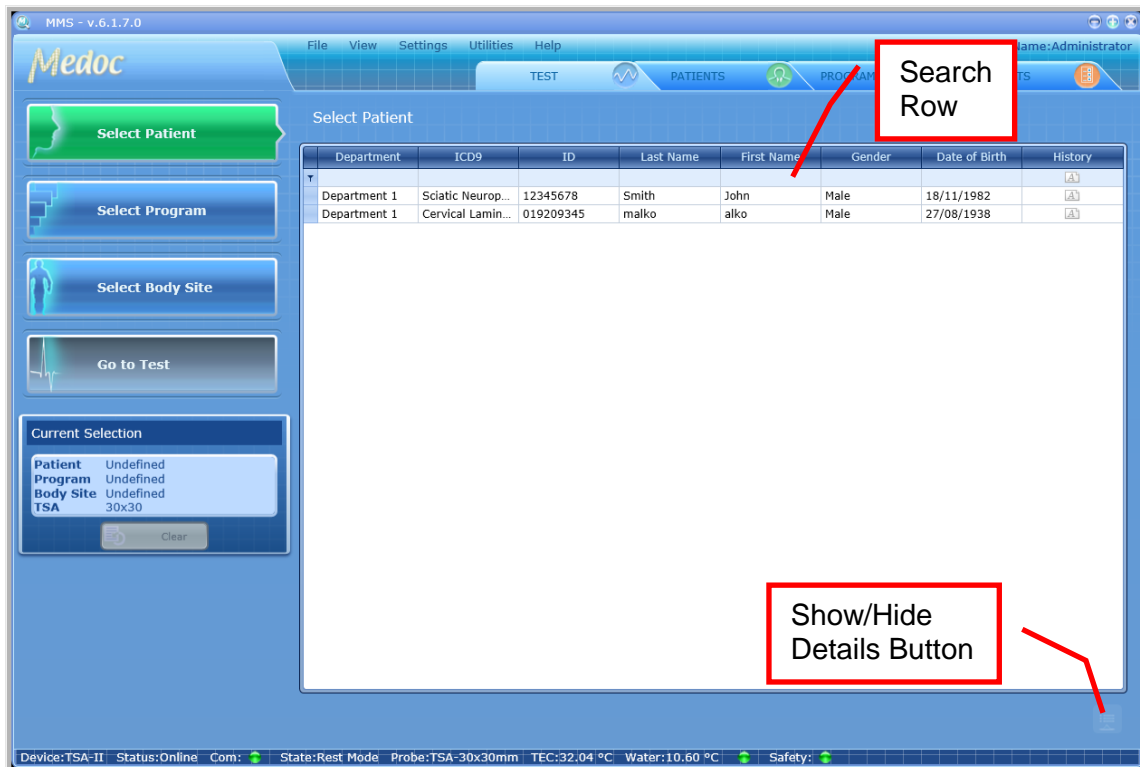



Figure 33: Patient Selection Menu

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 (section 8, page 75).

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.

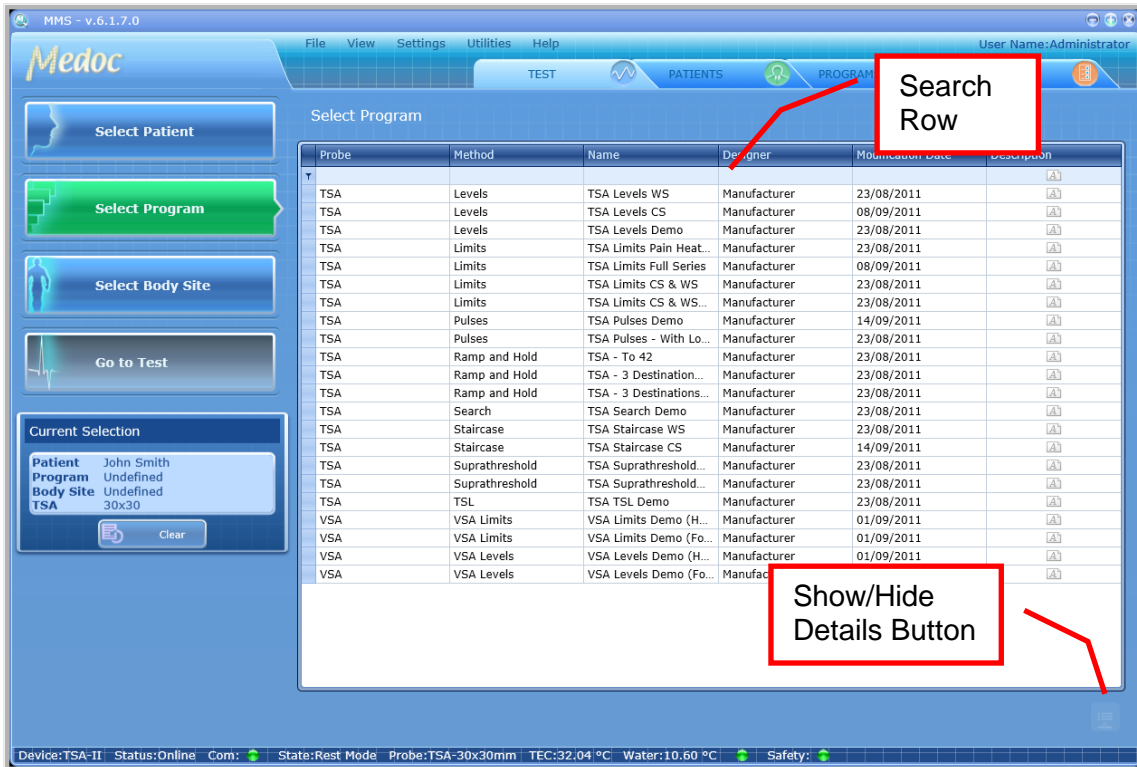


Figure 34: Program Selection Menu





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 (section 7, page 55).

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 35: Body Site Selection Menu

2. Click on the Dermatome (Dermatome 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 36: 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:

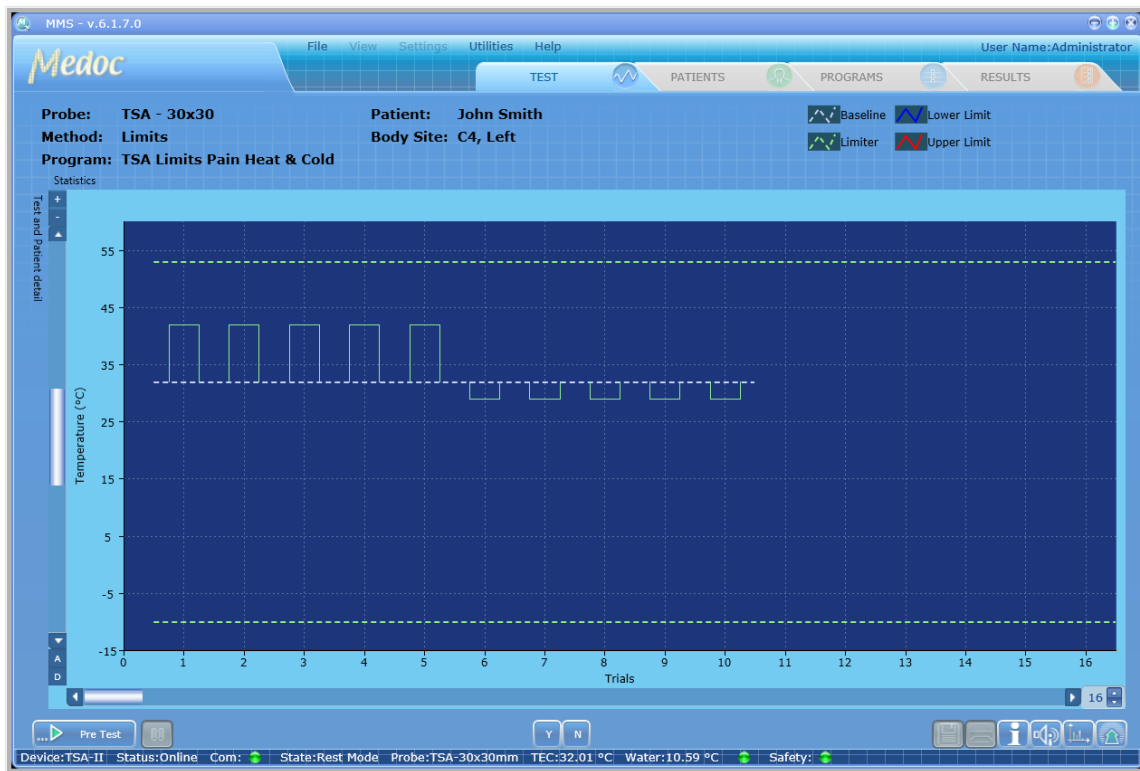



Figure 37: Pre-Test Screen

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 cursor 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

	Automatic zoom along the temperature axis. The temperature axis scale expands according to maximum temperature currently displayed on the screen. To reset the automatic zoom click the button again. Alternatively, change zoom manually by using the +/- buttons.
	Reset the zoom to the original (default) scale.
	Change the zoom along the time/trial axis, by changing the value in the spin box at the bottom right of the graph. Use the up/down arrows or type the value in the box.
	Print test results as a report. Refer to section 9.3 for details.
	Save the stimulation data.
	Display test instructions for the subject. To create or edit the default instructions, refer to section 10.3.2.1 page 109.
	Play audio test instructions for the subject. To assign an audio file with default instructions, refer to section 10.3.2.2, page 112.
	Return back to the Test Navigator to start a new test. Test results are not saved automatically. Remember to save the test results if needed, before leaving the Test Screen.
	Indicates positive subject response in Limits, Levels, TSL and Search protocols.
	Indicates negative subject response in Limits, Levels, TSL and Search protocols.
	Trigger the next stimulus. Available only when the manual trigger option is selected. The button is enabled only when the system expects a trigger.
	Edit the program locally. The edited parameters are effective only in the specific test and the program parameters are not changed in the data base.



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



After concluding a stimulation session, always clean the Thermode contact plate. For further details, refer to section 19, page 138.



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:

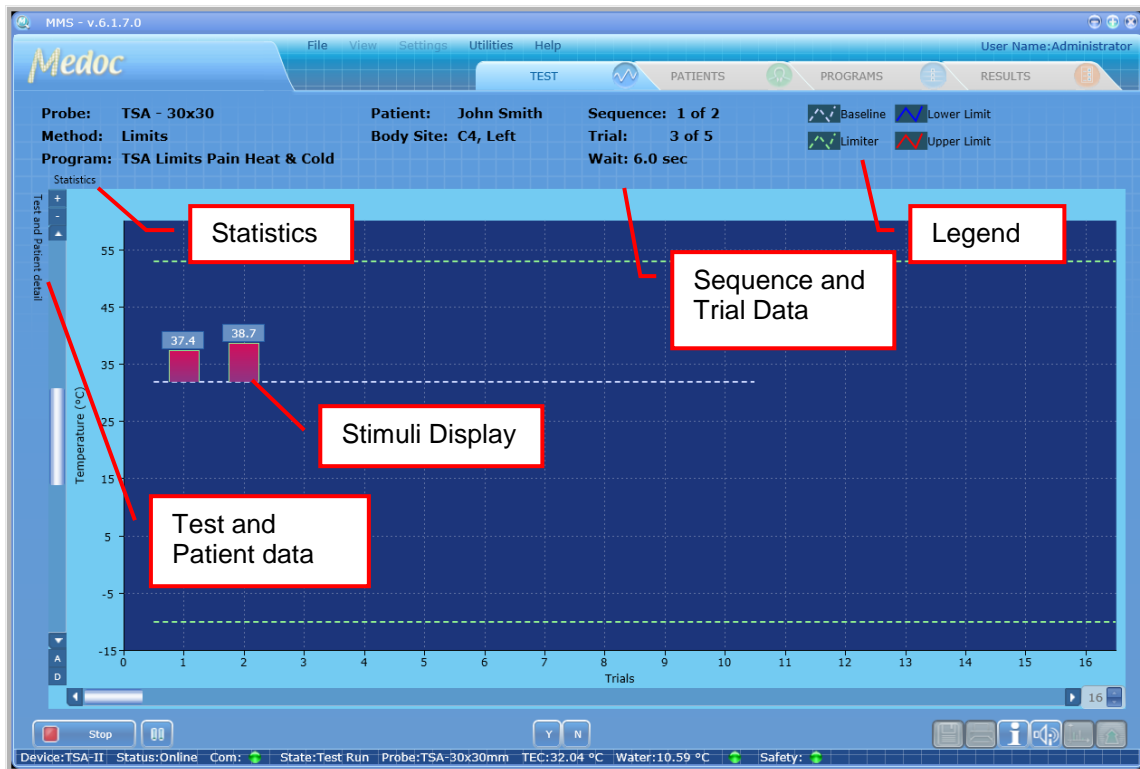


Figure 38: Real-Time Test









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. Program Management

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

7.1 Program List

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

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

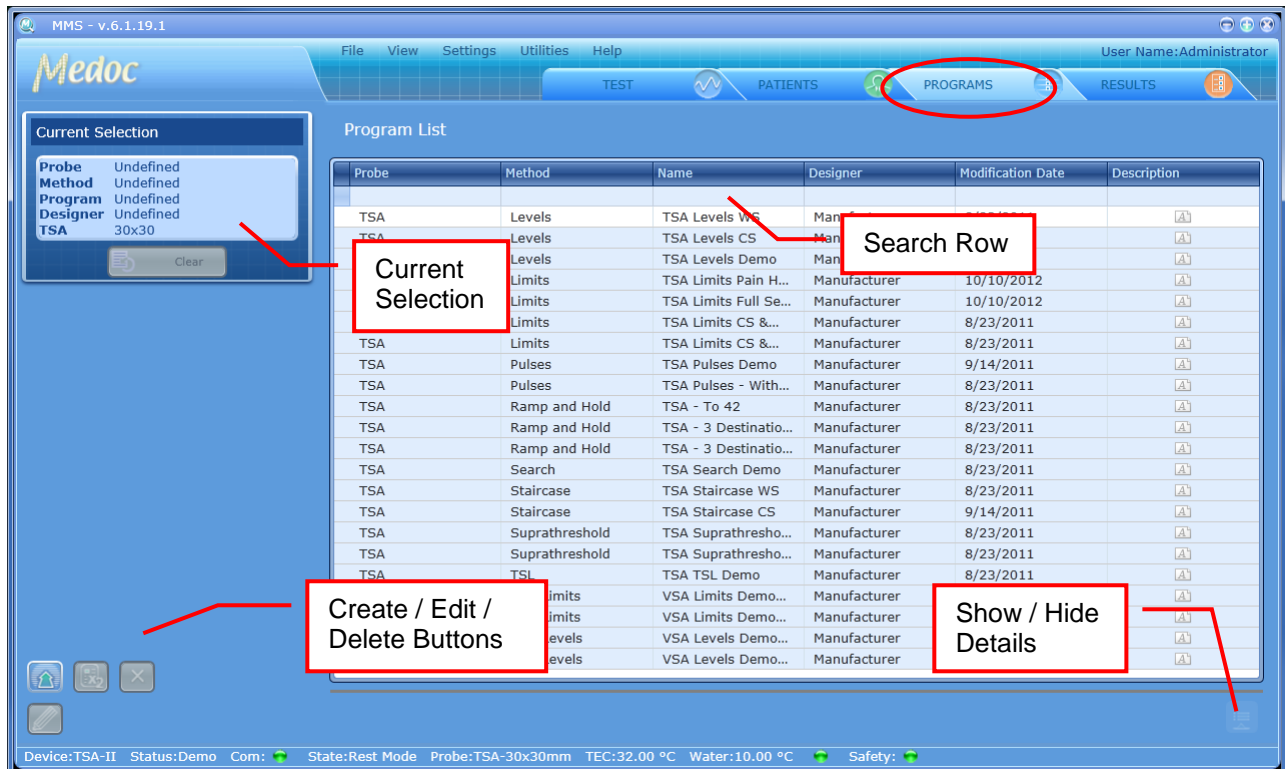








Figure 39: Program Management screen

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

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

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

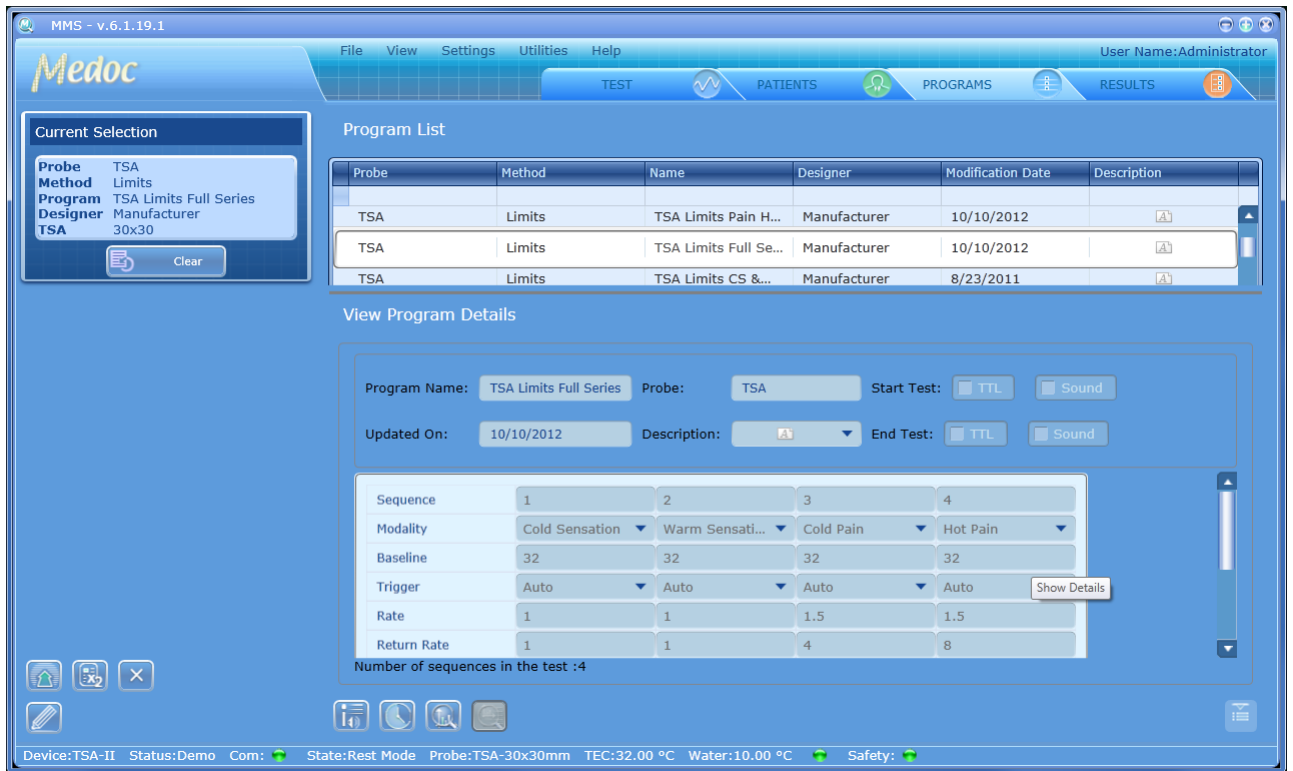






Figure 40: Program Management - Program Preview

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


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



Program details cannot be edited from the Program Details view.

7.2 Creating a New Program

To create a new program, perform the following procedure:

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

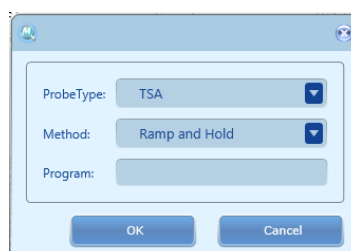


Figure 41: New Program Screen

2. From the **Probe Type** drop-down list, select the required probe:
 - 2.1. Select TSA for a Thermal Program
 - 2.2. Select VSA for a Vibratory Program
3. From the **Method** drop-down list, select the required stimulation method
4. Enter a program name and click **OK** to create a new program.
5. Edit the program parameters in the Program Editor, see section 7.3 below.

7.3 Program Editor



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

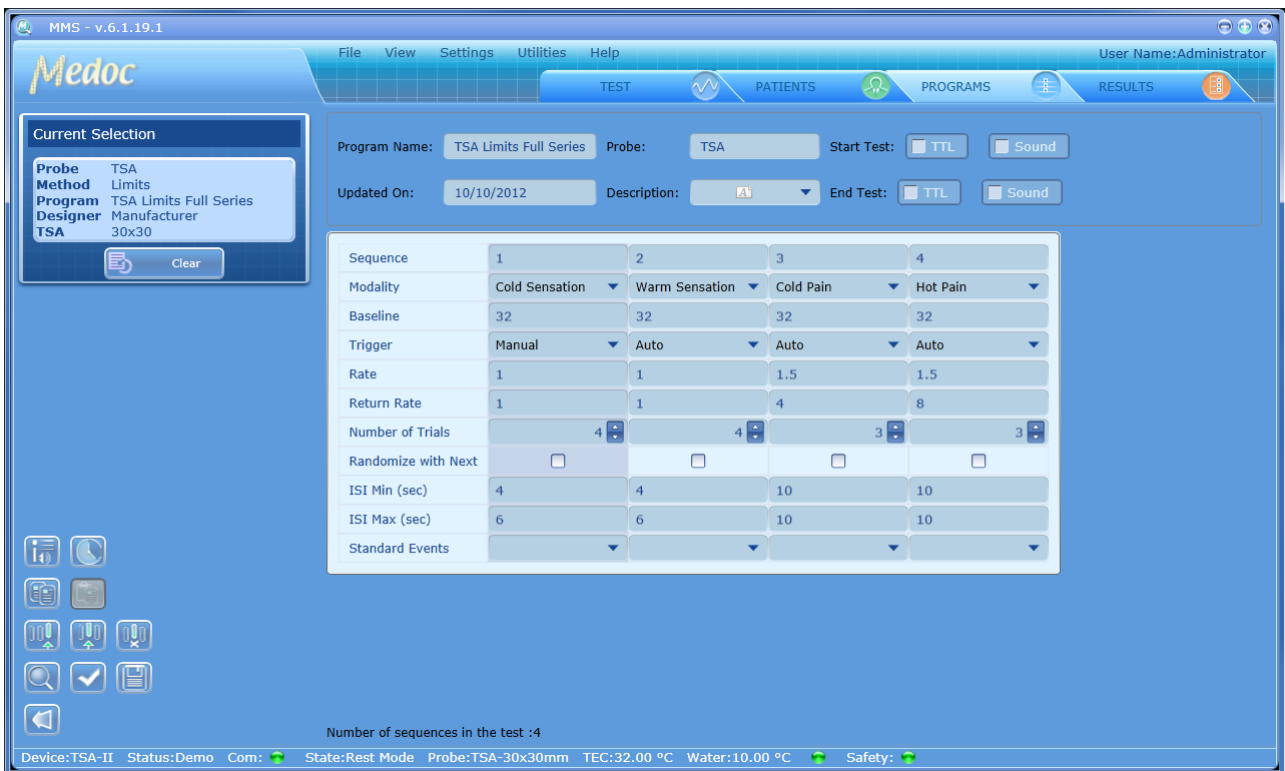


Figure 42: Program Editor Screen












The top part of the program editor displays global details which are available for all methods. The lower part of the program editor displays the specific program parameters according to the selected method. For detailed information about the program parameters, continue to section 7.4.

The following program details are available:

Table 10: Program Details

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

The following options are available from the Program Editor screen:



	View program revision history by version date and username.
	Edit text and audio instructions. Refer to section 7.6, page 72
	Exit Program Editor screen
	Copy the selected sequence
	Paste the copied sequence
	Add a new sequence at the end of the test
	Add a new sequence after the selected sequence
	Delete the selected sequence
	Preview the temperature graph
	Check that all program parameters are valid
	Save changes



When adding or editing programs, follow these rules:

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



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

7.4 Program Details

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

7.4.1 Limits

In this method, the system generates a number of stimuli of continuously changing intensity. With each stimulus, when the subject perceives a predefined sensation, he/she manually stops the stimulus. For an additional description of the method refer to section 2.7.1, page 25.

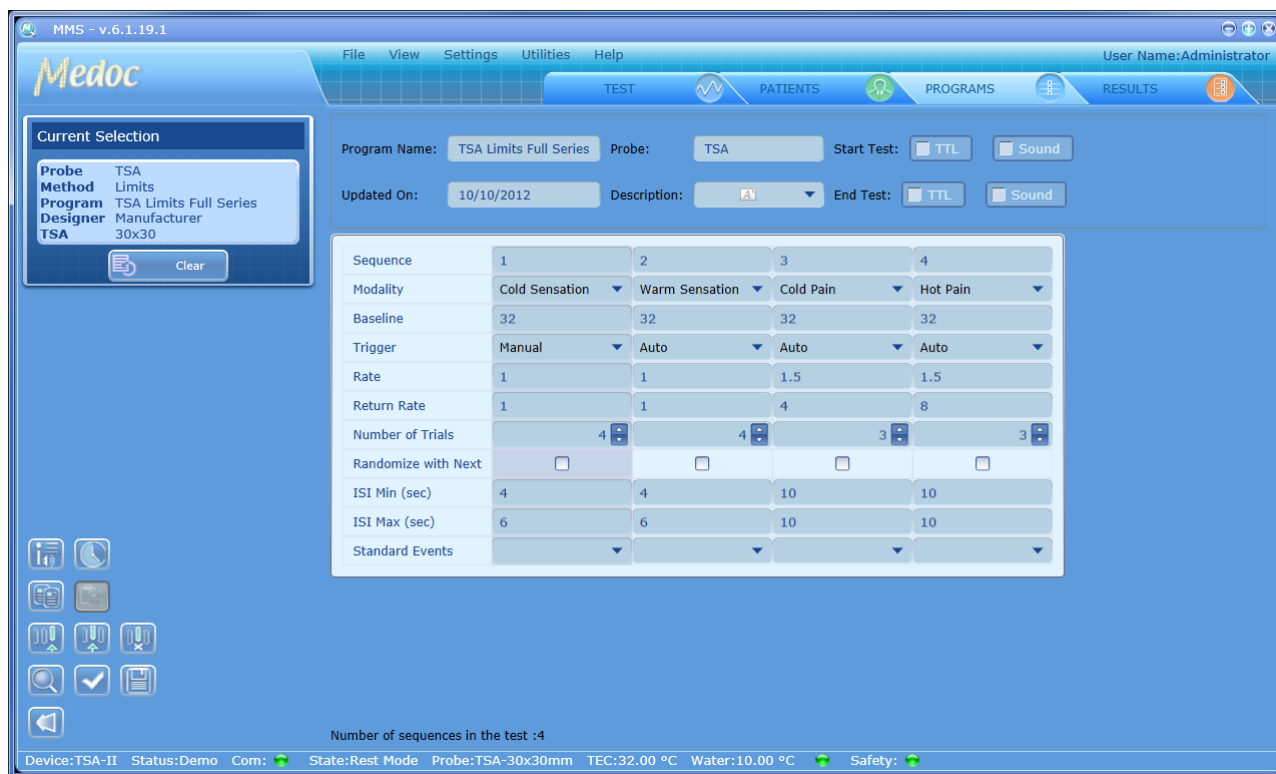


Figure 43: Program Editor – Limits

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

Table 11: Program Parameters

Parameter	Description
Modality	Four different types of sensation can be delivered to the subject: Warm sensation; Cold sensation; Hot pain; Cold pain.
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 10°C to 45°C.
Trigger	Trigger mode: <ul style="list-style-type: none"> Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). Manual – The operator will initiate the onset of the stimulus after the defined ISI. External – The onset of the stimulus will be initiated by an external system via TTL In (see Technical Specifications)
Rate (°C/sec)	Defines the temperature change rate from the baseline temperature until the subject responds. Valid range: 0.1 to 4°C/Sec.

Return Rate (°C/sec)	Defines the temperature change rate when stimulus returns to baseline temperature after the subject has responded. Valid range: 0.1 to 8°C/Sec.
Number of Trials	The number of trials per sequence. Valid range: 1 to 100
Randomize with next	Randomize trials with next sequence
ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
ISI Max (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Standard Events	Different evens which can be indicated during the test via TTL or Sound See section 7.5.2.1



The above program parameters refer to Thermal Limits method. Parameter values or definitions may vary slightly for Vibratory tests.

7.4.2 Levels

In this method, the system generates a number of stimuli of changing intensity according to the subject response. With each stimulus, the subject receives a stimulation of varying intensity which is determined according to his previous response. Test is terminated after predefined temperature step size and number of alternations is achieved. For a method explanation, refer to section 0, page 25.

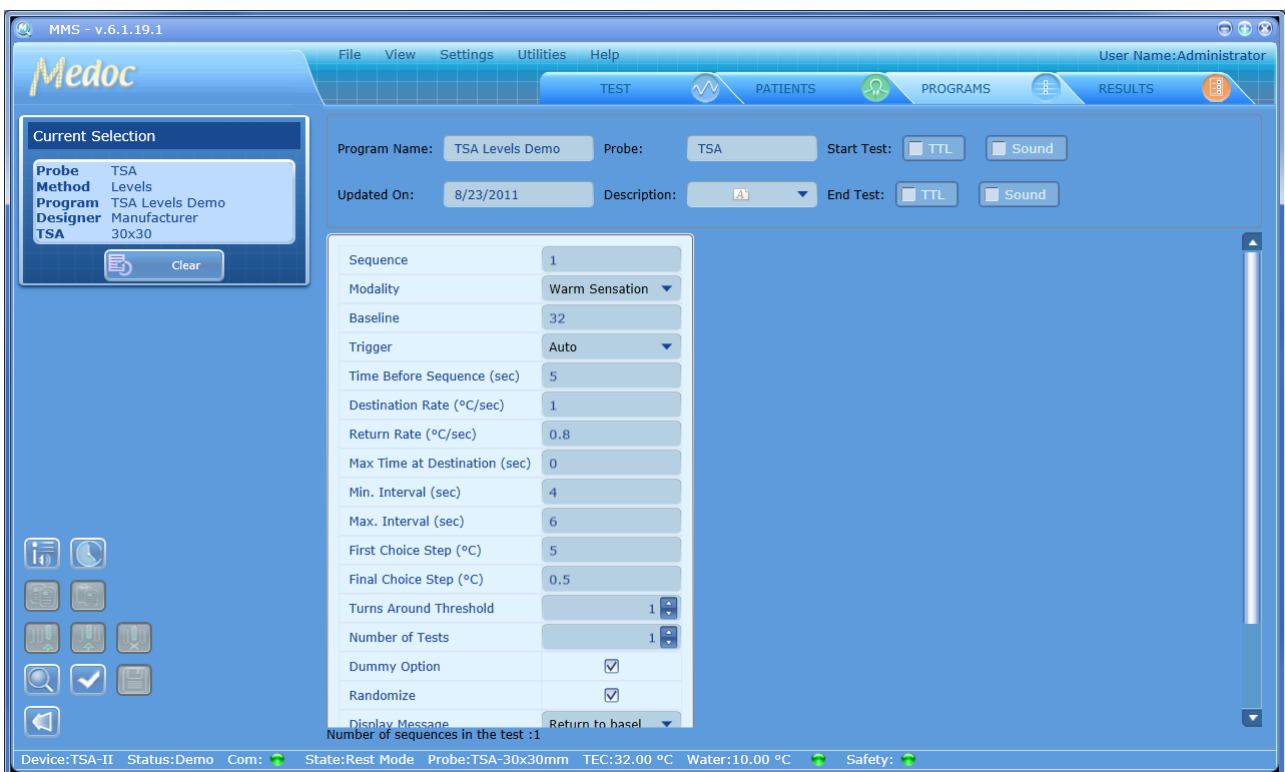


Figure 44: Program Editor – Levels

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

Table 12: Program Parameters

Parameter	Description
Modality	Two different types of sensation can be delivered to the subject: Warm Sensation and Cold Sensation.
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 20°C to 45°C.
Trigger	Trigger mode: <ul style="list-style-type: none"> • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). • Manual – The operator will initiate the onset of the stimulus after the defined ISI. • External – The onset of the stimulus will be initiated by an external system via TTL In (see Technical Specifications)
Time Before Sequence (sec)	The time interval before the first trial. Valid range: 0 to 600 (sec).
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. Valid range: 0.1 to 5°C/Sec
Return Rate (°C/sec)	Defines the temperature change rate from destination back to baseline temperature. Valid range: 0.1 to 5°C/Sec.
Max. Time at Destination (sec)	Defines the maximum duration for Thermode temperature to remain at destination temperature before returning to baseline. If subject's response is 'YES' – the temperature will immediately return to baseline. If subject's response is 'NO' – the temperature will remain at destination for the maximum duration as specified. Valid range: 0 to 600 (sec). May be limited by safety limitations.
Min. Interval (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
Max. Interval (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
First Choice Step (°C)	The initial step size that is used until the first 'YES' response is given. Valid range: 0.2 to 5 °C
Final Choice Step (°C)	The smallest step size that is used in the final Turns Around Threshold. Valid range: 0.1 to 2 °C
Turns Around Threshold	The number of turns (alternating 'YES' and 'NO' responses) at the Final Choice Step which is required to complete the test. Valid range: 1 to 10.
Number of Tests	The number of repetitions for entire test. Valid range: 1 to 5.
Dummy Option	Randomized dummy trials where no actual stimulus is given to increase test reliability. Frequency of dummy trials is randomized with an average of 10% of all trials.
Randomize	Randomize between trials of several tests.

Display Message	Define when message to respond is displayed: <ul style="list-style-type: none"> • Destination – Display message upon reaching destination temperature • Return to Baseline – Display message after temperature returns to baseline.
No Response on Destination	Define program behavior if subject responds with 'NO' before the Maximum Time at Destination duration is over. <ul style="list-style-type: none"> • Always Accept – Accept the test subject response and continue test according to it • Always Repeat – Ignore the test subject response and repeat same trial again • Manually Select – Save the test subject response and prompt the test Operator to decide whether to Accept (A) the response or Ignore (I) and repeat same trial.
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.5.2.1
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.5.1 .



The above program parameters refer to Thermal Levels method. Parameter values or definitions may vary slightly for Vibratory tests.

7.4.3 Thermal Sensory Limen (TSL)

In this method, the system generates warm sensation and cold sensation stimuli, alternating according to the subject response. The stimuli direction changes after each subject response. For a method explanation, refer to section [2.7.3](#), page [25](#).

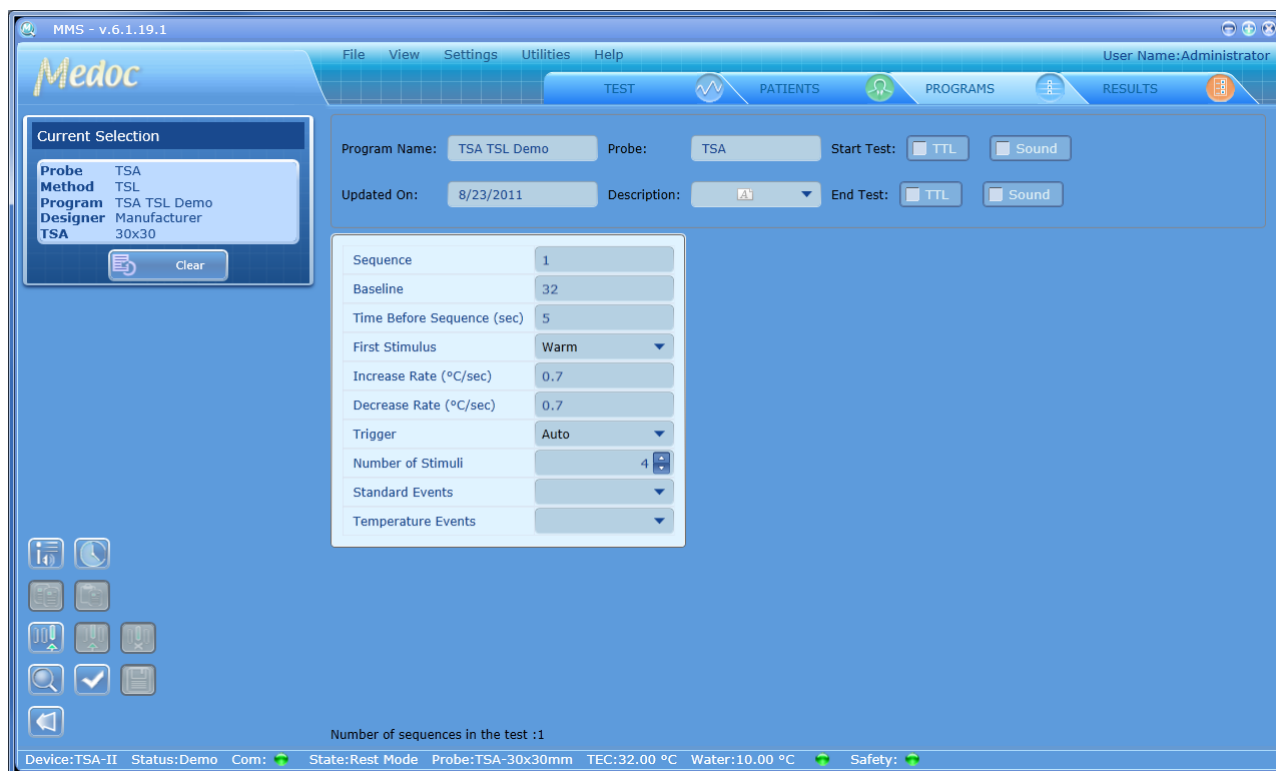


Figure 45: Program Editor – TSL

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

Table 13: Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 20°C to 45°C.
Time Before Sequence (sec)	The time interval before the first trial. Valid range: 0 to 600 (sec).
First stimulus	Define direction of first stimulus: warm or cold
Increase Rate (°C/sec)	Defines the temperature change rate for increasing temperature. Valid range: 0.1 to 8°C/sec.
Decrease Rate (°C/sec)	Defines the temperature change rate for decreasing temperature. Valid range: 0.1 to 8°C/sec.
Number of stimuli	Number of stimuli until the test ends (each subject response is counted as one stimulus).
Trigger	Trigger mode: <ul style="list-style-type: none"> Automatic – the stimuli will start automatically Manual – The operator will initiate the onset of the stimuli External – The onset of the stimuli will be initiated by an external system via TTL In (see Technical Specifications)
Standard Events	Different events which can be indicated during the test via TTL or Sound See section 7.5.2.3
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.5.1 .

7.4.4 Suprathreshold

In this method, the temperature rises (or falls) to a predetermined destination, at a predetermined rate, remains there for a predetermined duration, and returns to the next destination. Patient estimation of perceived magnitude of sensation is recorded for each stimulus. For a method explanation, refer to section 2.7.4, page 25.

Sequence	1	2	3	4
Baseline	32	32	32	32
Trigger	Auto	Auto	Auto	Auto
Destination Rate	1.5	2	2	2
Number of Trials	1	2	1	1
Destination Temperature (°C)	10	38	41	44
Duration Time (sec)	10	6	6	6
ISI min	4	4	4	4
ISI max	4	4	4	4
Randomize with Next	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Standard Events	[dropdown]	[dropdown]	[dropdown]	[dropdown]
Temperature Events	[dropdown]	[dropdown]	[dropdown]	[dropdown]

Number of sequences in the test : 4

Device:TSA-II Status:Demo Com: [green] State:Rest Mode Probe:TSA-30x30mm TEC:32.00 °C Water:10.00 °C [green] Safety: [green]

Figure 46: Program Editor – Suprathreshold

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

Table 14: Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 20°C to 40°C.
Trigger	Trigger mode: <ul style="list-style-type: none"> Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). Manual – The operator will initiate the onset of the stimulus after the defined ISI. External – The onset of the stimulus will be initiated by an external system via TTL In (see Technical Specifications)
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. Valid range: 0.1 to 8°C/Sec
Number of Trials	The number of trials per sequence. Valid range: 1 to 100
Destination Temperature (°C)	Defines the destination temperature for all trials in the current sequence. Valid range is limited by safety limitations and depends on the duration time.
Duration Time (sec)	Defines the duration for Thermode temperature to remain at destination temperature before returning to baseline. Valid range: 0 to 600 (sec)

ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
ISI Max (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.5.2
Temperature Points	Indicate when Thermode temperature reaches specific temperature points. See section 7.5.1.

7.4.5 Staircase

In this method, the system generates a number of stimuli of changing intensity according to the subject response. With each stimulus, the subject receives a stimulation of varying intensity which is determined according to his previous response. Test is terminated after predefined temperature step size and numbers of negative responses (NO) are achieved. For a method explanation, refer to section 0, page 26.

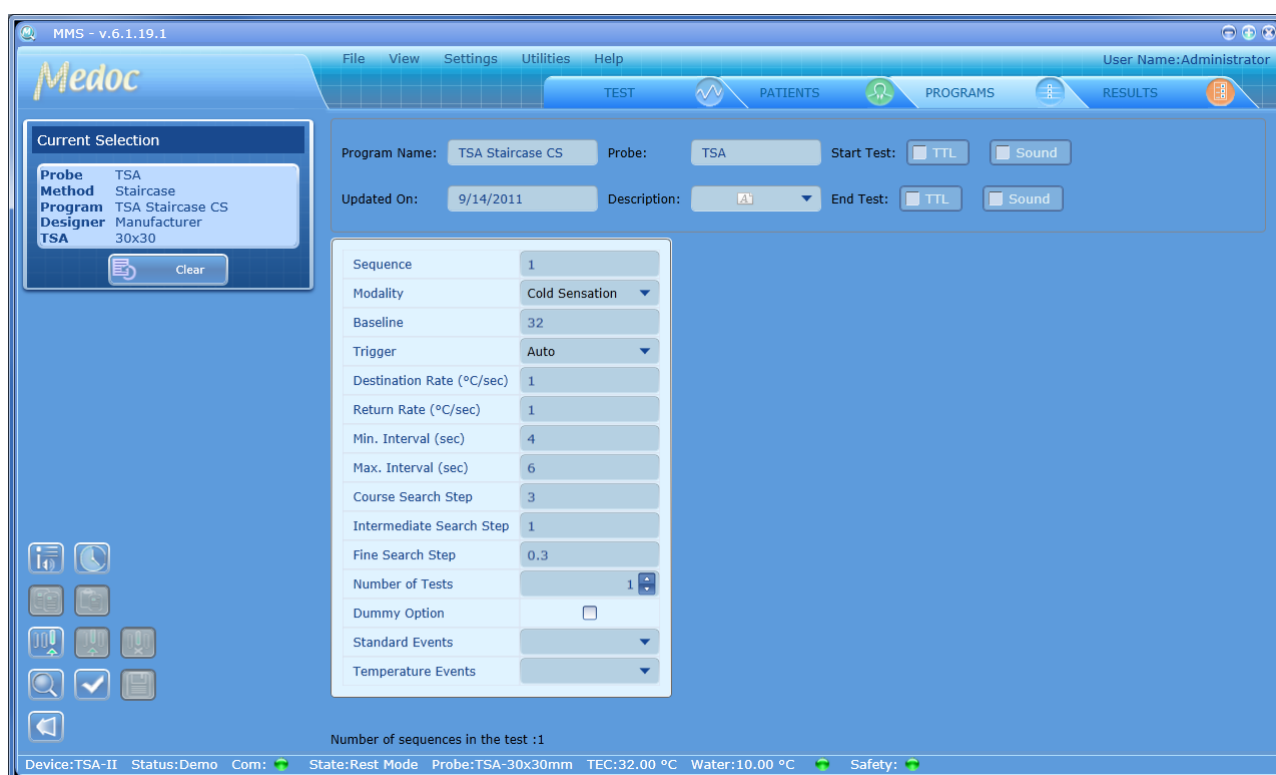


Figure 47: Program Editor – Staircase

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

Table 15: Program Parameters

Parameter	Description
Modality	Two different types of sensation can be delivered to the subject: Warm Sensation and Cold Sensation.
Baseline (°C)	Temperature from which each new stimulation sequence begins – between 20°C to 45°C.

Trigger	Trigger mode: <ul style="list-style-type: none"> Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). Manual – The operator will initiate the onset of the stimulus after the defined ISI. External – The onset of the stimulus will be initiated by an external system via TTL In (see Technical Specifications)
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. Valid range: 0.1 to 5°C/Sec
Return Rate (°C/sec)	Defines the temperature change rate from destination back to baseline temperature. Valid range: 0.1 to 5°C/Sec.
Min. Interval (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)
Max. Interval (sec)	Maximum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec). Actual ISI will be randomized between min and max values.
Course Search Step (°C)	The initial step size that is used until the first 'YES' response is given. Valid range: 0.5 to 10 °C
Intermediate Search Step (°C)	The step size that the stimuli is decreased by until the first 'NO' response is given. Valid range: 0.3 – 5 °C
Fine Search Step (°C)	The smallest step size that is used in the final Turns Around Threshold. Valid range: 0.3 to 1 °C
Number of Tests	The number of repetitions for entire test. Valid range: 1 to 5.
Dummy Option	Randomized dummy trials where no actual stimulus is given to increase test reliability. Frequency of dummy trials is randomized with an average of 10% of all trials.
Standard Events	Different events which can be indicated during the test via TTL or Sound. See section 7.5.2.1
Temperature Events	Indicate when Thermode temperature reaches specific temperature points. See section 7.5.1 .

7.4.6 Chain Program Option

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

As can be viewed in [Figure 48](#), a program list is present for the user to choose from, when constructing the master program.

Each sub-program is defined by the following factors:

Table 26: Chain sub program parameters

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

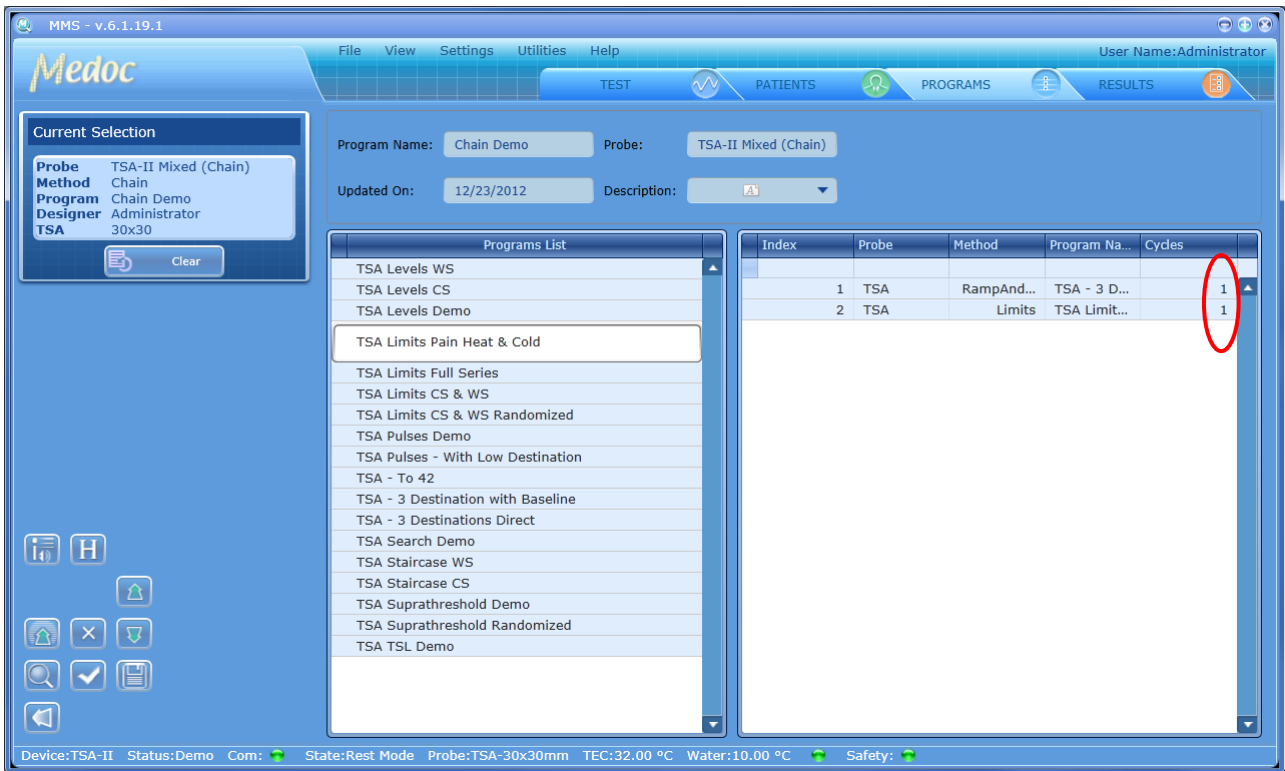


Figure 48: Program Chain

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

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

Table 16: Program Details

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

Table 17: Program Table

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

The following additional functions are available:



Adds the program selected from the Program List to the chained list, below the selected program in the chained program list.



Deletes the selected program from the chained program list.



Moves the selected program up the index (up the list).



Moves the selected program down the index (down the list).

7.5 Marking Events

The purpose of these options is to draw attention to various events that occur during the test. Each event can be marked by a 1-bit TTL, which can be assigned a sound or textual alert.

An event can be:

- Specific temperature – for example, when the temperature drops to 28.5°C.
- Standard events – for example, when a test sequence starts (onset).

Standard and Temperature events can be acquired in the following way:

- 1-bit TTL – through the front panel **TTL Out** D-type connector and custom made cable (can be ordered from Medoc).



1-bit TTL is sent only if an event is marked.

7.5.1 Temperature Events

This function enables you to mark temperatures, at which the behavior of the tested subject is of interest. It is possible to mark the arrival of the stimuli at five temperature points, either when heating-up or when cooling-down. A temperature point is indicated by an asterisk (*), and can be accompanied by either a TTL signal, or by a sound, or by both.

1. From the Program Details screen, click the **Temperature points** arrow at the bottom of the relevant sequence setting (column).

The following dialog is displayed:

		Temperature Events			Direction	
		TTL	Snd	Temp		
<input type="checkbox"/>	Temp. Point :	<input type="checkbox"/>	<input type="checkbox"/>	40	<input type="button" value="Up"/>	<input type="button" value="Down"/>
<input type="checkbox"/>	Temp. Point :	<input type="checkbox"/>	<input type="checkbox"/>	40	<input type="button" value="Up"/>	<input type="button" value="Down"/>
<input type="checkbox"/>	Temp. Point :	<input type="checkbox"/>	<input type="checkbox"/>	40	<input type="button" value="Up"/>	<input type="button" value="Down"/>
<input type="checkbox"/>	Temp. Point *	<input type="checkbox"/>	<input type="checkbox"/>	40	<input type="button" value="Up"/>	<input type="button" value="Down"/>
<input type="checkbox"/>	Temp. Point !	<input type="checkbox"/>	<input type="checkbox"/>	40	<input type="button" value="Up"/>	<input type="button" value="Down"/>

Figure 49: Temperature Points Dialog

2. Mark the desired alert type:

- 10.1. TTL – by issuing a TTL signal

- 10.2. Snd – by sounding an audio signal.
- 3. Type the desired alerted temperature.
- 4. Mark whether the set temperature will be marked on the ascending slope (Up) or on the descending slope (Down).
- 5. Click anywhere on the screen, or on the X mark at the corner of the window, to close the Temperature Points dialog.

7.5.2 Standard Events

This function enables you to mark standard events that occur along the test, such as arrival at the target temperature.

Standard events vary according to the activated test method.



In the Search method, the Standard events are temperature points.

7.5.2.1 Limits

- a. From the **Program Details** screen, click the **Standard events** arrow at the bottom of the relevant sequence setting (column). The following dialog is displayed, listing the standard events, applicable to the Limits method:



Figure 50: Limits – Standard Events Dialog



1-bit TTL is always sent in each event that is marked.

The following event can be marked:

Table 18: Events - Limits

Parameter	Description
Onset 1 – Onset 5	The beginning of the trial, using the Limits method.

- b. Mark the desired alert type:
 - 1. TTL – by issuing a TTL signal.
 - 2. Snd – by sounding an audio signal.
- c. Click anywhere on the screen, or on the X mark at the corner of the window, to close the Standard Events dialog.

7.5.2.2 Levels

- From the **Program Details** screen, click the **Standard events** arrow at the bottom of the sequence setting (column).

The following dialog is displayed, listing the standard events applicable to the Levels method:

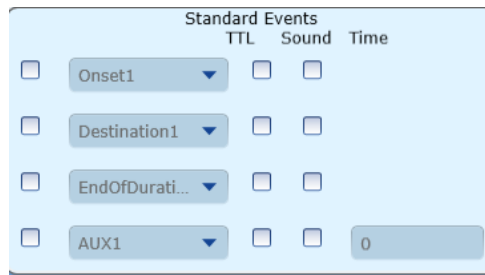


Figure 51: Levels – Standard Events Dialog



1-bit TTL is always sent in each event that is marked.

The following events can be marked:

Table 19: Events - Levels

Parameter	Description
Onset 1 – Onset 5	The beginning of the trial, using the Levels method.
Destination 1 – Destination 5	The arrival at the target temperature.
End of duration 1 – End of Duration 5	The beginning of temperature descent.
AUX 1 – AUX 5	The auxiliary time, from onset to the initial temperature change.

- Mark the desired alert type:
 - TTL – by issuing a TTL signal.
 - Snd – by sounding an audio signal.
- Click anywhere on the screen, or on the X mark at the corner of the window, to close the Standard Events dialog.

7.5.2.3 TSL

- From the **Program Details** screen, click the **Standard events** arrow at the bottom of the relevant sequence setting (column).

The following dialog is displayed, listing the standard events applicable to the TSL method:

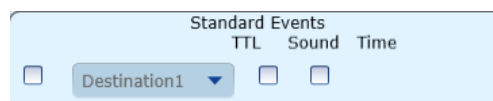


Figure 52: TSL – Standard Events Dialog



1-bit TTL is always sent in each event that is marked.

The following events can be marked:

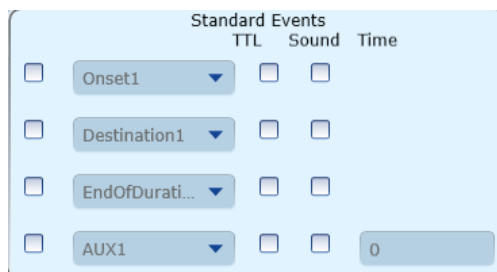
Table 20: Events - TSL

Parameter	Description
Destination 1 – Destination 5	User response was detected.

2. Mark the desired alert type:
 1. TTL – by issuing a TTL signal.
 2. Snd – by sounding an audio signal.
3. Click anywhere on the screen, or on the X mark at the corner of the window, to close the Standard Events dialog.

7.5.2.4 Suprathreshold

- From the **Program Details** screen, click the **Standard events** arrow at the bottom of the sequence setting (column).
The following dialog is displayed, listing the standard events applicable to the Levels method:

**Figure 53: Suprathreshold – Standard Events Dialog**

1-bit TTL is always sent in each event that is marked.

The following events can be marked:

Table 21: Events - Suprathreshold

Parameter	Description
Onset 1 – Onset 5	The onset of the stimulus in each trial.
Destination 1 – Destination 5	The arrival at the target temperature.
End of duration 1 – End of Duration 5	The beginning of temperature descent.
AUX 1 – AUX 5	The auxiliary time, from onset to the initial temperature change.

- Mark the desired alert type:
 3. TTL – by issuing a TTL signal.
 4. Snd – by sounding an audio signal.
- Click anywhere on the screen, or on the X mark at the corner of the window, to close the Standard Events dialog.

7.5.2.5 Staircase

- From the **Program Details** screen, click the **Standard events** arrow at the bottom of the sequence setting (column).

The following dialog is displayed, listing the standard events applicable to the Levels method:

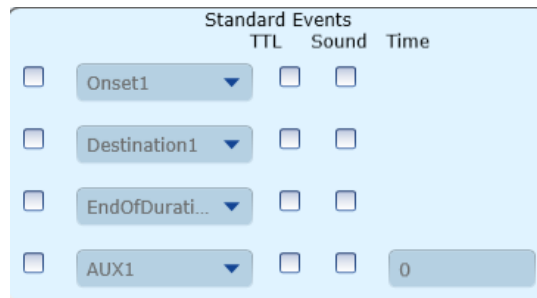


Figure 54: Staircase – Standard Events Dialog



1-bit TTL is always sent in each event that is marked.

The following events can be marked:

Table 22: Events - Staircase

Parameter	Description
Onset 1 – Onset 5	The onset of the stimulus in each trial.
Destination 1 – Destination 5	The arrival at the target temperature.
End of duration 1 – End of Duration 5	The beginning of temperature descent.
AUX 1 – AUX 5	The auxiliary time, from onset to the initial temperature change.

- Mark the desired alert type:
- TTL – by issuing a TTL signal.
- Snd – by sounding an audio signal.
- Click anywhere on the screen, or on the X mark at the corner of the window, to close the Standard Events dialog.



The polarity of Standard and Temperature events can be configured through Hardware Settings, as described in section 10.2.1 page 106.




Refer to section 1.9, regarding TTL properties.

7.6 Unique Test Instructions


In some cases, the general program instructions do not fully apply to specific programs, and unique instructions are required.

To enter unique instructions, perform to the following procedure. All other (standard) tests will be assigned the standard instructions, as entered in section 10.3.2, page 111.

- From the program list at the left, select the required program, and double-click, or click the Edit

program details button .

The **Programs** menu is displayed.

- Click the Accesses test instructions button . The following screen is displayed:

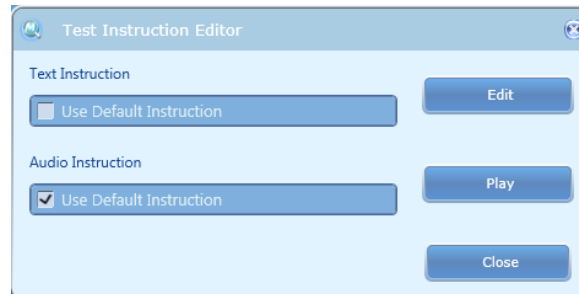



Figure 55: Test Instructions Editor

- To edit the textual instructions,
 - Deselect the relevant **Use default instruction** checkbox. The **Edit** button becomes enabled.
 - Click the **Edit** button. The text editor is displayed, displaying the standard instructions.
 - Edit the instructions as required, as described in section [10.3.2.1](#), page [111](#).
- To replace the audio instructions,
 - Deselect the relevant **Use default instruction** checkbox. The **Play** button becomes an enabled **Browse** button.
 - Click the **Browse** button. The Audio instruction screen is displayed.
 - Replace the instructions file, as described in section [10.3.2.2](#), page [112](#)


7.7 Removing A Program

To remove a program from the program list:

- Click the **Remove** icon (.
- Click **Yes** to the prompt. The selected program is deleted.

7.8 Duplicate A Program


To duplicate a program from the program list:

- Click the **Duplicate** icon (.
- The selected program was duplicated and given a unique name automatically (the name is editable).

7.9 Edit A Program

To edit a program from the program list:



1. Click the **Edit** icon ().
2. The selected program details screen is open and can be edited.

7.10 Import / Export Program

Program details can be imported to and exported from MEDOC Main Station using a secure and unique format which is readable from MEDOC software only. The file extension is TSA.



Note that importing and exporting program data between different software versions may result in compatibility errors and loss of data. Check database compatibility before proceeding.

In order to export TSA-II programs follow the procedure below:

- Open the program list in the **Programs** screen.
- Select the programs to export. Multiple selection is possible by holding down the **Ctrl** and **Shift** buttons on the keyboard
- Click **File** → **Export**.
- Select the location and name of the exported programs.
- Click the **Save** button.
The selected programs are saved to the selected location under the selected name.

In order to import TSA-II programs follow the procedure below:

1. Click **File** → **Import**.
2. Browse to the location of the exported programs and select the program you want to import.
3. Click on the **Open** button.
The imported programs are added to your program list.



MEDOC Main Station identifies and allows you to manually solve any conflicts that may arise when importing programs. For example, programs with the same name.

8. Patient Management

8.1 Patients List

The Patients screen enables you to manage patients (add, remove, edits etc.) and department information.

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

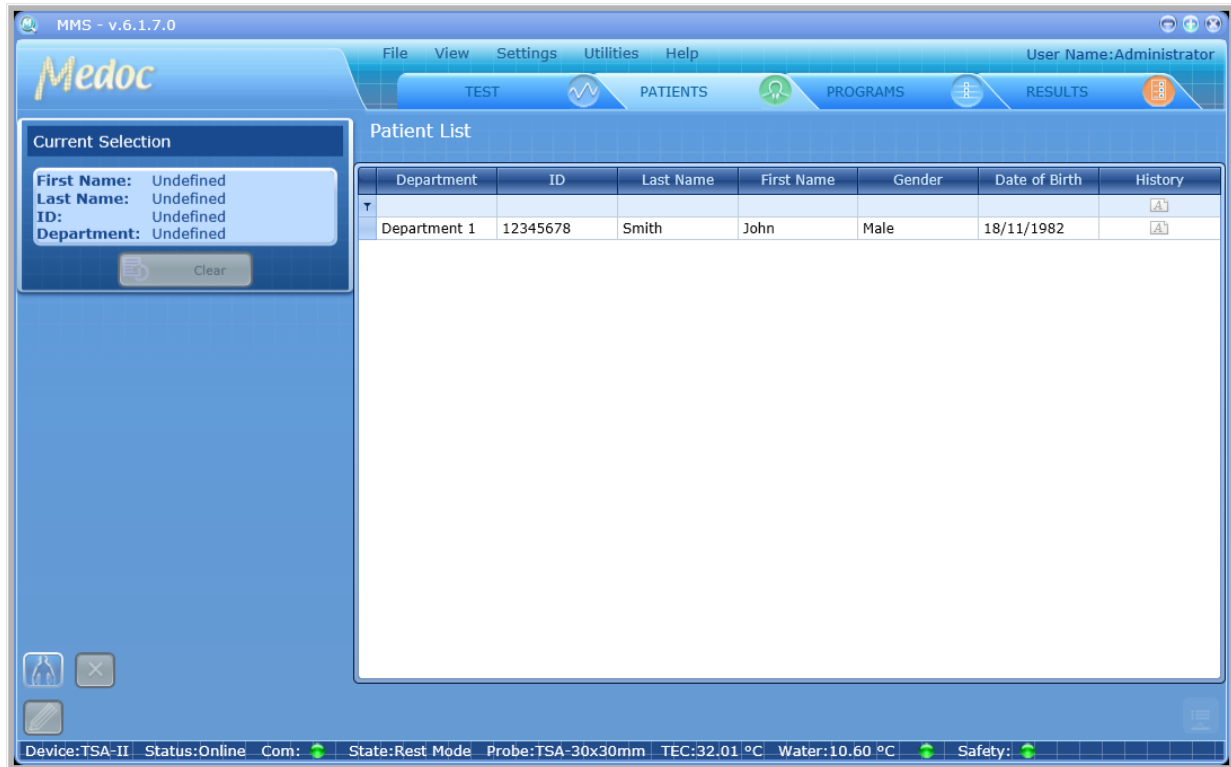


Figure 56: Patients List

2. To narrow down the displayed list use the filter row.



The more criteria you define using the filter, the shorter the list that will be displayed.

3. To clear the filtered list, select the **(All)** option from the filter drop down list.








In order to add / remove fields from Patient table, see section 10.1.2, page 92.



It is possible to change column order by drag and drop it to required place.

The following options are available in the Patient Management screen:

	Create new Patient
	Delete selected program
	Edit selected program
 or 	Show or Hide program preview

- Current Selection control - displays the selected program information.

When you open the Patient Preview bar, the following screen is displayed:

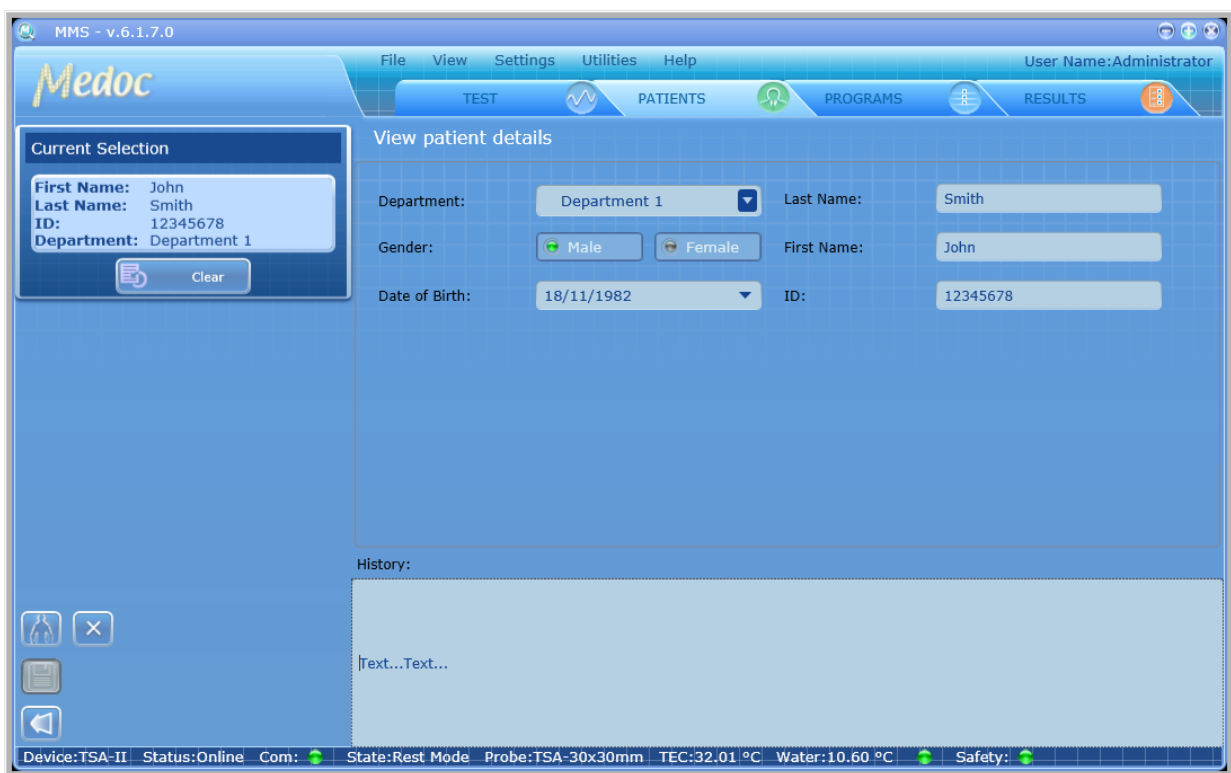


Figure 57: Patient Management – Patient details preview



Patient details cannot be edited from the preview control screen

8.2 Add New Patient



To add a patient to the patients list:

1. Click the **Add** icon ().
The **Patient details** screen is displayed:


Figure 58: Patients Editor Screen

2. Insert all the relevant patient data.



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

3. Click the **Save** icon ().

4. After adding and saving all the required patients, click the **Return** icon () to return to the **Patients list** screen.




Adding a department can only be done by an administrator. See section 8.5 page 78.



The information displayed on the screen (field names) can be customized according to the setup defined by each user. Refer to section 10.1.2, page 92.


8.3 Remove Patient

To remove a patient from the patients list:

3. Click the **Delete** icon ().
4. Click **Yes** to the prompt.
The selected patient is deleted.

8.4 Edit Patient Details

To edit a patient from the patients list:

5. Click the **Edit** icon ().
6. The selected patient parameters screen is open and can be edited.

8.5 Department Management

MEDOC Main Station enables you to manage (Add, Edit, Remove) your patient department.



Department management is enabled according to the authorization level of the current user. For further information, refer to section 10.1.5, page 100.

- a. From the **Utilities** menu at the top of the screen, select the **Department** option.
The *Edit departments* menu is displayed:

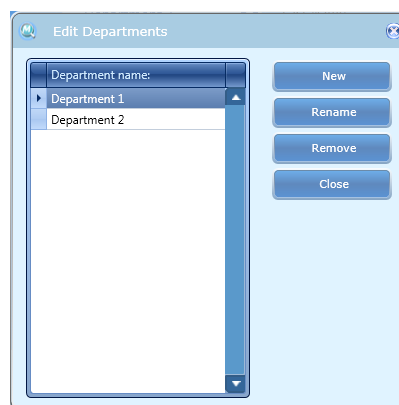


Figure 59: Edit Department Menu

- b. To define a new department, click the **New** button; then, type the department name.
- c. To rename a department, select the required department; then click the **Rename** button.
(Available only for System Administrators and Medical Supervisors)
- d. To remove a department, select the required department; then click the **Remove** button. At the prompt click the **OK** button.
(Available only for System Administrators and Medical Supervisors)
- e. To close the dialog, click the **Close** button.

8.6 Import / Export Patient Lists

Patient details can be imported to and exported from MEDOC Main Station using a secure and unique format which is readable from MEDOC software only. The file extension is TSA.



Note that importing and exporting Patient data between different software versions may result in compatibility errors and loss of data. Check database compatibility before proceeding.

In order to export TSA-II patients follow procedure below:

1. Open the patient list in the **Patient** screen.
2. Select the patients to export. Multiple selection is possible by holding down the **Ctrl** and **Shift** buttons on the keyboard
3. Click **File → Export**.
4. Select the location and name of the exported patients.
5. Click the **Save** button.
The selected patients are saved to the selected location under the selected name.

In order to import TSA-II patients follow the procedure below:

1. Click **File → Import**.
2. Browse to the location of the exported patients and select the patients you want to import.
3. Click on the **Open** button.
The imported patients are added to your patients list.



MEDOC Main Station software identifies and allows you to manually solve any conflicts that may arise when importing patients. For example, patients with the same unique field.

9. Results Management

The Results List screen lists the results of the recent test.

9.1 Results List

The Results screen enables you to manage Results (view, print, delete, etc.).

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

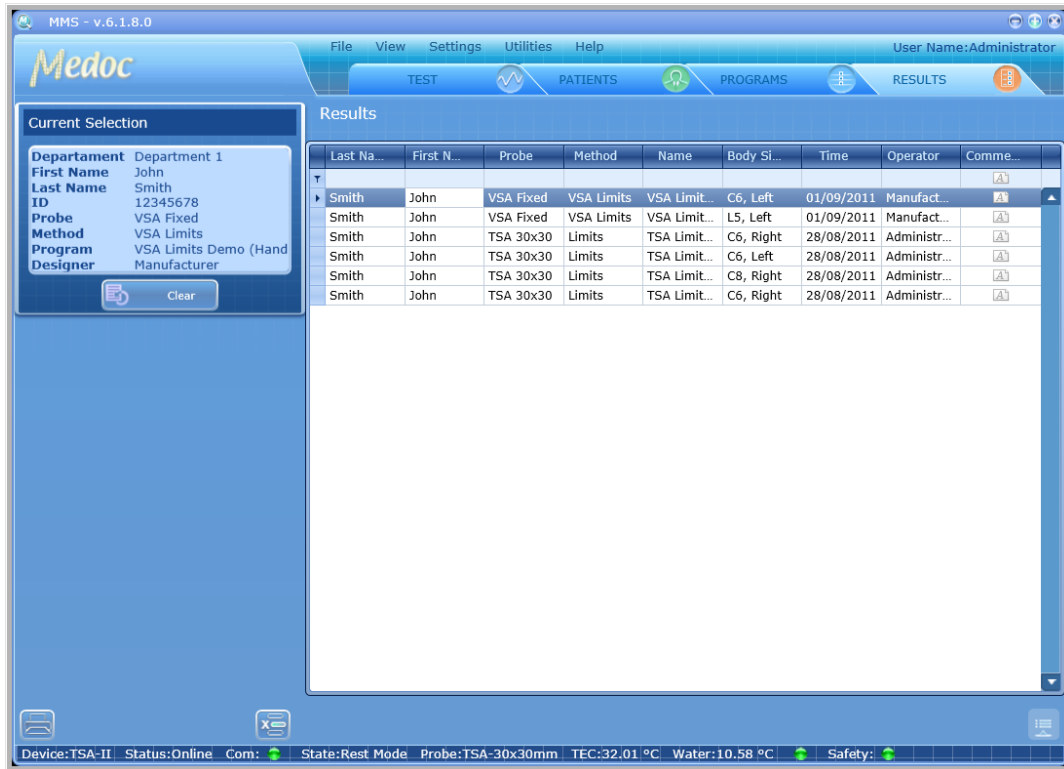


Figure 60: Results List

2. To narrow down the displayed list use the filter row.



The more criteria you define using the filter, the shorter the list that will be displayed.

3. To clear the filtered list, select the **(All)** option from the filter drop down list.

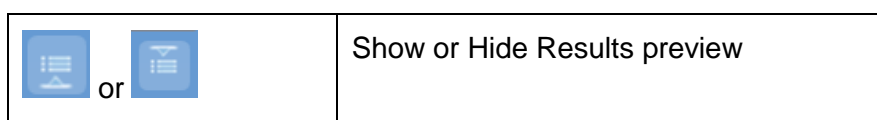




In order to add / remove fields from Results table, see section 10.1.3, page 94.



It is possible to change column order by drag and drop it to required place.

The following options are available in the results management screen:



	Print Selected Results file / files
	Delete selected Results file from Medoc Main Station Data Base

- Current Selection control - displays the selected program information.
 1. Current Thermode control - displays the Thermode that is used for the selected program.
- When you open the Results preview bar, the following screen is displayed:

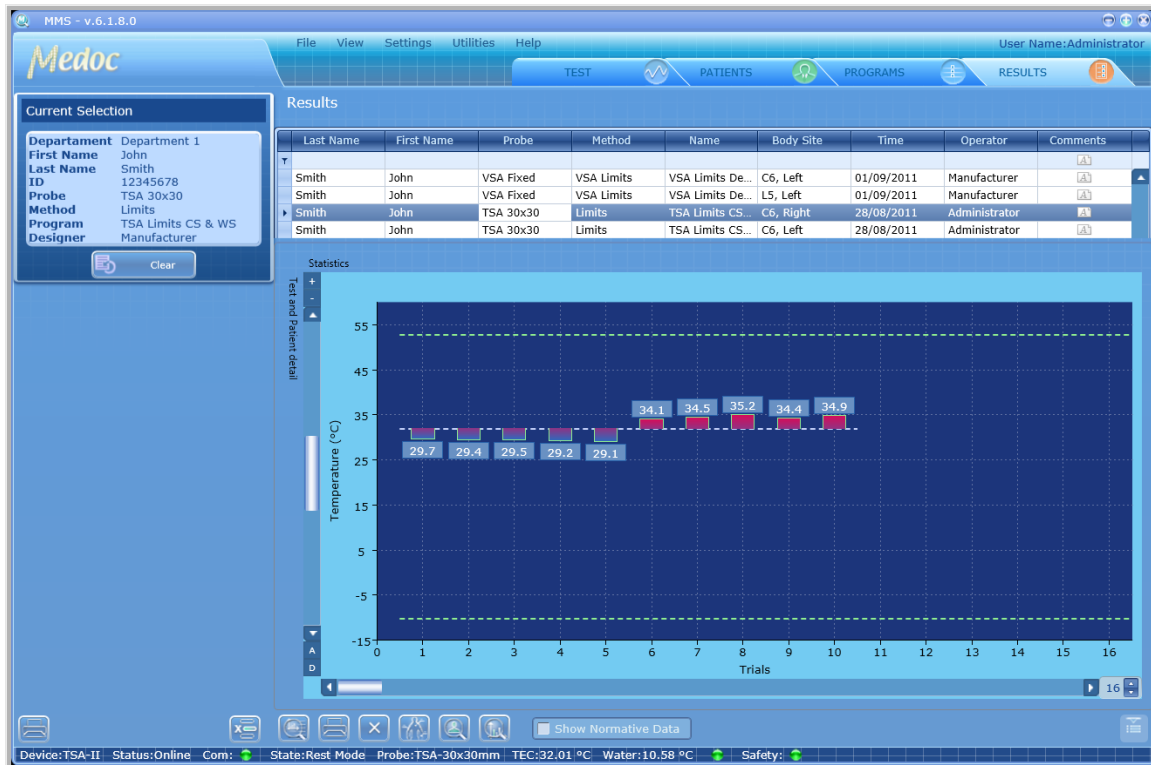








Figure 61: Result preview display

The following options are available:

	Display Pateint details.
	Display Results graph preview. Available on selected methods.
	Display test subject details preview.
	Display the Result Body Site. Available only if a Body Site was selected.
	Delete selected results file.
	Print selected results file.
Check box	Show / Hide Normative Data display.
Check	Show / Hide COVAS graph.

box	
-----	--

9.2 Import / Export Results

Test Results can be imported to and exported from MEDOC Main Station using a secure and unique format which is readable from MEDOC software only. The file extension is TSA. Alternatively, results can be exported as an excel file (.xls) for further analysis.



Note that importing and exporting test results between different software versions may result in compatibility errors and loss of data. Check database compatibility before proceeding.

In order to export TSA-II Results to **.ats** format follow the procedure below:

1. Open the results list in the **Results** screen.
2. Select the results to export. Multiple selection is possible by holding down the **Ctrl** and **Shift** buttons on the keyboard
3. Click **File** → **Export**.
4. Select the location and name of the exported results.
5. Click the **Save** button.
The selected results are saved to the selected location under the selected name.

In order to export TSA-II Results to **.xls** format follow the procedure below:

1. Open the results list in the **Results** screen.
2. Select the results to export.
3. Click **File** → **Export to Excel**.
4. Select the location for the exported results.
5. Click the **Save** button.
The selected results are saved to the selected location.

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

The resulting Excel file is divided into two tabs:

Description: containing general patient and test data:

	A	B
1	Summary	
2	Department	Department 1
3	Patient	Smith, John
4	Probe	TSA
5	Model	30x30
6	Method	Limits
7	Program	TSA Limits CS & WS
8	Comments	
9	Start time	28/08/2011 11:57
10	End time	28/08/2011 11:59
11	Patient Details	
12	Department	Department 1
13	ID	12345678
14	Last Name	Smith
15	First Name	John
16	Gender	Male
17	Date of Birth	18/11/1982
18	History	
19	Program Details	
20	Program Name	TSA Limits CS & WS
21	Probe	TSA
22	Description	
23	Updated on	23/08/2011 12:41
24	Body Site	
25	Body Site Main	C6
26	Body Site Specific	Hand Palmar Thenar Eminence
27	Body Site Side	Right
28		
29		
30		
31		
32		
33		

Figure 62: Export Result File Opened In Excel – Description Tab Sample

Data: containing the detailed information of the test:

	C	D	E	F	G	H	I	J
1	Tec [C]	Water [C]	PCB [C]	COVAS	Baseline [C]	LimiterMax [C]	LimiterMin [C]	Events
2	32.01			0				
3	32.01			0				
4	32.01			0				
5	32.01	20.21		0	32	59		-10
6	32.01	20.21		0	32	59		-10
7	32.01	20.21		0	32	59		-10
8	32.01	20.21		0	32	59		-10
9	32.01	20.21		0	32	59		-10
10	32.01	20.21		0	32	59		-10
11	32.01	20.21		0	32	59		-10
12	32.01	20.21		0	32	59		-10
13	32.01	20.21		0	32	59		-10
14	32.01	20.21		0	32	59		-10
15	32.01	20.21		0	32	59		-10
16	32.01	20.21		0	32	59		-10
17	32.01	20.21		0	32	59		-10
18	32.04	20.21		0	32	59		-10
19	32.04	20.21		0	32	59		-10
20	32.04	20.21		0	32	59		-10
21	32.04	20.21		0	32	59		-10
22	32.04	20.21		0	32	59		-10
23	32.04	20.21		0	32	59		-10
24	32.04	20.21		0	32	59		-10
25	32.04	20.21		0	32	59		-10
26	32.01	20.21		0	32	59		-10
27	32.01	20.21		0	32	59		-10
28	32.01	20.21		0	32	59		-10
29	32.01	20.21		0	32	59		-10
30	32.01	20.21		0	32	59		-10
31	32.01	20.21		0	32	59		-10
32	32.01	20.21		0	32	59		-10
33	32.01	20.21		0	32	59		-10
34	32.01	20.21		0	32	59		-10
35	32.01	20.21		0	32	59		-10
36	32.01	20.21		0	32	59		-10
37	32.01	20.21		0	32	59		-10
38	32.01	20.21		0	32	59		-10
39	32.01	20.21		0	32	59		-10
40	32.01	20.21		0	32	59		-10
41	32.01	20.21		0	32	59		-10

Figure 63: Export Result File Opened In Excel – Data Tab Sample

In order to import TSA-II results, follow the procedure below:

1. Click **File** → **Import**.
2. Browse to the location of the exported results and select the results you want to import (only for .ats format)

3. Click on the **Open** button.
The imported results are added to your results list.



MEDOC Main Station identifies and allows you to manually solve any conflicts that may rise when importing results. For example, results with same patient name date and time.



Saved Results cannot be edited or modified.

9.3 Print Results and Reports

MEDOC Main Station has a powerful Analysis and Results Report Generator that can be customized for user needs.

Follow these steps to print your results:

1. Select the relevant results file or files from the list in the results screen.
2. Click on the **Print** button

The following screen is displayed:

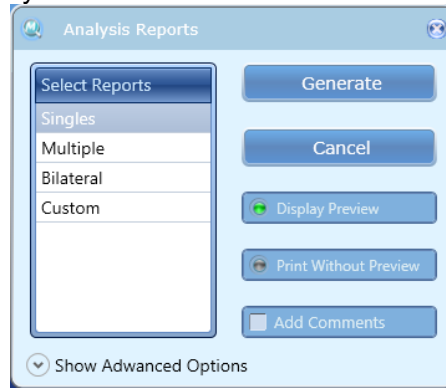


Figure 64: Analysis Reports Dialog

3. Configure the Reports options according to your needs.
4. Press on the button of the Report Type you want to use from available options. Only available reports type are enabled according to your results file selection.
5. Report is generated. Report may have Preview or not according to your preferences.
 - a. Print with Preview
Print Preview is displayed according to the active template and test method. Refer to [2](#), page [92](#) for details regarding Printing Options.
Press the **Print** icon or select one of the export options.
 - b. Print without Preview
Report is sent to a connected printer.
Select your Printing preferences according to the available printers and print your report.

9.3.1 Analysis Report Dialog

The Analysis Report Dialog allows Medoc Main Station user to generate Reports of TSA-II tests.

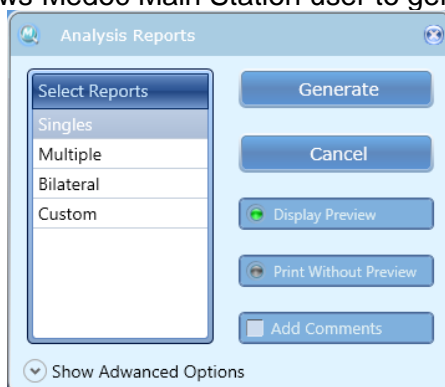


Figure 65: Analysis Report

9.3.1.1 Analysis Report Type

Report type defines the template and content of the report and analysis to be displayed.



Report template can be edited and customized according to specific needs. Refer to 2, page 95 for details

The following templates are available:

Table 23: Report Analysis Configuration

Report Type	Description	Restrictions
Singles	Print a single report for each selected Test Results according to active template.	None
Multiple	Print results statistic summary of selected tests.	<ol style="list-style-type: none"> 1. Test Method: TSL, Levels, Limits 2. Selection of 2 or more result files
Bilateral	Compare test statistics of same body site of two sides (Left and Right) for same body site and test subject.	<ol style="list-style-type: none"> a. Test Method: TSL, Levels, Limits b. Selection of 2 result files c. Identical Test Subject d. Identical Test Program e. Identical Main and Specific body site f. Opposite body site sides
Site to Site	Compare test statistics of same test subject in two different Body Sites.	<ol style="list-style-type: none"> 1. Test Method: TSL, Levels, Limits 2. Selection of 2 result files 3. Identical Test Subject 4. Identical Test Program 5. Different Main and / or Specific Site

Report Type	Description	Restrictions
Pre / Post	Compare test statistics of same test subject and site, performed in different date and time	<ol style="list-style-type: none"> 1. Test Method: TSL, Levels, Limits 2. Selection of 2 result files 3. Identical Test Subject 4. Identical Test Program 5. Identical Body Site
Trend	Display test statistic trend vs. test date and time.	<ol style="list-style-type: none"> 1. Test Method: TSL, Levels, Limits 2. Selection of 2 result files or more 3. Identical Test Subject 4. Identical Test Program 5. Identical Body Site
Custom	Custom report with custom analysis and restrictions.	<p>Vary according to report analysis</p> <ol style="list-style-type: none"> 2. Contact Medoc Service for Details.

Reports Examples:

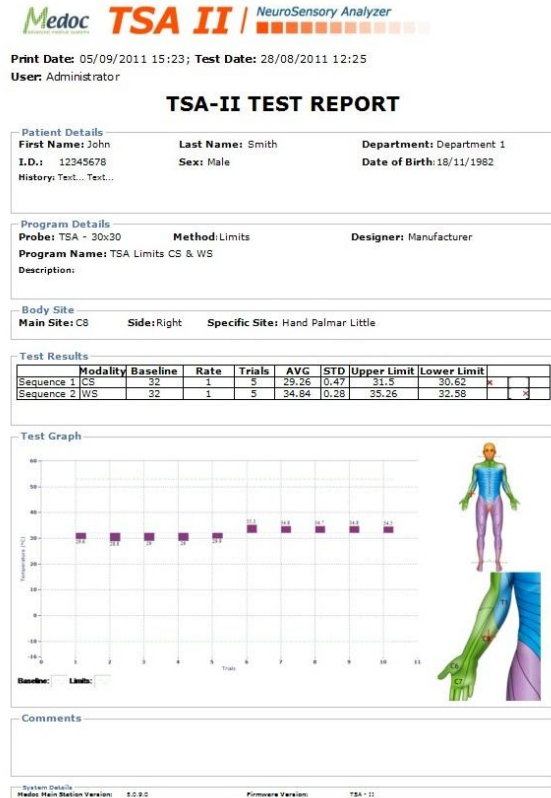


Figure 66: Single Results Report

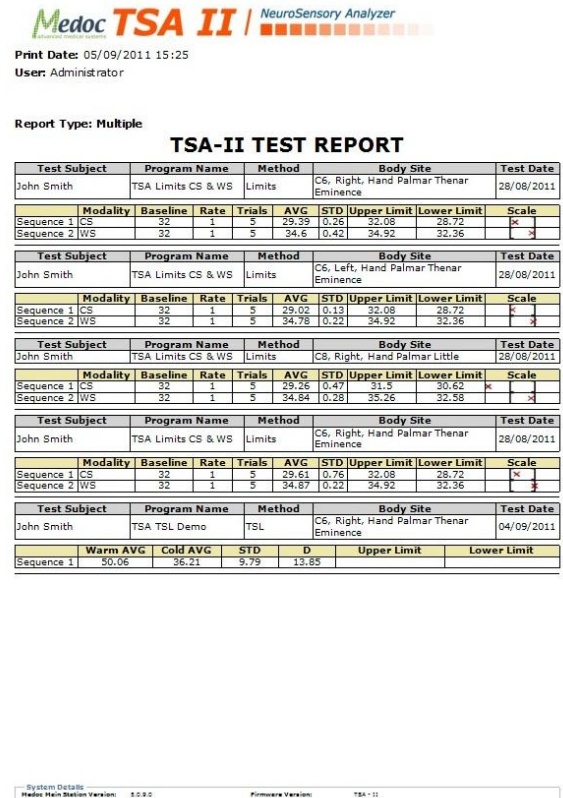
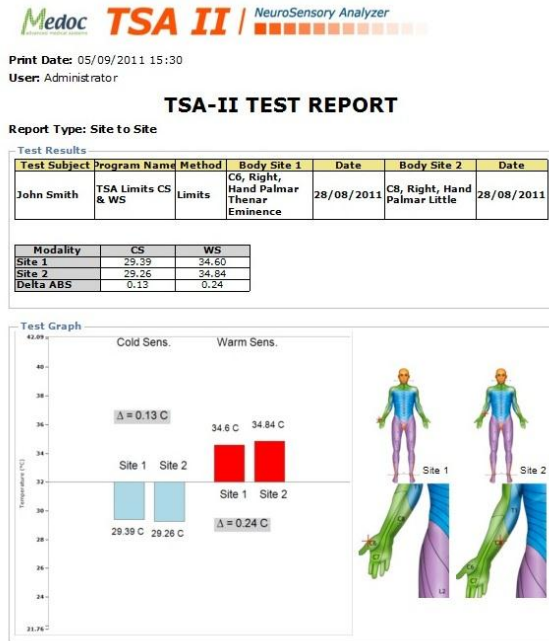


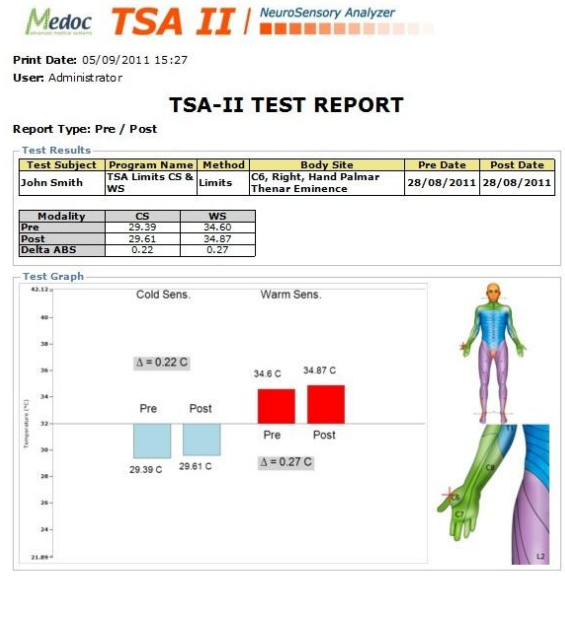
Figure 67: Multiple Results Report

Analysis Report Examples:



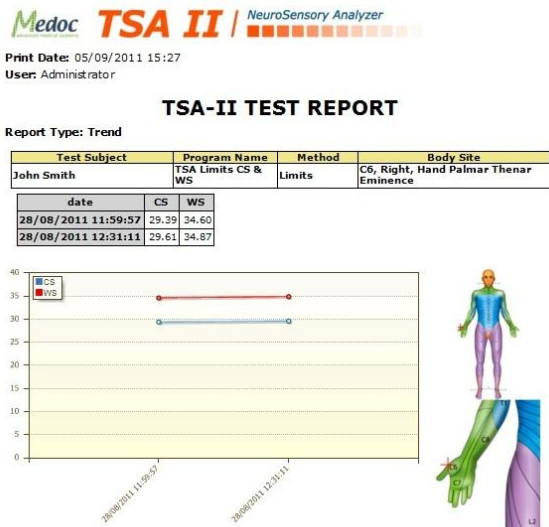
System Details
Medoc Main Station Version: 5.0.0.0 Firmware Version: TSA - 11

Figure 68: Site to Site Results Report



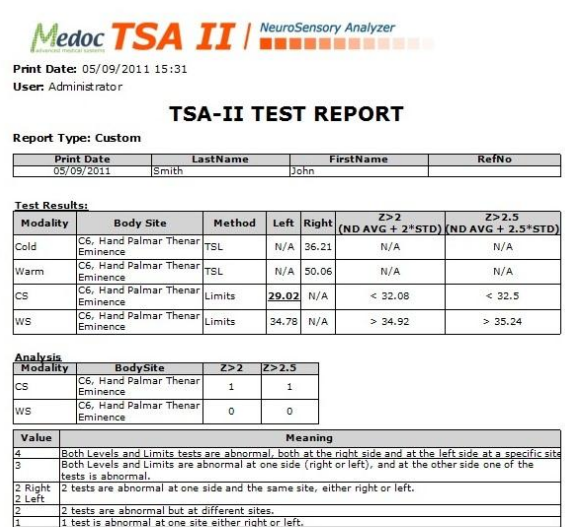
System Details
Medoc Main Station Version: 5.0.0.0 Firmware Version: TSA - 11

Figure 69: Pre / Post Results Report



System Details
Medoc Main Station Version: 5.0.0.0 Firmware Version: TSA - 11

Figure 70: Trend Results Report



System Details
Medoc Main Station Version: 5.0.0.0 Firmware Version: TSA - 11

Figure 71: Custom Report Results



Figure 72: Bilateral Results Report

9.3.1.2 Reports Configuration

Report configurations allow defining basic reports settings and display options. The following configurations are available:

Table 24: Report Analysis Configuration

Parameter	Description
Display Preview	Displays report preview before sending to print.
Print Without Preview	Send report to print without a preview.
Mode	Automatic Mode – automatically calculate test graph display Manual Mode – manual settings of graph display
Number of Trails (Manual Mode)	Determine how many trails to display for trail based tests. Available for Limits and Levels.
Start Time (Manual Mode)	Determine the display of test graph start time for time based tests. Available for Pulses, Ramp and Hold, Search and TSL.
End Time (Manual Mode)	Determine the display of test graph end time for time based tests. Available for Pulses, Ramp and Hold, Search and TSL.
Min. Value. (Manual Mode)	Determine display of the test graph minimum temperature. Available for Pulses, Ramp and Hold, Search and TSL.
Max. Value. (Manual Mode)	Determine display of the test graph maximum temperature. Available for Pulses, Ramp and Hold, Search and TSL.
Add Comments	Allow adding comments for the generated report. Available for all report type beside Singles.

10. System Configuration

TSA-II system configuration is performed via three different setting menus:

1. Software Settings
2. Hardware Settings
3. Test Setting



System configuration is allowed according to software authorization levels. Refer to section 10.1.5, page 100.

10.1 Software Settings

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

To access the software settings screens, from the **Settings** option in the menu bar; select **Software Settings**.

The following screen is displayed:

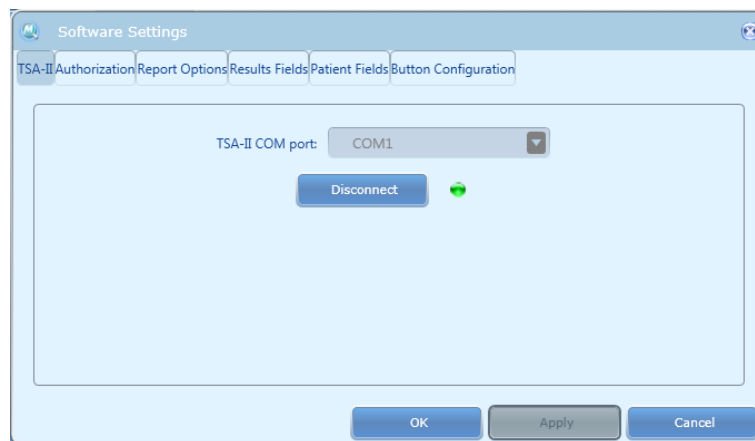


Figure 73: Software Settings Dialogue

The software settings menu includes the following tabs (additional tabs may be visible according to license):

TSA-II

Authorization

Buttons Configuration

Patient's Fields

Results Field

Report Options

10.1.1 TSA-II

The TSA-II Software Settings screen enables you to configure communication settings (see [Figure 73](#) above). Configuration options are described in the table below.

Table 25: Software Settings – TSA-II

Parameter	Description
COM Port	Set the COM port to which the TSA-II system is connected to the computer:

Parameter	Description
	<p>Auto Detect – Automatically scan all available ports.</p> <p>Simulator – Work in Demo Mode (MEDOC Main Station will not connect to TSA-II system).</p> <p>COM X – Set the specific port the TSA-II is connected to. Click Connect to establish communication.</p>

10.1.2 Patient Fields

This dialog configures the displayed fields in the patient details dialog and patient table.

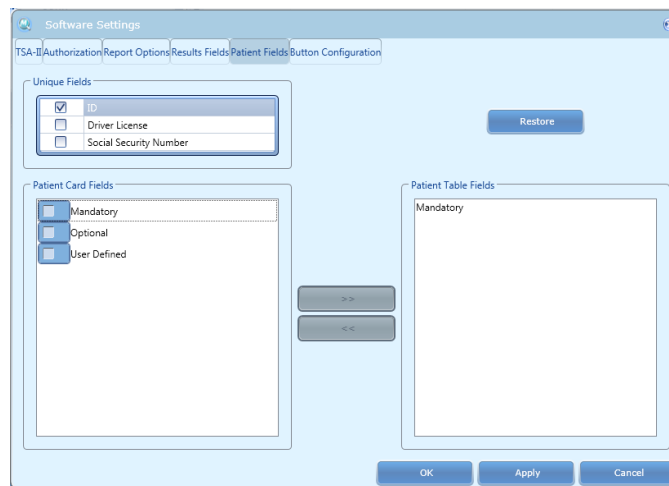


Figure 74: Patient Fields Configuration Screen

Table 26: Patient’s Field


Parameter	Description
Unique Fields	The marked fields are used for conclusive patient identification (more than one can be used). Any other field can be repeated in various patients (for example, John can appear as first name for more than one patient).
Patient Card Fields	<p>The marked fields are displayed in the patient details dialog.</p> <ol style="list-style-type: none"> 1. Mandatory fields – used for patient identification and cannot be deleted (unselected) 2. Optional fields – built in commonly used fields that can be added / removed from patient card by check / uncheck the field 3. User Defined fields – custom fields that can be edited according to requirement and then added / removed from patient card by check / uncheck the field
Patient Table Fields	The fields which are displayed in the patient list and can be searched by.

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


1. From the **Patient Card Fields** list, select the required field or add field name.
2. Click the **Apply** button.

To add Patient Fields to **Patient Table**:

1. Select field to be added from the **Patient Card Fields** list.

2. Click the  button to add field to **Patient Table Fields**.
3. Click the **Apply** button.

To remove Patient Fields from **Patient Table**:

1. Select field to be removed from the **Patient Table Fields** list.
2. Click the  button to remove field from **Patient Table Fields**.
3. Click the **Apply** button.

To restore the default Patient Fields:

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

10.1.3 Results Fields

This dialog configures the displayed fields in the Results list.

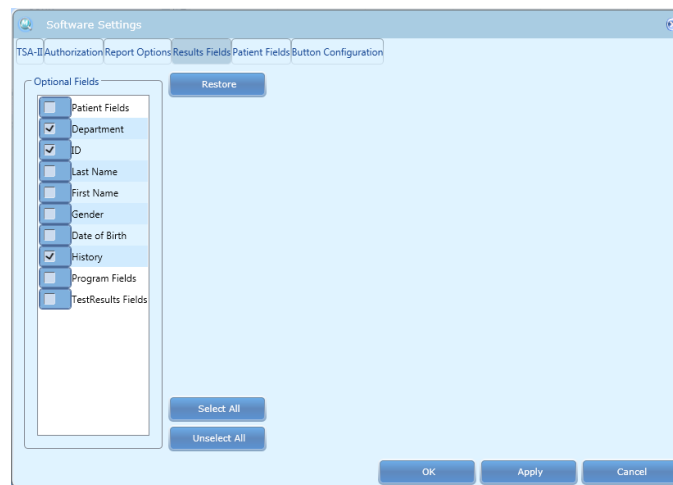


Figure 75: Results Fields Configuration Screen

Table 27: Patient's Field

Parameter	Description
Patient Fields	Available fields from patient card
Program Fields	Program related fields
Test Results Fields	Test related fields

To add field to the **Results Table**:

1. From **Optional Fields** list, select (check) field to be added to Results Table.
2. Click the **Apply** button.

To remove field from the **Results Table**:

3. In **Optional Fields** list, uncheck field to be removed from Results Table.
4. Click the **Apply** button.

To restore the default **Results Fields**:

1. Click the **Restore** button to restore **Results Fields** defaults.
2. Click the **Apply** button.

10.1.4 Report Options

MEDOC Main Station enables to generate test reports, which contain the test results and data according to the system definitions when the test was saved.

Each test method has a unique report template, which is used when the user selects to print the test results.

The Report Options tab enables users to manage their reports and edit reports templates.

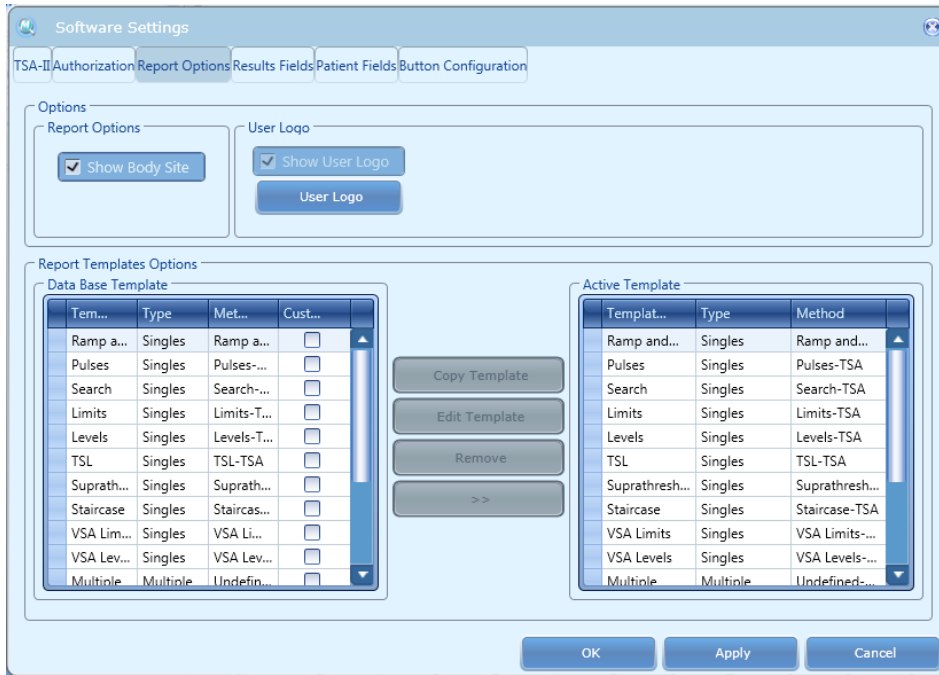


Figure 76: Report Options tab

Available Options:

Table 28: Report Options

Parameter	Description
Report Options	Enables selection between two types of reports: <ol style="list-style-type: none"> 1. Detailed Report <ol style="list-style-type: none"> a. Configure body site display using check box 2. Simple Print (basic information only)
User Logo	Enables and configure display of customized user Logo to the report printouts
Report Templates Options*	Enables editing Detailed Report templates: <ol style="list-style-type: none"> 1. Manage Report templates data base 2. Edit custom made reports 3. Manage Active Templates list <p>* Available Only when Detailed Report Option is selected</p>

10.1.4.1 Detailed Report

Detailed Report option contains all required test information and varies according to test method.

Every test method may have more than one template in the Medoc Main Station data base, but only one template is used each time when printing a report. The template type is selected by MEDOC Main Station according to the selected test method.
 TSA-II user may select the active template for each method from the templates data base.
 Templates can be edited and modified according to custom needs.



Print Date: 05/09/2011 15:23; **Test Date:** 28/08/2011 12:25
User: Administrator

TSA-II TEST REPORT

Patient Details
First Name: John **Last Name:** Smith **Department:** Department 1
I.D.: 12345678 **Sex:** Male **Date of Birth:** 18/11/1982
History: Text... Text...

Program Details
Probe: TSA - 30x30 **Method:** Limits **Designer:** Manufacturer
Program Name: TSA Limits CS & WS
Description:

Body Site
Main Site: C8 **Side:** Right **Specific Site:** Hand Palmar Little

Test Results

	Modality	Baseline	Rate	Trials	AVG	STD	Upper Limit	Lower Limit		
Sequence 1	CS	32	1	5	29.26	0.47	31.5	30.62	*	
Sequence 2	WS	32	1	5	34.84	0.28	35.26	32.58		*

Test Graph

Temperature (°C) vs Trials

Baseline: Limits:

Comments

System Details
 Medoc Main Station Version: 5.0.9.0 Firmware Version: TSA - 11

Figure 77: Detailed Report example

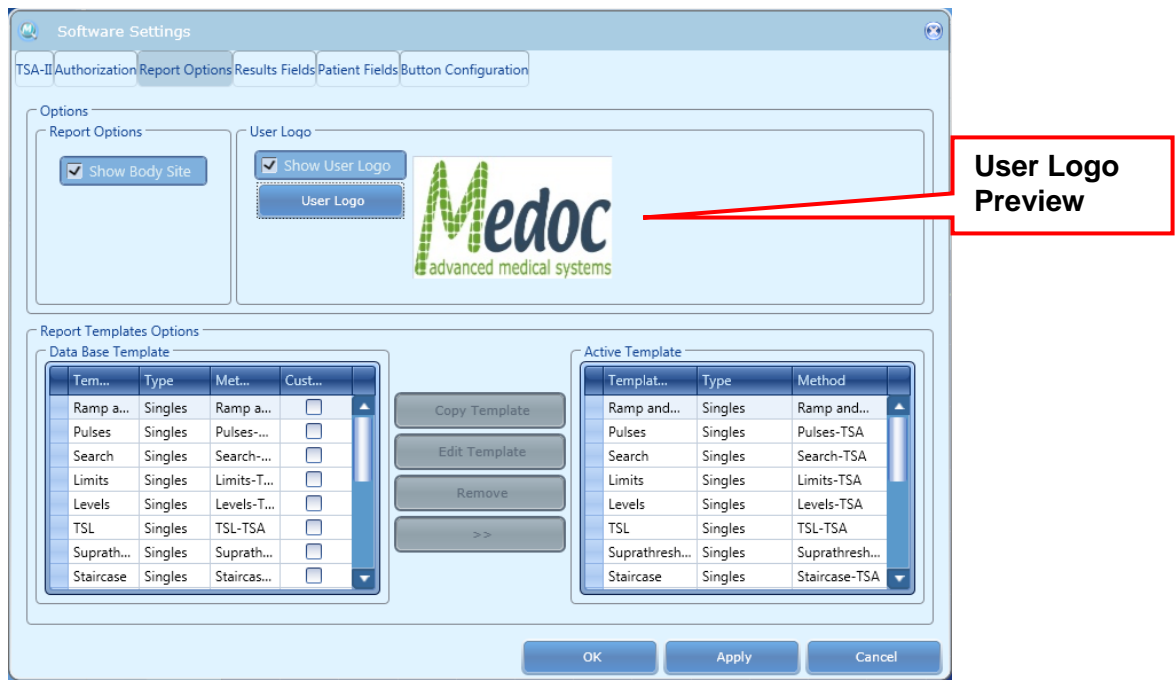


Figure 78: Detailed Report Options

The following actions are available in the Detailed Report:

Table 29: Report Options

Parameter	Description
Show Body Site	When Show Body Site option is checked, the name of the body site that was used during a test (Main Site, Side and Specific Site) will be displayed in the final report.
User Logo	User Logo button may be used in order to import a custom made logo that will appear on the TSA-II reports. Logo preview will appear on the right side when custom logo is in use. 1. Acceptable formats: .GIF; .JPG; .PNG; .BMP only.
Reports data base management	Enables managing template options, Copy Template, Edit Template, Remove template and set Active template (>>). Active Template is the template that is used for each test method and type when pressing the Print button and selecting the report type to be print.

10.1.4.1.1 Data Base Templates

The data base templates option displays the available templates from the Medoc Main Station data base. Each test method can have several templates according to the user needs.

Data base templates are characterized by the following parameters:

1. Template Name
2. Type – determine the report type the template refers to.
3. Method – determine the test method the template support.
4. Custom (checked / unchecked) – determine whether the template was made by Manufacture or User.

The original Medoc Main Station data base contains a template for each of the TSA-II methods. These templates cannot be customized, edited or removed from the data base.

Editing Data Base template:



Editing a report template is an advanced action that requires basic knowledge of data base structure and programming.

Medoc Main Station enables the editing of custom made reports only. For editing a report, copy a template from the existing data base, rename it and then edit it. The following steps describe the process of editing a report:

1. Select a template for editing from the Data Base Template list.
2. Press the **Copy Template** button.
the following screen is displayed:

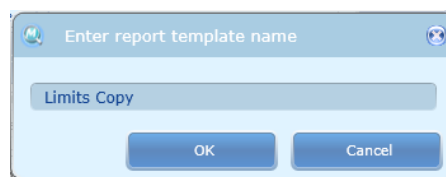


Figure 79: Custom made Report Name dialog

3. Enter a name for the new report you create and press the **OK** button.
4. Select the report name you have entered from the Report data base list.
5. Press **Edit Template** button (only custom made templates can be edited).
6. The Report Editor screen is displayed:

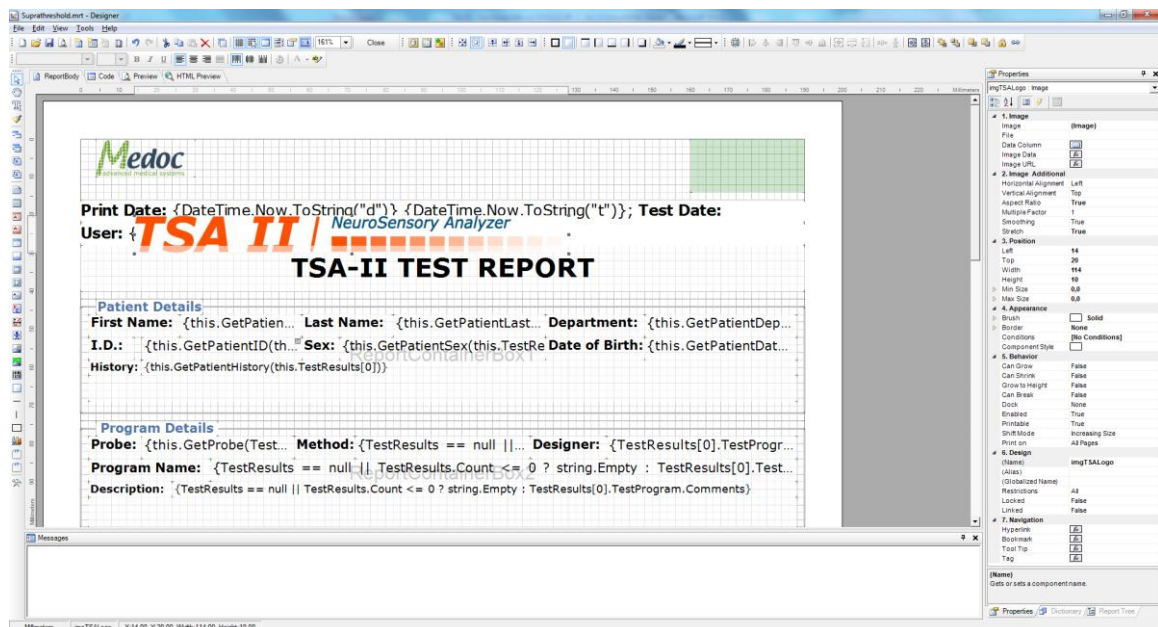


Figure 80: Report Editor Screen

7. Edit Report template according to your needs.
 - a. All report parameters may be edited.
 - b. All existing data may be accessed through the Medoc Main Station data base.
8. Press the **Save** button when you complete editing your template.
9. Use the **>>** button in order to set your template as active.
Your template will replace the Active template of the selected method.

10. Use the **Remove** button in order to delete a template from the Medoc Main Station data base (only custom templates can be deleted).



A special report design can be prepared upon request by Medoc LTD.

Setting Active Template:

1. Select the template you want to use as Active template.
2. Use the >> button in order to set selected template as active.
The selected template will replace the active template of the selected method.

10.1.4.2 Simple Print

Simple Print option displays basic test graph and information. It applies to all test methods without any difference.

When selecting Simple Print option, the following report template is used for all test methods when selecting to print Single report:



Department: Department 1
Patient: John Smith
Print Date: 06 October 2011 13:37



Operator: Administrator
Method: Limits
Program: TSA Limits CS & WS
Probe: TSA - 30x30

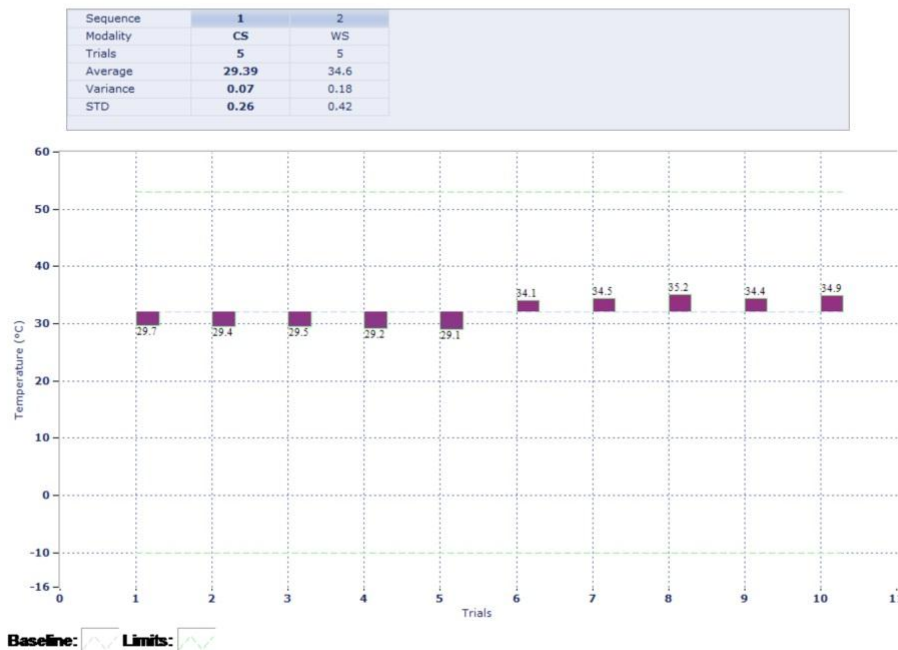


Figure 81: TSA-II Simple Print replace

10.1.5 Button Configuration

This dialog enables you to customize the behavior of various buttons according to your preferences and requirements. Currently the configurable buttons include the **New Test** and the **New Patient** which are visible on the test run screen and adjust the test parameters for the following test.

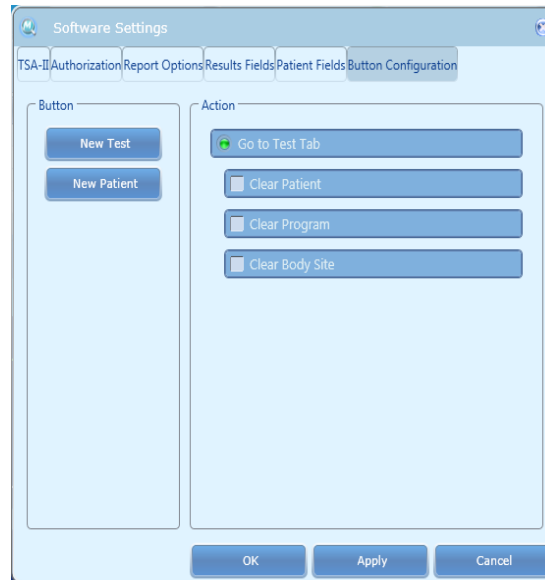


Figure 82: Buttons configuration Software Settings

To customize button settings:

1. Select button to be customized from the Button list.
2. Select button Action from the available options.
3. Click the **Apply** button.

10.1.6 Authorization

MEDOC Main Station supports user authorization levels, enabling you to restrict user permissions and privileges according to user level.

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



See Table 31 for details regarding the permissions and privileges of each authorization level.

This dialog allows you to add and remove MEDOC Main Station users and set their authorization level.



A user can create only equal or lower level authorized user.

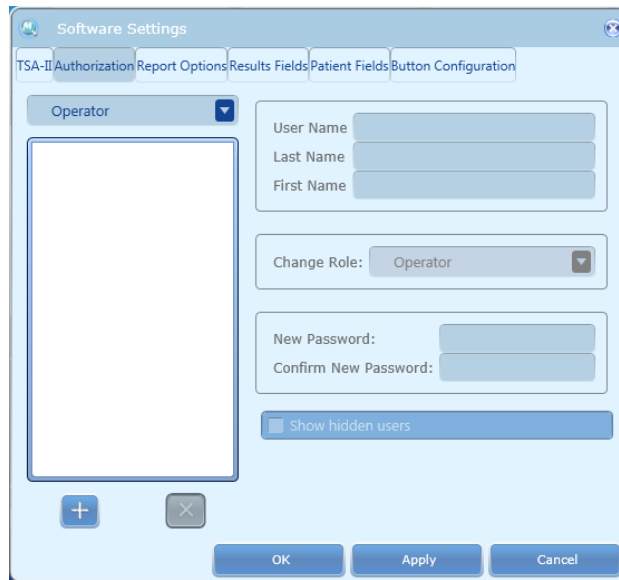


Figure 83: User Authorization Software Settings

Table 30: Authorization parameters

Parameter	Description
User name	User name used to log on to the Main Station and differentiate from other users.
Last name	The user’s last name.
First name	The user’s first name.
Change role	Drop-down menu for changing the user’s authorization level.
New password	Set a password for the user to use when logging on to the Main Station
Confirm password	Password confirmation field.
Show hidden users	Hidden users are unauthorized users which exist in the database only as a result of retrieved data. Enable/disable visibility of these users.

In order to create a MEDOC Main Station user follow these instructions:



1. Click the add user button  at the bottom of the user list.
2. Enter the relevant information, according to the table above.
3. From the **Change role** drop-down menu, select the required authorization level.
4. If you want to change the user’s authorization level, select the required user from the list; then from the **Change role** drop-down menu, choose the required authorization level.
5. Click the **Apply** button.
6. Click the **OK** button.
7. To remove a user from an authorization list, click the remove button .

Table 31: Authorization Levels

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
Patient	Add Patient	√	√	√	√
	Edit Patient	√	√	√	√
	Delete patient	√	√	√	X
	Edit ICD9	√	√	√	X
Programs	Add Program	√	√	√	X
	Edit Program	√	√	√	X
	Delete Program	√	√	√	X
	Duplicate Program	√	√	√	X
	Program Preview	√	√	√	√
Results	View Graph	√	√	√	√
	View Program Details	√	√	√	√
	Delete	√	X	√	X
Test	View Patient Details	√	√	√	√
	View Program Details	√	√	√	√
	Clear	√	√	√	√
	Go to Test...	√	√	√	√
Tool bar - File	Export	√	√	√	√
	Import	√	√	√	√
	Export to Excel	√	√	√	√
	Print	√	√	√	√
	Log Off	√	√	√	√
	Exit	√	√	√	√
Tool bar - View	Test	√	√	√	√
	Patient	√	√	√	√
	Programs	√	√	√	√
	Results	√	√	√	√
Tool bar - Settings	Software Settings				
	<u>Patient's fields</u>				
	View	√	√	√	√
	Edit	√	√	√	X
	<u>Results fields</u>				
	View	√	√	√	√
Edit	√	√	√	X	

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	<u>Report options</u>				
	View	√	√	√	√
	Edit	√	√	√	X
	<u>Buttons configuration</u>				
	View	√	√	√	√
	Edit	√	√	√	X
	<u>Authorization</u>				
	View	√	√	√	√
	Add	√	√	√	X
	Edit	√	√	√	X
	Delete	√	√	√	X
	Hardware Settings				
	<u>General</u>				
	View	√	√	√	√
	TTL out Pulses duration (msec)	√	√	√	X
	TTL Polarity	√	√	√	X
	TTL Diagnostic	√	√	√	√
	Device Mode	√	√	√	√
	<u>Safety</u>				
	View	√	√	√	√
	Edit	X	X	X	X
	<u>Probes</u>				
	View	√	√	√	√
	General	√	√	√	X
	Model	√	√	√	√
	Manual calibration	√	√	√	X
	<u>CoVAS</u>				
	Select Type	√	√	√	√
	View	√	√	√	√
	Calibrate	√	√	√	√
	Test settings				
	<u>Test configuration</u>				
	View	√	√	√	√
	Edit	√	√	√	X

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	<u>Instruction Configuration</u>				
	View	√	√	√	√
	Edit	√	√	√	X
	<u>Sound Configuration</u>				
	View	√	√	√	√
	Edit	√	√	√	√
	<u>Body sites</u>				
	View	√	√	√	√
	Edit	√	√	√	X
	<u>Events marker</u>				
	View	√	√	√	√
	Edit	√	√	√	X
	language	√	√	√	√
	status				
	On-line	√	√	√	√
Tool bar - Utilities	Test Instructions	√	√	√	√
	Department				
	Add Department	√	√	√	√
	Delete Department	√	X	√	X
	Rename Department	√	X	√	X
	ICD9				
	Add ICD9	√	√	√	√
	Delete ICD9	√	X	√	X
	Edit ICD9	√	X	√	X
	Normative data				
	View	√	√	√	√
	Edit	√	√	√	X
	Delete	√	√	√	X
	Import/Export	√	√	√	X
	Black Box				
	<u>Software</u>				
	View	√	√	√	√
	Export	√	√	√	√
	<u>Hardware settings</u>				

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	View	√	√	√	√
	Export	√	√	√	√
	Device recovery	√	√	√	X
Tool bar - Help	About...	√	√	√	√

10.2 Hardware Settings

This menu enables you to set up and test the parts of the system hardware. This can include setting up parameters such as, Thermode types used; pulse duration and polarity; timeout limitations; detection delay, etc., or testing TTL output.

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

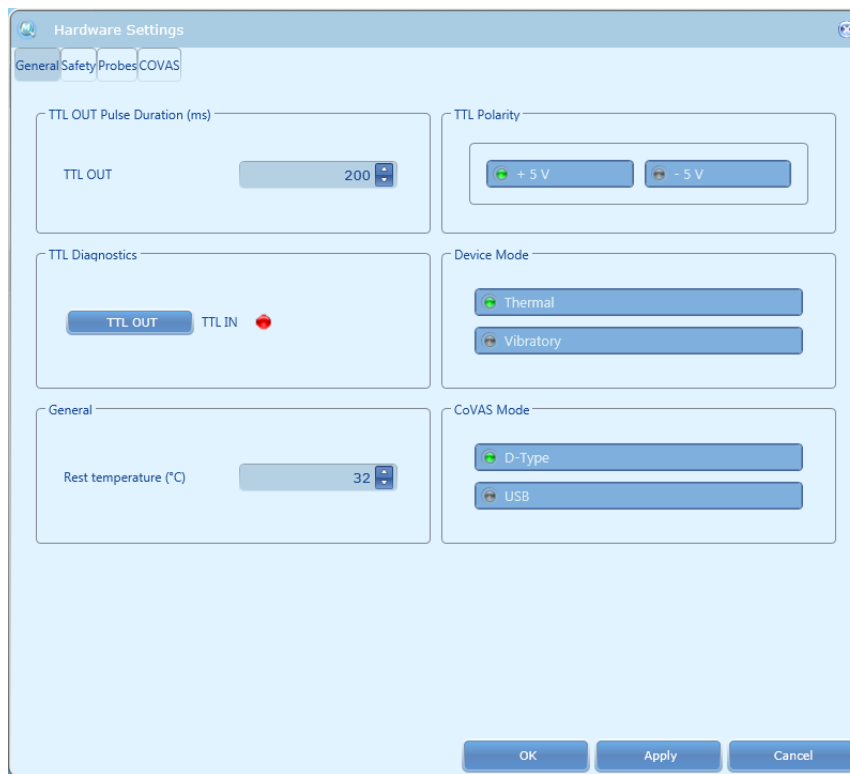


Figure 84: Hardware settings – General tab

The following options are available:

Table 32: Hardware Settings Tab Sheets

Parameter	Description
General	For setting default hardware parameters.
Safety	For displaying safety parameters.
Probes	For setting thermode and VSA3 parameters and calibration.
COVAS	For COVAS calibration.

³ According to license agreement

10.2.1 General

The following options are available in the General tab:

Table 33: Hardware Settings – General tab options

Parameter	Description
TTL OUT Pulse Duration (ms)	For setting default TTL Out pulse duration – between 50 to 1000 msec.
TTL Polarity	For setting the polarity of the TTL In and TTL Out pulses – ±5V.
TTL Diagnostics	Test button for TTL out signal Indicator for checking if the TTL detects incoming signals.
Device Mode	Select device to be used from available options: 1. Thermal – for using TSA-II Thermode 2. Vibratory – for using VSA probe
Reset temperature (°C)	Sets the temperature in which the system remains, when it is on but not in use.

10.2.2 Safety

The safety tab presents the software temperature time limitations which are allowed according to the program safety regulations. In addition, it presents a list of the self-tested parts, and built-in test (BIT) parameters.

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

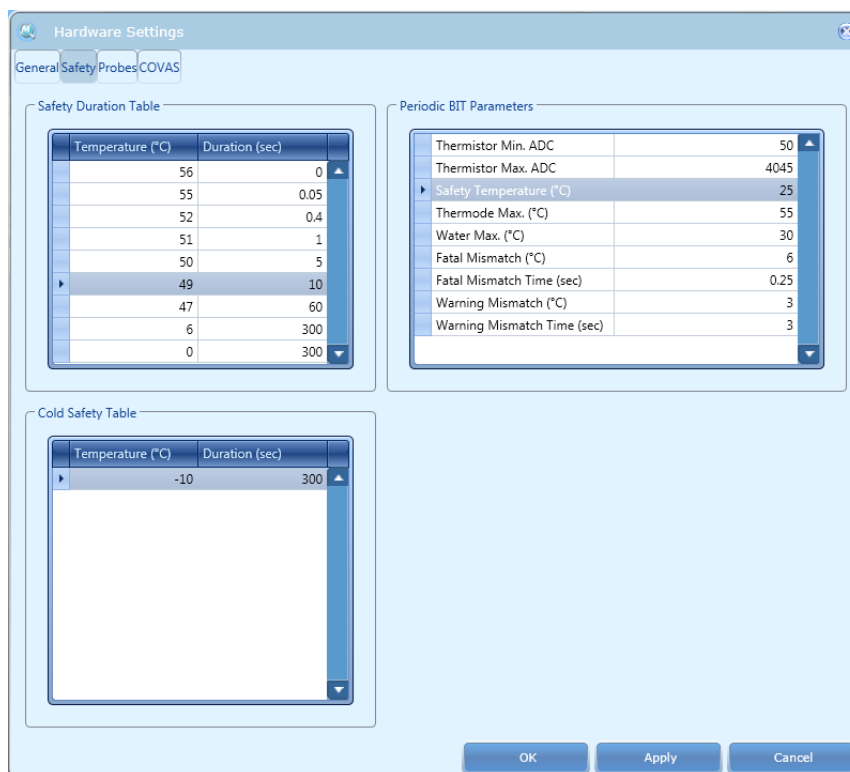


Figure 85: Hardware settings – Safety tab

10.2.3 Thermode

The thermode tab presents all the thermode data and calibration tables. Refer to the Thermode Management section in the Service Manual for further explanation.

Additional available functions are:

Thermode calibration.

Thermode management.

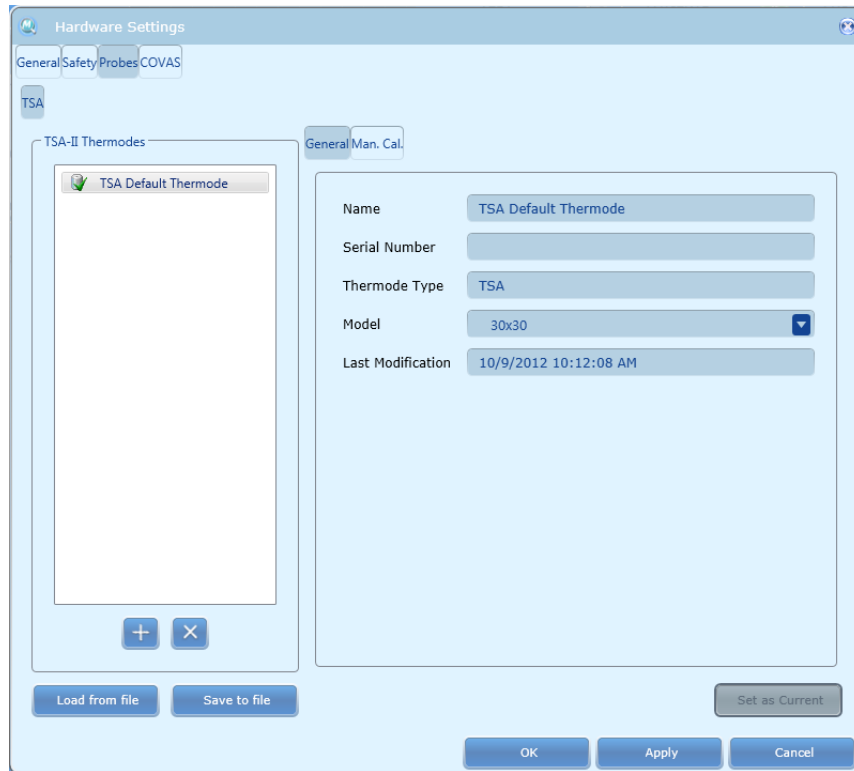


Figure 86: Hardware settings – Thermode tab

10.2.4 CoVAS

COVAS4 tab allows calibrating the COVAS scale. Refer to the COVAS calibration section in the Service Manual.

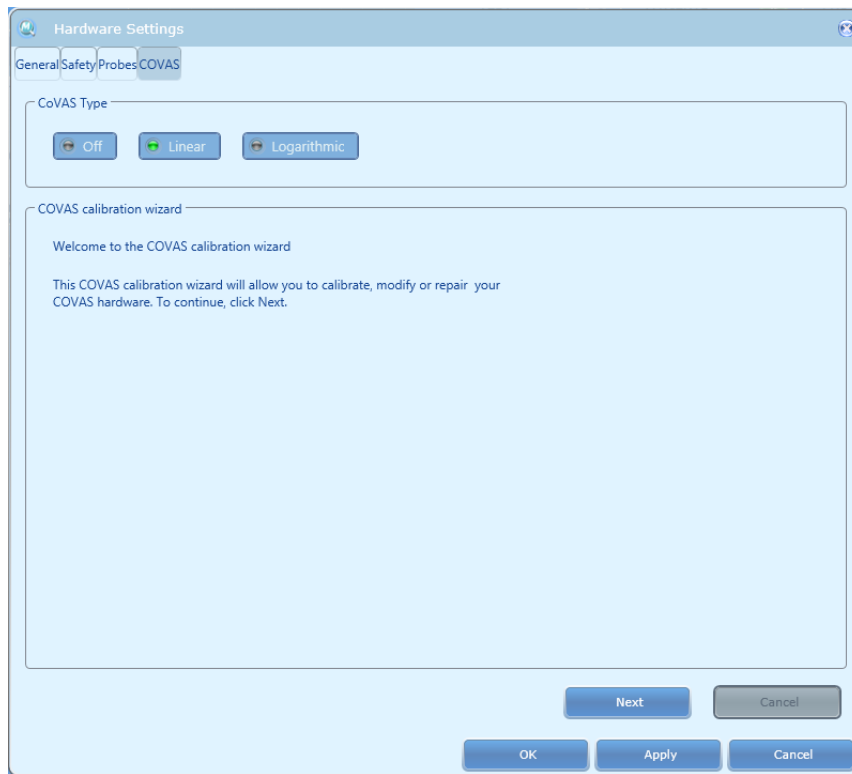


Figure 87: Hardware settings – COVAS tab

Table 34: Hardware Settings – CoVAS tab options

Parameter	Description
CoVAS Type	Select CoVAS mode from available options: <ul style="list-style-type: none"> • OFF – CoVAS not in use (Remember to connect CoVAS key) • Linear – use when connected to linear CoVAS • Logarithmic – use when connected to logarithmic CoVAS
CoVAS Calibration Wizard	Refer to the COVAS calibration section in the Service Manual.

10.3 Test Settings

Test settings enable you to set up the basic test settings for all tests run on the current system.

To access the Test settings menu, perform the following procedure:

1. From the **Settings** menu, select the **Test settings** option.
The dialog below is displayed.

The following options are available:

Table 35: Test Settings Tab Sheets

Parameter	Description
Test Configuration	For setting default test parameters.

4 According to license agreement

Parameter	Description
Instructions Configuration	For setting test instructions.
Event Sound Configuration	For assigning special sound effects to selected events.
Event Marker	For special events marking configuration.
Body Sites	For Body Site name management.

10.3.1 Test Configuration

The Test Configuration option enables you to set default test parameters.

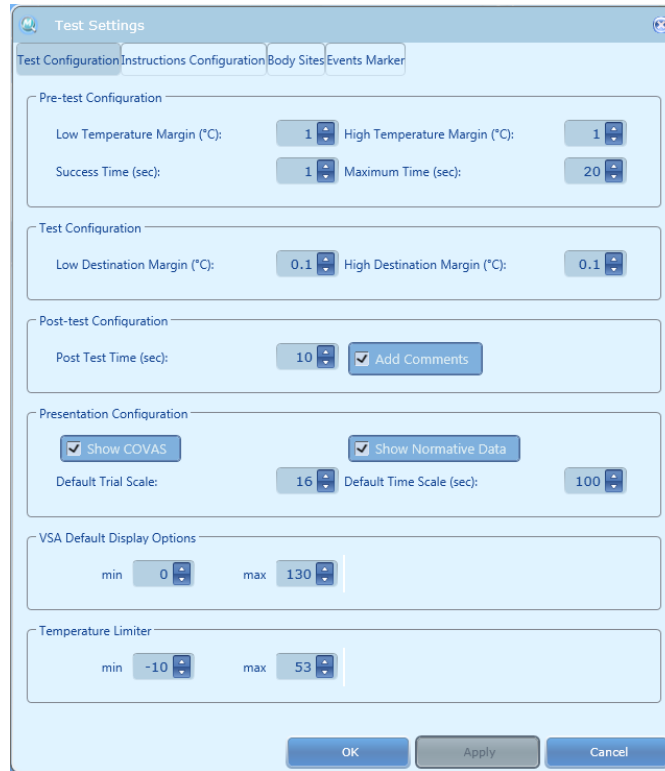


Figure 88: Test Configuration Settings

The following options are available:

10.3.1.1 Pre-test settings

Table 36: Pre-test parameters

Parameter	Description
Low temperature margin	The bottom margin for a stabilized temperature, allowed for a successful pre-test.
High temperature margin	The top margin for a stabilized temperature, allowed for a successful pre-test.
Success time	The stabilized temperature duration, required to render a successful pre-test.

Parameter	Description
Maximum time	The maximal time allowed for stabilizing trials (during the pre-test sequence).

10.3.1.2 Test Configuration

Table 37: Test configuration parameters

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

10.3.1.3 Post Test

Table 38: Post test parameters

Parameter	Description
Post test time	Post-test temperature stabilization is required by safety standards. This setup is used to add time for post-test monitoring.
Add Comments	When Add Comments option is checked, a dialog box allowing adding comments to the test will be open when a test ends. These comments will be displayed in the final report.

10.3.1.4 Presentation Configuration

Table 39: Presentation configuration

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

10.3.1.5 VSADisplay Options⁵

Table 40: Additional test parameters

Parameter	Description
Default Offset	Sets the default amplitude scale to display during VSA tests.

10.3.1.6 Temperature Limiter

Table 41: Temperature limiter parameters

Parameter	Description
-----------	-------------

⁵ According to license agreement

Parameter	Description
Temperature Limiter	Sets the minimum and maximum temperature that is allowed during a test for TSA Thermode. This parameter does not replace the safety limitation of the TSA-II; it allows limiting the stimulus temperature to a specific range, according to unique requirements.

10.3.2 Instructions Configuration

The Instructions Configuration option sets the default files that will be available to provide information concerning the various test methods.

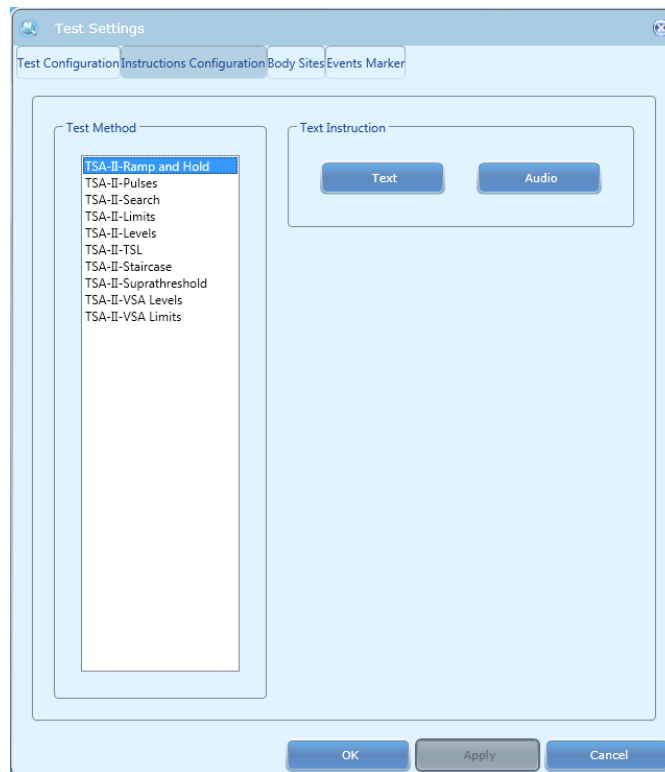


Figure 89: Instructions Configuration

Two formats are available:

Text – a textual (written) description.

Audio – a vocal description, in wav, wma or mp3 format.

10.3.2.1 Text

To create textual instructions for a test method:

1. Choose the desired test type – Ramp and Hold, Pulses, Search, or Limits.
2. Click the **Text** button.
The following screen is displayed:

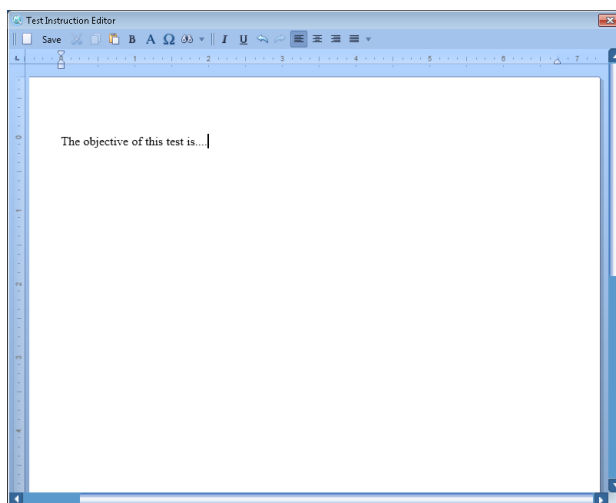


Figure 90: Test Instructions Editor

3. Enter the required text.
4. Click the **Save** button.
5. Close the window.

The following formatting functions are available:

New – clears the entire document for entering new instructions.

Save – saves the entered text.

Cut – cuts the selected text from the section to a virtual clipboard. The proceeding text moves back to fill the blank space.

Copy – copies the selected text to a virtual clipboard.

Paste – pastes the text currently in the virtual clipboard to the location of the cursor.

B – Turns the selected text to bold typeface.

Find – invokes a text-locating tool.

I – turns the selected text to italicized typeface.

U – Underlines the selected text.

Undo – undoes the recent entries in the editor.

Redo – redoes the entries that were undone.

Left – left-adjusts the current paragraph.

Center – center-adjusts the current paragraph.

Right – right-adjusts the current paragraph.

10.3.2.2 Audio

To enter vocal instructions for a test method:

1. Create an audio file of the instructions in one of the following formats:
WAV, WMA, MP3
2. Choose the desired test type – Ramp and Hold, Pulses, Search, or Limits.

3. Browse to the desired folder, and select the audio file.
4. Click the **Open** button.

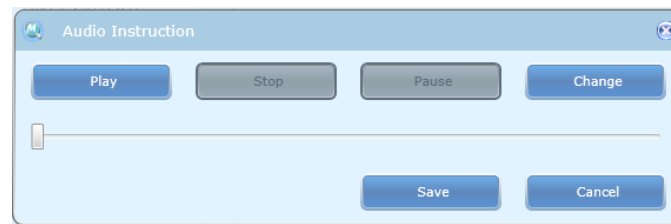


Figure 91: Audio save button

5. Click the **Save** button.
6. Close the window.

The following functions are available:

Play – Plays the audio file.

Stop – Stops the playback. **Play** will start from the beginning.

Pause – Pauses playback. **Play** will continue from paused place.

Change – Reopens browser to allow replacing the current file with another one.

10.3.3 Event Sound Configuration

The Event Sound Configuration option sets the sound effects that will accompany various events.

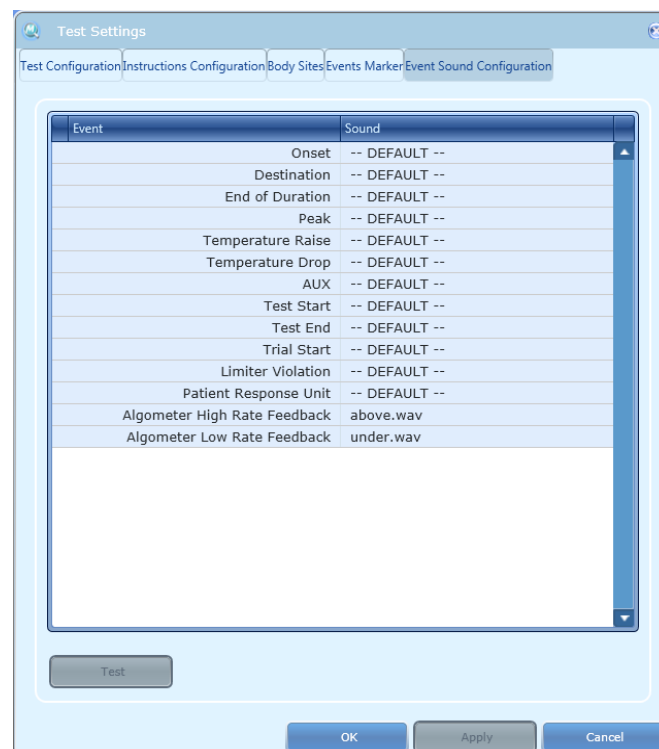



Figure 92: Instructions Configuration

There are two methods for assigning a sound effect to an event:

Use the sound effect library.

Use a custom sound effect.

To use the sound effect library:

1. Click the drop-down arrow  at the right end of the required event.
The sound effect list is displayed:

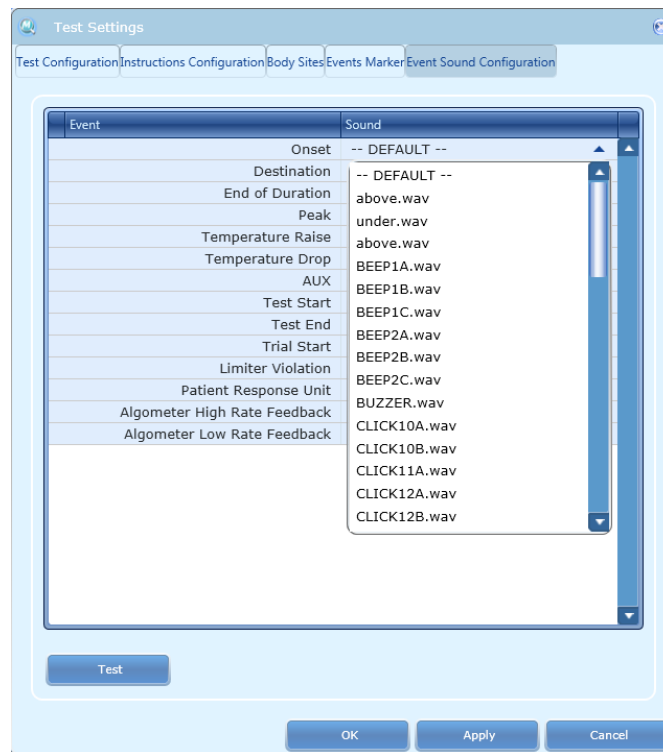



Figure 93: Sound Effect Library

2. Choose the required sound effect.
The selected filename replaces the value displayed under the Sound column.
3. Click the **Test** button, to listen to the selected sound effect.

To use a custom sound effect:

1. Click the ellipsis  at the right end of the required event.
A warning message that long sounds may affect the test execution is displayed.
2. Click the **OK** button.
3. Browse to the required folder, and select the required file.
The selected filename replaces the value displayed under the Sound column.
4. Click the **Test** button, to listen to the selected sound effect.

10.3.4 Event Marker

Event Marker option enables you to mark specific events by adding messages that will be displayed during the test. The events are also saved with test results and can be viewed the excel export.

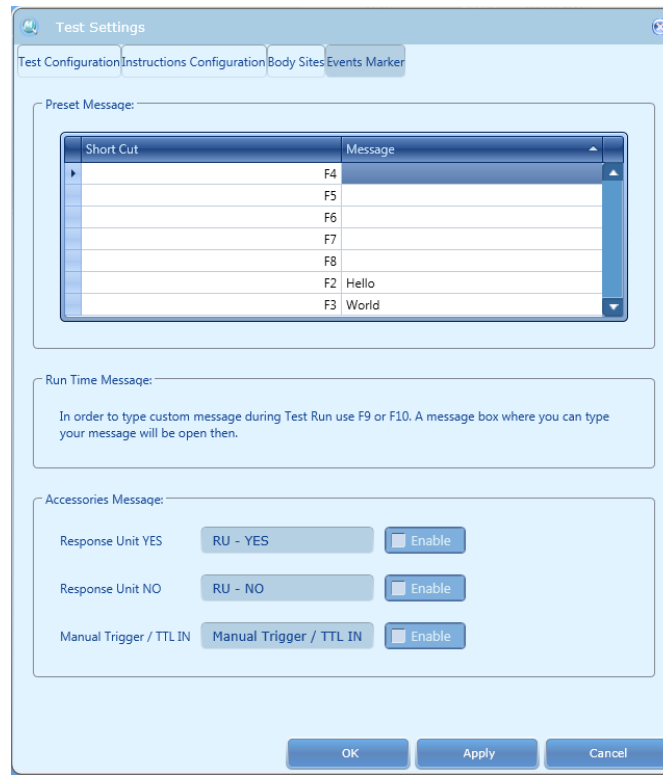


Figure 94: Event Marker

There are three types of messages that can be added:

1. **Preset Messages** – F2 – F8 keys are used to display a preset message during the test. The preset message can be edited for each key separately, by using the Message line. Preset message may contain Numbers, Letters and Symbols.
2. **Run Time Messages** – F9 or F10 keys are used to add a message while the test is running. Press one of these keys and type the message in the dialog box. Use **Shift+Enter** to begin a new line when typing the message and **Enter** to save the message.
3. **Accessories Messages** - Change the text displayed when the patient response unit is pressed and/or manual trigger is used. The option can be used for example in methods such as ramp and hold to indicate different sensations felt by the subject.

10.3.5 Body Site Editor

The Body Site Editor option displays the complete Body Sites list as set by the Manufacturer, and enables the user to create a personal list of tested body sites.

The Body Site Editor is divided into two sections:

1. Manufacturer Body Sites
2. User Body Sites



Figure 95: Body Sites Editor

10.3.5.1 Manufacturer Body Sites

The Manufacturer Body Sites section displays the complete list of body sites (Dermatomic areas) as set by the manufacturer.

The following information is available:

1. Main Site – C1...C8; T1...T12; L1...L5; S1...S5.
2. Side – Left or Right.
3. Secondary Site – matches the Dermatonic areas.
4. Normative Data – indicates if relevant normative data is available in the Normative Data list.
5. Hide – enables the user to hide a site from the Body Site selection screen.

1. To narrow down the displayed list use the filter row.

The following actions are available in the Manufacturer Body Sites Editor:

1. Export Body Site list to an excel file.
2. Import .ats binary Body Site list.
3. Select Hide or Display site in the Body Site selection screen by using the check box.

10.3.5.2 User Body Sites

The User Body site section enables the user to manage a customized Body Site list according to specific needs.

The following information is available:

1. Main Site – C1...C8; T1...T12; L1...L5; S1...S5.

2. Side – Left or Right.
3. Secondary Site – matches the Dermatonic area.
4. Normative Data – indicates if relevant normative data is available in Normative Data list.
5. Hide – enables the user to hide a site from the Body Site selection screen.

2. To narrow down the displayed list use the filter row.

The following actions are available in the User Body Sites Editor:

1. Export Body Site list to an excel file.
2. Import Body Site list from an excel file (Compatible files only).
3. Edit Body Site entry.
4. Delete Body Site entry.
5. Select Hide or Display site in the Body Site selection screen by using the check box.

11. System Information

The System Information menu displays the system details.

The following information is displayed:

Software version

Firmware Version

Firmware Serial Number

Supported Devices (according to license)

Supported Thermodes (according to license)

Supported Add-ons (according to license)

MEDOC contact information.

In order to see the system information:

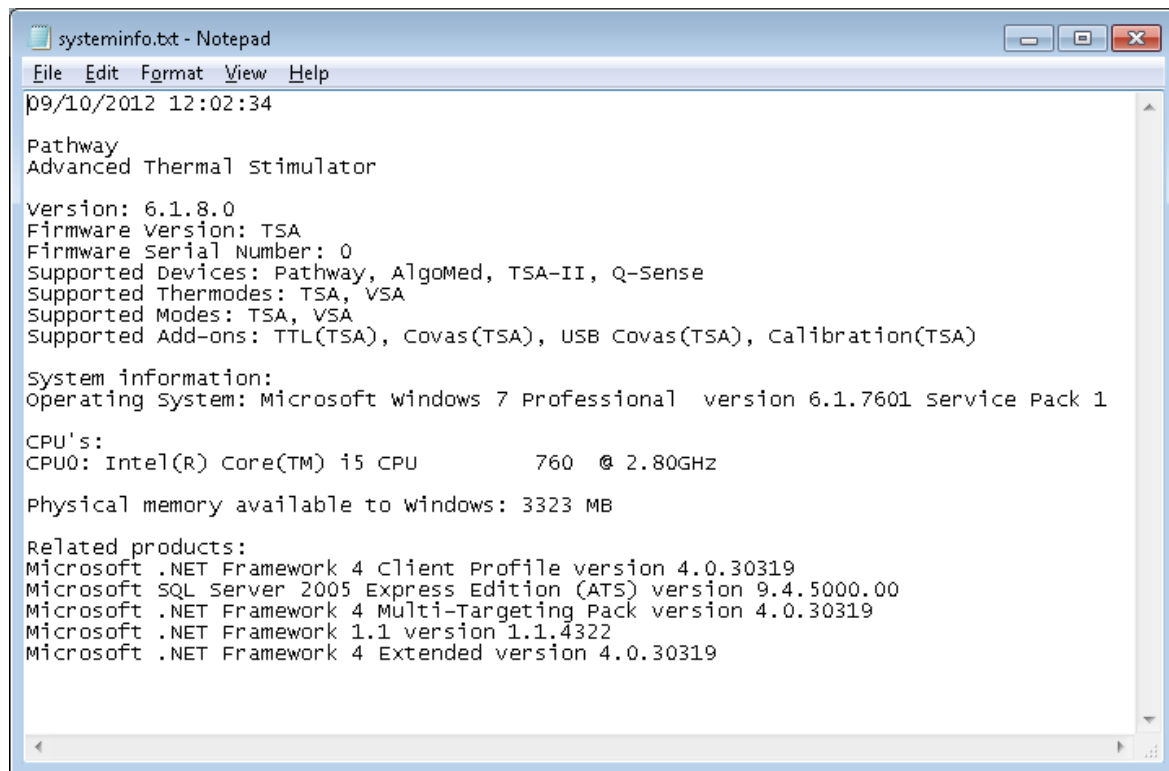
1. From the **Help** menu, select the **About Medoc Main Station** option. The following screen is displayed:



Figure 96: System Information

In order to send full system information to Medoc:

1. Click the **Sysinfo** button. A system information file similar to the following, is created and displayed:



```
systeminfo.txt - Notepad
File Edit Format View Help
09/10/2012 12:02:34

Pathway
Advanced Thermal stimulator

Version: 6.1.8.0
Firmware Version: TSA
Firmware Serial Number: 0
Supported Devices: Pathway, AlgoMed, TSA-II, Q-Sense
Supported Thermodes: TSA, VSA
Supported Modes: TSA, VSA
Supported Add-ons: TTL(TSA), Covas(TSA), USB Covas(TSA), Calibration(TSA)

System information:
Operating System: Microsoft Windows 7 Professional version 6.1.7601 Service Pack 1

CPU's:
CPU0: Intel(R) Core(TM) i5 CPU          760  @ 2.80GHz

Physical memory available to windows: 3323 MB

Related products:
Microsoft .NET Framework 4 Client Profile version 4.0.30319
Microsoft SQL Server 2005 Express Edition (ATS) version 9.4.5000.00
Microsoft .NET Framework 4 Multi-Targeting Pack version 4.0.30319
Microsoft .NET Framework 1.1 version 1.1.4322
Microsoft .NET Framework 4 Extended version 4.0.30319
```

Figure 97: Sysinfo File Sample

2. Save the file and send it by mail to your Medoc Service contact.

12. The Black Box



This feature is not available in Medoc Main Station version 5.0

MEDOC Main Station is installed with a “black box” or logger that records and documents software and system information in case of error or failure. The files can be exported to excel and sent to Medoc support in order to identify the nature and cause of any technical malfunction.

12.1 Exporting the Black Box File

Follow these steps to export a black box file:

1. From the **Utilities** menu, select **Black Box**; The following screen is displayed:

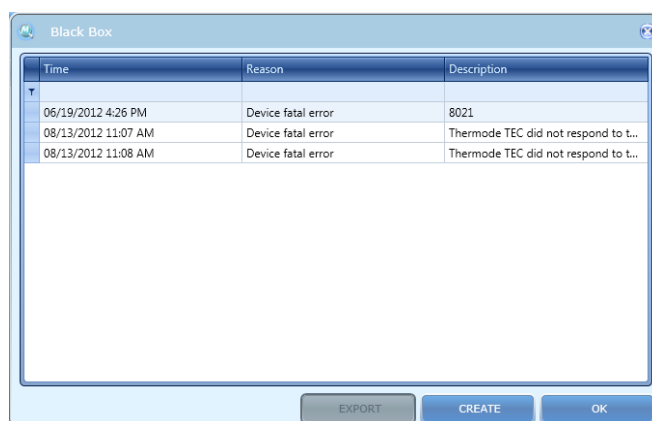


Figure 98: Black Box – Software

2. Select the entry to export and click **Export** button.
3. The **Save As** window is displayed.
4. Browse to the folder into which you want to save the Excel file, type the file name, and click the **Save** button.
The **Exporting data, please wait** prompt is displayed.
You can abort the exporting process at any time, by clicking the **Cancel** button.
5. After Export is completed, click **OK**.
6. To close the **Black Box** window, click the **OK** button.

12.2 Creating a Black Box Entry on Demand

1. From the **Utilities** menu, select **Black Box**.
2. Click the **Create** button.
3. MEDOC Main Station will generate a Black Box entry and record the current status of the system.
4. Exit the **Black Box** window by clicking the **OK** button and reopen it from the utilities menu.
5. A new entry will appear with the reason: On demand (see [Figure 98](#)).
6. Follow instructions in previous section in order to export this entry.

12.3 The Contents of the Black Box File

The Black Box file is exported in an Excel format, and viewed for analysis by other users (such as system administrators) or Medoc Technical staff.

The Excel file is divided into two tabs:

Description: containing the general entry data, as displayed in the Black Box window:

	A	B
1	Creation time	2/21/2011 1:02:24 PM
2	Reason	Device fatal error
3	Description	Thermode TEC did not respond to temperature changes. Error Code: 8007
4		

Figure 99: Black Box Excel – Description Tab Sample

Data: containing the detailed information of the entry:

1	A	B	C	D	E	F	G	H	I	J	K	L
Timestamp [msec]	Error	Time	Data source	Device State	Heater [C]	TEC [C]	Water [C]	COVAS	Response unit	External trigger	TTL 1-Bit	
152	25020		Status	WritingBlackBox		20.46	17.57		0 Yes: Off, No: Off	False		
153	25020		Status	SafeMode	17.18	20.48	17.6		0 Yes: Off, No: Off	False		
154	25040		Status		17.21							
155	25100	TCU error code: 800D,	2/21/2011 1:01:00 PM	Status								
156	25140		Status	WritingBlackBox	17.2	20.46	17.57		0 Yes: Off, No: Off	False		
157	25160		Status		17.19							
158	25180		Status	WritingBlackBox	17.11	20.46	17.55		0 Yes: Off, No: Off	False		
159	25200		Status		17.14							
160	25220		Status	WritingBlackBox	17.19	20.41	17.57		0 Yes: Off, No: Off	False		
161	25240		Status		17.23							
162	25260		Status		17.13							
163	25280		Status	WritingBlackBox	17.16	20.44	17.58		0 Yes: Off, No: Off	False		
164	25300		Status		17.17							
165	25320		Status	WritingBlackBox	17.16	20.44	17.57		0 Yes: Off, No: Off	False		
166	25340		Status		17.2							
167	25360		Status		17.17							
168	25380		Status	WritingBlackBox	17.17	20.4	17.56		0 Yes: Off, No: Off	False		

Figure 100: Black Box Excel – Data Tab Sample

13. Appendix A – Normative Data

The Normative Data component contains data that was collected in various studies, which is shown on the screen during test execution.

Normative Data enables the following options:

1. View Manufacturer Normative Data.
2. Create personal Normative Data.
3. Display Normative Data on the screen during test run.



Using Manufacturer Normative Data is according to the terms and conditions as specified during the installation of MEDOC Main Station!

13.1 Normative Data Editor

To access Normative Data list go to **Utilities**→**Normative Data**.

The following screen is displayed:

Meth...	Mod...	Baseli...	Rate	Age...	Gender	Main...	Side	Specif...	N	AVG	STD	Uppe...	Lower...
Limits	Warm...	32	1	60-69	Male	L5	Left	Knee...	13	39.27	2.8	44.87	33.67
Limits	ColdS...	32	1	50-59	Male	C8	Left	Hand...	17	30.5	0.69	31.88	29.12
Levels	Warm...	32	1	60-69	Female	L5	Right	Foot...	13	35.43	2.24	39.91	30.95
Limits	ColdS...	32	1	40-49	Female	C6	Left	Hand...	47	30.23	0.84	31.91	28.55
Limits	ColdS...	32	1	20-29	Female	L4	Left	Knee...	19	30.8	0.68	32.16	29.44
Limits	ColdS...	32	1	20-29	Male	T1	Right	Uppe...	19	31.05	0.38	31.81	30.29
Limits	Warm...	32	1	20-29	Female	C2	Right	Opht...	19	33.26	0.89	35.04	31.48

Figure 101: Normative Data Editor Screen

The Normative Data Editor screen is divided into two sections:

1. Manufacturer Normative Data
2. User Normative Data

13.1.1 **Manufacturer Normative Data**

The Manufacturer Normative Data is information displayed by default, which was collected by Medoc Ltd.

The following information is available:

Table 42: Manufacture Normative Data information

Column Title	Description
Method	The test method that was used to collect the specified normative data.
Modality	The modality of the test method that was used to collect the specified normative data.
Baseline	The baseline that was used to collect the specified normative data.
Rate	The temperature change rate that was used to collect the specified normative data.
Age Group	The age group that the collected normative data refers to (In years).
Sex	The gender of subject that the collected normative data refers to.
Main Site	The main body site that was used to collect the specified normative data.
Side	The anatomic side that was used to collect the specified normative data.
Specific Site	The specific body site that was used to collect the specified normative data.
N	The number of subjects which the normative data statistics is based on.
AVG	The average threshold of the subjects that were tested to collect the specified normative data.
STD	The standard deviation of the threshold of a sample subject who was tested to collect the specified normative data.
Upper Limit	The upper limit as calculated from the normative data. Upper Limit = AVG + 2xSTD.
Lower Limit	The lower limit as calculated from the normative data. Lower Limit = AVG – 2xSTD.

The following actions are available:

Table 43: Manufacture Normative Data options

Button	Function
Import	Import is not available for manufacturer normative data
Export	Export normative data table to excel / .csv file or .ats format
Additional Options	Function
Filter	Enables the user to filter and sort data, according to personal needs.

13.1.2 **User Normative Data**

The User Normative Data is customized information that the user can add to the Medoc Main Station database.

13.1.2.1 **Available Fields**

The following information is available:

Table 44: User Normative Data information

Column Title	Description
Method	The test method that was used to collect the specified normative data.
Modality	The modality of the test method that was used to collect the specified normative data.


Baseline	The baseline that was used to collect the specified normative data.
Rate	The temperature change rate that was used to collect the specified normative data.
Age Group	The age group that the collected normative data refers to (In years).
Sex	The gender of subject that the collected normative data refers to.
Main Site	The main body site that was used to collect the specified normative data.
Side	The anatomic side that was used to collect the specified normative data.
Specific Site	The specific body site that was used to collect the specified normative data.
N	The number of subjects which the normative data statistics is based on.
AVG	The average threshold of the subjects that were tested to collect the specified normative data.
STD	The standard deviation of the threshold of a sample subject who was tested to collect the specified normative data.
Upper Limit	The upper limit as calculated from the normative data. Upper Limit = AVG + 2xSTD.
Lower Limit	The lower limit as calculated from the normative data. Lower Limit = AVG – 2xSTD.

The following actions are available:

Table 45: User Normative Data options

Button	Function
Import	Import normative data table to the database from an excel file.
Export	Export normative data table to excel / .csv file.
Add Entry	Add a new entry to the database.
Remove Entry	Remove an existing entry from normative data database.
Edit Entry	Edit an entry in the normative data database.
Additional Options	Function
Filter	Enables the user to filter and sort data, according to personal needs.

13.1.2.2 Adding Normative Data Via the Program Editor

1. To add a new entry to the table click the  button
2. Fill in the required fields (a required field will be highlighted in red until filled correctly).
3. Add more entries as needed. To Save click “Apply” and then “OK” to exit the editor.

13.1.2.3 Importing Normative Data from a File

Normative Data can be created and edited in a excel file and then be imported into the Medoc Main Station Database. Please note the following restrictions apply when importing normative data from a file:

1. The file must be in MS Excel 97-2003 workbook (use compatibility mode when using later versions of MS Excel).
2. All fields must be included (non required fields don't have to be filled)
3. Data is case sensitive
4. Data must all be in one worksheet named “Normative Data”.
5. Importing Normative Data will override all exiting user normative data.
6. It is recommended to export the manufacturer data to an Excel file and use the same format.

13.2 Normative Data Display

The Normative Data can be displayed on the test screen when its parameters match the current test parameters.



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

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



Figure 102: Normative Data display in test screen

- You may choose to display Normative Data as a default. Go to **Settings** → **Test Configuration** → **Presentation Configuration** and mark the relevant check box.

14. Appendix D – fMRI Conditional TSA-II



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



TSA-II Cart and MR filters are defined and marked as MR Unsafe equipment according to the ASTM F2503–08.



WARNING:

Make sure that the Thermode is unblemished in order to prevent potential burn to the tested subject.



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

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

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

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

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



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







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



Using the TSA-II in the fMRI configuration is allowed only using fMRI Thermode and accessories and an external cooling unit.

14.1 TSA-II system configuration in fMRI mode:

The fMRI TSA-II system includes the following components:

4.  TSA-II Unit
5.  fMRI Emergency button extended cable
6.  fMRI COVAS (optional)
7.  fMRI Response Unit (optional)
8.  fMRI TSA filter
9.  fMRI TSA Thermode

The TSA-II fMRI filter is an electronic filter designed to reduce magnetic noise from the MR environment, which might be transferred to the Thermode. The fMRI filter includes:

10. 8 UNC-2Api, C2L filters and Feed-Thru Capacitors with the following specifications:
 - a. Damping: 10MHz/14dB, 100MHz/55dB, and 1GHz/70dB.
 - b. Voltage: up to 200V.
 - c. Current: up to 15A.



The filters are located in an Aluminum Cylinder, and they should be installed in an approximately 2.5” hole in the MRI room.

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



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

14.2 Installation – TSA-II MR Filter

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

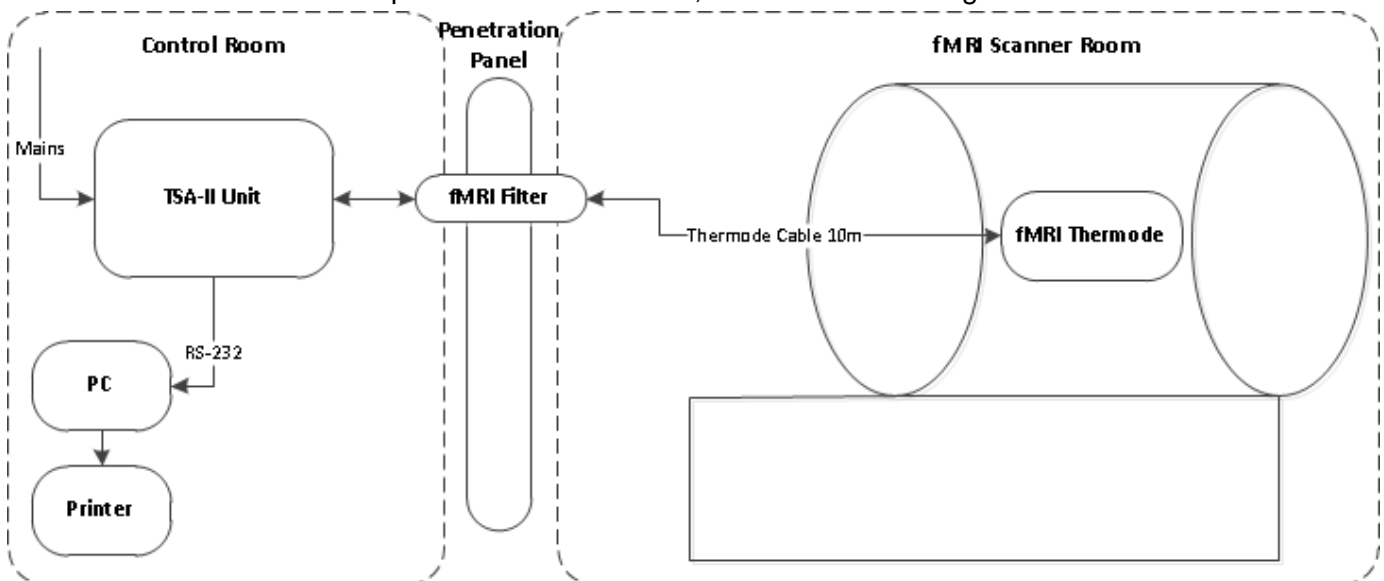


Figure 103: System Block Diagram



The external laptop and printer should be connected to power through the system isolation transformer only.

- b. Make sure your laptop, TSA-II unit and printer (optional) are all OFF.
- c. Install the fMRI filter according to the following instructions:
 - i. Install the filter on your MRI room penetration panel. You can use 4 screws that join the two main aluminum parts of the filter.

- ii. The fMRI Thermode connectors should be placed inside the fMRI room. All the other devices' connectors should be placed outside of the fMRI room.

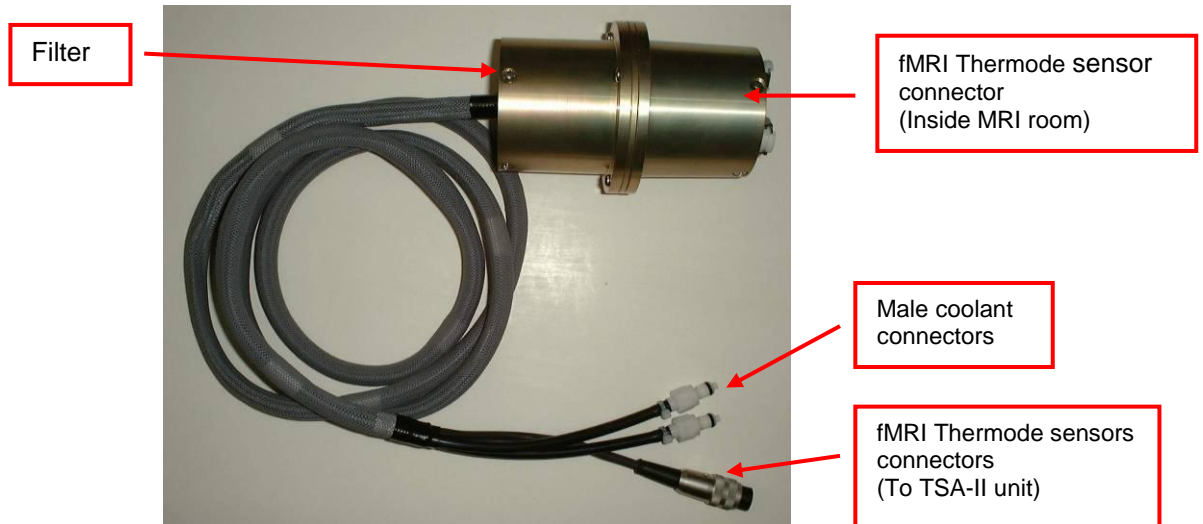


Figure 104: fMRI TSA filter

- d. Connect the coolant tubes connectors to the TSA-II panel that fits the Thermode you are using.
- e. See [Figure 105: fMRI filter front view](#), page 128 for description of the fMRI Thermode components:
 - i. Coolant tubes unit connectors (white connectors).
 - ii. fMRI Thermode main plug connector (black plug).
 - iii. Hollow passage for COVAS and Response unit accessories. Note: This is not the passage for the emergency button. You must transfer the emergency button to the fMRI room through another passage.



Figure 105: fMRI filter front view

- f. Connect the printer cable to the laptop.
 - g. Connect the main power cord to the TSA-II system.
3. Connect the required devices and accessories, as described in section 4.5, page 33.
 4. Conduct a Grounding conductivity test: using DVM measure resistance between the ground pin of the power cord, fMRI filter body and ground pin of fMRI penetration panel. The measured resistance must be less than 0.150 Ohm.
 5. Conduct three phantom tests:
 - a. Conduct the test, when the TSA-II is OFF,
 - b. Conduct the test, when the TSA-II is ON and software is OFF,
 - c. Conduct the test, when the TSA-II and software are ON and software test is running.

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



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

15. Appendix F – Data Base Back Up and Restore

15.1 Backing Up and Restoring the Database



It is highly recommended to back up the database, on a monthly basis.

To backup or restore the TSA-II system database, perform the following procedure:

- a. From the Start menu select **All Programs** → **Medoc** → **MEDOC Main Station** → **Database Configuration Utility**.
The following menu is displayed:

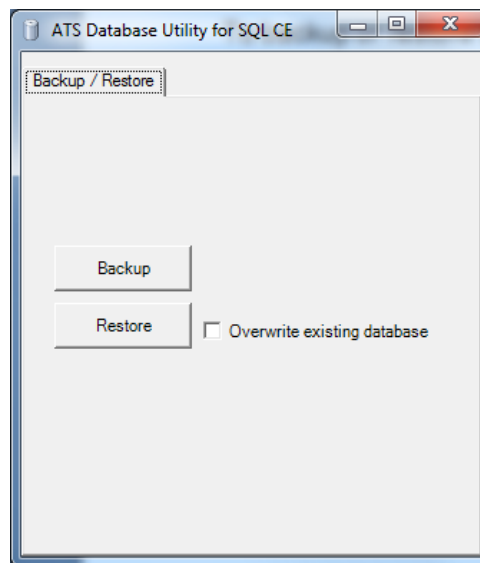


Figure 106: Database Utility

- b. Ensure that the **Backup/Restore** tab is selected.
- c. To backup the data base, click the **Backup** button.
A **Saving** dialog box is displayed. Use a meaningful name for better identification.



Save the Data Base back up file in the default location set by Medoc Main Ststion.





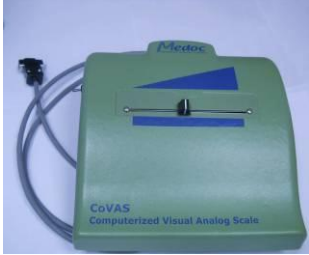
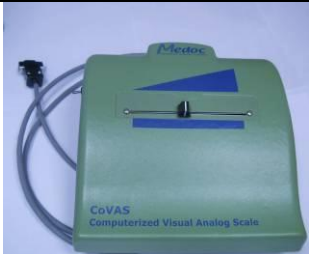
- d. To restore a database, click the **Restore** button, ensure that the **Overwrite existing database** checkbox is selected.
- e. At the prompt, click the **OK** button.
A dialog box that allows choosing the data base source will open and allow choosing the data base you'd like to use.
- f. Choose the desired data base and click the **Open** button.
- g. The selected data base will be restored.




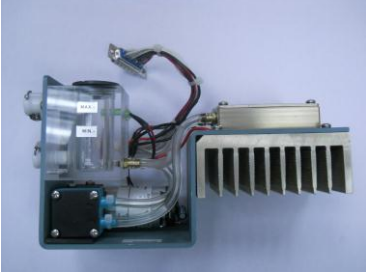
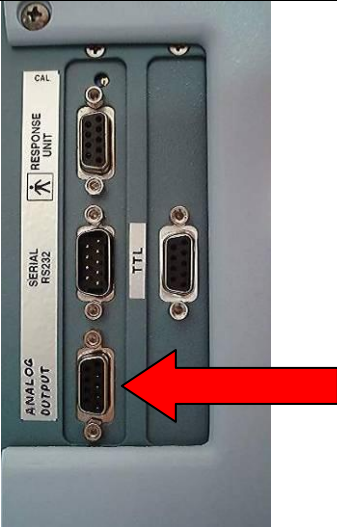
16. Appendix G – Accessories



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 46: Accessories

Description	Cat. No.	
<p>Standard TSA 30x30mm Thermode This is the standard thermal probe, which is capable of heating the skin. Used on large body sites.</p>	AS 00024	
<p>Small Thermode - 16x16mm</p>	AS 00023	
<p>Small Thermode - 5x5mm</p>	AS 00048	
<p>Small Thermode - 2x2mm</p>	AS 00049	
<p>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.</p>	AS 00051 / AS 00052	

Description	Cat. No.	
<p>Standard Strap - 39 cm (15.3") The standard strap is used for securing the Thermode to the hand.</p>	AS 00004	
<p>Face/Leg Strap – 66 cm (25.9") For securing the Thermode to locations on the face and leg.</p>	AS 00044	
<p>Back/Chest Strap – 122 cm (48") For securing the Thermode to larger areas of the body such as the back and chest.</p>	AS 00045	
<p>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.</p>	AS 00147	
<p>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.</p>		
<p>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.</p>		

Description	Cat. No.	
<p>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.</p>		
<p>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.</p>		
<p>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.</p>	<p>AS 00062</p>	
<p>Electronic Cooling Unit In the standard <i>TSA-II</i> configuration it is possible to descend to 0°C in Cold Pain (CP) stimuli. In order to descend in CP till -10°C, an electronic cooling unit must be added. This unit increases the cooling of the water. It is also possible to descend in CP to -10°C with the aid of a special software license.</p>	<p>HP 00050</p>	
<p>Analog Output This is an optional Service port on the <i>TSA II</i> 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</p>	<p>UP 00007</p>	

Description	Cat. No.	
<p>TTL (Transistor Transistor Logic) Output</p> <p>A TTL signal can be sent out of the <i>TSA II</i> 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 <i>TSA II</i> to MRI devices and used in TPS (Thermal Pain Stimulator). This option can be added at a later stage of the purchase.</p>	<p>UP 00008</p>	
<p>TTL (Transistor Transistor Logic) Input/Output</p> <p>In addition to TTL Output, the Input option used for triggering the <i>TSA II</i> 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 <i>TSA II</i> unit. To add this option at a later stage, the <i>TSA II</i> unit must be returned to Medoc.</p>	<p>UP 00009</p>	



"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.

17. Appendix H – System and Module Description

17.1 System Description

The TSA II modular design makes it easy to troubleshoot and replace parts.

The system consists of several main modules:

11. Main board (Communication and Temperature Control Unit)
12. Cooling Unit
13. System power-supplies
14. Thermode (attached to the patient's skin)
15. Patient Response Unit
16. Capacitors and Safety Relay board
17. Computer and printer (external)
18. Option: Vibrator Control Board and Vibrator Head

For a detailed description of the accessories, refer to [Appendix G – Accessories](#) page 131.

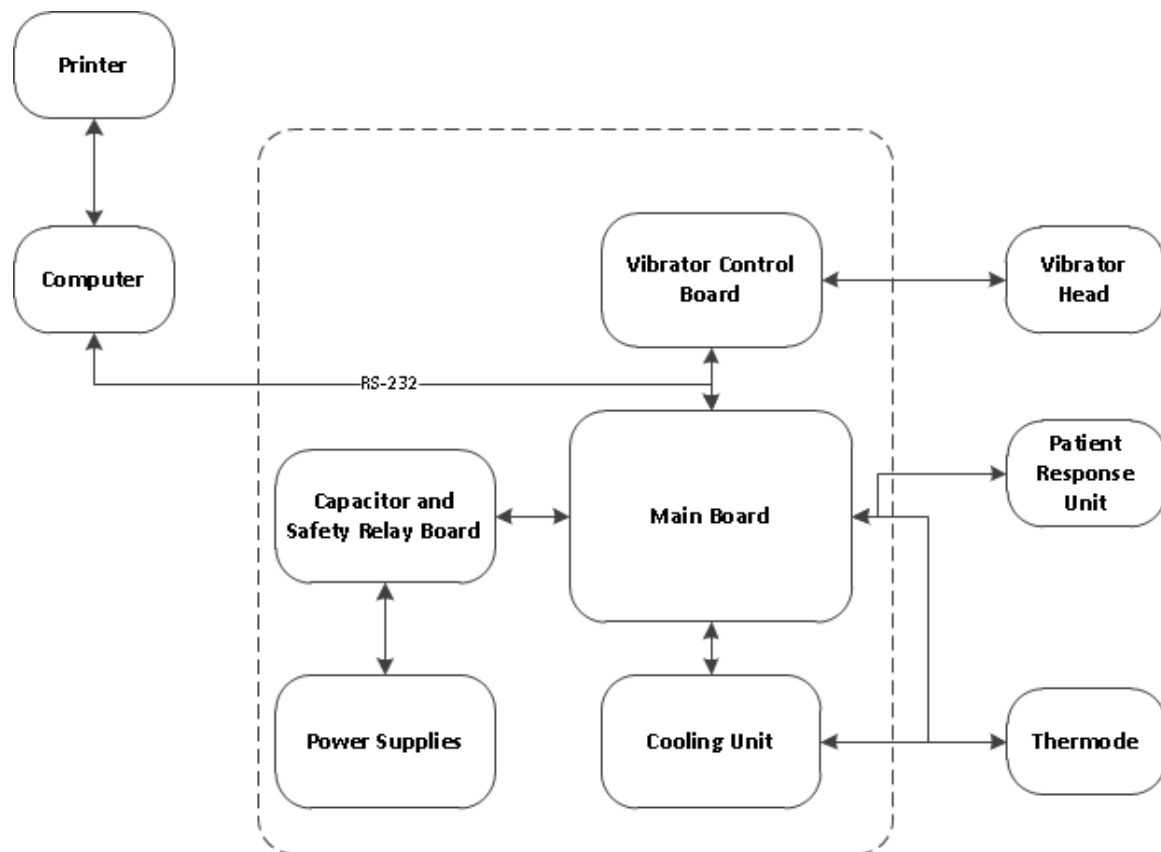


Figure 107: TSA-II System Diagram

18. Appendix I – Preventive and Periodical Maintenance

This chapter describes periodic maintenance procedures.

18.1 Periodical System Run and Visual Check

A periodical system run and visual examination are necessary for maintaining performance of TSA-II system. The periodical run keeps all TSA-II accessories and subunits in operational condition at all times.



Periodical system run is required, if the system or any of the supplied Thermodes are not used on a regular basis, or if it has not been in use for a period of one month or more.



Visual check is required in order to make sure that there is no physical damage to system components, particularly to the Thermodes.

1. Check all accessories and Thermodes visually.
 - o Check that accessories connector is intact.
 - o Check that accessories body is intact.
 - o Check that there is no visible damage to the Thermode heads.
2. Install available Thermode types, according to your license type, to the TSA-II system.
3. Connect all available TSA-II accessories (Response Unit, Panic Button, TTL cables, COVAS) to the TSA-II system.
4. Add coolant to the Cooling Unit, if required.
5. Connect the communication cable from the TSA-II system to the computer running MEDOC Main Station.
6. Power ON the TSA-II system.
7. Start MEDOC Main Station and ensure that communication is established.
8. Run the system for about 10 minutes; check for leakage or any other visible malfunctions.
9. Run a few different test protocols such as Limits, Levels, TSL.
10. Repeat steps 8 and 9 with all the Thermodes supplied with the system.



Switch Thermodes only when the TSA-II system is turned OFF!



Remember to change calibration tables prior switching to different TSA Thermode type (30x30mm, 16x16mm, etc.).

11. If the system is not planned for use for three weeks or more, perform the following instructions:
 1. Turn OFF the TSA-II system through the main switch.
 2. Disconnect the TSA-II system from the main inlet and outlet.
 3. Disconnect all accessories from the TSA-II system, and store them in a dry place.
 4. Disconnect all Thermodes from the TSA-II system, cover the Thermode heads with soft cloth and store in dark dry place.

18.2 Periodical Thermode Calibration

Thermode Calibration is necessary for the TSA-II system performance.

Perform Thermode Calibration according to the Thermode calibration service manual.

18.3 Ground Conductivity Test (for fMRI system only)

The procedure should be performed after system installation in fMRI, after fMRI filter installation or at least once a year.

Using DVM, measure resistance between the ground pin of the power cord, fMRI filter body and ground pin of fMRI penetration panel. The measured resistance must be less than 0.150 Ohm.

18.4 Periodical Thermode Maintenance

1. Inspect Thermode to confirm mechanical integrity and no visual damage before use on patient.
2. Send Thermode to Medoc for periodical maintenance. Maintenance period may vary depending on Thermode specifications and use. Generally, it is recommended to conduct Thermode maintenance and refurbishing after 2 years of use.

19. Appendix J – Cleaning and Disinfecting

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

1. Thoroughly clean the Thermode contact surface using alcohol wipes.
2. Allow to air-dry.
3. Store the Thermode in a clean, dry area.

20. Appendix K – List of Accompanying Documents

Packing list.

Release Notes.

21. Appendix L – Transportation and Storage conditions

The environment 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.

22. Appendix M – Environmental Conditions

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

An ambient temperature range of +10 °C to +40 °C

A relative humidity range of 30% to 75%, including condensation

An atmospheric pressure range of 700 hPa to 1060 hPa

Appendix N – Troubleshooting – Operator Level

The troubleshooting section describes some of the TSA-II most frequent Error messages and Warnings; it helps you resolve them at operator level.

There are two types of malfunctions: Software and Hardware.

1. Software malfunctions consist of lost or damaged files that can result, for example, in missing or incomplete tested subject information.
2. Hardware malfunctions manifest themselves either as occurrences that you become aware of, such as Thermode not responding, or as a malfunction message displayed on the screen.

If you detect a malfunction, do the following:

1. If the malfunction you have encountered is an Error or other message refer to section [22.1.1](#), page [142](#).

For other malfunctions, see alternative solutions in the following sections.

22.1 Numbered Software Error and Warning Messages

The design of all the TSA-II Error messages and Warning messages is similar to this sample message:

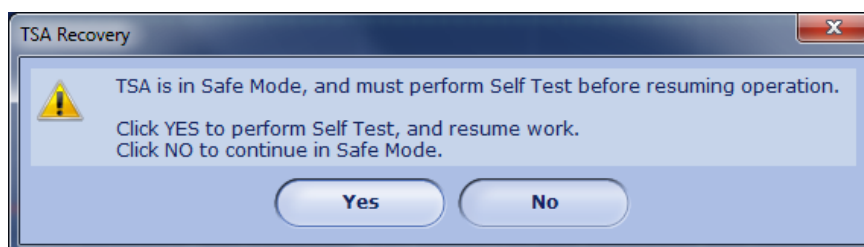


Figure 108: Error and Warning Messages Sample

The text displayed in the message box varies according to the detected malfunction.

22.1.1 Frequent Warning Messages

Table 47: Warnings

No	Warning	Explanation
1	The application is about to start TSA-II recovery and self test. Make sure the thermode is not attached to the patient and press OK.	The application needs to perform a self test. <ol style="list-style-type: none"> a. Remove Thermode from subject. b. Click the OK button to start performing a Self Test.
2	TSA is in Safe Mode, and must perform Self Test before resuming operation. Click YES to perform Self Test, and resume work. Click NO to continue in Safe Mode.	The TSA II system is in Safe Mode and must perform Self Test before it continues with normal operation. <ol style="list-style-type: none"> 1. Click YES if you wish to resume the Self Test. 2. Click NO if you do not want to resume the Self Test.

№	Warning	Explanation
3	<p>A conflict occurred while importing a user-defined field.</p> <p>Please resolve the conflict by performing one of the next actions:</p> <ol style="list-style-type: none"> 1. Choose the local definition for this field. 2. Choose the imported definition for this field. 	<p>There is a conflict between the existing user-defined entry in the data base and the one you have imported.</p> <ol style="list-style-type: none"> 6. Select the entry you wish to keep: local definition, or imported definition.
4	<p>A conflict occurred while importing a user.</p> <p>Please resolve the conflict by performing one of the next actions:</p> <ol style="list-style-type: none"> 1. Choose one of the local users. 2. Edit the conflicting fields in the imported user. 	<p>There is a conflict between the existing TSA-II user entry in the data base and the one you have imported.</p> <ol style="list-style-type: none"> 1. Select the entry you wish to keep: local user, or imported user, or modify the conflicting fields in the imported user.
5	<p>A conflict occurred in department name.</p> <p>Please resolve this conflict by performing one of the next actions:</p> <ol style="list-style-type: none"> 1. Choose the local department. 2. Edit the imported department name. 	<p>There is a conflict between the existing department name in the data base and the one you have imported.</p> <ol style="list-style-type: none"> 1. Select the entry you wish to keep: local department, or imported department, or modify the imported department name.
6	<p>A conflict occurred while importing a patient.</p> <p>Please resolve the conflict by performing one of the next actions:</p> <ol style="list-style-type: none"> 1. Choose one of the local patients. 2. Edit the conflicting fields in the imported patient. 	<p>There is a conflict between the existing patient in the data base and the one you have imported.</p> <ol style="list-style-type: none"> 1. Select the entry you wish to keep, local patient, or imported patient, or modify the imported department name
7	<p>Patient details were changed.</p> <ol style="list-style-type: none"> 1. Press Yes to save the patient. 2. Press No to discard changes. 3. Press Cancel to continue editing. 	<p>The patient details have been modified but not saved.</p> <p>Select one of the presented options and continue.</p>
8	<p>Are you sure you want to delete this patient?</p> <p>Press YES to delete the patient and all corresponding test results.</p> <p>Press NO to abort.</p>	<p>You are about to delete a patient from the TSA-II data base.</p> <p>Select one of the presented options and continue.</p>


№	Warning	Explanation
9	<p>Are you sure you want to delete selected patients?</p> <p>Press YES to delete all selected patients and their test results.</p> <p>Press NO to abort.</p>	<p>You are about to delete patients from the TSA-II data base.</p> <p>Select one of the presented options and continue.</p>
10	<p>Another department with this name already exists. Please enter different name for the department.</p>	<p>A Department with the name you have selected already exists in the data base.</p> <p>Modify the department name and continue.</p>
11	<p>The department cannot be deleted because it has some patients.</p>	<p>You cannot delete a department that contains patients.</p> <ol style="list-style-type: none"> 1. Delete all patients from this department. 2. Delete the department form data base.
12	<p>Are you sure you want to delete the selected department?</p>	<p>You are about to delete a department from the TSA-II data base.</p> <p>Select one of the presented options and continue.</p>
13	<p>Configuration data was changed.</p> <p>Press YES to save the configuration data.</p> <p>Press No to discard changes.</p> <p>Press Cancel to continue editing.</p>	<p>The TSA-II configuration data has been changed.</p> <p>Select one of the presented options and continue.</p>
14	<p>Test results are not saved.</p> <p>Press YES to save results.</p> <p>Press NO to continue without saving.</p> <p>Press Cancel to remain in current view.</p>	<p>The results of the test you have performed have not been saved to the data base.</p> <p>Select one of the presented options and continue.</p>
15	<p>Are you sure you want to delete selected programs?</p> <ol style="list-style-type: none"> 1. Click YES if you wish to delete the selected program. 2. Click NO if you do not wish to delete the selected program. 	<p>You are about to delete some programs from the TSA-II data base.</p> <p>Select one of the presented options and continue.</p>
16	<p>Are you sure you want to delete specified results?</p> <ol style="list-style-type: none"> 1. Click YES if you wish to delete the selected results. 2. Click NO if you do not wish to delete the selected results. 	<p>You are about to delete some results from the TSA-II data base.</p> <p>Select one of the presented options and continue.</p>
17	<p>Are you sure you want to delete this result?</p> <ol style="list-style-type: none"> 1. Click YES if you wish to delete the selected result. 2. Click NO if you do not wish to delete the selected result. 	<p>You are about to delete a test result from the TSA-II data base.</p> <p>Select one of the presented options and continue.</p>

№	Warning	Explanation
18	<p>Program violates safety limitations, and cannot be saved. Modify program settings, and retry saving.</p> <p>Violations: Sequence: ##, Temperature: ##, Actual time (sec): ##, Allowed time (sec): ##</p>	<p>The program you have designed violates the TSA-II safety limitations and therefore can not be saved to the data base.</p> <p>You have to modify the program parameters that are stated as violation according to the TSA-II safety table before saving this program.</p>
19	<p>Violation of the defined Onset-to-Onset time</p>	<p>The program you have created violates the requested Onset-to-Onset time.</p> <ol style="list-style-type: none"> 1. Increase the minimum and maximum ISI in order to allow performing the test. <p>Or</p> <ol style="list-style-type: none"> 2. Change the Time between Trials to the End-to-Onset method.
20	<p>The program name you have used ("Program Name") already exists.</p> <ol style="list-style-type: none"> 1. Click YES if you wish Medoc Main Station to create a unique program name. 2. Click NO if you wish to replace the program name manually. 	<p>A program with the same name as you have selected already exists in the TSA-II data base.</p> <p>Select one of the presented options and continue.</p>
21	<p>Some of the program parameters are invalid. Press YES to continue editing. Press NO to discard all changes.</p>	<p>One or more of the program parameters is not valid and must be modified.</p> <p>Select one of the presented options and continue.</p>
22	<p>Are you sure you want to delete this instruction?</p> <ol style="list-style-type: none"> 1. Click YES to delete this instruction. 2. Click NO to abort. 	<p>You are about to delete the selected instructions from TSA-II data base.</p> <p>Select one of the presented options and continue.</p>
23	<p>The default instruction is not defined for this program.</p>	<p>No test instructions are defined for the selected method.</p> <p>You can add instructions through Settings → Test Settings → Instructions Configuration</p>
24	<p>Thermode calibration data was changed but not saved. Press Ok to exit calibration and discard the new calibration data. Press Cancel to continue calibration.</p>	<p>The Thermode calibration data was not saved.</p> <p>Select one of the presented options and continue.</p>
25	<p>The program cannot be executed because it requires Probe type that is not supported.</p>	<p>The program you are trying to run requires a Probe type which is not available.</p> <p>Make sure that the Probe type you wish to run the test with, is connected to the TSA-II system and enabled (Settings → Hardware Settings → General)</p>

№	Warning	Explanation
26	Test is in process. Are you sure you want to abort the test and Exit the program? 1. Click YES to Exit the program. 2. Click NO to abort.	You have requested to abort the test before it is completed. Select one of the presented options and continue.
27	The new user was not saved. Are you sure you want to select another user and discard all unsaved data? 1. Click YES to select another user and discard unsaved data. 2. Click NO to abort.	You have selected not to save the new user you have defined. Select one of the given options and continue.
28	The changes will take effect only after the system restarts. 1. Click YES to restart now. 2. Click NO to continue with the same setup.	The configuration changes you have defined require program restart. Select one of the presented options and continue.

22.1.2 Frequent Error Messages

Table 48: Errors

№	Error Message	Solution
1		The appearance of this icon, beside a configurable field or parameter, states that the parameter value is illegal. 7. Move the cursor over the sign for further information.
2	User Name or Password are incorrect.	The username or password you have entered is not the right ones. a. Verify that you have typed the correct user name and password. b. Try to log in. If the problem persists, try the <i>admin</i> user name and password.

№	Error Message	Solution
3	<p>The following safety limitation has been violated.</p> <p>Temperature: 56 °C; Allowed time: 0 (sec).</p> <p>Error Code: 8002</p>	<p>The TSA-II system detected that a safety limitation was violated during a test run, and switched automatically to safe mode in order to prevent any damage.</p> <p>The violated temperature and the time of the event are displayed, together with the error code.</p> <ol style="list-style-type: none"> 1. Check that the parameters of the program you ran are valid. 2. Check that the Thermodes are intact and undamaged. 3. Run Self Test to verify that the TSA-II system is enabled to continue work. <p>If the problem persists, stop using the TSA-II system and contact Medoc service.</p>
4	<p>Static sensor mismatch. Error Code: 8003</p>	<p>The TSA-II system has detected a mismatch between its sensors, and therefore switched to Safe Mode in order to prevent any damage.</p> <ol style="list-style-type: none"> 1. Check that the Thermodes are intact and undamaged. 2. Run the Self Test to verify that the TSA-II system is enabled to continue work. 3. Run Thermode calibration. <p>If the problem persists, stop using the TSA-II system and contact Medoc service.</p>
5	<p>Static sensor mismatch. Mismatch (difference) temperature 4 (°C). Error Code: 8003</p>	<p>The TSA-II system has detected a mismatch between its sensors during static temperature measurement, and therefore switched to Safe Mode in order to prevent any damage.</p> <p>The mismatched temperature that was measured is as reported in the message.</p> <ol style="list-style-type: none"> 1. Check that the Thermode is intact and undamaged. 2. Run Self Test to verify that the TSA-II system is enabled to continue work. <p>If the problem persists, stop using the TSA-II system and contact Medoc service.</p>

№	Error Message	Solution
6	Dynamic sensor temperature mismatch. Mismatch temperature: 10 (°C). Error Code: 8004	<p>The TSA-II system has detected a mismatch between its sensors during a dynamic temperature change, and therefore switched to Safe Mode in order to prevent any damage.</p> <p>The mismatched temperature that was measured is as reported in the message.</p> <ol style="list-style-type: none"> 1. Check that the Thermode is intact and undamaged. 2. Run the Self Test to verify that the TSA-II system is enabled to continue work. <p>If the problem persists, stop using the TSA-II system and contact Medoc service.</p>
7	Water overheat. Water temperature: 31 (°C). Error Code: 8008	<p>The TSA-II system has detected that the coolant temperature is above the allowed temperature, and therefore switched to Safe Mode in order to prevent any damage.</p> <ol style="list-style-type: none"> 1. Press the emergency button and wait to see whether the water temperature in the Status Bar is decreasing. 2. Check that the water temperature display on the front cover of the TSA-II system is decreasing. 3. Run Self Test to verify that the TSA-II system is enabled to continue work. <p>If the problem persists, stop using the TSA-II system and contact Medoc service.</p>
8	TEC sensor is shorted or disconnected. Error Code: 800A	<p>The TSA-II system has detected that the TEC (part of the Thermode) sensor is shorted or not connected, and therefore switched to Safe Mode in order to prevent any damage.</p> <ol style="list-style-type: none"> 1. Check that the Thermode is intact and undamaged. 2. Run Self Test to verify that the TSA-II system is enabled to continue work. <p>If the problem persists, stop using the TSA-II system and contact Medoc service.</p>

No	Error Message	Solution
9	Water sensor is shorted or disconnected. Error Code: 800B	The TSA-II system has detected that the coolant sensor is shorted or not connected, and therefore switched to Safe Mode in order to prevent any damage. 1. Check that the Thermode is intact and undamaged. 2. Run Self Test to verify that the TSA-II system is enabled to continue work. If the problem persists, stop using the TSA-II system and contact Medoc service.
10	System could not establish communication! Retry: The system will restart, and retry to establish communication. Demo: The system will restart, and operate in the Demo mode.	The program was unable to establish communication with the TSA-II system. Select one of the presented options and continue.
11	Some of the Safety parameters (Temp Vs. Time) are violating the TSA-II safety limitations. 1. Click OK to continue working with current non-approved safety parameters. 2. Click Restore to restore safety parameters to the TSA-II definition.	The TSA-II system has detected that the modified safety limitations do not comply with safety regulations. Select one of the presented options and continue. In is not allowed to perform any tests on human subjects when violating safety limitations without written approval!

22.2 Faulty System Responses

Table 49: Faulty System Responses

Malfunction	Solution
Thermode does not heat	The Thermode does not heat or cool, but remains at room temperature. The TSA-II Temperature status display on the status line indicates a temperature other than 32°C, and touching the Thermode will slightly change the status reading. The problem may be caused by the Thermode, Main board (TCU) or the voltage supplied to the Main board. Operator: a. Power off the <i>TSA II</i> . b. Replace the Thermode. c. Power on the <i>TSA II</i> and check if the Thermode is heating. Technician: a. Replace the Main board and check if the Thermode is heating. b. Replace the Capacitors and Safety Relay board and check if the Thermode is heating.. c. If the problem is still unresolved, check the voltage connections according to the circuit diagrams.

Malfunction	Solution
Pump is noisy	<p>This might be caused by one of two problems:</p> <ol style="list-style-type: none"> 1. There is not enough water in the reservoir. 2. The pump voltage is not calibrated. <p>Operator: Check the water in the reservoir and refill if necessary according to instructions in TSA-II Service Manual</p> <p>Technician: Adjust the pump voltage according to instructions in TSA-II Service Manual</p>
Power Failure	<p>Operator: Check the fuses in the power socket and replace if necessary according to instructions in TSA-II Service Manual</p> <p>Technician: Check the power connections according to the circuit diagrams. * If the problem persists, contact Medoc service for support.</p>
Patient Response Unit is faulty	<p>Operator:</p> <ol style="list-style-type: none"> 1. Make sure the Patient Response Unit is connected properly to the TSA-II
Thermode vibration	<p>Technician:</p> <ol style="list-style-type: none"> 1. Power off the unit and remove the power connector. Remove the Cooling Unit according to instructions in TSA-II Service Manual. 2. Unscrew the small gray stopper from the shock absorber. 3. Turn the Cooling Unit upside down to empty any water that might have penetrated the shock absorber. 4. Screw the stopper back on. 5. Check the water level in the reservoir according to instructions in TSA-II Service Manual. 6. Replace the Cooling Unit according to instructions in TSA-II Service Manual. 7. Reconnect the power connector. 8. Power on the system.

Malfunction	Solution
<p>No vibration</p>	<p>Operator:</p> <ol style="list-style-type: none"> 1. Check that the communication cable and Vibratory head are properly connected. 2. Enter the Settings→Software Settings menu and verify that the COM defined in the Medoc Main Station Setup agrees with the connection to your computer. 3. Replace the Vibratory head. <p>Technician:</p> <ol style="list-style-type: none"> 1. Check 76 ± 5 Ohm between pins 4 and 8 in Vibratory Dtype 9-pin male connector. 2. Check the communication cable. 3. Check the wiring connections according to the circuit diagram. 4. Check voltages on Vibratory board 15-pin connector. <ul style="list-style-type: none"> • If voltages are OK, replace the Vibratory board according to instructions in TSA-II Service Manual. • If voltages are incorrect, check transformer and its wiring.
<p>Vibration is weak or Vibration is constant</p>	<p>Operator:</p> <ol style="list-style-type: none"> a. Replace the Vibratory head. <p>Technician:</p> <ol style="list-style-type: none"> 1.1. Check the wiring connections according to the circuit diagram. 1.2. Check voltages on Vibratory board 15-pin connector. <ul style="list-style-type: none"> • If voltages are OK, replace the Vibratory board according to instructions in TSA-II Service Manual. • If voltages are incorrect, check transformer and its wiring.

Malfunction	Solution
Constant Communication problems	<ol style="list-style-type: none"> 1. Perform COM port check. <ol style="list-style-type: none"> 1. Check that MEDOC Main Station is set for automatic COM port detection (Settings→Software Settings). 2. Perform Power checks (see above). 3. Perform communication cable check. <ol style="list-style-type: none"> 2. Check that the communication cable is connected properly. 3. One end must be connected to the back of the TSA-II box; the other end to your laptop. 4. Turn ON the TSA-II system. 5. Disconnect and then reconnect the communication cable from the back of the TSA-II box, while the TSA-II system (software and hardware) is running. 6. RS232/USB adaptor installation check. <ol style="list-style-type: none"> 8. Check if the PROMAG RS232/USB adaptor is listed in your laptop port list (see the service manual). 9. If required, install the PROMAG adaptor driver from the MEDOC Main Station installation CD (see the service manual). 7. Restart the TSA-II system.
Water Temperature Too Hot	<ol style="list-style-type: none"> a. Power and communication check. b. Thermode connection check. 1. Make sure that all enabled Thermodes are connected properly to the TSA-II system. <ol style="list-style-type: none"> c. Water level check. <ol style="list-style-type: none"> 1. Check that no Coolant is missing in the cooling unit. 2. Fill coolant if its level is low according to instructions in TSA-II Service Manual. <ol style="list-style-type: none"> d. Coolant cooling check. <ol style="list-style-type: none"> a. Check if coolant temperature is cooling down. <p>* If the problem persists, contact Medoc service for support.</p>